VERSION 7.2.12

CALYX RIM

Data Migration Document

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Contents

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Introduction

This document provides all migration requirements for the standard migration of Calyx RIM 7.2.11 to Calyx RIM 7.2.12.

Data Administration Updates

EU 3.1

The eCTD Code for Northern Ireland country will be updated to xi or whole country added if does not already exist to the Application Maintenance – Country Values section in Data Administration. County-Health Authority Values will be added or updated to the Application Maintenance – Country Values section in Data Administration if they do not already exist. List of new values can be found in table below:

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/default.aspx
FR	France	National Agency for the Safety of Medicines and Health Products	ANSM	FR-ANSM	http://ansm.sante.fr/
DE	Germany	BfArM - Federal Institute for Drugs and Medical Devices	BfArM	DE-BFARM	http://www.bfarm.de/

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
GR	Greece	Greek 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 / Medicinal Products Control Agency	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 Authority	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, IP	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/

Country Code	Country Name	Health Authority Name	Health Authority Abbreviation	Health Authority eCTD Code	Health Authority Website
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/

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.
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

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

Sub Filing Type	Countries
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, Portugal, 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, Portugal, 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, Portugal, 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, Portugal, 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, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, 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 EU-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	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 – Redacted 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

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, 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	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 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	eu-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	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 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	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 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	eu-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	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 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	eu-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

WHO v1.0

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

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

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

WHO	World Health Organization	WHO	whopqt	https://extranet.who.int/prequal/

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.
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 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
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 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 WHO-1-0 DTD/Schema is added to the value. List of new values can be found in table below:

Application Type (Display Name)	Applicable 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

Application Type (Display Name)	Applicable DTD/Schema	eCTD Code	Agency Abbreviation	Limit to Cross Application Only
Active Pharmaceutical Ingredient Master File	WHO-1-0	APIMF		No

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

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 WHO-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
Annual Report (FVP)	WHO-1-0	AR	FPP, FVP, APIPQ, APIMF
APIMF Procedure	WHO-1-0	APIMF	FPP, FVP, APIPQ, APIMF
New Emergency Use Listing (EUL) Application (FPP,FVP)	WHO-1-0	EUL	FPP, FVP, APIPQ, APIMF
Post-PQ Change (API, FFP, FVP)	WHO-1-0	PPQC	FPP, FVP, APIPQ, APIMF
New Prequalification Application (API, FFP, FVP)	WHO-1-0	PQP	FPP, FVP, APIPQ, APIMF
Reassessment (FVP)	WHO-1-0	REAS	FPP, FVP, APIPQ, APIMF
Requalification Application (FPP)	WHO-1-0	RQAP	FPP, FVP, APIPQ, APIMF

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 WHO-1-0 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
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)

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

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

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. List of new values can be found in table below:

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 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

EU 3.1

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 following:

- Updates the eCTD Code for Northern Ireland country xi or whole country is added if does not already exist to the Application Maintenance – Country Values section in Data Administration.

- Updates EU County-Health Authority Values in the Application Maintenance – Country Values section in Data Administration if they do not already exist. List of new or updated values can be found below:
    - AT-BASG
    - BE-FAMHP
    - HR-HALMED
    - CY-PHS
    - CZ-SUKL
    - 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, 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 following values:
    - Article 18 Filing
- Updates **Submission Maintenance – Sub Filing Type Values** with following values:
    - Initial
    - Validation Response
    - Response
    - Additional Information
    - Closing Information
    - Consolidating
    - Corrigendum
    - Reformat
    - Re-examination

WHO 1.0

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

- 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, to make it activated (if inactive) and updates to include the WHO country.
- Updates **Application Maintenance – Application type Values** with following values and assigns corresponding eCTD codes:
    - Finished Pharmaceutical Product
    - Finished Vaccine Product
    - Active Pharmaceutical Ingredient

Active Pharmaceutical Ingredient Master File

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

- Updates **Sequence Maintenance – Filing Type Values** with following values and assigns 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 following values and assigns 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
- Updates **Submission Maintenance – Regulatory Activity Lead Values** with following values and assigns corresponding eCTD codes:
    - Initial
    - Validation Response
    - Response
    - Additional Info
    - Reformat
- Updates **Submission Maintenance – Submission Product Type Values** with following values and assigns corresponding eCTD codes:
    - Biotherapeutic Product
    - Finished Pharmaceutical Product