Ennov InSight Data Migration

Contents

Chapter 1. Ennov InSight Database Migration Release Notes

The Ennov InSight Database Migration Release Notes and the Ennov InSight Data Migration Documents provide information about the SQL database scripts and other procedures required to perform Ennov InSight database migrations. The installation and migration script package provides a convenient means for distributing the Ennov InSight database scripts and guidance for upgrading the Ennov InSight database.

Ennov InSight data migration documentation provides essential information to support new installations and upgrades, and to assist your migration planning and execution. It should be read with the Ennov InSight Release Notes, which describe the updates that have been implemented in each release.

Before executing any database scripts, verify that you have the most current version of the Ennov InSight Database Migration package. See the FTP site or contact Technical Support to confirm.

Prerequisites

Users and groups who use the Ennov InSight 7.3 system should have their accounts created in Azure AD and provide the User Object IDs for the user migration phase. For Data Migration requirements, see Ennov InSight 7.3 Data Migration Requirements.

Note: *For data migration and installation assistance, contact your Business Development Representative.*

Chapter 2. Ennov InSight Database Migration Details

The migration package includes SQL database scripts that are run on an Oracle database to establish the database instance for Ennov InSight.

You can use the database scripts as a guide for migrating your earlier version of Ennov InSight to a current release.

Note: *The migration scripts delete all saved queries.*

The scripts are supplied in ZIP files:

- DB Upgrade 70 to 71.zip (DB_update7_1_0_0000_0112.zip) (To migrate to Ennov InSight 7.1 from Ennov InSight 7.0, see:*Data Migration Documents*)
- DB Upgrade 71 to 711.zip (DB_update7_1_1_0000_0001.zip) (To migrate to Ennov InSight 7.1.1 from Ennov InSight 7.1, see: *Data Migration Documents*)
- DB Upgrade 711 to 712.zip (DB_update7_1_2_0000_0001.zip) (To migrate to Ennov InSight 7.1.2 from Ennov InSight 7.1.1, see:*Data Migration Documents*)
- DB Upgrade 712 to 713.zip (DB_update7_1_3_0000_0020.zip) (To migrate to Ennov InSight 7.1.3 from Ennov InSight 7.1.2, see:*Data Migration Documents*)
- DB Upgrade 716 to 7111.zip (DB_update7_1_11_0000_0004.zip) (running the migration script does not result in any functional changes to the Data Administration data. The script provided to fix issues that occur after Oracle upgrade to the 19.17.0.0.221018 version).
- DB Upgrade 715 to 72.zip (DB_update7_2_0_0000_0096.zip) (To migrate to Ennov InSight 7.2 from Ennov InSight 7.1.5, see:*Data Migration Documents*)
- DB Upgrade 72 to 721.zip (DB_update7_2_1_0000_0002.zip)
- DB Upgrade 721 to 722.zip (DB_update7_2_2_0000_0011.zip)
- DB Upgrade 722 to 724.zip (DB_update7_2_4_0000_0003.zip)
- DB Upgrade 724 to 725.zip (DB_update7_2_5_0000_0006.zip)
- DB Upgrade 725 to 726.zip (DB_update7_2_6_0000_0012.zip)
- DB Upgrade 726 to 727.zip (DB_update7_2_7_0000_0014.zip)
- DB Upgrade 727 to 728.zip (DB_update7_2_8_0000_0002.zip)
- DB Upgrade 727 to 7.3.zip (DB_update7_3_0_0000_0146.zip)
- DB Upgrade 73 to 731.zip (DB_update7_3_1_0000_0025.zip)
- DB Upgrade 731 to 732.zip (DB_update7_3_2_0000_0101.zip)
- DB Upgrade 732 to 733.zip (DB_update7_3_3_0066_0058.zip)
- DB Upgrade 733 to 734.zip
- DB Upgrade 734 to 734-reg.zip
- 735.zip

Chapter 3. Ennov InSight Autumn 2025 Updates

Introduction

This document provides all migration requirements for the standard migration of Ennov InSight 7.3.4 to Ennov InSight Autumn 2025.

Pre-Migration Scripts

pre_mig_sdk_migrate.sql

Pre-migration script pre_mig_sdk_migrate.sql helps to identify sender-defined keywords (SDK) not assigned to any field and to be deleted upon migration. After running of the pre-migration script, the user can either assign needed SDK to a field, so type is identified, delete it manually, or ignore to let migration script to delete given SDK. Upon run script will include Application Name, Application ID, SDK Code, SDK Name, Sequence Name, Folder Name, SDK Type.

Pre-migration script helps to identify sender-defined keywords assigned to multiple fields, so their type cannot be identified. After running of the pre-migration script, the user can either unassign needed SDK from the extra fields, delete it manually, or ignore to let migration script to create copies of given SDK and assign one per each field.

pre_mig_qnty_unit_not_migrate.sql

Pre-migration script pre_mig_qnty_unit_not_migrate.sql helps to identify Quantity Unit values which will not migrate due to the changes for the field. After running the script, the user will have the list of values in particular PDSs and PDSs->Components which will not be migrated due to changes in the Ennov InSight version.

Script consists of the following columns: PFNAME, APPLICATIONNAME, EVENTNAME, PRODUCTNAME, PDSNAME, COMPONENTNAME, QUANTITYUNIT.

Data Administration Updates

Event Maintenance ->Secondary Event Type Values

Secondary Event Type Values list is now having an extra field as OOTB functionality.

Other Maintenance ->Origin of Substance Values

Origin of Substance Values list is now mapped to the SPOR RMS ‘Origin of Substance’ master list through the Associate Term functionality.

Other Maintenance ->Units of Measurement Values

There is a new field 'Include in Quantity Unit' with ‘Yes/No’ values and ‘No’ defaulted in Units of Measurement Values list to indicate whether the value will be included in the PDS Packaging Node-> Package Item Device Quantity Unit field. After migration a new field will be shown with the value ‘No’.

Other Maintenance ->MAH/Development Sponsor/Organisation Values ->OMS

Back-end changes have been implemented for the OMS values based on the SPOR API update:

- UI label - API Attribute
- Version type - version-type-name
- Version comment - version-comment

Product Family ->Substance Values -> SMS tab

Changed for SMS tab:

- added new
- ‘SVG Flag’
- ‘EV Code’
- ‘UNII Code’
- ‘Substance Type’
- ‘Category’ has been replaced with ‘Status’
- ‘Active Flag’ has been hidden

There are changes available for Term Search widget on SMS tab:

- Added ‘EV Code’
- Added ‘SVG Flag’
- ‘Domain’ has been replaced with ‘UNII Code’
- ‘Category’ has been replaced with ‘Status’
- ‘Data Classification’ has been renamed to ‘Substance Type’
- ‘Code’ is deleted

Product Detail Set Maintenance ->Species Values

‘Species Values’ list is now having extra fields as OOTB functionality and mapped to the Species SPOR list via RMS tab.

Product Detail Set Maintenance ->Target Species Values

There is a new value list in Product Details Maintenance section of Data Administration called ‘Target Species Values’. It consists of ‘Target Species Name’ field, RMS tab and extra fields available OOTB. It maps with SPOR ‘Target Species’.

Registration Maintenance ->National Classification ATC Values

There is a new value list in Registration Maintenance section of Data Administration called ‘National Classification ATC’. It consists of ‘National Classification ATC Name’ field and RMS tab. It maps with SPOR ‘National Classification’ master list.

Registration Maintenance ->Content Change Values

‘Content of Change Values’ list has been renamed to ‘Change of Scope Values’.

Registration Maintenance ->Provenance Reason Values

‘Provenance Reason Values’ list has been renamed to ‘Message Reason Values’ list.

Units of Measurements Values

A new field Include in Quantity Unit is added to the Units of Measurement Values list in Data Administration. It is now possible to include the “countable unit(s)” value from the Data Administration list Units of Measurement on PDS Packaging Detail > Device Quantity Unit by selecting Yes for the new field Include in Quantity Unit under Units of Measurement Values in Data Administration.

SPOR Master List

There are new SPOR Master Lists available:

- ‘National Classification’, mapped via API to SPOR list #200000016508.
- ‘Origin of Substance’, mapped via API to SPOR list #200000027811.
- ‘Species’, mapped via API to SPOR list #200000000019.
- ‘Species Target Species’, mapped via API to SPOR list #100000108853.
- ‘Record Status’, mapped via API to SPOR list #200000005003.
- ‘Anatomical Therapeutic Chemical Classification System – Veterinary’, mapped via API to SPOR list #100000116677.
- ‘Regulatory Regulating Authority Submission Unit Type’, mapped via API to SPOR list #100000155552.
- ‘EU Territorial Authority’, mapped via API to SPOR list #100000160680.
- ‘Tissue’, mapped via API to SPOR list #100000072054.

Existed list Substance updated to include new fields and updates for existing ones:

- New fields are:
    - ‘SVG Flag’
    - ‘EV Code’
    - ‘Source of Information’
    - ‘Description’
    - ‘UNII Code’
- Fields updated:
    - ‘Data Classification’ has been renamed to ‘Substance Type'.
    - GUI Field Size has been changed from 500 to 1800 char for the field ‘Name’.
- A new field to extract from RMS Application Applicability = term-applicability / applicable-to @name with CURRENT value is added for the following RMS lists:
    - Data Classification
    - Ingredient Role
    - Legal Status of Supply
    - Medicinal Product Type
    - Medicine Profile
    - Regulatory Entitlement Type
    - Quantity Operator

RMS Term Search Widgets

There is a change to the value lists below for the RMS Term Search widgets, a new column Status/App is added:

- Data Classification Values
- Ingredient Role Values
- Legal Status of Supply Values
- Medicinal Product Type Values
- Medicine Profile Values
- Regulatory Entitlement Type Values
- Quantity Operator Values

Singapore 1.0

If the SG region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'SG' in the database. Otherwise, the SG region is added with the values:

Region Abbreviation	Region Name	Active Flag
SG	Singapore	Active

New SG country in the Application Maintenance – Country Values in Data Administration, will be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
SG	Singapore	sg	Singapore	Active

Health Authority name for SG country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, will be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
SG	Singapore	Health Sciences Authority	HSA	SG-HSA	https://www.hsa.gov.sg/

If the Malay, Tamil, Singaporean Mandarin languages already exist in the Other – Language Values section in Data Administration, it will be activated (if inactive). Otherwise, the following values are to be added with values listed in the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Malay	ms	msa	Active
Singaporean Mandarin	zh	zho	Active
Tamil	ta	tam	Active

If the Malay, Tamil, Singaporean Mandarin languages under the Singapore in the Application Maintenance – Country Values

section in Data Administration are not associated yet, they will be associated with Singapore country.

If the SG-1-0' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value SG-1-0'. Otherwise, the SG-1-0' Assembly DTD/Schema will be added.

The 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration will be activated (if inactive) and updated to include Singapore country, in addition to already added countries.

Application Category Values will be added to the Application Maintenance – Application Category Values section in Data Administration if they do not already exist. The list of new values can be found in the table below:

Application Category Name	Active Flag
Therapeutic Products	Active

Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
SG-NP	Therapeutic Products	Therapeutic Products	New Drug Application	Therapeutic Products	Singapore

Application Type eCTD codes Values will be added to the Application Maintenance – Application Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for SG-1-0 DTD/Schema is added to the value. A list of new values can be found in the table below:

Application Type (Display Name)	Applicable DTD/Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Therapeutic Products	sg-1-0	app-type-1		No

The Therapeutic Products Application Type gets Default Flag set to Yes upon associating it with Singapore country.

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist, otherwise updated. A complete list of affected values can be found in table below:

Filing Type	Display Name	Countries
Baseline	Baseline	Australia, China, Singapore, South Africa
DMF Filing	DMF Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Undefined, United Kingdom
Transfer MA Filing	Transfer MA Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy,

		Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Switzerland, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
NDA	NDA	Singapore
NDA-V	NDA-V	Singapore
GDA	GDA	Singapore
GDA-V/CECA	GDA-V/CECA	Singapore
MAV1	MAV1	Singapore
MAV1-V	MAV1-V	Singapore
MAV2	MAV2	Singapore
MIV1-PI	MIV1-PI	Singapore
MIV1-PI-V	MIV1-PI-V	Singapore
MIV1-CMC	MIV1-CMC	Singapore
MIV1-CMC-V	MIV1-CMC-V	Singapore
MIV2-N	MIV2-N	Singapore
MIV2-DnT	MIV2-DnT	Singapore
PV-EDU/RMP Materials	PV-EDU/RMP Materials	Singapore
PV-PBRER/RMP Reports	PV-PBRER/RMP Reports	Singapore
Reg Cond (non-PV)	Reg Cond (non-PV)	Singapore
Other Regulatory Activity	Other Regulatory Activity	Singapore

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for SG-1-0 DTD/Schema is added to the value. List of new values can be found in table below:

Filing Type (Display Name)	**Applicable DTD/Schema**	**eCTD Code**	**Available for Application Type**
NDA	sg-1-0	sub-type-1	Therapeutic Products
NDA-V	sg-1-0	sub-type-2	Therapeutic Products
GDA	sg-1-0	sub-type-3	Therapeutic Products
GDA-V/CECA	sg-1-0	sub-type-4	Therapeutic Products

MAV1	sg-1-0	sub-type-5	Therapeutic Products
MAV1-V	sg-1-0	sub-type-6	Therapeutic Products
MAV2	sg-1-0	sub-type-7	Therapeutic Products
MIV1-PI	sg-1-0	sub-type-8	Therapeutic Products
MIV1-PI-V	sg-1-0	sub-type-9	Therapeutic Products
MIV1-CMC	sg-1-0	sub-type-10	Therapeutic Products
MIV1-CMC-V	sg-1-0	sub-type-11	Therapeutic Products
MIV2-N	sg-1-0	sub-type-12	Therapeutic Products
MIV2-DnT	sg-1-0	sub-type-13	Therapeutic Products
PV-EDU/RMP Materials	sg-1-0	sub-type-14	Therapeutic Products
PV-PBRER/RMP Reports	sg-1-0	sub-type-15	Therapeutic Products
Reg Cond (non-PV)	sg-1-0	sub-type-16	Therapeutic Products
DMF Filing	sg-1-0	sub-type-17	Therapeutic Products
Baseline	sg-1-0	sub-type-18	Therapeutic Products
Transfer MA Filing	sg-1-0	sub-type-20	Therapeutic Products
Other Regulatory Activity	sg-1-0	sub-type-21	Therapeutic Products

Sub Filing Type Values will be updated in the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, Singapore country is added to the value. List of new values can be found in table below:

Sub Filing Type	**Counties**
Initial	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom
Supplementary Information	Singapore, South Africa
Closing Information	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom

Submission Withdrawal	Singapore, South Africa
Response	Austria, Belgium, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Sub Filing Type eCTD code Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for SG-1-0 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type	**Applicable DTD/Schema**	**eCTD Code**	**Available for Filing Type**
Initial	sg-1-0	seq-type-1	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Supplementary Information	sg-1-0	seq-type-2	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Response	sg-1-0	seq-type-3	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Closing Information	sg-1-0	seq-type-4	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity
Submission Withdrawal	sg-1-0	seq-type-5	NDA, NDA-v, GDA, GDA-V/CECA, MAV1, MAV1-V, MAV2, MIV1-P1, MIV1-P1-V, MIV1-CMC, MIV1-CMC-V, , M1V2-N, M1V2-DnT, PV-EDU/RMP Materials, PV-PBRER/RMP Reports, Reg Cond (non-PV), DMF Filing, Baseline, Transfer MA Filing, Other Regulatory Activity

Applicant Contact Type Values will be added to the Submission Maintenance – Applicant Contact Type Values section in Data Administration, if they do not already exist. List of new values can be found in table below:

eCTD Standard Type	**Region**	**Regulatory Code**	**Applicant Contact Type**

eCTD 3.2	Singapore	contact-type-1	Regulatory
eCTD 3.2	Singapore	contact-type-2	Technical
eCTD 3.2	Singapore	contact-type-3	Agent Singapore

Telephone Number Type Values will be added to the Submission Maintenance – Telephone Number Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for SG-1-0 DTD/Schema is added to the value. List of new values can be found in table below:

Region	Regulatory Code	Applicant Contact Type
Singapore	sg-phone-type-1	Business Telephone Number

Valid Values 6.0

Upon migration the new stf-2-2-6-0 XML definition to be added under the Assembly->Assembly DTD/Schema files.

ZA 3.1 updates

Application Category Values

Application Category Values will be added to the Application Maintenance – Application Category Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Active Flag
Emergency Use Listing	Active
REA - Work Sharing - Country	Active

Application Type Values

Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
EUL	Emergency Use Listing	Emergency Use Listing	New Drug Application	Emergency Use Listing	South Africa
REA-WS	REA - Work Sharing - Country	REA - Work Sharing - Country	New Drug Application	REA - Work Sharing - Country	South Africa

Application Type Values will be updated in the Application Maintenance – Application Type Values section in Data Administration if they exist, otherwise added. List of affected values can be found in table below:

Old Application Type	New Application Type	New Name	New Display Name	New Entity XML Type Name	New Application Category	Countries
AMAP	REA AMAP	REA - AMA Procedure	REA - AMA Procedure	New Drug Application	REA AMA Procedure	South Africa
JR	RIA JR	RIA - ZAZIBONA Joint Review	RIA - ZAZIBONA Joint Review	New Drug Application	ZAZIBONA Joint Review	South Africa
WHO-PQ	RIA WHO-PQ	RIA - WHO-PQ	RIA - WHO-PQ	New Drug Application	WHO-PQ	South Africa

WHO-CRP	RIA WHO-CRP	RIA - WHO-SRA CRP	RIA - WHO-SRA CRP	New Drug Application	RIA WHO SRA CRP	South Africa
CH-GHP	RIA CH-GHP	RIA - Swissmedic MAGHP	RIA - Swissmedic MAGHP	New Drug Application	Swissmedic MAGHP	South Africa
EU-M4ALL	RIA EU-M4ALL	RIA - EU M4ALL	RIA - EU M4ALL	New Drug Application	EU M4ALL	South Africa

Application Type eCTD codes

Application Type eCTD Code Values will be updated under the Application Maintenance – Application Type Values section in Data Administration if they exist, otherwise added. List of affected values can be found in table below:

Applicable DTD/Schema	eCTD Code	Application Type	Limit to Cross Application Only
za-3-1	app-type-8	Emergency Use Listing	No
za-3-1	app-type-9	REA - Work Sharing - Country	No

Filing Type Values

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Filing Type	Display Name	Countries
Type IB - Inspectorate	Type IB - Inspectorate	South Africa
z-Code - Type IAin	z-Code - Type IAin	South Africa
z-Code - Type IB	z-Code - Type IB	South Africa
Type II - Grouped Variation N and S	Type II - Grouped Variation N and S	South Africa
z-Code - Type IA	z-Code - Type IA	South Africa

Filing Type Values will be updated to the Sequence Maintenance – Filing Type Values section in Data Administration if they do exist, otherwise added. List of affected values can be found in table below:

Old Filing Type	Filing Type	Display Name	Countries
Line extension - New Application	Line extension - New Application (De-Linking of Application)	Line extension - New Application (De-Linking of Application)	South Africa
Type I-Inspectorate	Type IA - Inspectorate	Type IA - Inspectorate	South Africa
Type I-Other	Type IAin - Inspectorate	Type IAin - Inspectorate	South Africa
z-Code-Quality	z-Code - Type II	z-Code - Type II	South Africa
Type IB-Related Clinical	Grouped Variation Clinical	Grouped Variation Clinical	South Africa
Type IB-Related Quality	Grouped Variation Quality	Grouped Variation Quality	South Africa
Type IB-Related Inspectorate	Grouped Variation Inspectorate	Grouped Variation Inspectorate	South Africa
Type II-Related Inspectorate	Type II - Inspectorate	Type II - Inspectorate	South Africa

Filing Type Values will be deactivated in the Sequence Maintenance – Filing Type Values section in Data Administration unless they are already deactivated. List of affected values can be found in table below:

Filing Type (Display Name)	Countries	Active Flag
Type II - Related Clinical	South Africa	Inactive
Type II - Related Quality	South Africa	Inactive

Filing Type eCTD codes

Filing Type eCTD codes will be added under the corresponding values in the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. List of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Type IB - Inspectorate	ZA-3-1	sub-type-45	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IAin	ZA-3-1	sub-type-47	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IB	ZA-3-1	sub-type-48	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II - Grouped Variation N and S	ZA-3-1	sub-type-49	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code - Type IA	ZA-3-1	sub-type-50	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

Filing Type eCTD codes will be updated under the corresponding values in the Sequence Maintenance – Filing Type Values section in Data Administration, if they do exist, otherwise added. List of affected values can be found in table below:

Old Filing Type	Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Line extension - New Application	Line extension - New Application (De-Linking of Application)	ZA-3-1	sub-type-14	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type I-Inspectorate	Type IA - Inspectorate	ZA-3-1	sub-type-22	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type I-Other	Type IAin - Inspectorate	ZA-3-1	sub-type-23	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
z-Code-Quality	z-Code - Type II	ZA-3-1	sub-type-32	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB-Related Clinical	Grouped Variation Clinical	ZA-3-1	sub-type-38	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB-Related Quality	Grouped Variation Quality	ZA-3-1	sub-type-39	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type IB-Related Inspectorate	Grouped Variation Inspectorate	ZA-3-1	sub-type-40	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS
Type II-Related Inspectorate	Type II - Inspectorate	ZA-3-1	sub-type-44	ZA-NP, REA AMAP, RIA JR, RIA WHO-PQ, RIA WHO-CRP, RIA CH-GHP, RIA EU-M4ALL, CTA, NDA, EUL, REA - WS

Sub Filing Type Values

Sub Filing Type Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-Screening	ZA-3-1	seq-type-13	All
Response-HPA Cert.Variation	ZA-3-1	seq-type-14	All
Response-Clinical 2	ZA-3-1	seq-type-15	All
Response-Quality 2	ZA-3-1	seq-type-16	All
Response-Inspectorate 2	ZA-3-1	seq-type-17	All
Response-N and S 2	ZA-3-1	seq-type-18	All
Response-Biological 2	ZA-3-1	seq-type-19	All
Response-Renewals 2	ZA-3-1	seq-type-20	All
Response-PV 2	ZA-3-1	seq-type-21	All

Sub Filing Type Values will be updated in the Submission Maintenance – Sub Filing Type Values section in Data Administration if they do exist, otherwise added. List of affected values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-Clinical 1	ZA-3-1	seq-type-3	All
Response-Quality 1	ZA-3-1	seq-type-4	All
Response-Inspectorate 1	ZA-3-1	seq-type-5	All
Response-N and S 1	ZA-3-1	seq-type-6	All
Response-Biological 1	ZA-3-1	seq-type-10	All
Response-Renewals 1	ZA-3-1	seq-type-11	All
Response-PV 1	ZA-3-1	seq-type-12	All

Evaluation Pathway Values

Evaluation Pathway Values will be updated in the Submission Maintenance – Evaluation Pathway Values section in Data Administration if it does exist, otherwise added. List of affected values can be found in table below:

Old Evaluation Pathway	New Evaluation Pathway	Applicable DTD/Schema	eCTD Code
Section 21	Section 21/EUL	ZA-3-1	eval-path-5

Regulatory Activity Lead Values

Regulatory Activity Lead Value will be added to the Submission Maintenance – Regulatory Activity Lead Values section in Data Administration if it does exist, otherwise added. List of new values can be found in table below:

Region	Regulatory Activity Lead	Applicable DTD/Schema	eCTD Code
South Africa	Medical Devices	ZA-3-1	sub-lead-7

Regulatory Activity Lead Value will be updated in the Submission Maintenance – Regulatory Activity Lead Values section in Data Administration if it does exist, otherwise added. List of affected values can be found in table below:

Old Regulatory Activity Lead	New Regulatory Activity Lead	Applicable DTD/Schema	eCTD Code
Complimentary	Complementary	ZA-3-1	sub-lead-2

Tunisia 1.1

If the TN region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'TN' in the database. Otherwise, the BA region is added with the values:

Region Abbreviation	Region Name	Active Flag
TN	Tunisia	Active

New TN country in the Application Maintenance – Country Values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
TN	Tunisia	tn	Tunisia	Active

Health Authority name for TN country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
TN	Tunisia	National Agency for Medicines and Health Products	ANMPS	TN-ANMPS	http://www.dpm.tn/

The French, Arabic and English languages will be added to the Tunisia in the Country – Language Values section in Data Administration. The Other - Language Values section will be updated with values listed on the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Arabic	ar	ARA	Active

If the 'TN-1-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'TN-1-1'. Otherwise, the 'TN-1-1' Assembly DTD/Schema will be added and mapped to the Tunisia region and Tunisia country.

Application Category Values will be added to the Application Maintenance – Application Category Values section in Data Administration if they do not already exist. The list of new values can be found in the table below:

Application Category Name	Active Flag
ANMPS National Procedure	Active
North African Joint Review	Active
WHO PQ CRP	Active

Reliance	Active
Emergency Use Licensing	Active

Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	Tunisia
WHO-CRP	WHO SRA CRP	WHO SRA CRP	New Drug Application	WHO SRA CRP	Tunisia
ANMPS	ANMPS National Procedure	ANMPS National Procedure	New Drug Application	ANMPS National Procedure	Tunisia
NAJR	North African Joint Review	North African Joint Review	New Drug Application	North African Joint Review	Tunisia
WHO-PQ - TN	WHO PQ CRP	WHO PQ CRP	New Drug Application	WHO PQ CRP	Tunisia
Reliance	Reliance	Reliance	New Drug Application	Reliance	Tunisia
EUL-TN	Emergency Use Licensing	Emergency Use Licensing	New Drug Application	Emergency Use Licensing	Tunisia

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Filing Type	Display Name	Countries
Amendment Filing	Amendment Filing	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See

		(Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Japan, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe, United States
Application Withdrawal/Cancellation	Application Withdrawal/Cancellation	South Africa, Tunisia
ASMF / DMF	ASMF / DMF	Australia, Tunisia
Baseline	Baseline	Australia, China, South Africa, Tunisia
Biological Master File (BMF)	Australia, Tunisia	Biological Master File (BMF)
Clinical Trial Application	Clinical Trial Application	Australia, South Africa, Tunisia
Clone	Clone	South Africa, Tunisia
Complementary Medicine - New	Complementary Medicine - New	Australia, South Africa, Tunisia
Line Extension Filing	Line Extension	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso,

		Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Line extension-New Application	Line extension-New Application	Tunisia
Line extension-New Dosage Form	Line extension-New Dosage Form	South Africa, Tunisia
Line extension-New Strength	Line extension-New Strength	South Africa, Tunisia
New Combination	New Combination	Australia, Switzerland, Tunisia
New Vaccines	New Vaccines	South Africa, Tunisia
Original Filing	Original Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland,

		Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, United States, Canada, Japan, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Great Britain, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Other Filing	Other Filing	United States, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam,

		Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Pharmacovigilance	Pharmacovigilance	Australia, South Africa, Tunisia
Plasma Master File (PMF)	Plasma Master File (PMF)	Australia, South Africa, Tunisia
Renewal Filing	Renewal Filing	Switzerland, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, China, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook

		Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Great Britain, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Jordan, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, South Africa, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Replica-Same	Replica-Same	South Africa, Tunisia
Technical Variation Filing	Technical Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African

		Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Tissue Master File (TMF)	Tissue Master File (TMF)	Australia, Tunisia
Undefined Regulatory Activity*	Undefined Regulatory Activity*	Australia, South Africa, Tunisia
Variation Filing	Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador,

		Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
New Chemical Entity	New Chemical Entity	Tunisia
New Generic (Multi-source)	New Generic (Multi-source)	Tunisia
New OTC	New OTC	Tunisia
New Radiopharmaceutical	New Radiopharmaceutical	Tunisia
New Gene and Cell Therapy	New Gene and Cell Therapy	Tunisia
New Blood Product	New Blood Product	Tunisia
New Biotherapeutic	New Biotherapeutic	Tunisia
New Biosimilar	New Biosimilar	Tunisia
New Traditional	New Traditional	Tunisia

New Excipient	New Excipient	Tunisia
New Vaccine Antigen Master File (VAMF)	New Vaccine Antigen Master File (VAMF)	Tunisia
Line Extension - New Route of Administration	Line Extension - New Route of Administration	Tunisia
Post Approval Commitment	Post Approval Commitment	Tunisia
VT Immediate Notification - Administrative	VT Immediate Notification - Administrative	Tunisia
VT Annual Notification - Administrative	VT Annual Notification - Administrative	Tunisia
VT Annual Notification - Quality	VT Annual Notification - Quality	Tunisia
VT Immediate Notification - Quality	VT Immediate Notification - Quality	Tunisia
VT Immediate Notification - Clinical	VT Immediate Notification - Clinical	Tunisia
VT Minor - Quality	VT Minor - Quality	Tunisia
VT Minor - Clinical	VT Minor - Clinical	Tunisia
VT Minor - Other	VT Minor - Other	Tunisia
VT Moderate - Quality	VT Moderate - Quality	Tunisia
VT Major - Safety (Clinical)	VT Major - Safety (Clinical)	Tunisia
VT Major - Safety and Efficacy (Clinical)	VT Major - Safety and Efficacy (Clinical)	Tunisia
VT Major - Quality	VT Major - Quality	Tunisia

VT Major - Change in Applicant - Relinquishing	VT Major - Change in Applicant - Relinquishing	Tunisia
VT Major - Change in Applicant - Acquiring	VT Major - Change in Applicant - Acquiring	Tunisia
Appeal	Appeal	Tunisia

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for TN-1-1 DTD/Schema is added to the value. List of new values can be found in table below:

Filing Type (Display Name)	**Applicable DTD/Schema**	**eCTD Code**	**Available for Application Type**
New Chemical Entity	tn-1-1	sub-type-1	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Combination	tn-1-1	sub-type-2	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Generic (Multi-source)	tn-1-1	sub-type-3	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New OTC	tn-1-1	sub-type-4	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Complementary Medicine - New	tn-1-1	sub-type-5	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccines	tn-1-1	sub-type-6	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Radiopharmaceutical	tn-1-1	sub-type-7	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Gene and Cell Therapy	tn-1-1	sub-type-8	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Blood Product	tn-1-1	sub-type-9	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biotherapeutic	tn-1-1	sub-type-10	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biosimilar	tn-1-1	sub-type-11	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Traditional	tn-1-1	sub-type-12	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

Clinical Trial Application	tn-1-1	sub-type-13	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Excipient	tn-1-1	sub-type-14	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
ASMF / DMF	tn-1-1	sub-type-15	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Plasma Master File (PMF)	tn-1-1	sub-type-16	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccine Antigen Master File (VAMF)	tn-1-1	sub-type-17	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Tissue Master File (TMF)	tn-1-1	sub-type-18	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Biological Master File (BMF)	tn-1-1	sub-type-19	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Dosage Form	tn-1-1	sub-type-20	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Strength	tn-1-1	sub-type-21	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line Extension - New Route of Administration	tn-1-1	sub-type-22	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Application	tn-1-1	sub-type-23	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Clone	tn-1-1	sub-type-24	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Replica-Same	tn-1-1	sub-type-25	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Post Approval Commitment	tn-1-1	sub-type-26	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Administrative	tn-1-1	sub-type-27	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Administrative	tn-1-1	sub-type-28	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Quality	tn-1-1	sub-type-29	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Quality	tn-1-1	sub-type-30	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Clinical	tn-1-1	sub-type-31	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP

			- TN, Reliance, EUL-TN
VT Minor - Quality	tn-1-1	sub-type-32	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Clinical	tn-1-1	sub-type-33	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Other	tn-1-1	sub-type-34	TN, Reliance, EUL-TN ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP
VT Moderate - Quality	tn-1-1	sub-type-35	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety (Clinical)	tn-1-1	sub-type-36	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety and Efficacy (Clinical)	tn-1-1	sub-type-37	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Quality	tn-1-1	sub-type-38	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Relinquishing	tn-1-1	sub-type-39	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Acquiring	tn-1-1	sub-type-40	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Baseline	tn-1-1	sub-type-41	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Renewal Filing	tn-1-1	sub-type-42	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Application Withdrawal/Cancellation	tn-1-1	sub-type-43	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Pharmacovigilance	tn-1-1	sub-type-44	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Undefined Regulatory Activity*	tn-1-1	sub-type-45	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Appeal	tn-1-1	sub-type-46	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

Applicant Contact Type Values will be added to the Submission Maintenance – Applicant Contact Type Values section in Data Administration if they do not already exist. A complete list of values can be found in table below:

eCTD Standard Type	Region	Regulatory Code	Applicant Contact Type

eCTD 3.2	Tunisia	contact-type-1	Local Applicant
eCTD 3.2	Tunisia	contact-type-2	Regulatory
eCTD 3.2	Tunisia	contact-type-3	Technical
eCTD 3.2	Tunisia	contact-type-4	Product Information

Sub Filing Type Values will be added to the Sequence Maintenance – Sub Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Sub Filing Type	Countries	Active Flag
Initial	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Supplementary Information	South Africa, Tunisia	Active
Closing Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Work Grouping Partial Withdrawal	Tunisia	Active
Submission Withdrawal	South Africa, Tunisia	Active
Response - Screening Content	Tunisia	Active
Response - Screening Payment	Tunisia	Active
Response - Evaluation Quality	Tunisia	Active
Response - Evaluation Clinical	Tunisia	Active
Response - Evaluation Admin	Tunisia	Active
Response - Pharmacovigilance	Tunisia	Active
Priority Response	Tunisia	Active

Sub Filing Type eCTD codes Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for TN-1-1 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type	Applicable	eCTD Code	Available for Filing Type

(Display Name)	DTD/Schema		
Initial	tn-1-1	seq-type-1	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Supplementary Information	tn-1-1	seq-type-2	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Content	tn-1-1	seq-type-3	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF),

			New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Payment	tn-1-1	seq-type-4	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Quality	tn-1-1	seq-type-5	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT

			Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Clinical	tn-1-1	seq-type-6	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Admin	tn-1-1	seq-type-7	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal

Response Pharmacovigilance	tn-1-1	seq-type-8	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Closing Information	tn-1-1	seq-type-9	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Work Grouping Partial Withdrawal	tn-1-1	seq-type-10	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF),

			Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Submission Withdrawal	tn-1-1	seq-type-11	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Priority Response	tn-1-1	seq-type-12	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate -

			Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal

Bosnia and Herzegovina 3.1

If the BA region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'BA' in the database. Otherwise, the BA region is added with the values:

Region Abbreviation	Region Name	Active Flag
BA	Bosnia and Herzegovina	Active

New BA country in the Application Maintenance – Country Values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
BA	Bosnia and Herzegovina	ba	Bosnia and Herzegovina	Active

Health Authority name for BA country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
BA	Bosnia and Herzegovina	Agency for medicinal products and medical devices of Bosnia and Herzegovina	ALMBIH	BA-ALMBIH	https://almbih.gov.ba/

The Bosnian, Serbian, and English languages will be added to the Bosnia and Herzegovina in the Country – Language Values section in Data Administration. The Other - Language Values section will be updated with values listed on the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Bosnian	bs	BOS	Active
Serbian	sr	SRP	Active

If the 'BA-3-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'BA-3-1'. Otherwise, the 'BA-3-1' Assembly DTD/Schema will be added and mapped to the Bosnia and Herzegovina region and Bosnia and Herzegovina country.

Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
CTA	Clinical Trial Authorisation	Clinical Trial Authorisation	Clinical Trial Application	Clinical Trial	Armenia,Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Ukraine, Undefined, United Kingdom, and all ROW countries.

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. A complete list of values can be found in table below:

Filing Type	Display Name	Countries
Article 16c (1c)i Referral	Article 16c (1c)i Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Northern Ireland, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Additional PV Activity in the RMP Related to PAM	Additional PV Activity in the RMP Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Annex II Condition Related to PAM	Annex II Condition Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg,

		Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Annual Reassessment Filing	Annual Reassessment Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 107i Referral	Article 107i Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 16c(4) Referral	Article 16c(4) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 18 Filing	Article 18 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 20 Referral	Article 20 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 29 Paediatric Referral	Article 29 Paediatric Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 29(4) Referral	Article 29(4) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 30 Referral	Article 30 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece,

		Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 31 Referral	Article 31 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 35 Referral	Article 35 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 5(3) Referral	Article 5(3) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 58 Filing	Article 58 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
ASMF Filing	ASMF Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
CEP Submission	CEP Submission	EDQM, Jordan, Bosnia and Herzegovina
Clinical Data for Publication – Final Version	Clinical Data for Publication – Final Version	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Clinical Data for Publication – Redacted Proposal	Clinical Data for Publication – Redacted Proposal	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg,

		Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Corrective/Preventive Action Related to PAM	Corrective/Preventive Action Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Extension Filing	Extension Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
Legally Binding Measure Related to PAM	Legally Binding Measure Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Lifting Suspension Filing	Lifting Suspension Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Marketing Authorisation Application	Marketing Authorisation Application	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom
National Variation Filing	National Variation Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
None	None	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom

Notification 61-3 Filing	Notification 61-3 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Article 29 Filing	PAED Article 29 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Article 45	PAED Article 45	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Article 46	PAED Article 46	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Related to PIP (Article 7, 8, 30)	PAED Related to PIP (Article 7, 8, 30)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Paediatric Submission Related to PAM (Article 45)	Paediatric Submission Related to PAM (Article 45)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Paediatric Submission Related to PAM (Article 46)	Paediatric Submission Related to PAM (Article 46)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAES Submission Related to PAM	PAES Submission Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

PASS Protocol Submission (Article 107n)	PASS Protocol Submission (Article 107n)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PASS Report Submission (Article 107q)	PASS Report Submission (Article 107q)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Periodic Safety Update Report	Periodic Safety Update Report	Australia, China, United States, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Switzerland, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Plasma Master File	Plasma Master File	Switzerland, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PSUR single assessment procedure	PSUR single assessment procedure	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Recommendation Related to PAM	Recommendation Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Repeat Use Procedure	Repeat Use Procedure	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Risk Management Plan Filing	Risk Management Plan Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
SDA Submission Related to PAM	SDA Submission Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Specific Obligation Related to PAM	Specific Obligation Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Transfer MA Filing	Transfer MA Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Switzerland, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
USR Filing	USR Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Variation 1A Filing	Variation 1A Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 1AIN Filing	Variation 1AIN Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom

Variation 1B Filing	Variation 1B Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 2 Filing	Variation 2 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Withdrawal Filing	Withdrawal	Undefined, United States, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Switzerland, South Africa, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for BA-3-1 DTD/Schema is added to the value. List of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Marketing Authorisation Application	ba-3-1	maa	CTA, NDA
Variation 1A Filing	ba-3-1	var-type1a	CTA, NDA
Variation 1AIN Filing	ba-3-1	var-type1ain	CTA, NDA
Variation 1B Filing	ba-3-1	var-type1b	CTA, NDA
Variation 2 Filing	ba-3-1	var-type2	CTA, NDA
National Variation Filing	ba-3-1	var-nat	CTA, NDA
Extension Filing	ba-3-1	extension	CTA, NDA
Repeat Use Procedure	ba-3-1	rup	CTA, NDA
Periodic Safety Update Report	ba-3-1	psur	CTA, NDA
PSUR single assessment procedure	ba-3-1	psusa	CTA, NDA
Risk Management Plan Filing	ba-3-1	rmp	CTA, NDA
Renewal Filing	ba-3-1	renewal	CTA, NDA
Specific Obligation Related to PAM	ba-3-1	pam-sob	CTA, NDA
Annex II Condition Related to PAM	ba-3-1	pam-anx	CTA, NDA
Additional PV Activity in the RMP Related to PAM	ba-3-1	pam-mea	CTA, NDA
Legally Binding Measure Related to PAM	ba-3-1	pam-leg	CTA, NDA
SDA Submission Related to PAM	ba-3-1	pam-sda	CTA, NDA
Corrective/Preventive Action Related to PAM	ba-3-1	pam-capa	CTA, NDA
Paediatric Submission Related to PAM (Article 45)	ba-3-1	pam-p45	CTA, NDA
Paediatric Submission Related to PAM (Article 46)	ba-3-1	pam-p46	CTA, NDA
PAES Submission Related to PAM	ba-3-1	pam-paes	CTA, NDA
Recommendation Related to PAM	ba-3-1	pam-rec	CTA, NDA
PASS Protocol Submission (Article 107n)	ba-3-1	pass107n	CTA, NDA
PASS Report Submission (Article 107q)	ba-3-1	pass107q	CTA, NDA
ASMF Filing	ba-3-1	asmf	CTA, NDA
Plasma Master File	ba-3-1	pmf	CTA, NDA
Article 20 Referral	ba-3-1	referral-20	CTA, NDA

Article 29(4) Referral	ba-3-1	referral-294	CTA, NDA
Article 29 Paediatric Referral	ba-3-1	referral-29p	CTA, NDA
Article 30 Referral	ba-3-1	referral-30	CTA, NDA
Article 31 Referral	ba-3-1	referral-31	CTA, NDA
Article 35 Referral	ba-3-1	referral-35	CTA, NDA
Article 5(3) Referral	ba-3-1	referral-5-3	CTA, NDA
Article 107i Referral	ba-3-1	referral-107i	CTA, NDA
Article 16c (1c)i Referral	ba-3-1	referral-16c1c	CTA, NDA
Article 16c(4) Referral	ba-3-1	referral-16c4	CTA, NDA
Annual Reassessment Filing	ba-3-1	annual-reassessment	CTA, NDA
USR Filing	ba-3-1	usr	CTA, NDA
Clinical Data for Publication – Redacted Proposal	ba-3-1	clin-data-pub-rp	CTA, NDA
Clinical Data for Publication – Final Version	ba-3-1	clin-data-pub-fv	CTA, NDA
PAED Related to PIP (Article 7, 8, 30)	ba-3-1	paed-7-8-30	CTA, NDA
PAED Article 29 Filing	ba-3-1	paed-29	CTA, NDA
PAED Article 45	ba-3-1	paed-45	CTA, NDA
PAED Article 46	ba-3-1	paed-46	CTA, NDA
Article 58 Filing	ba-3-1	article-58	CTA, NDA
Notification 61-3 Filing	ba-3-1	notification-61-3	CTA, NDA
Transfer MA Filing	ba-3-1	transfer-ma	CTA, NDA
Lifting Suspension Filing	ba-3-1	lifting-suspension	CTA, NDA
Withdrawal Filing	ba-3-1	withdrawal	CTA, NDA
CEP Submission	ba-3-1	cep	CTA, NDA
None	ba-3-1	none	CTA, NDA
Article 18 Filing	ba-3-1	article-18	CTA, NDA

Sub Filing Type Values will be added to the Sequence Maintenance – Sub Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Sub Filing Type	Countries	Active Flag
Initial	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Closing Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Validation Response	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Response	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Additional Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Consolidating	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece,	Active

	Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	
Corrigendum	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Reformat	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Re-examination	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active

Sub Filing Type eCTD codes Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for BA-3-1 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type (Display Name)	**Applicable DTD/Schema**	**eCTD Code**	**Available for Filing Type**
Initial	ba-3-1	initial	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission

			Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Validation Response	ba-3-1	validation-response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Response	ba-3-1	response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV

			Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Additional Information	ba-3-1	additional info	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Closing Information	ba-3-1	closing	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation

			Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Consolidating	ba-3-1	consolidating	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA

			Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Corrigendum	ba-3-1	corrigendum	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Reformat	ba-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing,

			USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Re-examination	ba-3-1	re-examination	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Entity Updates

Pharmaceutical Product

A new not required multi-select field ‘Manufactured Items’ is added to the Pharmaceutical Product entity. It will show only those Manufactured Items which are created under selected Components in the field above.

Pharmaceutical Product Reference Substance

It is now possible to have more than one Reference Substance for Pharmaceutical Product Substance. Cardinality for the entities has been updated.

Manufactured Item Reference Substance

It is now possible to have more than one Reference Substance for Manufactured Item Substance. Cardinality for the entities has been updated.

Event

Following changes apply:

- Event:
  - A new field ‘Pending Changes’ is added to indicate if with the Event Closure as ‘Approved’ were existing pending changes applied or not by the user.
- Country tab:
  - A new column called ‘Original Projected Date’ is added.
  - A new icon called ‘Save Projected Date(s)’ is added.
- Country Schedule’s tab:
  - A new column called ‘Original Projected Date’ is added.
- Pending Changes tab:
  - A new icon ‘Set Filter’ papers after migration.

Event-Country Status

A new read-only field called ‘Original Projected Date’ is added to the Event-Country Status entity. This field will be auto populated with data from ‘Projected Date’ when user selects ‘Save Projected Date(s)’ button.

PDS Manufacturer Detail

The Copy URL icon is available for Manufacturer Nodes across the PDS Tree.

PDS Package Detail

The ‘Data Carrier Identifier' field is now hidden OOTB from the UI.

PDS Packaging Detail

Following changes apply:

- Fields have been renamed OOTB in UI:
  - Device Quantity Operator to Package Item Device Quantity Operator
  - Device Quantity to Package Item Device Quantity
  - Device Quantity Unit to Package Item Device Quantity Unit
- Default value has been changed from ‘Equal’ to ‘Select’ for:
  - Package Item Quantity Operator
  - Package Item - MI Quantity Operator
  - Package Item Device Quantity Operator
- ‘Package Item - MI Quantity Unit’ field now shows only ‘Unit of Measurements’ value list from Data Administration

The ‘Package Item Device Quantity Unit’ field includes only countable values from the ‘Units of Measurement’ value list with Yes selected in the field 'Include in Quantity Unit'.

IDMP Tab

PMSID Country has been deleted from IDMP tab on Application Attributes screen.

Registration Package Set Type

Following changes apply:

- The field ‘ATC Code Flag’ is renamed in UI to ‘ATC Request’.
- A new not required drop-down field ‘National Classification’ is added to the Registration entity.

PCIDs

The tab has been updated:

- A new field ‘Medicinal Product’ which shows in a format Medicinal Product Name + PMSID
- A new field ‘MPID’ depending on the selection for ‘Medicinal Product’
- Country field was deleted

PCID Tab is now have the following column order:

- PCID
- Medicinal Product in a format Medicinal Product Name + PMSID
- Version
- Version Date

Full Product Presentation

The Full Product Presentation Name has been updated to a text area which supports format with separate lines with line breaks in UI.

Medicinal Product

New fields have been added to the entity:

- ‘PMSID’, a not required text field is now available.
- 'Ennov Medicinal Product', a read only field with the ability to be updated through API is added.
- 'IDMP Last Submission Date', a not required data field is added.
- A new db only field ‘Ennov IDMP ID MP’.

The fields updated:

- ‘Genetically Modified Organisms’ is updated to show True/False values. Previous values to be migrated as Yes=True and No=False, respectively.
- ‘Registrations’ field is now a hyperlink to ‘Registration Attributes’ screen.
- ‘Product’ field is now a hyperlink to ‘Product Attributes’ screen.
- ‘Package Sets’ field is now a hyperlink to ‘Registration-Package Set Attributes’ screen.

The new icons have been added:

- ‘Copy URL’ icon is now available.
    - When Medicinal Product has PMSID value copied link will include it, if not the entity ID from the data base will be shown.
- ‘Create Ennov IDMP Medicinal Product’ icon is now available to trigger Ennov IDMP REST API for IDMP Medicinal Product(s).

PMSIDs

The tab is no longer available on the Medicinal Product Attributes screen.

MPIDs

The ‘MPID’ is updated:

- PMSID is a read only field
- Country has been deleted

Medicinal Product Name

The field ‘Trademark or Company Name Part’ is renamed in UI to ’Company Name Part’.

Medicinal Product Actions

The entity has been updated with:

- ‘Sequence’ field is now not required OOTB field.
- ‘Ennov IDMP Submission Plan’, a new not required read only field is added under Medicinal Product Name. Can be updated via API.
- ‘Regulatory Application Submission Type’ field is now not required OOTB field.
- ‘FHIR Protocol Type’ is now Hidden OOTB field.
- ‘Content of Change’ has been renamed in UI to ‘Content Scope’.
- ‘Provenance Reason’ has been renamed in UI to ‘Message Reason’.
- ‘Status’ field is now not required OOTB field.

The creation of Medicinal Product Actions has been changed, only those Medicinal Products can be selected from required field which include value in the ‘Ennov Medicinal Product’ field. After migration there will be no Medicinal Product Actions added for previous versions due to change in the creation rules for the entity.

The ‘Create Ennov IDMP Submission Plan’ icon is now available. When executed ‘Ennov IDMP Submission Plan’ will be updated though API with hyperlinked value to navigate in Ennov IDMP system.

Selection Widget Replacement

Selection widget has been replaced by new moder version for:

- Data Administration -> Certificate Master File Values:
    - Related Application field.
- Pharmaceutical Product Selection:
    - Create Medicinal Product ->Pharmaceutical Products field
    - Pharmaceutical Products tab on Medicinal Product Attributes screen ->Associate/Dissociate Pharmaceutical Products
    - Create Full Product Presentation ->Pharmaceutical Products field
    - Pharmaceutical Products tab on Full Product Presentation Attributes screen ->Associate/Dissociate Pharmaceutical Products
- Registration Attachment Selection:
    - Registration FPP Attachment -> Attachment Name field.
- Product Selection:
    - Event -> Copy Event ->Products field.
- Associate Change Detail to Event:
    - Select Change Detail(s) field.
- Substance Selection in Querying:
    - Applications Submitted and/or Approved and/or Terminated within a Date Range report -> Active Ingredient field.

- List of Manufacturers From Data Administration report -> Detail Name ->Substance.

IDMP Strength Rules for Tables

The IDMP entities which holds IDMP Strength information have been updated to display it. After migration tab information will be shown following by the rules below.

For IDMP Presentation and Concentration Strength information:

- If the 'Presentation Single/Low Limit Denominator - Unit of Presentation/Measurement' attribute is not blank, then append the displayed value with '/ ' in any related grid, tab, or table.

- If a value for 'Presentation Single/Low Limit Denominator Value' is not equal to '1'. '1.0', or blank, then include that value in the IDMP Presentation Strength display.

  - Example: If value is 1.0, display as 4.0 milligram(s) / millitre(s). If 2.0, display as 4.0 milligram(s) / 2.0 millitre(s).

- The same rules apply for High Limit values.

If a Strength (Presentation) Quantity Operator other than Range was selected, only values for the Low Limit fields are displayed.

- If Range is selected, both Low and High values are shown.

Rules applied to the following entities:

- Component Active Ingredient/Reference Active Ingredient
- Pharmaceutical Product Active Ingredient /Reference Active Ingredient
- Pharmaceutical Product Substance/Reference Substance
- Manufactured Item Active Ingredient /Reference Active Ingredient
- Manufactured Item Substance/Reference Substance
- Pharmaceutical Product tab
- Pharmaceutical Product Selection on Medicinal Product/Full Product Presentation

xEVMPD Submission Wizard

The xEVMPD Submission Wizard now includes special characters to support separate lines format for the Full Product Presentation Name on Full Product Presentation entity.

SEARCH -> Product Detail Sets

The Product Detail Sets option is now available for selection for SEARCH capability on Home page. When configured additional functionality with different search mechanisms is available, to enable functionality a check box must be selected for PowerSearch option.

For more information, please refer to the best practices document created for PowerSearch.

Querying -> Administration -> Entity Audit

The Entity Audit Trail Query now includes following entities:

- Product Component

- Comparator
- PDS Shelf Life Detail

Sender-defined keywords

Upon migration every sender-defined keyword (SDK) gets a Keyword Type assigned. The Type is defined based on the following rules:

- SDK that is already assigned to a field – a type basing on a keyword type defined for this field.
- SDK that is not assigned to any field – such SDK is to be deleted from the database
- The same SDK assigned to more than one field – additional SDK to be generated, one per each field, with the same name. The code to avoid duplication gets increment added in the end, after underscore: prdct_1, prdct_2.

Valid Values 6.0

Upon migration the Default Publishing Settings Library Template (PLT) gets stf-2-2-6-0 selected in XML Definitions.

Veeva integration

Upon migration the links to all Veeva documents keep the same look and feel for the user.

Verify Migration Script Updates

Singapore 1.0

The migration script will perform multiple changes to Data Administration data related to SG 1.0. These should be verified, and where necessary, updated. The script does following:

- Creates or updates the Singapore region to have the code value 'SG' in the database.
- Creates or updates the Singapore country and associates it with the Singapore region.
- Updates Health Authority Name to Health Sciences Authority, Health Authority Abbreviation to HSA, Health Authority eCTD Code to SG-HSA and Health Authority Website to https://www.hsa.gov.sg/ in Application Maintenance – Country Values.
- Adds the 'SG-1-0' assembly DTD type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it does not already exist.
- Updates 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration, to make it activated (if inactive) and updates to include the Singapore country.
- Updates Application Maintenance – Application Type Values with Therapeutic Products value and assigns app-type-1 eCTD code.
- Creates Therapeutic Products Application Category in Application Maintenance – Application Category Values.
- Creates or updates the Malay, Tamil, Singaporean Mandarin languages in Other – Language Values.

- Assigns English, Malay, Tamil, Singaporean Mandarin languages to Singapore country.
- Updates Sequence Maintenance – Filing Type Values with following values and assigns corresponding eCTD codes:
    - NDA
    - NDA-V
    - GDA
    - GDA-V/CECA
    - MAV1
    - MAV1-V
    - MAV2
    - MIV1-PI
    - MIV1-PI-V
    - MIV1-CMC
    - MIV1-CMC-V
    - MIV2-N
    - MIV2-DnT
    - PV-EDU/RMP Materials
    - PV-PBRER/RMP Reports
    - Reg Cond (non-PV)
    - DMF Filing
    - Baseline
    - Transfer MA Filing
    - Other Regulatory Activity
- Updates **Submission Maintenance – Sub Filing Type Values** with following values and assigns corresponding eCTD codes:

        - Initial
        - Supplementary Information
        - Response
        - Closing Information
        - Submission Withdrawal
- Updates Submission Maintenance – Applicant Contact Type Values with following values and assigns corresponding codes:
        - Regulatory
        - Technical
        - Agent Singapore
- Updates Submission Maintenance – Telephone Number Type Values with following value and assigns corresponding code:
        - Business Telephone Number

Tunisia 1.1

The migration script will perform multiple changes to Data Administration data related to TN 1.1. These should be verified, and where necessary, updated. The script performs the following updates:

- Creates or updates the Tunisia region to have the code value 'TN' in the database.
- Creates or updates the Tunisia country and associates it with the Tunisia region.
- Updates Health Authority Name to "National Agency for Medicines and Health Products", Health Authority Abbreviation to ANMPS, Health Authority eCTD Code to TN-ANMPS and Health Authority Website to http://www.dpm.tn/ in Application Maintenance – Country Values
- Creates or updates the Arabic language in Other-Language Values and associates it with the Tunisia country, as well as French and English.
- Adds the 'TN-1-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it did not exist before If existed, it will be activated (if inactive) and updated to have the code value 'TN-1-1'.
- Adds following Application Category values in the Application Maintenance – Application Category Values section in Data Administration:
    - ANMPS National Procedure
    - North African Joint Review
    - WHO PQ CRP
    - Reliance
    - Emergency Use Licensing

- Updates Application Maintenance – Application Type Values with following values, including assignment of corresponding eCTD codes:
    - AMA Procedure value and assigns app-type-2 eCTD code.
    - WHO SRA CRP value and assigns app-type-5 eCTD code.
    - ANMPS National Procedure value and assigns app-type-1 eCTD code.
    - North African Joint Review value and assigns app-type-3 eCTD code.
    - WHO PQ CRP value and assigns app-type-4 eCTD code.
    - Reliance value and assigns app-type-6 eCTD code.
    - Emergency Use Licensing value and assigns app-type-7 eCTD code.
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
    - New Chemical Entity
    - New Combination
    - New Generic (Multi-source)
    - New OTC
    - Complementary Medicine - New
    - New Vaccines
    - New Radiopharmaceutical
    - New Gene and Cell Therapy
    - New Blood Product
    - New Biotherapeutic
    - New Biosimilar
    - New Traditional
    - Clinical Trial Application
    - New Excipient
    - ASMF / DMF
    - Plasma Master File (PMF)
    - New Vaccine Antigen Master File (VAMF)
    - Tissue Master File (TMF)
    - Biological Master File (BMF)
    - Line extension-New Dosage Form
    - Line extension-New Strength
    - Line Extension - New Route of Administration
    - Line extension-New Application
    - Clone
    - Replica-Same
    - Post Approval Commitment
    - VT Immediate Notification - Administrative
    - VT Annual Notification - Administrative
    - VT Annual Notification - Quality
    - VT Immediate Notification - Quality
    - VT Immediate Notification - Clinical
    - VT Minor - Quality

    - VT Minor - Clinical
    - VT Minor - Other
    - VT Moderate - Quality
    - VT Major - Safety (Clinical)
    - VT Major - Safety and Efficacy (Clinical)
    - VT Major - Quality
    - VT Major - Change in Applicant - Relinquishing
    - VT Major - Change in Applicant - Acquiring
    - Baseline
    - Renewal Filing
    - Application Withdrawal/Cancellation
    - Pharmacovigilance
    - Undefined Regulatory Activity*
    - Appeal
- Updates Applicant Contact Type values in the Submission Maintenance – Applicant Contact Type Values with the following values:
    - Local Applicant
    - Regulatory
    - Technical
    - Product Information
- Updates Submission Maintenance – Sub Filing Type Values with following values and assigns corresponding eCTD codes:
    - Initial
    - Supplementary Information
    - Response - Screening Content
    - Response - Screening Payment
    - Response - Evaluation Quality
    - Response - Evaluation Clinical
    - Response - Evaluation Admin
    - Response - Pharmacovigilance
    - Closing Information
    - Work Grouping Partial Withdrawal
    - Submission Withdrawal
    - Priority Response

Bosnia and Herzegovina 3.1

The migration script will perform multiple changes to Data Administration data related to BA 3.1. These should be verified, and where necessary, updated. The script performs the following updates:

- Creates or updates the Bosnia and Herzegovina region to have the code value ‘BA’ in the database.
- Creates or updates the Bosnia and Herzegovina country and associates it with the Bosnia and Herzegovina region.
- Updates Health Authority Name to ‘Agency for medicinal products and medical devices of Bosnia and Herzegovina’, Health Authority Abbreviation to ALMBIH, Health Authority eCTD Code to BA-ALMBIH and

Health Authority Website to https://almbih.gov.ba/ in Application Maintenance – Country Values

- Creates or updates the Bosnian and Serbian languages in Other-Language Values and associates them with the Bosnia and Herzegovina country, as well as English.
- Adds the 'BA-3-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it did not exist before If existed, it will be activated (if inactive) and updated to have the code value 'BA-3-1'.
- Updates Application Maintenance – Application Type Values with following value:
    - Clinical Trial Authorisation
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
    - Marketing Authorisation Application
    - Variation 1A Filing
    - Variation 1AIN Filing
    - Variation 1B Filing
    - Variation 2 Filing
    - National Variation Filing
    - Extension Filing
    - Repeat Use Procedure
    - Periodic Safety Update Report
    - PSUR single assessment procedure
    - Risk Management Plan Filing
    - Renewal Filing
    - Specific Obligation Related to PAM
    - Annex II Condition Related to PAM
    - Additional PV Activity in the RMP Related to PAM
    - Legally Binding Measure Related to PAM
    - SDA Submission Related to PAM
    - Corrective/Preventive Action Related to PAM
    - Paediatric Submission Related to PAM (Article 45)
    - Paediatric Submission Related to PAM (Article 46)
    - PAES Submission Related to PAM
    - Recommendation Related to PAM
    - PASS Protocol Submission (Article 107n)
    - PASS Report Submission (Article 107q)
    - ASMF Filing
    - Plasma Master File
    - Article 20 Referral
    - Article 29(4) Referral
    - Article 29 Paediatric Referral
    - Article 30 Referral
    - Article 31 Referral
    - Article 35 Referral

    - Article 5(3) Referral
    - Article 107i Referral
    - Article 16c (1c)i Referral
    - Article 16c(4) Referral
    - Annual Reassessment Filing
    - USR Filing
    - Clinical Data for Publication – Redacted Proposal
    - Clinical Data for Publication – Final Version
    - PAED Related to PIP (Article 7, 8, 30)
    - PAED Article 29 Filing
    - PAED Article 45
    - PAED Article 46
    - Article 58 Filing
    - Notification 61-3 Filing
    - Transfer MA Filing
    - Lifting Suspension Filing
    - Withdrawal Filing
    - CEP Submission
    - None
    - Article 18 Filing
- Updates Submission Maintenance – Sub Filing Type Values with following values and assigns corresponding eCTD codes:
    - Initial
    - Validation Response
    - Response
    - Additional Information
    - Closing Information
    - Consolidating
    - Corrigendum
    - Reformat
    - Re-examination

Chapter 4. Ennov InSight 7.3.4-Reg-Update Updates

Data Administration Updates

Tunisia 1.1

If the TN region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'TN' in the database. Otherwise, the BA region is added with the values:

Region Abbreviation	Region Name	Active Flag
TN	Tunisia	Active

New TN country in the Application Maintenance – Country Values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
TN	Tunisia	tn	Tunisia	Active

Health Authority name for TN country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
TN	Tunisia	National Agency for Medicines and Health Products	ANMPS	TN-ANMPS	http://www.dpm.tn/

The French, Arabic and English languages will be added to the Tunisia in the Country – Language Values section in Data Administration. The Other - Language Values section will be updated with values listed on the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Arabic	ar	ARA	Active

If the 'TN-1-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'TN-1-1'. Otherwise, the 'TN-1-1' Assembly DTD/Schema will be added and mapped to the Tunisia region and Tunisia country.

Application Category Values will be added to the Application Maintenance – Application Category Values section in Data Administration if they do not already exist. The list of new values can be found in the table below:

Application Category Name	**Active Flag**
ANMPS National Procedure	Active
North African Joint Review	Active
WHO PQ CRP	Active
Reliance	Active
Emergency Use Licensing	Active

Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	South Africa, Tunisia
WHO-CRP	WHO SRA CRP	WHO SRA CRP	New Drug Application	WHO SRA CRP	South Africa, Tunisia
ANMPS	ANMPS National Procedure	ANMPS National Procedure	New Drug Application	ANMPS National Procedure	Tunisia
NAJR	North African Joint Review	North African Joint Review	New Drug Application	North African Joint Review	Tunisia
WHO-PQ - TN	WHO PQ CRP	WHO PQ CRP	New Drug Application	WHO PQ CRP	Tunisia
Reliance	Reliance	Reliance	New Drug Application	Reliance	Tunisia
EUL-TN	Emergency Use Licensing	Emergency Use Licensing	New Drug Application	Emergency Use Licensing	Tunisia

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Filing Type	Display Name	Countries
Amendment Filing	Amendment Filing	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Japan, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe, United States

Filing Type	Display Name	Countries
Application Withdrawal/Cancellation	Application Withdrawal/Cancellation	South Africa, Tunisia
ASMF / DMF	ASMF / DMF	Australia, Tunisia
Baseline	Baseline	Australia, China, South Africa, Tunisia
Biological Master File (BMF)	Australia, Tunisia	Biological Master File (BMF)
Clinical Trial Application	Clinical Trial Application	Australia, South Africa, Tunisia
Clone	Clone	South Africa, Tunisia
Complementary Medicine - New	Complementary Medicine - New	Australia, South Africa, Tunisia
Technical Mistake	Technical Mistake	Ukraine
Line Extension Filing	Line Extension	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe

Filing Type	Display Name	Countries
Line extension-New Application	Line extension-New Application	South Africa, Tunisia
Line extension-New Dosage Form	Line extension-New Dosage Form	South Africa, Tunisia
Line extension-New Strength	Line extension-New Strength	South Africa, Tunisia
New Combination	New Combination	Australia, Switzerland, Tunisia
New Vaccines	New Vaccines	South Africa, Tunisia
Original Filing	Original Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, United States, Canada, Japan, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Great Britain, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Other Filing	Other Filing	United States, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin,

Filing Type	Display Name	Countries
		Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Pharmacovigilance	Pharmacovigilance	Australia, South Africa, Tunisia
Plasma Master File (PMF)	Plasma Master File (PMF)	Australia, South Africa, Tunisia
Renewal Filing	Renewal Filing	Switzerland, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, China, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Great Britain, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Jordan, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia,

Filing Type	Display Name	Countries
		Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, South Africa, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Replica-Same	Replica-Same	South Africa, Tunisia
Technical Variation Filing	Technical Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay,

Filing Type	Display Name	Countries
		Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Tissue Master File (TMF)	Tissue Master File (TMF)	Australia, Tunisia
Undefined Regulatory Activity*	Undefined Regulatory Activity*	Australia, South Africa, Tunisia
Variation Filing	Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
New Chemical Entity	New Chemical Entity	Tunisia
New Generic (Multi-source)	New Generic (Multi-source)	Tunisia
New OTC	New OTC	Tunisia
New Radiopharmaceutical	New Radiopharmaceutical	Tunisia

Filing Type	Display Name	Countries
New Gene and Cell Therapy	New Gene and Cell Therapy	Tunisia
New Blood Product	New Blood Product	Tunisia
New Biotherapeutic	New Biotherapeutic	Tunisia
New Biosimilar	New Biosimilar	Tunisia
New Traditional	New Traditional	Tunisia
New Excipient	New Excipient	Tunisia
New Vaccine Antigen Master File (VAMF)	New Vaccine Antigen Master File (VAMF)	Tunisia
Line Extension - New Route of Administration	Line Extension - New Route of Administration	Tunisia
Post Approval Commitment	Post Approval Commitment	Tunisia
VT Immediate Notification - Administrative	VT Immediate Notification - Administrative	Tunisia
VT Annual Notification - Administrative	VT Annual Notification - Administrative	Tunisia
VT Annual Notification - Quality	VT Annual Notification - Quality	Tunisia
VT Immediate Notification - Quality	VT Immediate Notification - Quality	Tunisia
VT Immediate Notification - Clinical	VT Immediate Notification - Clinical	Tunisia
VT Minor - Quality	VT Minor - Quality	Tunisia
VT Minor - Clinical	VT Minor - Clinical	Tunisia
VT Minor - Other	VT Minor - Other	Tunisia
VT Moderate - Quality	VT Moderate - Quality	Tunisia
VT Major - Safety (Clinical)	VT Major - Safety (Clinical)	Tunisia

Filing Type	Display Name	Countries
VT Major - Safety and Efficacy (Clinical)	VT Major - Safety and Efficacy (Clinical)	Tunisia
VT Major - Quality	VT Major - Quality	Tunisia
VT Major - Change in Applicant - Relinquishing	VT Major - Change in Applicant - Relinquishing	Tunisia
VT Major - Change in Applicant - Acquiring	VT Major - Change in Applicant - Acquiring	Tunisia
Appeal	Appeal	Tunisia

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for TN-1-1 DTD/Schema is added to the value. List of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
New Chemical Entity	tn-1-1	sub-type-1	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Combination	tn-1-1	sub-type-2	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Generic (Multi-source)	tn-1-1	sub-type-3	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New OTC	tn-1-1	sub-type-4	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Complementary Medicine - New	tn-1-1	sub-type-5	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccines	tn-1-1	sub-type-6	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Radiopharmaceutical	tn-1-1	sub-type-7	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Gene and Cell Therapy	tn-1-1	sub-type-8	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Blood Product	tn-1-1	sub-type-9	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biotherapeutic	tn-1-1	sub-type-10	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Biosimilar	tn-1-1	sub-type-11	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Traditional	tn-1-1	sub-type-12	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Clinical Trial Application	tn-1-1	sub-type-13	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Excipient	tn-1-1	sub-type-14	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
ASMF / DMF	tn-1-1	sub-type-15	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Plasma Master File (PMF)	tn-1-1	sub-type-16	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
New Vaccine Antigen Master File (VAMF)	tn-1-1	sub-type-17	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Tissue Master File (TMF)	tn-1-1	sub-type-18	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Biological Master File (BMF)	tn-1-1	sub-type-19	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA

			CRP - TN, Reliance, EUL-TN
Line extension-New Dosage Form	tn-1-1	sub-type-20	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Strength	tn-1-1	sub-type-21	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line Extension - New Route of Administration	tn-1-1	sub-type-22	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Line extension-New Application	tn-1-1	sub-type-23	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Clone	tn-1-1	sub-type-24	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Replica-Same	tn-1-1	sub-type-25	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Post Approval Commitment	tn-1-1	sub-type-26	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Administrative	tn-1-1	sub-type-27	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Administrative	tn-1-1	sub-type-28	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Annual Notification - Quality	tn-1-1	sub-type-29	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Quality	tn-1-1	sub-type-30	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Immediate Notification - Clinical	tn-1-1	sub-type-31	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Quality	tn-1-1	sub-type-32	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Clinical	tn-1-1	sub-type-33	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Minor - Other	tn-1-1	sub-type-34	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Moderate - Quality	tn-1-1	sub-type-35	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety (Clinical)	tn-1-1	sub-type-36	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Safety and Efficacy (Clinical)	tn-1-1	sub-type-37	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Quality	tn-1-1	sub-type-38	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Relinquishing	tn-1-1	sub-type-39	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
VT Major - Change in Applicant - Acquiring	tn-1-1	sub-type-40	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Baseline	tn-1-1	sub-type-41	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Renewal Filing	tn-1-1	sub-type-42	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Application Withdrawal/Cancellation	tn-1-1	sub-type-43	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Pharmacovigilance	tn-1-1	sub-type-44	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Undefined Regulatory Activity*	tn-1-1	sub-type-45	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN
Appeal	tn-1-1	sub-type-46	ANMPS, AMAP-TN, NAJR, WHO-PQ - TN, WHO-SRA CRP - TN, Reliance, EUL-TN

Applicant Contact Type Values will be added to the Submission Maintenance – Applicant Contact Type Values section in Data Administration if they do not already exist. A complete list of values can be found in table below:

eCTD Standard Type	Region	Regulatory Code	Applicant Contact Type
eCTD 3.2	Tunisia	contact-type-1	Local Applicant
eCTD 3.2	Tunisia	contact-type-2	Regulatory
eCTD 3.2	Tunisia	contact-type-3	Technical
eCTD 3.2	Tunisia	contact-type-4	Product Information

Sub Filing Type Values will be added to the Sequence Maintenance – Sub Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Sub Filing Type	Countries	Active Flag
Initial	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Supplementary Information	South Africa, Tunisia	Active
Closing Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Work Grouping Partial Withdrawal	South Africa, Tunisia	Active
Submission Withdrawal	South Africa, Tunisia	Active
Response - Screening Content	Tunisia	Active
Response - Screening Payment	Tunisia	Active
Response - Evaluation Quality	Tunisia	Active
Response - Evaluation Clinical	Tunisia	Active
Response - Evaluation Admin	Tunisia	Active
Response - Pharmacovigilance	Tunisia	Active
Priority Response	Tunisia	Active

Sub Filing Type eCTD codes Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for TN-1-1 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	tn-1-1	seq-type-1	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Supplementary Information	tn-1-1	seq-type-2	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Content	tn-1-1	seq-type-3	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Screening Payment	tn-1-1	seq-type-4	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval

			Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Quality	tn-1-1	seq-type-5	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Clinical	tn-1-1	seq-type-6	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Evaluation Admin	tn-1-1	seq-type-7	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Response - Pharmacovigilance	tn-1-1	seq-type-8	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New

			Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Closing Information	tn-1-1	seq-type-9	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Work Grouping Partial Withdrawal	tn-1-1	seq-type-10	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Submission Withdrawal	tn-1-1	seq-type-11	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate -

			Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal
Priority Response	tn-1-1	seq-type-12	New Chemical Entity, New Combination, New Generic (Multi-source), New OTC, Complementary Medicine - New, New Vaccines, New Radiopharmaceutical, New Gene and Cell Therapy, New Blood Product, New Biotherapeutic, New Biosimilar, New Traditional, Clinical Trial Application, New Excipient, ASMF / DMF, Plasma Master File (PMF), New Vaccine Antigen Master File (VAMF), Tissue Master File (TMF), Biological Master File (BMF), Line extension-New Dosage Form , Line extension-New Strength , Line Extension - New Route of Administration, Line extension-New Application , Clone, Replica-Same , Post Approval Commitment, VT Immediate Notification - Administrative, VT Annual Notification - Administrative, VT Annual Notification - Quality, VT Immediate Notification - Quality, VT Immediate Notification - Clinical, VT Minor - Quality, VT Minor - Clinical, VT Minor - Other, VT Moderate - Quality, VT Major - Safety (Clinical), VT Major - Safety and Efficacy (Clinical), VT Major - Quality, VT Major - Change in Applicant - Relinquishing, VT Major - Change in Applicant - Acquiring, Baseline, Renewal Filing, Application Withdrawal/Cancellation , Pharmacovigilance, Undefined Regulatory Activity*, Appeal

Bosnia and Herzegovina 3.1

If the BA region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'BA' in the database. Otherwise, the BA region is added with the values:

Region Abbreviation	Region Name	Active Flag
BA	Bosnia and Herzegovina	Active

New BA country in the Application Maintenance – Country Values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
BA	Bosnia and Herzegovina	ba	Bosnia and Herzegovina	Active

Health Authority name for BA country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
BA	Bosnia and Herzegovina	Agency for medicinal products and medical devices of Bosnia and Herzegovina	ALMBIH	BA-ALMBIH	https://almbih.gov.ba/

The Bosnian, Serbian, and English languages will be added to the Bosnia and Herzegovina in the Country – Language Values section in Data Administration. The Other - Language Values section will be updated with values listed on the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Bosnian	bs	BOS	Active
Serbian	sr	SRP	Active

If the 'BA-3-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'BA-3-1'. Otherwise, the 'BA-3-1' Assembly DTD/Schema will be added and mapped to the Bosnia and Herzegovina region and Bosnia and Herzegovina country.
Application Type Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Type	**Name**	**Display Name**	**Entity XML Type Name**	**Application Category**	**Countries**
CTA	Clinical Trial Authorisation	Clinical Trial Authorisation	Clinical Trial Application	Clinical Trial	Armenia,Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tunisia, Ukraine, Undefined, United Kingdom, and all ROW countries.

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. A complete list of values can be found in table below:

Filing Type	**Display Name**	**Countries**
Article 16c (1c)i Referral	Article 16c (1c)i Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Northern Ireland, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Additional PV Activity in the RMP Related to PAM	Additional PV Activity in the RMP Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Annex II Condition Related to PAM	Annex II Condition Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Annual Reassessment Filing	Annual Reassessment Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Filing Type	Display Name	Countries
Article 107i Referral	Article 107i Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 16c(4) Referral	Article 16c(4) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 18 Filing	Article 18 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 20 Referral	Article 20 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 29 Paediatric Referral	Article 29 Paediatric Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 29(4) Referral	Article 29(4) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 30 Referral	Article 30 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 31 Referral	Article 31 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 35 Referral	Article 35 Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 5(3) Referral	Article 5(3) Referral	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Article 58 Filing	Article 58 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
ASMF Filing	ASMF Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen

Filing Type	Display Name	Countries
CEP Submission	CEP Submission	EDQM, Jordan, Bosnia and Herzegovina
Clinical Data for Publication – Final Version	Clinical Data for Publication – Final Version	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Clinical Data for Publication – Redacted Proposal	Clinical Data for Publication – Redacted Proposal	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Corrective/Preventive Action Related to PAM	Corrective/Preventive Action Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Extension Filing	Extension Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
Legally Binding Measure Related to PAM	Legally Binding Measure Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Lifting Suspension Filing	Lifting Suspension Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Marketing Authorisation Application	Marketing Authorisation Application	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom
National Variation Filing	National Variation Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
None	None	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom
Notification 61-3 Filing	Notification 61-3 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Article 29 Filing	PAED Article 29 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Filing Type	Display Name	Countries
PAED Article 45	PAED Article 45	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Article 46	PAED Article 46	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAED Related to PIP (Article 7, 8, 30)	PAED Related to PIP (Article 7, 8, 30)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Paediatric Submission Related to PAM (Article 45)	Paediatric Submission Related to PAM (Article 45)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Paediatric Submission Related to PAM (Article 46)	Paediatric Submission Related to PAM (Article 46)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PAES Submission Related to PAM	PAES Submission Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PASS Protocol Submission (Article 107n)	PASS Protocol Submission (Article 107n)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PASS Report Submission (Article 107q)	PASS Report Submission (Article 107q)	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Periodic Safety Update Report	Periodic Safety Update Report	Australia, China, United States, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Switzerland, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Plasma Master File	Plasma Master File	Switzerland, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
PSUR single assessment procedure	PSUR single assessment procedure	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Filing Type	Display Name	Countries
Recommendation Related to PAM	Recommendation Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Repeat Use Procedure	Repeat Use Procedure	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Risk Management Plan Filing	Risk Management Plan Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
SDA Submission Related to PAM	SDA Submission Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Specific Obligation Related to PAM	Specific Obligation Related to PAM	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Transfer MA Filing	Transfer MA Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Switzerland, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
USR Filing	USR Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Variation 1A Filing	Variation 1A Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 1AIN Filing	Variation 1AIN Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 1B Filing	Variation 1B Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 2 Filing	Variation 2 Filing	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom

Filing Type	Display Name	Countries
Withdrawal Filing	Withdrawal	Undefined, United States, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Switzerland, South Africa, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for BA-3-1 DTD/Schema is added to the value. List of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Marketing Authorisation Application	ba-3-1	maa	CTA, NDA
Variation 1A Filing	ba-3-1	var-type1a	CTA, NDA
Variation 1AIN Filing	ba-3-1	var-type1ain	CTA, NDA
Variation 1B Filing	ba-3-1	var-type1b	CTA, NDA
Variation 2 Filing	ba-3-1	var-type2	CTA, NDA
National Variation Filing	ba-3-1	var-nat	CTA, NDA
Extension Filing	ba-3-1	extension	CTA, NDA
Repeat Use Procedure	ba-3-1	rup	CTA, NDA
Periodic Safety Update Report	ba-3-1	psur	CTA, NDA
PSUR single assessment procedure	ba-3-1	psusa	CTA, NDA
Risk Management Plan Filing	ba-3-1	rmp	CTA, NDA
Renewal Filing	ba-3-1	renewal	CTA, NDA
Specific Obligation Related to PAM	ba-3-1	pam-sob	CTA, NDA
Annex II Condition Related to PAM	ba-3-1	pam-anx	CTA, NDA
Additional PV Activity in the RMP Related to PAM	ba-3-1	pam-mea	CTA, NDA
Legally Binding Measure Related to PAM	ba-3-1	pam-leg	CTA, NDA
SDA Submission Related to PAM	ba-3-1	pam-sda	CTA, NDA
Corrective/Preventive Action Related to PAM	ba-3-1	pam-capa	CTA, NDA
Paediatric Submission Related to PAM (Article 45)	ba-3-1	pam-p45	CTA, NDA
Paediatric Submission Related to PAM (Article 46)	ba-3-1	pam-p46	CTA, NDA
PAES Submission Related to PAM	ba-3-1	pam-paes	CTA, NDA
Recommendation Related to PAM	ba-3-1	pam-rec	CTA, NDA
PASS Protocol Submission (Article 107n)	ba-3-1	pass107n	CTA, NDA
PASS Report Submission (Article 107q)	ba-3-1	pass107q	CTA, NDA
ASMF Filing	ba-3-1	asmf	CTA, NDA
Plasma Master File	ba-3-1	pmf	CTA, NDA
Article 20 Referral	ba-3-1	referral-20	CTA, NDA
Article 29(4) Referral	ba-3-1	referral-294	CTA, NDA
Article 29 Paediatric Referral	ba-3-1	referral-29p	CTA, NDA
Article 30 Referral	ba-3-1	referral-30	CTA, NDA
Article 31 Referral	ba-3-1	referral-31	CTA, NDA

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Article 35 Referral	ba-3-1	referral-35	CTA, NDA
Article 5(3) Referral	ba-3-1	referral-5-3	CTA, NDA
Article 107i Referral	ba-3-1	referral-107i	CTA, NDA
Article 16c (1c)i Referral	ba-3-1	referral-16c1c	CTA, NDA
Article 16c(4) Referral	ba-3-1	referral-16c4	CTA, NDA
Annual Reassessment Filing	ba-3-1	annual-reassessment	CTA, NDA
USR Filing	ba-3-1	usr	CTA, NDA
Clinical Data for Publication – Redacted Proposal	ba-3-1	clin-data-pub-rp	CTA, NDA
Clinical Data for Publication – Final Version	ba-3-1	clin-data-pub-fv	CTA, NDA
PAED Related to PIP (Article 7, 8, 30)	ba-3-1	paed-7-8-30	CTA, NDA
PAED Article 29 Filing	ba-3-1	paed-29	CTA, NDA
PAED Article 45	ba-3-1	paed-45	CTA, NDA
PAED Article 46	ba-3-1	paed-46	CTA, NDA
Article 58 Filing	ba-3-1	article-58	CTA, NDA
Notification 61-3 Filing	ba-3-1	notification-61-3	CTA, NDA
Transfer MA Filing	ba-3-1	transfer-ma	CTA, NDA
Lifting Suspension Filing	ba-3-1	lifting-suspension	CTA, NDA
Withdrawal Filing	ba-3-1	withdrawal	CTA, NDA
CEP Submission	ba-3-1	cep	CTA, NDA
None	ba-3-1	none	CTA, NDA
Article 18 Filing	ba-3-1	article-18	CTA, NDA

Sub Filing Type Values will be added to the Sequence Maintenance – Sub Filing Type Values section in Data Administration if they do not already exist. Complete list values can be found in table below:

Sub Filing Type	Countries	Active Flag
Initial	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active
Closing Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Tunisia, Undefined, United Kingdom	Active

Sub Filing Type	Countries	Active Flag
Validation Response	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Response	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Additional Information	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Consolidating	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Corrigendum	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Reformat	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active
Re-examination	Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom	Active

Sub Filing Type eCTD codes Values will be added to the Submission Maintenance – Sub Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for BA-3-1 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Initial	ba-3-1	initial	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Validation Response	ba-3-1	validation-response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Response	ba-3-1	response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Additional Information	ba-3-1	additional-info	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Closing Information	ba-3-1	closing	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Consolidating	ba-3-1	consolidating	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Corrigendum	ba-3-1	corrigendum	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing,

			Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Reformat	ba-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing
Re-examination	ba-3-1	re-examination	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing

Verify Migration Script Updates

Tunisia 1.1

The migration script will perform multiple changes to Data Administration data related to TN 1.1. These should be verified, and where necessary, updated. The script performs the following updates:

- Creates or updates the Tunisia region to have the code value 'TN' in the database.
- Creates or updates the Tunisia country and associates it with the Tunisia region.
- Updates Health Authority Name to "National Agency for Medicines and Health Products", Health Authority Abbreviation to ANMPS, Health Authority eCTD Code to TN-ANMPS and Health Authority Website to http://www.dpm.tn/ in Application Maintenance – Country Values
- Creates or updates the Arabic language in Other-Language Values and associates it with the Tunisia country, as well as French and English.
- Adds the 'TN-1-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it did not exist before If existed, it will be activated (if inactive) and updated to have the code value 'TN-1-1'.
- Adds following Application Category values in the Application Maintenance – Application Category Values section in Data Administration:
    - ANMPS National Procedure
    - North African Joint Review
    - WHO PQ CRP
    - Reliance
    - Emergency Use Licensing
- Updates Application Maintenance – Application Type Values with following values, including assignment of corresponding eCTD codes:
    - AMA Procedure value and assigns app-type-2 eCTD code.
    - WHO SRA CRP value and assigns app-type-5 eCTD code.
    - ANMPS National Procedure value and assigns app-type-1 eCTD code.
    - North African Joint Review value and assigns app-type-3 eCTD code.
    - WHO PQ CRP value and assigns app-type-4 eCTD code.
    - Reliance value and assigns app-type-6 eCTD code.
    - Emergency Use Licensing value and assigns app-type-7 eCTD code.
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
    - New Chemical Entity
    - New Combination
    - New Generic (Multi-source)
    - New OTC
    - Complementary Medicine - New
    - New Vaccines
    - New Radiopharmaceutical
    - New Gene and Cell Therapy
    - New Blood Product
    - New Biotherapeutic
    - New Biosimilar
    - New Traditional
    - Clinical Trial Application
    - New Excipient
    - ASMF / DMF
    - Plasma Master File (PMF)
    - New Vaccine Antigen Master File (VAMF)
    - Tissue Master File (TMF)
    - Biological Master File (BMF)
    - Line extension-New Dosage Form
    - Line extension-New Strength
    - Line Extension - New Route of Administration
    - Line extension-New Application

    - Clone
    - Replica-Same
    - Post Approval Commitment
    - VT Immediate Notification - Administrative
    - VT Annual Notification - Administrative
    - VT Annual Notification - Quality
    - VT Immediate Notification - Quality
    - VT Immediate Notification - Clinical
    - VT Minor - Quality
    - VT Minor - Clinical
    - VT Minor - Other
    - VT Moderate - Quality
    - VT Major - Safety (Clinical)
    - VT Major - Safety and Efficacy (Clinical)
    - VT Major - Quality
    - VT Major - Change in Applicant - Relinquishing
    - VT Major - Change in Applicant - Acquiring
    - Baseline
    - Renewal Filing
    - Application Withdrawal/Cancellation
    - Pharmacovigilance
    - Undefined Regulatory Activity*
    - Appeal
- Updates Applicant Contact Type values in the Submission Maintenance – Applicant Contact Type Values with the following values:
    - Local Applicant
    - Regulatory
    - Technical
    - Product Information
- Updates Submission Maintenance – Sub Filing Type Values with following values and assigns corresponding eCTD codes:
    - Initial
    - Supplementary Information
    - Response - Screening Content
    - Response - Screening Payment
    - Response - Evaluation Quality
    - Response - Evaluation Clinical
    - Response - Evaluation Admin
    - Response - Pharmacovigilance
    - Closing Information
    - Work Grouping Partial Withdrawal
    - Submission Withdrawal
    - Priority Response

Bosnia and Herzegovina 3.1

The migration script will perform multiple changes to Data Administration data related to BA 3.1. These should be verified, and where necessary, updated. The script performs the following updates:

- Creates or updates the Bosnia and Herzegovina region to have the code value 'BA' in the database.
- Creates or updates the Bosnia and Herzegovina country and associates it with the Bosnia and Herzegovina region.
- Updates Health Authority Name to 'Agency for medicinal products and medical devices of Bosnia and Herzegovina', Health Authority Abbreviation to ALMBIH, Health Authority eCTD Code to BA-ALMBIH and Health Authority Website to https://almbih.gov.ba/ in Application Maintenance – Country Values

- Creates or updates the Bosnian and Serbian languages in Other-Language Values and associates them with the Bosnia and Herzegovina country, as well as English.

- Adds the 'BA-3-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it did not exist before If existed, it will be activated (if inactive) and updated to have the code value 'BA-3-1'.
- Updates Application Maintenance – Application Type Values with following value:
    - Clinical Trial Authorisation
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
    - Marketing Authorisation Application
    - Variation 1A Filing
    - Variation 1AIN Filing
    - Variation 1B Filing
    - Variation 2 Filing
    - National Variation Filing
    - Extension Filing
    - Repeat Use Procedure
    - Periodic Safety Update Report
    - PSUR single assessment procedure
    - Risk Management Plan Filing
    - Renewal Filing
    - Specific Obligation Related to PAM
    - Annex II Condition Related to PAM
    - Additional PV Activity in the RMP Related to PAM
    - Legally Binding Measure Related to PAM
    - SDA Submission Related to PAM
    - Corrective/Preventive Action Related to PAM
    - Paediatric Submission Related to PAM (Article 45)
    - Paediatric Submission Related to PAM (Article 46)
    - PAES Submission Related to PAM
    - Recommendation Related to PAM
    - PASS Protocol Submission (Article 107n)
    - PASS Report Submission (Article 107q)
    - ASMF Filing
    - Plasma Master File
    - Article 20 Referral
    - Article 29(4) Referral
    - Article 29 Paediatric Referral
    - Article 30 Referral
    - Article 31 Referral
    - Article 35 Referral
    - Article 5(3) Referral
    - Article 107i Referral
    - Article 16c (1c)i Referral
    - Article 16c(4) Referral
    - Annual Reassessment Filing
    - USR Filing
    - Clinical Data for Publication – Redacted Proposal
    - Clinical Data for Publication – Final Version
    - PAED Related to PIP (Article 7, 8, 30)
    - PAED Article 29 Filing
    - PAED Article 45
    - PAED Article 46
    - Article 58 Filing
    - Notification 61-3 Filing
    - Transfer MA Filing
    - Lifting Suspension Filing
    - Withdrawal Filing
    - CEP Submission

    - None
    - Article 18 Filing
- Updates Submission Maintenance – Sub Filing Type Values with following values and assigns corresponding eCTD codes:
    - Initial
    - Validation Response
    - Response
    - Additional Information
    - Closing Information
    - Consolidating
    - Corrigendum
    - Reformat
    - Re-examination

Chapter 5. Ennov InSight 7.3.4 Updates

Data Administration Updates

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

Composition Grouping Description Values

There is a new value list Composition Grouping Description in the Other section with the following attributes:

- Composition Grouping Description – required, text area field.

Country Values

For the following list of Countries: Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo:

- The "Region" tab contains only the "West African Health Organization" value and no longer contains the "Rest of World" value.
- The "Application Type Details" tab contains the following values:
    - Clinical Trial Authorisation
    - Marketing Authorisation Application (Default Flag = Y)
        - Not present if there is an NDA application for the current Country in the system, due to the fact that NDA and MAA application types have the same Application Category type.
    - Marketing Authorisation Application – Animal Health
    - New Drug Application
        - Present only if there was at least one NDA application for the abovementioned list of Countries before the migration (Default Flag = Y in this scenario)
- The "Procedure Type Details" tab contains the following values:
    - National
    - WAHO Centralized Procedure (Default Flag = Y)
- The "Languages" tab contains the following values:
    - English (Default Flag = Y)
    - French
    - Portuguese

File Identifier Type Values

The File Identifier Type Values in Other section is now mapped to the list #200000026028 in RMS SPOR.

Manufacturing Values

The extra fields are enabled for theManufacturer->Manufacturing Authorisation Reference Number sub-entity in the Product Detail Set Maintenance section.

Procedure Type Values

All Procedures that have the Internal Procedure Code set to “CP” have a new “Assigned Region” field post-migration with the following OOTB values:

- For EU CP Procedures, the “Assigned Region" field is populated with the “EU” value.
- For the WAHO CP Procedure, the “Assigned Region” field is populated by the “WAHO” value.

Region Values

The “Rest of World” region no longer contains the following Countries: Benin, Burkina Faso, Cabo Verde, Côte d’Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo.

Substance Values

The SMS sub-tab is now have enabled Disassociate Term and Associate Term buttons in preparation for IDMP integration with SMS from SPOR.

UA v1.0

If the region UA already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value ‘UA’ in the database. Otherwise, the UA region is added with the values:

Region Abbreviation	Region Name	Active Flag
UA	Ukraine	Active

UA - Application Maintenance – Country Values

New Country, UA, in the Application Maintenance – Country Values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
UA	Ukraine	ua	Ukraine	Active

Health Authority name for UA country, in the Application Maintenance – Country Values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
UA	Ukraine	The State Expert Center of MOH of Ukraine	SECMOH	UA-SECMOH	https://www.dec.gov.ua

UA - Other Language Values

If the 'Ukrainian' language already exists under the Ukraine in the Other – Language Values section in Data Administration, it will be activated (if inactive). Otherwise, the 'UA-1-0' Assembly DTD/Schema will be added with values listed in the table below:

Language Name	Language Code	ISO ALPHA-3 CODE (field value hidden, but such field label exists in UI)	Active Flag
Ukrainian	ua	UKR	Active

If the 'Ukrainian' language under the Ukraine in the Application Maintenance – Country Values section in Data Administration is not associated yet, it will be associated with Ukraine country.

UA - Assembly - Assembly DTD/Schema Types

If the 'UA-1-0' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'UA-1-0'. Otherwise, the 'UA-1-0' Assembly DTD/Schema will be added and mapped to the region Ukraine and the country Ukraine.

UA - Application Maintenance - Procedure Type

The 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration will be activated (if inactive) and updated to include the country Ukraine, in addition to the countries that have already been added.

UA - Sequence Maintenance – Filing Type

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. The complete list values can be found in table below:

Filing Type	Display Name	Countries
Amendenment Filing	Amendenment Filing	Afghanistan, Albania, Algeria, Ameri- can Samoa, Andorra, Angola, Anguil- la, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijanjan, Bahamas, Bangladesh, Barba- dos, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia,

Filing Type	Display Name	Countries
		Cameroon, Canada, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea- Bissau, Haiti, Heard Island and Mc- donald Islands, Holy See (Vatican City State), Honduras, Hong Kong, In- dia, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Japan, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, North- ern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philip-

Filing Type	Display Name	Countries
		pines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, To- go, Tokelau, Tonga, Trinidad and To- bago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanza- nia, United States Minor Outlying Is- lands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futu- na, Western Sahara, Zambia, Zimbab- we, United States
Extension Filing	Extension Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxem- bourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, Ukraine, United Arab Emirates, Yemen
Line Extension Filing	Line Extension Filing	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and

Filing Type	Display Name	Countries
		barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bou- vet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Re- public, Chad, Christmas Island, Co- cos (Keeling) Islands, Comoros, Con- go, Congo, The Democratic Republic Of The, Cook Islands, Costa Ri- ca, Cote D'Ivoire, Cuba, Djibouti, Do- minica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grena- da, Guadeloupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyr- gyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Is- lands, Martinique, Mauritania, Mau- ritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongo-

Filing Type	Display Name	Countries
		lia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Nor- folk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Mari- no, Sao Tome and Principe, Sene- gal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Tai- wan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Is- lands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Out- lying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Marketing Authorisation Application	Marketing Authorisation Application	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania,

Filing Type	Display Name	Countries
		Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom
None	None	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxem- bourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom
Original Filing	Original Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Nor- way, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Un- defined, United Kingdom, United States, Canada, Japan, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands,

Filing Type	Display Name	Countries
		Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatori-al Guinea, Eritrea, Ethiopia, Faroe Is- lands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Great Britain, Greenland, Grenada, Guade- loupe, Guam, Guatemala, Guinea, Guinea-Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Mada- gascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montser- rat, Morocco, Mozambique, Myan- mar, Namibia, Nauru, Nepal, Nether- lands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Pakistan, Palau, Palestinian Territo- ry, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation,

Filing Type	Display Name	Countries
		Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Sene- gal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lan- ka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Tai- wan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Is- lands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Other Filing	Other Filing	United States, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Bearus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christ- mas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica,

Filing Type	Display Name	Countries
		Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea- Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Re- public Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Ko- rea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia,

Filing Type	Display Name	Countries
		Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swazi- land, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thai- land, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Is- lands, Uganda, Ukraine, United Re- public Of Tanzania, United States Mi- nor Outlying Islands, Uruguay, Uzbek- istan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Renewal Filing	Renewal Filing	Switzerland, Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, China, Christ- mas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Re- public, Egypt, El Salvador, Equatori-al Guinea, Eritrea, Ethiopia, Faroe Is- lands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland,

Filing Type	Display Name	Countries
		Great Britain, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea- Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Jordan, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montser-rat, Morocco, Mozambique, Myan-mar, Namibia, Nauru, Nepal, Nether- lands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nige-ria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, South Africa, Sri Lanka, Sudan,

Filing Type	Display Name	Countries
		Svalbard and Jan Mayen, Swaziland, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Toba- go, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cay- man Islands, Central African Republic, Chad, China, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Re- public Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Croatia, Cuba, Djibouti, Dominica, Dominican Re- public, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Is- lands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Great Britain, Grenada, Guadeloupe, Guam, Guatemala, Guinea, GuineaBissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, Iceland, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Jordan, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Liechtenstein, Macao, Macedonia,

Filing Type	Display Name	Countries
		The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montser- rat, Morocco, Mozambique, Myan- mar, Namibia, Nauru, Nepal, Nether- lands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nige- ria, Niue, Norfolk Island, Northern Ireland, Northern Mariana Islands, Norway, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pit- cairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, South Africa, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Switzerland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Thailand, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Toba- go, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe, Austria,

Filing Type	Display Name	Countries
		Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Ger- many, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Mal- ta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen
Technical Mistake	Technical Mistake	Ukraine
Technical Variation Filing	Technical Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Is- land, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Cay- man Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea- Bissau, Haiti, Heard Island and Mcdonald Islands,

Filing Type	Display Name	Countries
		Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Republic Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Ko- rea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, Northern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea, Philippines, Pitcairn, Puerto Rico, Re-union, Russian Federation, Rwan- da, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Sey- chelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lan-ka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Tai- wan, Province Of China, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Is-

Filing Type	Display Name	Countries
		lands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, United Republic Of Tanzania, United States Minor Outlying Islands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Transfer MA Filing	Transfer MA Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Den- mark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ire- land, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Nor- way, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom, Switzerland, Bahrain, Kuwait, Oman, Qatar, Sau- di Arabia, Ukraine, United Arab Emi- rates, Yemen
Variation 1 and 2 Filing	Variation 1 and 2 Filing	Ukraine
Variation 1A Filing	Variation 1A Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Den- mark, Estonia, European Union, Fin- land, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 1AIN Filing	Variation 1AIN Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia,

Filing Type	Display Name	Countries
		Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 1B Filing	Variation 1B Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation 2 Filing	Variation 2 Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Den- mark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, Undefined, United Kingdom
Variation Filing	Variation	Afghanistan, Albania, Algeria, American Samoa, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Azerbaijan, Bahamas, Bangladesh, Barbados, Belarus, Belize, Benin, Bermuda, Bhutan, Bolivia, Bosnia and Herzegovina, Botswana, Bouvet Island, British Indian Ocean Territory, British Virgin Islands, Brunei Darussalam, Burkina Faso, Burundi,

Filing Type	Display Name	Countries
		Cambodia, Cameroon, Cape Verde, Cayman Islands, Central African Republic, Chad, Christmas Island, Cocos (Keeling) Islands, Comoros, Congo, Congo, The Democratic Republic Of The, Cook Islands, Costa Rica, Cote D'Ivoire, Cuba, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador, Equatorial Guinea, Eritrea, Ethiopia, Faroe Islands, Fiji, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Ghana, Gibraltar, Greenland, Grenada, Guadeloupe, Guam, Guatemala, Guinea, Guinea- Bissau, Haiti, Heard Island and Mcdonald Islands, Holy See (Vatican City State), Honduras, Hong Kong, India, Indonesia, Iran, Islamic Re- public Of, Iraq, Israel, Jamaica, Jersey, Kazakhstan, Kenya, Kiribati, Korea, Democratic People's Republic Of, Korea, Republic Of, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Lesotho, Liberia, Libyan Arab Jamahiriya, Macao, Macedonia, The Former Yugoslav Republic Of, Madagascar, Malawi, Malaysia, Maldives, Mali, Marshall Islands, Martinique, Mauritania, Mauritius, Mayotte, Mexico, Micronesia, Federated States Of, Moldova, Republic Of, Monaco, Mongolia, Montenegro, Montserrat, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands Antilles, New Caledonia, New Zealand, Nicaragua, Niger, Nigeria, Niue, Norfolk Island, North- ern Mariana Islands, Pakistan, Palau, Palestinian Territory, Occupied, Panama, Papua New Guinea,

Filing Type	Display Name	Countries
		Philip-pines, Pitcairn, Puerto Rico, Reunion, Russian Federation, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and The Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Serbia, Serbia and Montenegro, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, Sri Lanka, Sudan, Svalbard and Jan Mayen, Swaziland, Syrian Arab Republic, Taiwan, Province Of China, Tajikistan, Timor-Leste, To- go, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Turks and Caicos Islands, Tuvalu, U.S. Virgin Islands, Uganda, Ukraine, Undefined, United Republic Of Tanzania, United States Minor Outlying Is- lands, Uruguay, Uzbekistan, Vanuatu, Venezuela, Vietnam, Wallis and Futuna, Western Sahara, Zambia, Zimbabwe
Withdrawal Filing	Withdrawal	Undefined, United States, Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates, Yemen, Switzerland, South Africa, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Ger- many, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Ukraine, Undefined, United Kingdom

UA - Filing Type eCTD Codes

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for UA-1-0 DTD/Schema is added to the value. The list of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Marketing Authorisation Application	ua-1-0	maa	Clinical Trial Authorisation, New Drug Application
Renewal Filing	ua-1-0	renewal	Clinical Trial Authorisation, New Drug Application
Variation 1A Filing	ua-1-0	var-type1a	Clinical Trial Authorisation, New Drug Application
Variation 1AIN Filing	ua-1-0	var-type1ain	Clinical Trial Authorisation, New Drug Application
Variation 1B Filing	ua-1-0	var-type1b	Clinical Trial Authorisation, New Drug Application
Variation 2 Filing	ua-1-0	var-type2	Clinical Trial Authorisation, New Drug Application
Variation 1 and 2 Filing	ua-1-0	var-type1-2	Clinical Trial Authorisation, New Drug Application
Technical Mistake	ua-1-0	var-tm	Clinical Trial Authorisation, New Drug Application
Extension Filing	ua-1-0	extension	Clinical Trial Authorisation, New Drug Application
Transfer MA Filing	ua-1-0	transfer-ma	Clinical Trial Authorisation, New Drug Application
Withdrawal Filing	ua-1-0	withdrawal	Clinical Trial Authorisation, New Drug Application
None	ua-1-0	none	Clinical Trial Authorisation, New Drug Application

AU v3.2

If the 'AU-3-2' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'AU-3-2'. Otherwise, the 'AU-3-2' Assembly DTD/Schema will be added and mapped to Australia region and Australia country.

AU - Sequence Maintenance – Filing Type

Filing Type Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration if they do not already exist. A complete list of values can be found in table below:

Filing Type	Display Name	Countries
Major Variation	Major Variation	Australia
Self Assessable Request/Variation	Self Assessable Request/Variation	Australia
Notification	Notification	Australia
Vigilance	Vigilance	Australia
Minor Variation (Cat 3)	Minor Variation (Cat 3)	Australia
Minor Editorial Change (MEC)	Minor Editorial Change (MEC)	Australia
Generic extension of indications	Generic extension of indications	Australia
Pre-Advice	Pre-Advice	Australia
Designation / Determination	Designation / Determination	Australia
S14/14A	S14/14A	Australia
Post-requirement or Administrative	Post-requirement or Administrative	Australia
RCM - New - 1	RCM - New - 1	Australia
RCM - New - 2	RCM - New - 2	Australia
RCM - New - 3	RCM - New - 3	Australia
RCM - New - 4	RCM - New - 4	Australia
RCM - New - 5	RCM - New - 5	Australia
RCM - Change - 1	RCM - Change - 1	Australia
RCM - Change - 2	RCM - Change - 2	Australia
RCM - Change - 3	RCM - Change - 3	Australia
RCM - Change - 4	RCM - Change - 4	Australia
Transition to full registration	Transition to full registration	Australia

Filing Type Values will be updated in the Sequence Maintenance – Filing Type Values section in Data Administration. The updated Filing Type value affects all the eCTD codes assigned to this value. A complete list of affected values can be found in the table below:

Affected Filing Type	New Filing Type Name	Comments
A - NCE New Chemical Entity	New Entity	
A - NCE Similar Biological Medicinal Product	Similar Biological Medicinal Product	
B - New Combination	New Combination	New Combination Filing Type already exists with mapping to Switzerland only. The change is in adding Australia to the list of Countries and proper AU 3.2 eCTD Code
C - Extension of Indication	Extension of Indication	
D - New Generic Medicine	New Generic Medicine	
J - PI Change requiring evaluation	PI Change requiring evaluation	
G - Minor Variation, New Register Entry - Change of Formulation	Minor Variation (Cat 1)	
F – Major Variation - New Strength	Major Variation	
E - Additional Tradename	Additional Tradename	
9D(1) - Correction of Register Entry	Correction of Register Entry	
9D(2) - Safety Related Request	Safety Related Request/Variation	
9D(3) - Change to PI (not J)	Self Assessable Request/Variation	
OTC - N1	OTC - New - 1	
OTC - N2	OTC - New - 2	
OTC - N3	OTC - New - 3	
OTC - N4	OTC - New - 4	
OTC - N5	OTC - New - 5	
OTC - C1	OTC - Change - 1	
OTC - C2	OTC - Change - 2	
OTC - C3	OTC - Change - 3	

Affected Filing Type	New Filing Type Name	Comments
OTC - C4	OTC - Change - 4	
Pharmacovigilance	Vigilance	

AU - Filing Type eCTD Codes

Filing Type eCTD codes Values will be added to the Sequence Maintenance – Filing Type Values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for AU-3-2 DTD/Schema is added to the value. The list of new values can be found in table below:

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
New Entity	au-3-2	seq-type-1	CTA, NDA
Similar Biological Medicinal Product	au-3-2	seq-type-3	CTA, NDA
New Combination	au-3-2	seq-type-4	CTA, NDA
Extension of Indication	au-3-2	seq-type-5	CTA, NDA
New Generic Medicine	au-3-2	seq-type-6	CTA, NDA
Major Variation	au-3-2	seq-type-8	CTA, NDA
PI Change requiring evaluation	au-3-2	seq-type-17	CTA, NDA
Minor Variation (Cat 1)	au-3-2	seq-type-13	CTA, NDA
Additional Tradename	au-3-2	seq-type-7	CTA, NDA
Change of Tradename	au-3-2	seq-type-15	CTA, NDA
Correction of Register Entry	au-3-2	seq-type-53	CTA, NDA
Safety Related Request/Variation	au-3-2	seq-type-54	CTA, NDA
Self Assessable Request/Variation	au-3-2	seq-type-55	CTA, NDA
Notification	au-3-2	seq-type-59	CTA, NDA
OTC - New - 1	au-3-2	seq-type-20	CTA, NDA
OTC - New - 2	au-3-2	seq-type-21	CTA, NDA

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
OTC - New - 3	au-3-2	seq-type-22	CTA, NDA
OTC - New - 4	au-3-2	seq-type-23	CTA, NDA
OTC - New - 5	au-3-2	seq-type-24	CTA, NDA
OTC - Change - 1	au-3-2	seq-type-25	CTA, NDA
OTC - Change - 2	au-3-2	seq-type-26	CTA, NDA
OTC - Change - 3	au-3-2	seq-type-27	CTA, NDA
OTC - Change - 4	au-3-2	seq-type-28	CTA, NDA
Ingredient - New	au-3-2	seq-type-30	CTA, NDA
Ingredient - Variation	au-3-2	seq-type-31	CTA, NDA
Complementary Medicine - New	au-3-2	seq-type-32	CTA, NDA
Complementary Medicine - Variation	au-3-2	seq-type-33	CTA, NDA
Biologicals - Class 1	au-3-2	seq-type-34	CTA, NDA
Biologicals - Class 2	au-3-2	seq-type-35	CTA, NDA
Biologicals - Class 3	au-3-2	seq-type-36	CTA, NDA
Biologicals - Class 4	au-3-2	seq-type-37	CTA, NDA
Biologicals - Variation	au-3-2	seq-type-38	CTA, NDA
ASMF / DMF	au-3-2	seq-type-40	CTA, NDA
Plasma Master File (PMF)	au-3-2	seq-type-41	CTA, NDA
Tissue Master File (TMF)	au-3-2	seq-type-42	CTA, NDA
Biological Master File (BMF)	au-3-2	seq-type-43	CTA, NDA
Vigilance	au-3-2	seq-type-44	CTA, NDA
Extension of provisional registration	au-3-2	seq-type-61	CTA, NDA
Supplementary information	au-3-2	seq-type-45	CTA, NDA
Baseline	au-3-2	seq-type-46	CTA, NDA

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Clinical Trial Application	au-3-2	seq-type-49	CTA, NDA
Product Withdrawal	au-3-2	seq-type-57	CTA, NDA
Undefined Regulatory Activity*	au-3-2	seq-type-52	CTA, NDA
Minor Variation (Cat 3)	au-3-2	seq-type-63	CTA, NDA
Minor Editorial Change (MEC)	au-3-2	seq-type-64	CTA, NDA
Generic extension of indications	au-3-2	seq-type-65	CTA, NDA
Pre-Advice	au-3-2	seq-type-66	CTA, NDA
Designation / Determination	au-3-2	seq-type-67	CTA, NDA
S14/14A	au-3-2	seq-type-68	CTA, NDA
Post-requirement or Administrative	au-3-2	seq-type-69	CTA, NDA
RCM - New - 1	au-3-2	seq-type-70	CTA, NDA
RCM - New - 2	au-3-2	seq-type-71	CTA, NDA
RCM - New - 3	au-3-2	seq-type-72	CTA, NDA
RCM - New - 4	au-3-2	seq-type-73	CTA, NDA
RCM - New - 5	au-3-2	seq-type-74	CTA, NDA
RCM - Change - 1	au-3-2	seq-type-75	CTA, NDA
RCM - Change - 2	au-3-2	seq-type-76	CTA, NDA
RCM - Change - 3	au-3-2	seq-type-77	CTA, NDA
RCM - Change - 4	au-3-2	seq-type-78	CTA, NDA
Transition to full registration	au-3-2	seq-type-79	CTA, NDA

AU - Submission Maintenance – Regulatory Activity Lead

Regulatory Activity Lead Values will be added to the Submission Maintenance – Regulatory Activity Lead Values section in Data Administration, if they do not already exist. A list of new values can be found in table below:

Region	Applicable	eCTD Code	Regulatory Activity Lead
Australia	au-3-2	reg-act-lead-1	Biologicals
Australia	au-3-2	reg-act-lead-2	Complementary
Australia	au-3-2	reg-act-lead-3	Medical Devices
Australia	au-3-2	reg-act-lead-4	OTC
Australia	au-3-2	reg-act-lead-6	Prescription meds-chemi- cal
Australia	au-3-2	reg-act-lead-7	Prescription meds-biologi-cal
Australia	au-3-2	reg-act-lead-8	Prescription meds-vaccine

AU - Sequence Description

Sequence Description Values will be added to the Submission Maintenance – Sequence Description Values section in Data Administration, if they do not already exist. A list of new values can be found in the table below:

Region	Applicable DTD/Schema	eCTD Code	Sequence Description	Sequence Description Additional Data Type
Australia	au-3-2	seq-desc-2	Initial	
Australia	au-3-2	seq-desc-3	Pre-Submission Meeting Package	
Australia	au-3-2	seq-desc-5	Response to Request	
Australia	au-3-2	seq-desc-11	Pre-Advisory Committee response	
Australia	au-3-2	seq-desc-13	Product Information	
Australia	au-3-2	seq-desc-15	Notification of a Safety Issue	
Australia	au-3-2	seq-desc-19	RMP	
Australia	au-3-2	seq-desc-20	PSUR for Period of {from-date:d} to {to-date:d}	Date Range
Australia	au-3-2	seq-desc-21	Unsolicited Data, {description:s}	Text

Region	Applicable DTD/Schema	eCTD Code	Sequence Description	Sequence Description Additional Data Type
Australia	au-3-2	seq-desc-22	Comments on evaluation reports	
Australia	au-3-2	seq-desc-23	Withdrawal	
Australia	au-3-2	seq-desc-24	Uncategorised, {description:s}	Text
Australia	au-3-2	seq-desc-25	Reformat	
Australia	au-3-2	seq-desc-26	Rolling data submission	
Australia	au-3-2	seq-desc-27	Partial withdrawal	
Australia	au-3-2	seq-desc-28	Annual Report	
Australia	au-3-2	seq-desc-29	CPD (Certified product details)	
Australia	au-3-2	seq-desc-30	Administrative update	
Australia	au-3-2	seq-desc-31	Early scientific advice	
Australia	au-3-2	seq-desc-32	International work-sharing information	
Australia	au-3-2	seq-desc-33	Final	
Australia	au-3-2	seq-desc-34	Errors of fact or omissions	

WHO v1.0

The migration script will perform multiple changes to Data Administration data related to WHO 1.0. These should be verified, and where necessary, updated.

WHO - Submission Maintenance – Sub Filing Type Values

The migration script performs the following updates:

Updates Submission Maintenance - Sub Filing Type Values with following values and assigns corresponding eCTD codes:

- EUL-Abridged (Emergency Use Listing)

Verify Migration Script Updates: Ennov InSight 7.3.4

After the migration script is run, changes must be verified and updated to the Data Administration data.

UA 1.0

The migration script will perform multiple changes to Data Administration data related to UA 1.0. These should be verified, and where necessary, updated. The script performs the following updates:

- Creates or updates the Ukraine region to have the code value 'UA' in the database.
- Creates or updates the Ukraine country and associates it with the Ukraine region.
- Updates Health Authority Name to The State Expert Center of MOH of Ukraine, Health Authority Abbreviation to SECMOH, Health Authority eCTD Code to UA-SECMOH and Health Authority Website to https://www.dec.gov.ua in Application Maintenance – Country Values.
- Creates or updates the Ukrainian language in Other-Language Values and associates it with the Ukraine country.
- Adds the 'UA-1-0' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'UA-1-0'. Otherwise, the 'UA-1-0' Assembly DTD/Schema will be added.
- Updates 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration, to make it activated (if inactive) and updates to include the Ukraine country.
- Updates 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration, to make it activated (if inactive) and updates to include the Ukraine country.
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
    - Technical Mistake
    - Variation 1 and 2 Filing
- Adds Ukraine country in Sequence Maintenance – Filing Type Values to the following values, and assign corresponding eCTD codes for each value:
    - Amendment Filing
    - Extension Filing
    - Line Extension Filing
    - Marketing Authorisation Application (Registration)
    - None
    - Original Filing
    - Other Filing
    - Baseline
    - Renewal Filing
    - Technical Variation Filing
    - Transfer MA Filing
    - Variation 1A Filing
    - Variation 1AIN Filing
    - Variation 1B Filing

- Variation 2 Filing
- Variation Filing
- Withdrawal

AU 3.2

The migration script will perform multiple changes to Data Administration data related to AU 3.2. These should be verified, and where necessary, updated. The script performs the following updates:

- Adds the 'AU-3-2' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'AU-3-2'. Otherwise, the 'AU-3-2' Assembly DTD/Schema will be added.
- Updates Sequence Maintenance – Filing Type Values with following values, including eCTD codes for each value:
  - Ingredient - New
  - Ingredient - Variation
  - Complementary Medicine - New
  - Complementary Medicine - Variation
  - Biologicals - Class 1
  - Biologicals - Class 2
  - Biologicals - Class 3
  - Biologicals - Class 4
  - Biologicals - Variation
  - ASMF / DMF
  - Plasma Master File (PMF)
  - Tissue Master File (TMF)
  - Biological Master File (BMF)
  - Extension of provisional registration
  - Supplementary information
  - Baseline
  - Clinical Trial Application
  - Product Withdrawal
  - Undefined Regulatory Activity*
  - Major Variation
  - Self Assessable Request/Variation
  - Notification
  - Vigilance
  - Minor Variation (Cat 3)
  - Minor Editorial Change (MEC)
  - Generic extension of indications
  - Pre-Advice
  - Designation / Determination

    - S14/14A
    - Post-requirement or Administrative
    - RCM - New - 1
    - RCM - New - 2
    - RCM - New - 3
    - RCM - New - 4
    - RCM - New - 5
    - RCM - Change - 1
    - RCM - Change - 2
    - RCM - Change - 3
    - RCM - Change - 4
    - Transition to full registration
    - New Entity
    - Similar Biological Medicinal Product
    - New Combination
    - Extension of Indication
    - New Generic Medicine
    - PI Change requiring evaluation
    - Minor Variation (Cat 1)
    - Additional Tradename
    - Change of Tradename
    - Correction of Register Entry
    - Safety Related Request/Variation
    - OTC - New - 1
    - OTC - New - 2
    - OTC - New - 3
    - OTC - New - 4
    - OTC - New - 5
    - OTC - Change - 1
    - OTC - Change - 2
    - OTC - Change - 3
    - OTC - Change - 4
- Updates Submission Maintenance – Regulatory Activity Lead Values with following values:
    - Biologicals
    - Complementary
    - Medical Devices
    - OTC
    - Prescription meds-chemical
    - Prescription meds-biological
    - Prescription meds-vaccine
- Updates Submission Maintenance – Sequence Description Values with following values:

- Biologicals
- Initial
- Pre-Submission Meeting Package
- Response to Request
- Pre-Advisory Committee response
- Product Information
- Notification of a Safety Issue
- RMP
- PSUR for Period of {from-date:d} to {to-date:d}
- Unsolicited Data, {description:s}
- Comments on evaluation reports
- Withdrawal
- Uncategorised, {description:s}
- Reformat
- Rolling data submission
- Partial withdrawal
- Annual Report
- CPD (Certified product details)
- Administrative update
- Early scientific advice
- International work-sharing information
- Final
- Errors of fact or omissions

WHO 1.0

The migration script will perform multiple changes to Data Administration data related to WHO 1.0. These should be verified, and where necessary, updated. The script performs the following updates:

Updates Submission Maintenance - Sub Filing Type Values with following value and assigns corresponding eCTD codes:

- EUL-Abridged (Emergency Use Listing)

Chapter 6. Ennov InSight 7.3.3 Updates

Data Administration Updates: Ennov InSight 7.3. 3

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
AT	Austria	Austrian Federal Office for Safety in Health Care / Austrian Medicines and Medical Devices Agency	BASG	AT-BASG	www.basg.gv.at
BE	Belgium	Federal agency for medicines and health products	FAMHP	BE-FAMHP	http://www.fagg-afmps.be/
HR	Croatia	Agency for Medicinal Products and Medical Devices of Croatia	HALMED	HR-HALMED	http://www.halmed.hr/
CY	Cyprus	Pharmaceutical Services Ministry of Health	PHS	CY-PHS	http://www.moh.gov.cy/
CZ	Czech Republic	State Institute for Drug Control	SUKL	CZ-SUKL	www.sukl.eu

DK	Denmark	Danish Medicines Agency	DKMA	DK-DKMA	www.lmst.dk
EE	Estonia	State Agency of Medicines	SAM	EE-SAM	ravimiregister.ravimiamet.ee/en/ de-fault.aspx
FR	France	National Agency for the Safety of Medicines and Health Products	ANSM	FR-ANSM	http://ansm.sante.fr/
DE	Germany	Federal Institute for Drugs and Medical Devices	BFARM	DE-BFARM	https://www.bfarm.de/EN/ Home/_-node.html
DE	Germany	Federal Institute for Vaccines and Bio-medicines	PEI	DE-PEI	https://www.pei.de/EN/home/ home-node.html
GR	Greece	National Organization for Medicines	EOF	EL-EOF	http://www.eof.gr/
HU	Hungary	National Institute of Pharmacy and Nutrition	OGYI	HU-OGYI	www.ogyei.gov.hu
IS	Iceland	Icelandic Medicines Agency	IMCA	IS-IMCA	http://www.ima.is/

IE	Ireland	The Health Products Regulatory Authority	HPRA	IE-HPRA	http://www.hpra.ie
IT	Italy	Italian Medicines Agency	AIFA	IT-AIFA	www.aifa.gov.it
LV	Latvia	State Agency of Medicines	ZVA	LV-ZVA	http://www.zva.gov.lv
LI	Liechtenstein	Office of Health / Department of Pharmaceuticals	LLV	LI-LLV	http://www.llv.li/
LT	Lithuania	State Medicines Control Agency	SMCA	LT-SMCA	http://www.vvkt.lt/
LU	Luxembourg	Ministry of Health	MINSANT	LU-MINSANT	www.ms.etat.lu
MT	Malta	Medicines Authori- ty	MRU	MT-MEDAUTH	http://www.medicinesauthority.gov.mt/
NL	Netherlands	Medicines Evaluation Board	MEB	NL-MEB	http://www.cbg-meb.nl/
NO	Norway	Norwegian Medical Products Agency	NOMA	NO-NOMA	https://www.dmp.no/

PL	Poland	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products	URPL	PL-URPL	http://www.urpl.gov.pl/
PT	Portugal	National Authority of Medicines and Health Products	INFARMED	PT-INFARMED	http://www.infarmed.pt/
SK	Slovakia	State Institute for Drug Control	SIDC	SK-SIDC	http://www.sukl.sk/
SI	Slovenia	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	JAZMP	SI-JAZMP	http://www.jazmp.si/
ES	Spain	Spanish Agency for Medicines and Health Products	AEMPS	ES-AEMPS	http://www.aemps.gob.es/
SE	Sweden	Medical Products Agency	MPA	SE-MPA	http:// www.lakemedelsverket.se/

Assembly - Assembly DTD/Schema Type

If the 'EU-3-1' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'EU-3-1'. Otherwise, the 'EU-3-1' Assembly DTD/Schema will be added. **Sequence Maintenance - Filing Type Values**

Filing Type values will be added to the Sequence Maintenance – Filing Type values section in Data Administration, if they do not already exist. List of new values can be found in table below:

Filing Type	Display Name	Countries
Article 18 Filing	Article 18 Filing	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Great Britain, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Submission Maintenance - Sub Filing Type Values

Sub Filing Type values will be added to the Submission Maintenance – Sub Filing Type values section in Data Administration, if they do not already exist. List of new values can be found in table below:

Sub Filing Type	Countries
Initial	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom
Closing Information	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Undefined, United Kingdom
Validation Response	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Response	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Additional Information	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portu- gal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Consolidating	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portu- gal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Corrigendum	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portu- gal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Reformat	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portu- gal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom
Re-examination	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Union, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Northern Ireland, Norway, Poland, Portu- gal, Romania, Slovakia, Slovenia, Spain, Sweden, Undefined, United Kingdom

Submission Maintenance - Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Submission Maintenance > Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for eu-3-1 DTD/Schema is added to them. The list of new values includes the following:

Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Marketing Authorisation Application	eu-3-1	maa	MAA, MAA-AH
Variation 1A Filing	eu-3-1	var-type1a	MAA, MAA-AH
Variation 1AIN Filing	eu-3-1	var-type1ain	MAA, MAA-AH

Variation 1B Filing	eu-3-1	var-type1b	MAA, MAA-AH
Variation 2 Filing	eu-3-1	var-type2	MAA, MAA-AH
National Variation Filing	eu-3-1	var-nat	MAA, MAA-AH
Extension Filing	eu-3-1	extension	MAA, MAA-AH
Repeat Use Procedure	eu-3-1	rup	MAA, MAA-AH
Periodic Safety Update Report	eu-3-1	psur	MAA, MAA-AH
PSUR single assessment procedure	eu-3-1	psusa	MAA, MAA-AH
Risk Management Plan Filing	eu-3-1	rmp	MAA, MAA-AH
Renewal Filing	eu-3-1	renewal	MAA, MAA-AH
Specific Obligation Related to PAM	eu-3-1	pam-sob	MAA, MAA-AH
Annex II Condition Related to PAM	eu-3-1	pam-anx	MAA, MAA-AH
Additional PV Activity in the RMP Related to PAM	eu-3-1	pam-mea	MAA, MAA-AH
Legally Binding Measure Related to PAM	eu-3-1	pam-leg	MAA, MAA-AH
SDA Submission Related to PAM	eu-3-1	pam-sda	MAA, MAA-AH
Corrective/Preventive Action Related to PAM	eu-3-1	pam-capa	MAA, MAA-AH
Paediatric Submission Related to PAM (Article 45)	eu-3-1	pam-p45	MAA, MAA-AH
Paediatric Submission Related to PAM (Article 46)	eu-3-1	pam-p46	MAA, MAA-AH
PAES Submission Related to PAM	eu-3-1	pam-paes	MAA, MAA-AH
Recommendation Related to PAM	eu-3-1	pam-rec	MAA, MAA-AH
PASS Protocol Submission (Article 107n)	eu-3-1	pass107n	MAA, MAA-AH
PASS Report Submission (Article 107q)	eu-3-1	pass107q	MAA, MAA-AH
ASMF Filing	eu-3-1	asmf	MAA, MAA-AH
Plasma Master File	eu-3-1	pmf	MAA, MAA-AH
Article 20 Referral	eu-3-1	referral-20	MAA, MAA-AH

Article 29(4) Referral	eu-3-1	referral-294	MAA, MAA-AH
Article 29 Paediatric Referral	eu-3-1	referral-29p	MAA, MAA-AH
Article 30 Referral	eu-3-1	referral-30	MAA, MAA-AH
Article 31 Referral	eu-3-1	referral-31	MAA, MAA-AH
Article 35 Referral	eu-3-1	referral-35	MAA, MAA-AH
Article 5(3) Referral	eu-3-1	referral-5-3	MAA, MAA-AH
Article 107i Referral	eu-3-1	referral-107i	MAA, MAA-AH
Article 16c (1c)i Referral	eu-3-1	referral-16c1c	MAA, MAA-AH
Article 16c(4) Referral	eu-3-1	referral-16c4	MAA, MAA-AH
Annual Reassessment Filing	eu-3-1	annual-reassessment	MAA, MAA-AH
USR Filing	eu-3-1	usr	MAA, MAA-AH
Clinical Data for Publication – Redact- ed Proposal	eu-3-1	clin-data-pub-rp	MAA, MAA-AH
Clinical Data for Publication – Final Version	eu-3-1	clin-data-pub-fv	MAA, MAA-AH
PAED Related to PIP (Article 7, 8, 30)	eu-3-1	paed-7-8-30	MAA, MAA-AH
PAED Article 29 Filing	eu-3-1	paed-29	MAA, MAA-AH
PAED Article 45	eu-3-1	paed-45	MAA, MAA-AH
PAED Article 46	eu-3-1	paed-46	MAA, MAA-AH
Article 58 Filing	eu-3-1	article-58	MAA, MAA-AH
Notification 61-3 Filing	eu-3-1	notification-61-3	MAA, MAA-AH
Transfer MA Filing	eu-3-1	transfer-ma	MAA, MAA-AH
Lifting Suspension Filing	eu-3-1	lifting-suspension	MAA, MAA-AH
Withdrawal Filing	eu-3-1	withdrawal	MAA, MAA-AH
CEP Submission	eu-3-1	cep	MAA, MAA-AH
None	eu-3-1	none	MAA, MAA-AH
Article 18 Filing	eu-3-1	article-18	MAA, MAA-AH

Submission Maintenance - Sub Filing Type eCTD Codes Values

Sub Filing Type eCTD codes values will be added to the Submission Maintenance – Sub Filing Type values section in Data Administration, if they do not already exist. If they already exist, the eCTD Code for ZA-3-0 DTD/Schema is added to the value. List of new values can be found in table below:

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Initial	eu-3-1	initial	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Addition- al PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Validation Response	eu-3-1	Validation response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safety Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM,

			Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication – Redacted Proposal, Clinical Data for Publication – Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Response	eu-3-1	response	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Re- lated to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Sub- mission, None, Article 18 Filing.

Additional Information	eu-3-1	additionalinfo	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Man- agement Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM,Corrective/Preventive Action Re- lated to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plas- ma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Closing Information	eu-3-1	closing	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM,Corrective/Preventive Action Re- lated to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Refer- ral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Re- ferral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral,

			Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Consolidating	eu-3-1	consolidating	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Arti- cle 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publicaion Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Corrigendum	eu-3-1	corrigendum	Marketing Authorisation Application,Variation 1AFiling,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM, Corrective/Preventive Action Re- lated to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Rec-

			Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plas- ma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Reformat	eu-3-1	reformat	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM,Corrective/Preventive Action Re- lated to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.
Reexamination	eu-3-1	reexamination	Marketing Authorisation Application,Variation 1A Filing,Variation 1AIN Filing, Variation 1B Filing, Variation 2 Filing, National Variation Filing, Extension Filing, Repeat Use Procedure, Periodic Safe- ty Update Report, PSUR single assessment procedure, Risk Management Plan Filing, Renewal Filing, Specific Obligation, Related to PAM, Annex II Condition Related to PAM, Additional PV Activity in

			the RMP Related to PAM, Legally Binding Measure Related to PAM, SDA Submission Related to PAM,Corrective/Preventive Action Related to PAM, Paediatric Submission Related to PAM (Article 45), Paediatric Submission Related to PAM (Article 46), PAES Submission Related to PAM, Recommendation Related to PAM, PASS Protocol Submission (Article 107n), PASS Report Submission (Article 107q), ASMF Filing, Plasma Master File, Article 20 Referral, Article 29(4) Referral, Article 29 Paediatric Referral, Article 30 Referral, Article 31 Referral, Article 35 Referral, Article 5(3) Referral, Article 107i Referral, Article 16c (1c)i Referral, Article 16c(4) Referral, Annual Reassessment Filing, USR Filing, Clinical Data for Publication - Redacted Proposal, Clinical Data for Publication - Final Version, PAED Related to PIP (Article 7, 8, 30), PAED Article 29 Filing, PAED Article 45, PAED Article 46, Article 58 Filing, Notification 61-3 Filing, Transfer MA Filing, Lifting Suspension Filing, Withdrawal Filing, CEP Submission, None, Article 18 Filing.

WHO v1.0 Updates Application Maintenance – Region Values

If the WHO region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value 'WHO' in the database. Otherwise, the WHO region is added with the values:

Region Abbreviation	Region Name	Active Flag
WHO	World Health Organization	Active

Application Maintenance - Country Values

New WHO country in the Application Maintenance – Country values in Data Administration, must be changed or added, if absent, with the following values:

Country Code	Country Name	eCTD Code	Region	Active Flag
WHO	World Health Organization	whopqt	World Health Organization	Active

Application Maintenance - Health Authority Name

Health Authority name for WHO country, in the Application Maintenance – Country values in Data Administration under the Health Authority tab, must be changed or added, if absent, to those listed in the following table:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority website
World Health Organization	World Health Organization	WHO	whopqt	https://extranet.who.int/ prequal/

Assembly - Assembly DTD/Schema Type Values

If the 'WHO-1-0' Assembly DTD/Schema type already exists in the Assembly - Assembly DTD/Schema Types section in Data Administration, it will be activated (if inactive) and updated to have the code value 'WHO-1-0'. Otherwise, the 'WHO-1-0' Assembly DTD/Schema will be added. **Application Maintenance - Procedure Type Values**

The 'National' Procedure Type in the Application Maintenance - Procedure Type values section in Data

Administration, it will be activated (if inactive) and updated to include WHO country, in addition to already added countries.

Application Maintenance - Application Type Values

The *Application Type Values* list will be added to the Data Administration > Application Maintenance section if it does not already exist. The list includes the following values:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
FPP	Finished Pharmaceutical Product	Finished Pharmaceutical Product	New Drug Application	Finished Pharmaceutical Product	World Health Organization
FVP	Finished Vaccine Product	Finished Vaccine Product	New Drug Application	Finished Vaccine Product	World Health Organization
APIPQ	Active Pharmaceutical Ingredient	Active Pharmaceutical Ingredient	New Drug Application	Active Pharmaceutical Ingredient	World Health Organization
APIMF	Active Pharmaceutical Ingredient Master File	Active Pharmaceutical Ingredient Master File	New Drug Application	Active Pharmaceutical Ingredient Master File	World Health Organization

The Finished Pharmaceutical Product Application Type gets Default Flag set to Yes upon associating it with WHO country.

Application Maintenance - Application Category Values

Application Category Values will be added to the Application Maintenance – Application Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Application Category Name	Active Flag
Finished Pharmaceutical Product	Active
Finished Vaccine Product	Active
Active Pharmaceutical Ingredient	Active
Active Pharmaceutical Ingredient Master File	Active

Application Maintenance - Application Type eCTD Codes

The Application Type eCTD Codes values will be added to the Application Maintenance > Application Type Values list in Data Administration if they do not already exist there. If they exist, the eCTD Code for who-1-0 DTD/Schema will be added to them. The list of new values includes the following:

Application Type (Display Name)	Application DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Finished Pharmaceutical Product	who-1-0	FPP		No
Finished Vaccine Product	who-1-0	FVP		No
Active Pharmaceutical Ingredient	who-1-0	APIPQ		No
Active Pharmaceutical Ingredient Master File	who-1-0	APIMF		No

Sequence Maintenance - Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Sequence Maintenance > Filing Type Values list in Data Administration if they do not already exist. If they exist, the eCTD Code for who-1-0 DTD/Schema is added to them. The list of new values includes the following:

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Annual Report (FVP)	who-1-0	AR	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
APIMF Procedure	who-1-0	APIMF	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Filing Type (Display)	Applicable DTD/ Schema	eCTD Code	Available for Application Types
New Emergency Use Listing (EUL) Application (FPP, FVP)	who-1-0	EUL	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Post-PQ Change (API, FFP, FVP)	who-1-0	PPQC	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
New Prequalification Application (API, FFP, FVP)	who-1-0	PQP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File
Reassessment (FVP)	who-1-0	REAS	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File

Requalification Application (FPP)	who-1-0	RQAP	Finished Pharmaceutical Product, Finished Vaccine Product, Active Pharmaceutical Ingredient, Active Pharmaceutical Ingredient Master File

Submission Maintenance - Sub Filing Type eCTD Codes

The Sub Filing Type eCTD Codes values will be added to the Submission Maintenance > Sub Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for who-1-0 DTD/Schema is added to them. The list of new values includes the following:

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Annual Notification (FPP)	WHO-1-0	AN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Abridged	WHO-1-0	PQA	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Immediate Notification (API)	WHO-1-0	AIN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Annual Notification (API)	WHO-1-0	AAN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Conversion	WHO-1-0	CONV	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
eCTD Baseline	WHO-1-0	eCTDB	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
EUL-Full (Emergency Use Listing)	WHO-1-0	EULF	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Full	WHO-1-0	Full	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Immediate Notification (FPP)	WHO-1-0	IN	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Major	WHO-1-0	Major	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Minor	WHO-1-0	Minor	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Parallel	WHO-1-0	Parallel	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Product Extension	WHO-1-0	PEX	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Standard	WHO-1-0	STD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Type A (Approval Before Implementation) (Major)(FVP)	WHO-1-0	AMAJ	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Type N (Immediate Notification) (Minor) (FVP)	WHO-1-0	NMI	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
Update	WHO-1-0	UPD	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
no Application Sub Type	WHO-1-0	none	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)
EUL-Abridged (Emergency Use Listing)	WHO-1-0	EULA	Annual Report (FVP), APIMF Procedure, New Emergency Use Listing (EUL) Application (FPP,FVP), Post-PQ Change (API, FFP, FVP), New Prequalification Application (API, FFP, FVP), Reassessment (FVP),Requalification Application (FPP)

Submission Maintenance - Regulatory Activity Lead Values

The Regulatory Activity Lead Values will be added to the Submission Maintenance > Regulatory Activity Lead Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
WHO	who-1-0	initial	Initial
WHO	who-1-0	validation-response	Validation Response
WHO	who-1-0	response	Response

WHO	who-1-0	additional-info	Additional Info
WHO	who-1-0	reformat	Reformat

Submission Maintenance Submission Product Type Values

Submission Product Type values will be added to the Submission Maintenance > Submission Product Type Values section in Data Administration if they do not already exist. List of new values can be found in table below:

Region	eCTD Code	Product Type	Applicable DTD/Schema
WHO	BTP	Biotherapeutic Product	WHO-1-0
WHO	FPP	Finished Pharmaceutical Product	WHO-1-0

Verify Migration Script Updates: Ennov InSight 7.3.3

After the migration script is run, changes must be verified and updated to the Data Administration data. The

script includes following updates:

— Creates or updates the WHO region to have the code value WHO in the database.

— Creates or updates the WHO country and associates it with the WHO region.

— Updates Health Authority Name to World Health Organization, Health Authority Abbreviation to WHO, Health Authority eCTD Code to whopqt and Health Authority Website to https://extranet.who.int/prequal/ in Application Maintenance > Country Values.

— Adds the WHO-1-0 assembly DTD type in the Assembly - Assembly DTD/Schema Types section in Data Administration, if it does not already exist.

— Updates National Procedure Type in the Application Maintenance-Procedure Type Values section in Data Administration values to make it activate (if inactive) and updates to include the WHO country.

— Updates Application Maintenance > Application Type Values with the following values and the assigns corresponding eCTD codes: Finished Pharmaceutical Product

- Finished Vaccine Product
- Active Pharmaceutical Ingredient
- Active Pharmaceutical Ingredient Master File

— The Finished Pharmaceutical Product Application Type will have Default Flag set to Yes upon associating it with WHO country.

— Updates Sequence Maintenance > Filing Type Values with the following values and assigns the corresponding eCTD codes:

- Annual Report (FVP)
- APIMF Procedure
- New Emergency Use Listing (EUL) Application (FPP,FVP)
- Post-PQ Change (API, FFP, FVP)
- New Prequalification Application (API, FFP, FVP)
- Reassessment (FVP)
- Requalification Application (FPP)

— Updates Submission Maintenance > Sub Filing Type Values with the following values and assigns the corresponding eCTD codes: • Annual Notification (FPP)

- Abridged
- Immediate Notification (API)
- Annual Notification (API)
- Conversion
- eCTD Baseline
- EUL-Full (Emergency Use Listing)
- Full
- Immediate Notification (FPP)
- Major
- Minor
- Parallel
- Product Extension
- Standard
- Type A (Approval Before Implementation)(Major)(FVP)
- Type N (Immediate Notification)(Minor) (FVP)
- Update
- no Application Sub Type
- EUL-Abridged (Emergency Use Listing)

— Updates Submission Maintenance > Regulatory Activity Lead Values with the following values and assigns the corresponding eCTD codes:

- Initial
- Validation Response
- Response
- Additional Info
- Reformat

— Updates Submission Maintenance > Submission Product Type Values with the following values and assigns the corresponding eCTD codes:

- Biotherapeutic Product
- Finished Pharmaceutical Product

EU 3.1 Updates

The migration script will perform multiple changes to Data Administration data related to EU 3.1. These should be verified, and where necessary, updated. The script does the following:

— Adds the country Northern Ireland to the Application Maintenance - Country Values section in Data Administration if it does not already exist.

— Updates EU County-Health Authority values in the Application Maintenance – Country values section in Data Administration if they do not already exist. The list of new or updated values can be found below:

- AT-BASG
- BE-FAMHP
- HR-HALMED
- CY-PHS
- CZ-SUKL
- DK-DKMA • EE-SAM
- DK-DKMA
- EE-SAM
- FR-ANSM
- DE-BFARM
- EL-EOF
- HU-OGYI
- IS-IMCA
- IE-HPRA
- IT-AIFA
- LV-ZVA
- LI-LLV
- LT-SMCA
- LU-MINSANT
- MT-MEDAUTH
- NL-MEB
- NO-NOMA
- PL-URPL
- PT-INFARMED
- SK-SIDC
- SI-JAZMP
- ES-AEMPS
- SE-MPA

— Adds the 'EU-3-1' Assembly DTD/Schema type in the Assembly - Assembly DTD/Schema Types section in Data Administration. If the 'EU-3-1' Assembly DTD/Schema already exists, it will be activated (if inactive) and updated to have the code value 'EU-3-1'. Otherwise, the 'EU-3-1' Assembly DTD/Schema will be added.

— Updates Sequence Maintenance – Filing Type values with the following values:

- Article 18 Filing

— Updates Submission Maintenance – Sub Filing Type values with the following values:

- Initial
- Validation Response
- Response
- Additional Information
- Closing Information
- Consolidating
- Corrigendum
- Reformat
- Re-examination

Chapter 7. Ennov InSight 7.3.2 Updates

Data Administration Updates: Ennov InSight 7.3. 2

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

ZA v3.1 Updates

If ZA region already exists in the Application Maintenance > Region Values section in Data Administration, it will be updated to have the ZA code value in the database. If ZA region does not exist, an error message will be generated, and the script will skip South Africa updates.

The Health Authority name for South Africa country must be changed to the following:

Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority website
South Africa	South African Health Products Regulatory Authority	SAHPRA	ZA-SAHPRA	https://ectd.sahpra.org.za/ index.html

The Health Authority name can be found in Application Maintenance > Country Values in Data Administration under the Health Authority tab

The South Africa country will be updated to belong to South Africa region if it does not belong to it already. The South Africa country will receive ZA as eCTD code.

If the ZA-3-1 Assembly DTD/Schema type already exists in the Assembly > Assembly DTD/Schema Types list in Data Administration, it will be activated (if inactive) and updated to have the ZA-3-1 code value. Otherwise, the ZA-3-1 Assembly DTD/Schema will be added.

If the National ZA Procedure Type already exists in the Application Maintenance > Procedure Type Values list in Data Administration, it will be activated (if inactive) and updated to have the National eCTD code value. Otherwise, the National ZA Procedure Type will be added.

Application Type Values

The *Application Type Values* list will be added to the Data Administration > Application Maintenance section if it does not already exist. The list includes the following values:

Application Type	Name	Display Name	Entity XML Type Name	Application Category	Countries
ZA-NP	SAHPRA National Procedure	SAHPRA National Procedure	New Drug Application	SAHPRA National Procedure	South Africa
AMAP	AMA Procedure	AMA Procedure	New Drug Application	AMA Procedure	South Africa
JR	ZAZIBONA Joint Review	ZAZIBONA Joint Review	New Drug Application	ZAZIBONA Joint Review	South Africa
WHO-PQ	WHO-PQ	WHO-PQ	New Drug Application	WHO-PQ	South Africa
WHO-CRP	WHO SRA CRP	WHO SRA CRP	New Drug Application	WHO SRA CRP	South Africa
CH-GHP	Swissmedic MAGHP	Swissmedic MAGHP	New Drug Application	Swissmedic MAGHP	South Africa
EU-M4ALL	EU M4ALL	EU M4ALL	New Drug Application	EU M4ALL	South Africa

Application Type eCTD Codes

The Application Type eCTD Codes values will be added to the Application Maintenance > Application Type Values list in Data Administration if they do not already exist there. If they exist, the eCTD Code for ZA-3-1 DTD/Schema will be added to them. The list of new values includes the following:

Application Type (Display Name)	Application DTD/ Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
SAHPRA National Procedure	ZA-3-1	app-type-1		No

AMA Procedure	ZA-3-1	app-type-2		No
ZAZIBONA Joint Review	ZA-3-1	app-type-3		No
WHO-PQ	ZA-3-1	app-type-4		No
WHO SRA CRP	ZA-3-1	app-type-5		No
Swissmedic MAGHP	ZA-3-1	app-type-6		No
EU M4ALL	ZA-3-1	app-type-7		No

Filing Type eCTD Codes

The Filing Type eCTD Codes values will be added to the Sequence Maintenance > Filing Type Values list in Data Administration if they do not already exist. If they exist, the eCTD Code for ZA-3-1 DTD/Schema is added to them. The list of new values includes the following:

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
A - NCE New Chemical Entity	ZA-3-1	sub-type-1	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
D - New Generic Medicine	ZA-3-1	sub-type-2	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Complementary Medicine - New	ZA-3-1	sub-type-3	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
New Biological	ZA-3-1	sub-type-4	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Biosimilar (na-bs)	ZA-3-1	sub-type-5	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Clinical Trial Application	ZA-3-1	sub-type-6	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
New Vaccines	ZA-3-1	sub-type-7	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
I: Vaccine Antigen Master File	ZA-3-1	sub-type-8	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA

New SMF	ZA-3-1	sub-type-9	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
New APIMF	ZA-3-1	sub-type-10	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Plasma Master File (PMF)	ZA-3-1	sub-type-11	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Line extension-New Strength	ZA-3-1	sub-type-12	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Line extension-New Dosage Form	ZA-3-1	sub-type-13	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Line extension-New Applica- tion	ZA-3-1	sub-type-14	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Clone	ZA-3-1	sub-type-15	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Replica-Same	ZA-3-1	sub-type-16	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA

Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
Type IA-Quality	ZA-3-1	sub-type-17	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IAin-Clinical	ZA-3-1	sub-type-18	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IAin-Quality	ZA-3-1	sub-type-19	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IB-Clinical	ZA-3-1	sub-type-20	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IB-Quality	ZA-3-1	sub-type-21	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type I-Inspectorate	ZA-3-1	sub-type-22	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type I-Other	ZA-3-1	sub-type-23	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA

Type II-Safety (Clinical)	ZA-3-1	sub-type-24	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II - Safety and Efficacy (Clinical)	ZA-3-1	sub-type-25	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Quality	ZA-3-1	sub-type-26	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Rescheduling	ZA-3-1	sub-type-27	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Proprietary Name Change	ZA-3-1	sub-type-28	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant- Relinquishing	ZA-3-1	sub-type-29	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant-Acquiring	ZA-3-1	sub-type-30	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Baseline	ZA-3-1	sub-type-31	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
z-Code-Quality	ZA-3-1	sub-type-32	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Pharmacovigilance	ZA-3-1	sub-type-33	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Filing Type (Display)	Applicable DTD/Schema	eCTD Code	Available for Application Types
USRN-Clinical and Pharma-covigilance	ZA-3-1	sub-type-34	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Application Withdrawal/ Can-cellation	ZA-3-1	sub-type-35	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, ND
Renewal Filing	ZA-3-1	sub-type-36	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Undefined Regulatory Activity*	ZA-3-1	sub-type-37	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA

Type IB-Related Clinical	ZA-3-1	sub-type-38	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IB-Related Quality	ZA-3-1	sub-type-39	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IB-Related Inspectorate	ZA-3-1	sub-type-40	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type IA-Clinical	ZA-3-1	sub-type-41	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Related Clinical	ZA-3-1	sub-type-42	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Related Quality	ZA-3-1	sub-type-43	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA
Type II-Related Inspectorate	ZA-3-1	sub-type-44	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CHGHP, EU-M4ALL, CTA, NDA

Sub Filing Type eCTD Codes

The Sub Filing Type eCTD Codes values will be added to the Submission Maintenance > Sub Filling Type Values section in Data Administration if they do not already exist. If they exist, the eCTD Code for ZA-3-1 DTD/ Schema is added to them. The list of new values includes the following:

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Initial	ZA-3-1	seq-type-1	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy

			(Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Supplementary Information	ZA-3-1	seq-type-2	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type

Response- Clinical	ZA-3-1	seq-type-3	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB-Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response- Quality	ZA-3-1	seq-type-4	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality,

			Pharma-covigilance, USRN-Clinical and Pharmacovigilance, Application With- drawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Response- Inspectorate	ZA-3-1	seq-type-5	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-N and S	ZA-3-1	seq-type-6	A - NCE New Chemical Entity, D - New Generic Medicine,

			Complementary Medicine - New, New Biological, Biosimilar (nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharma-covigilance, USRN-Clinical and Pharmacovigilance, Application With-drawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
Closing Information	ZA-3-1	seq-type-7	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy

			(Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Work Grouping Partial Withdrawal	ZA-3-1	seq-type-8	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*Type IBRelated Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type

Submission Withdrawal	ZA-3-1	seq-type-9	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II-Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB-Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-Biological	ZA-3-1	seq-type-10	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality,

			Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Sub Filing Type (Display Name)	Applicable DTD/ Schema	eCTD Code	Available for Filing Type
ResponseRenewals	ZA-3-1	seq-type-11	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar (na-bs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type II- Proprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharmacovigilance, USRN-Clinical and Pharmacovigilance, Application Withdrawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate
Response-PV	ZA-3-1	seq-type-12	A - NCE New Chemical Entity, D - New Generic Medicine, Complementary Medicine - New, New Biological, Biosimilar

			(nabs), Clinical Trial Application, New Vaccines, I: Vaccine Antigen Master File, New SMF, New APIMF, Plasma Master File (PMF), Line extension-New Strength, Line extension-New Dosage Form, Line extension-New Application, Clone, ReplicaSame, Type IA-Quality, Type IAin-Clinical, Type IAin-Quality, Type IB-Clinical, Type IB-Quality, Type I-Inspectorate, Type IOther, Type II-Safety (Clinical), Type II - Safety and Efficacy (Clinical), Type II-Quality, Type II-Rescheduling, Type IIProprietary Name Change, Type II-Change in ApplicantRelinquishing, Type II-Change in Applicant-Acquiring, Baseline, z-Code-Quality, Pharma-covigilance, USRN-Clinical and Pharmacovigilance, Application With-drawal/Cancellation, Renewal Filing, Undefined Regulatory Activity*, Type IB- Related Clinical, Type IB-Related Quality, Type IB-Related Inspectorate, Type IA-Clinical, Type II-Related Clinical, Type II-Related Quality, Type II-Related Inspectorate

Regulatory Activity Lead Values

The Regulatory Activity Lead Values will be added to the Submission Maintenance > Regulatory Activity Lead Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa	ZA-3-1	sub-lead-1	Biologicals
South Africa	ZA-3-1	sub-lead-2	Complimentary
South Africa	ZA-3-1	sub-lead-3	Master Files
South Africa	ZA-3-1	sub-lead-4	Orthodox
South Africa	ZA-3-1	sub-lead-5	Pharmacovigilance
South Africa	ZA-3-1	sub-lead-6	Veterinary

Evaluation Pathway Values

The Evaluation Pathway Values will be added to the Submission Maintenance > Evaluation Pathway Values list in Data Administration if they do not already exist. The list of new values includes the following:

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa			
South Africa			
South Africa			
South Africa			
South Africa			

Applicant Contact Type Values

The Applicant Contact Type Values will be added to the Submission Maintenance > Applicant Contact Type Values section in Data Administration if they do not already exist. The list of new values includes the following:

eCTD Standard Type	Region	Regulatory Code	Applicant Contact Type
eCTD 3.2	South Africa	contact-type-1	Local Applicant
eCTD 3.2	South Africa	contact-type-2	Regulatory
eCTD 3.2	South Africa	contact-type-3	Technical
eCTD 3.2	South Africa	contact-type-4	Product Information
eCTD 3.2	South Africa	contact-type-5	General

Verify Migration Script Updates

After the migration script is run, changes must be verified and updated to the Data Administration data. The script includes following updates:

— Updates ZA region to have the ZA code value in the database.

— Updates Health Authority Name to South African Health Products Regulatory Authority, Health Authority Abbreviation to SAHPRA, Health Authority eCTD Code to ZA-SAHPRA and Health Authority Website to https://ectd.sahpra.org.za/index.html in Application Maintenance > Country Values Data Administration list.

— Adds the ZA-3-1 assembly DTD type in the Assembly > Assembly DTD/Schema Types Data

Administration list, if it does not already exist.

— Activates National ZA Procedure Type in the Application Maintenance > Procedure Type Values Data Administration list and adds the National eCTD code value to it.

— Updates Application Maintenance > Application Type Values with the following values and the corresponding eCTD codes assigned to them:

- SAHPRA National Procedure
- AMA Procedure

- ZAZIBONA Joint Review
- WHO-PQ
- WHO SRA CRP
- Swissmedic MAGHP
- EU M4ALL

— Updates Sequence Maintenance > Filing Type Values with the following values and the corresponding eCTD codes assigned to them: • A - NCE New Chemical Entit

- D - New Generic Medicine
- Complementary Medicine - New
- New Biological
- Biosimilar (na-bs)
- Clinical Trial Application
- New Vaccines
- I: Vaccine Antigen Master File
- New SMF
- New APIMF
- Plasma Master File (PMF)
- Line extension-New Strength
- Line extension-New Dosage Form
- Line extension-New Application
- Clone
- Replica-Same
- Type IA-Quality
- Type IAin-Clinical
- Type IAin-Quality
- Type IB-Clinical
- Type IB-Quality
- Type I-Inspectorate
- Type I-Other
- Type II-Safety (Clinical)
- Type II - Safety and Efficacy (Clinical)
- Type II-Quality
- Type II-Rescheduling
- Type II-Proprietary Name Change
- Type II-Change in Applicant-Relinquishing
- Type II-Change in Applicant-Acquiring
- Baseline
- z-Code-Quality
- Pharmacovigilance

- USRN-Clinical and Pharmacovigilance
- Application Withdrawal/Cancellation
- Renewal Filing
- Undefined Regulatory Activity*
- Type IB-Related Clinical
- Type IB-Related Quality
- Type IB-Related Inspectorate
- Type IA-Clinical
- Type II-Related Clinical
- Type II-Related Quality
- Type II-Related Inspectorate

— Updates Submission Maintenance > Sub Filing Type Values with the following values and the corresponding eCTD codes assigned to them:

- Initial
- Supplementary Information
- Response-Clinical
- Response-Quality
- Response-Inspectorate
- Response-N and S
- Closing Information
- Work Grouping Partial Withdrawal
- Submission Withdrawal
- Response-Biological
- Response-Renewals
- Response-PV

— Updates Submission Maintenance > Regulatory Activity Lead Values with the following values and the corresponding eCTD codes assigned to them:

- Biologicals
- Complimentary
- Master Files
- Orthodox
- Pharmacovigilance
- Veterinary

— Updates Submission Maintenance > Evaluation Pathway Values with the following values and the corresponding eCTD codes assigned to them:

- Priority
- Full Evaluation
- Abridged Evaluation
- Rolling Review
- Section 21

— Updates Submission Maintenance > Applicant Contact Type Values with the following values for South Africa and the corresponding eCTD codes assigned to them:

- Local Applicant
- Regulatory
- Technical
- Product Information
- General

Ennov InSight 7.3.1 Updates

Chapter 8. Ennov InSight 7.3.1 Updates

Security Administration Updates

Security Administration Updates: Ennov InSight 7.3.1

Updates Security Administration to include the following.

XEVMPD License Module

For users with Data Administration rights set to **NO**, 7.3.1 now allows access to both XEVMPD Acknowledgement and XEVMPD Submission wizards from the **Home** > **Wizards** menu.

Entities

Entity Updates: Ennov InSight 7.3.1

New changes and implementations are included in Ennov InSight 7.3.1 to conform to regulatory requirements.

Registrations Attachments

A new **2nd Attachment Language** field has been added to the *Registrations Attachments* page to confirm to the EMA XEVMPD requirements for the countries with more than one official language. The **2nd Attachment Language** is not required. The drop-down field shows values from **Application Maintenance** > **Country Values** Data Administration list.

Chapter 9. Ennov InSight 7.3 Updates

Security Administration and Job Requests

Security Administration and Job Requests Updates: Ennov InSight 7.3

Updates to Security Administration and Job Requests by data migration.

XEVMPD License Module

To manage IDMP and xEVMPD features separately, the IDMP and xEVMPD license modules are separated in Security Administration. Upon migration, the IDMP license appears with Select value by default. The xEVMPD license shows the value selected in previous Ennov InSight version.

Job Requests

The *Job Requests* window now includes a new IDMP Data Generation Initial Flow:

MedicinalProductAction: [Action Name] option for IDMP. The option will be available after data is generated using IDMP Data Generation wizard.

Data Administration Updates

Data Administration Updates: Ennov InSight 7.3

Running the migration script updates Data Administration with latest changes. The changes must be reviewed, and updated, as necessary.

API Updates

All Data Administration lists are updated with create, update, and deactivate API functionality.

Orphan Status Values

The entity type name in dadmin.TERMINOLOGY_SYSTEM_LIST and

mgr.entity_type.ASSOCIATE_DB_TABLE is updated to Orphan Status Type from Regulatory Entitlement Status so that the database is consistent with the Data Administration list name.

The Out-of-the-box (OOTB) value for the new orphan_status_type table must be the same as in the regulatory_entitlement_status _type table.

Qualified Person Responsible for Pharmacovigilance (QPPV) Values

The SPOR mapping for the RMS tab associated RMS search widget functionality is removed from the Qualified

Person Responsible for Pharmacovigilance (QPPV) Values list as it was incorrectly mapped. Any existing SPOR RMS mapping values must be deleted.

Ennov InSight 7.3 Data Migration Documentation

Security Administration and Job Requests

Substance Role Values

The SPOR mapping for the RMS tab associated RMS search widget functionality is removed from the Substance Role Values list as it was incorrectly mapped. Any existing SPOR RMS mapping values must be deleted.

Substance Type Values

The SPOR mapping for the RMS tab associated RMS search widget functionality is added to the Substance Type Values list and maps to the new RMS list Ingredient Role that exists in the SPOR Master Lists section of *Data Administration*.

Regulatory Entitlement Status Values

The Regulatory Entitlement Status Values is a new Data Administration list with SPOR mapping for the RMS tab with associated RMS search widget functionality that was added to the Application Maintenance section of *Data Administration*. This new Data Administration list maps to the existing RMS list Regulatory Entitlement Status that exists in the SPOR Master Lists section of *Data Administration*.

Attached Document Content Type Values

The Attached Document Content Type Values list had SPOR mapping for the RMS tab with associated RMS search widget functionality added to map to new RMS lists eCTD EU Context of Use, Regulating Authority Submission Unit Type and existing RMS list Product Information Document Type.

Product Information Document Type

The Product Information Document Type list is deleted as it was a duplicate of Attached Document Content Type Values.

Registration Status Values

The Registration Status Values list is corrected to retrieve only the Regulatory Entitlement Status RMS list instead of retrieving all RMS lists in the association widget.

Source of Information Values

The Source of Information Values is a new Data Administration list with SPOR mapping for the RMS tab with associated RMS search widget functionality that was added to the Other section of *Data Administration*. This new

Data Administration list maps to new RMS list Source of Information that exists in the SPOR Master Lists section of

Data Administration. **Data Carrier Values**

The SPOR mapping for the RMS tab associated RMS search widget functionality is added to the Data Carrier Values list and maps to the new RMS list Source of Information that exists in the SPOR Master Lists section of *Data Administration*.

Device – Type of Combination Values

The SPOR mapping for the RMS tab associated RMS search widget functionality is added to the Device – Type of Combination Values list and maps to the new RMS list Medical Device Legislative Category that exists in the SPOR Master Lists section of *Data Administration*.

Ennov InSight 7.3 Data Migration

Documentation Data Administration Updates

Intended Effect Values

The SPOR mapping for the RMS tab associated RMS search widget functionality is added to the Intended Effect Values list and maps to the new RMS list Medicine Profile that exists in the SPOR Master Lists section of *Data Administration*.
Device Classification Values

The Device Classification Values list was hidden and is now restored in the Ennov InSight . The SPOR mapping for the RMS tab associated RMS search widget functionality is added to the Device Classification Values list and maps to the new RMS list Medical Device Classification that exists in the SPOR Master Lists section of *Data Administration*.
Component Type Values

The Component Type Values list is corrected to retrieve new RMS list Container Category in the association widget.

SPOR Master Lists

The following new RMS lists are added to the SPOR Master Lists section of *Data Administration*: — Medicinal Product Type

— Source of Information

— Medical Device Legislative Category

— Medicine Profile

— Medical Device Classification

— Container Category

— eCTD EU Context of Use

— Regulating Authority Submission Unit Type **Telephone Number Type Values**

The new OOTB values added to the Telephone Number Type Values with following fields:

Region	Regulatory Code	Telephone Number Type	Active Flag
United States	WP	eCTD 4.0 Business Telephone Number	Active
United States	FAX	eCTD 4.0 Fax Telephone Number	Active
United States	MC	eCTD 4.0 Mobile Telephone Number	Active

Applicant Contact Type Values

Upon migration all existing values get eCTD 3.2 as value in the eCTD Standard Type field. Ennov

InSight 7.3 Data Migration

Documentation Data Administration Updates

Entities

Entities Updates:Ennov InSight 7.3

New changes and implementations are included in Ennov InSight 7.3 to conform to the eCTD 4.0, IDMP and regulatory requirements.

Manufactured Item

The Manufactured Item Quantity Operator field is added, mapped to the Data Administration > Concentration Measure Type Values is added to the Manufactured Item entity.

Sequence

Migrating adds a new field Sequence Standard Type for each existing sequence with eCTD 3.2 as the default value

Assemblies

Migrating adds a new field eCTD Standard Type for each existing assembly template with eCTD 3.2 as the default value.

Attached Document

— Attached Document upon migration is available for all application procedure types.

— Attached Document Type linked to the Product Information Document Type Values list is deleted. — The Content Type field linked to the Attached Document Content Type Values list is renamed to Attached Document Type.

— The Effective Date field is renamed to Attached Document Effective Date.

— The Language field is renamed to Attached Document Language.

— The Attachment Document Status field with values from Data Administration > Attached Document Status Values is added.

— The Attached Document URL browse field is added.

PDS Pack Size

The Quantity Operator field, mapped to Data Administration > Concentration Measure Type Values is added to PDS Pack Size Detail Attributes.

PDS Packaging

The Quantity Operator field mapped to Data Administration > Concentration Measure Type Values is added to PDS Packaging detail.

PDS Medical Devices

The following new fields are added to the Medical Devices Node: Device Description, Device Description of Intended Purpose, Device Description Language (values from Data Administration > Language list), Device Classification (values from Data Administration > List Medical Device Classification list).

Ennov InSight 7.3 Data Migration Documentation

Entities

Upon migration there will be two new child nodes for Medical Devices Node: Function and Manufacturer.

PDS Indication – Intended Effects/Comorbidities/Countries

The data is migrated the following way for PDS Indication – Intended Effects, Comorbidities and Countries:

— With multiple intended effect by country by comorbidity, existing data will be migrated in a table in one group. Then migrate the countries per indication, effects per the same indication and comorbidities per the same indication and merge these values by creating a record for each combination.

— If an indication country is not defined, migration is optional.

— If an indication does not have intended effects or comorbidities, no sub node must be created.

— When migrating a PDS based on Centralized Application with new rule that only EU should be available for selection on the Indication screen, the logic should be based on the application country (same as MRP/DCP app even though IDMP will collect only EU and EEA country data for CP). We should have the Intended Use and Comorbidity defined for all indication countries.

Medicinal Product Actions

Data Visualization (DV) icon is added for the Medicinal Product Action entity. The DV icon becomes active when there are correct security rights applied for the IDMP license module and when the IDMP Data Generation is completed for the medicinal product.

Ennov InSight 7.3 Data Migration Documentation

Entities

Wizards

Chapter 9. Wizards

Wizards: Ennov InSight 7.3

New features and fields are included in Ennov InSight 7.3 to conform to the regulatory requirements.

The following table lists the new and renamed fields in Ennov InSight 7.3.

Wizard Name	Page/Option Name	Change
XEVMPD Submission Wizard	*Authrorized Product Selection*	The *Select XEVPRM Sections* page along with its corresponding fields are removed from the wizard. Upon migration, only the Authorized Product Selection is available for XEVMPD file creation. .
IDMP Data Generation Wizard	Initial Generation	This new wizard is added and will be available for a user with IDMP license module rights.

Chapter 10. Common Functionality

Substance Selection Widget:Ennov InSight 7.3

New updates to the Substance Selection Widget.

Substance Selection Widget

The updated Substance Selection widget is available on the following pages and entity sections:

— Modify Product Family page.

— Add Substance PDS Detail (including PDS Template) page.

— Create/Edit Comparator page.

— Update Product Detail Set GPP -> Select Search option or Summary page:

- Active Ingredient
- Substance

— Component Reference Active Ingredient entity.

— Pharmaceutical Product Substance entity.

— Pharmaceutical Product Reference Substance entity.

— Manufactured Item Substance entity.

— Manufactured Item Reference Substance entity.

— Queries:

- List of Active Ingredient Function Manufacturers
- List of Active Ingredient Manufacturers
- List of Active Ingredient Material Manufacturers
- List of Product Families
- List of Excipient Manufacturers
- List of Registrations with Excipients
- List of Registrations with Active Ingredients
- Applications Sent, Submitted, or Approved - Searched by INN or Active Ingredient
- List of Products with Registration and Flu Strain Details — Manufacturer Global Details Set list in Data Administration.

— Certificate Master File list in Data Administration.

Chapter 11. Database Script Error messages

Description of database script errors that you may encounter when running the scripts.

Upgrade path	Error	Description/Resolution
7.2.7 to 7.3	ORA-30674: identity column cannot have a default value	Ignore
7.3 to 7.3.1	ORA-30674: identity column cannot have a default value	Ignore
7.3.1 to 7.3.2	ORA-30674: identity column cannot have a default value	Ignore

The following are the common errors you may encounter when migrating to a subsequent version. Table 1: Common Errors

Error	Description
SP2-0310: unable to open file "define.passwords"	Ignore
SP2-0310: unable to open file "define.application"	Ignore
ORA-02264: name already used by an existing constraint	DO NOT IGNORE. Contact Technical Support

Errors Message - Example

Errors for PACKAGE BODY ISM.PRODUCT_FAMILY_COPY LINE/COL

ERROR ----------

971/11 PL/SQL: SQL Statement ignored

973/21 PL/SQL: ORA-00942: table or view does not exist

977/9 PLS-00364: loop index variable 'IREC' use is invalid

977/9 PL/SQL: Statement ignored

978/9 PLS-00364: loop index variable 'IREC' use is invalid

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Documentation Errors Message - Example Database Script Error messages

978/9 PL/SQL: Statement ignored

979/9 PLS-00364: loop index variable 'IREC' use is invalid

979/9 PL/SQL: Statement ignored 980/9 PLS-00364: loop index variable 'IREC' use is invalid

980/9 PL/SQL: Statement ignored 982/9 PL/SQL: SQL Statement ignored

LINE/COL ERROR

--991/35 PL/SQL: ORA-00904: "IREC"."PRODUCT_ID": invalid identifier

993/9 PL/SQL: SQL Statement ignored 993/25 PL/SQL: ORA-00942: table or view does not exist

1004/11 PL/SQL: SQL Statement ignored

1006/21 PL/SQL: ORA-00942: table or view does not exist

1010/9 PLS-00364: loop index variable 'IREC' use is invalid

1010/9 PL/SQL: Statement ignored

1011/9 PLS-00364: loop index variable 'IREC' use is invalid

991/35 PLS-00364: loop index variable 'IREC' use is invalid