

VERSION 7.2.10

CALYX RIM

Data Migration Document



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Introduction

This document provides all migration requirements for the standard migration of Calyx RIM 7.2.9 to Calyx RIM 7.2.10.

Data Administration Updates

South Africa v3.0

If the ZA region already exists in the Application Maintenance – Region Values section in Data Administration, it will be updated to have the code value ‘ZA’ in the database. Otherwise, an error message will be generated, and the script will skip South Africa updates.

Health Authority name for South Africa country, that already exists 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
South Africa	South African Health Products Regulatory Authority	SAHPRA	ZA-SAHPRA	https://ectd.sahpra.org.za/index.html

‘South Africa’ country will be updated to belong to South Africa region if it does not belong to it already.

‘South Africa’ country will receive ‘za’ as eCTD code.

If the 'ZA-3-0' 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 'ZA-3-0'. Otherwise, the 'ZA-3-0' Assembly DTD/Schema will be added.

If the ‘National ZA’ Procedure Type already exists in the Application Maintenance - Procedure Type values section in Data Administration, it will be activated (if inactive) and updated to have the eCTD code value ‘national’. Otherwise, the ‘National ZA’ Procedure Type will be added.

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
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 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 ZA-3-0 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
SAHPRA National Procedure	ZA-3-0	app-type-1		No
AMA Procedure	ZA-3-0	app-type-2		No
ZAZIBONA Joint Review	ZA-3-0	app-type-3		No
WHO-PQ	ZA-3-0	app-type-4		No
WHO SRA CRP	ZA-3-0	app-type-5		No
Swissmedic MAGHP	ZA-3-0	app-type-6		No
EU M4ALL	ZA-3-0	app-type-7		No

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 ZA-3-0 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
A - NCE New Chemical Entity	ZA-3-0	sub-type-1	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
D - New Generic Medicine	ZA-3-0	sub-type-2	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Complementary Medicine - New	ZA-3-0	sub-type-3	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Biological	ZA-3-0	sub-type-4	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Biosimilar (na-bs)	ZA-3-0	sub-type-5	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Clinical Trial Application	ZA-3-0	sub-type-6	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New Vaccines	ZA-3-0	sub-type-7	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
I: Vaccine Antigen Master File	ZA-3-0	sub-type-8	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New SMF	ZA-3-0	sub-type-9	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
New APIMF	ZA-3-0	sub-type-10	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Plasma Master File (PMF)	ZA-3-0	sub-type-11	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Strength	ZA-3-0	sub-type-12	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Dosage Form	ZA-3-0	sub-type-13	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Line extension-New Application	ZA-3-0	sub-type-14	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Clone	ZA-3-0	sub-type-15	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Replica-Same	ZA-3-0	sub-type-16	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Type IA-Quality	ZA-3-0	sub-type-17	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Clinical	ZA-3-0	sub-type-18	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IAin-Quality	ZA-3-0	sub-type-19	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Clinical	ZA-3-0	sub-type-20	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type IB-Quality	ZA-3-0	sub-type-21	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Inspectorate	ZA-3-0	sub-type-22	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type I-Other	ZA-3-0	sub-type-23	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Safety (Clinical)	ZA-3-0	sub-type-24	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II - Safety and Efficacy (Clinical)	ZA-3-0	sub-type-25	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Quality	ZA-3-0	sub-type-26	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Rescheduling	ZA-3-0	sub-type-27	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Proprietary Name Change	ZA-3-0	sub-type-28	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant-Relinquishing	ZA-3-0	sub-type-29	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Type II-Change in Applicant-Acquiring	ZA-3-0	sub-type-30	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Baseline	ZA-3-0	sub-type-31	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
z-Code-Quality	ZA-3-0	sub-type-32	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Application Type
Pharmacovigilance	ZA-3-0	sub-type-33	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
USRN-Clinical and Pharmacovigilance	ZA-3-0	sub-type-34	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Application Withdrawal/Cancellation	ZA-3-0	sub-type-35	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Renewal Filing	ZA-3-0	sub-type-36	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA
Undefined Regulatory Activity*	ZA-3-0	sub-type-37	ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA

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	ZA-3-0	seq-type-1	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Supplementary Information	ZA-3-0	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, 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*
Response-Clinical	ZA-3-0	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-Quality	ZA-3-0	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, 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*
Response-Inspectorate	ZA-3-0	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-N and S	ZA-3-0	seq-type-6	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, 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*
Closing Information	ZA-3-0	seq-type-7	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Work Grouping Partial Withdrawal	ZA-3-0	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, 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*
Submission Withdrawal	ZA-3-0	seq-type-9	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-Biological	ZA-3-0	seq-type-10	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, 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*
Response-Renewals	ZA-3-0	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, 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*

Sub Filing Type (Display Name)	Applicable DTD/Schema	eCTD Code	Available for Filing Type
Response-PV	ZA-3-0	seq-type-12	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, 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*

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
South Africa	ZA-3-0	sub-lead-1	Biologicals
South Africa	ZA-3-0	sub-lead-2	Complimentary
South Africa	ZA-3-0	sub-lead-3	Master Files
South Africa	ZA-3-0	sub-lead-4	Orthodox
South Africa	ZA-3-0	sub-lead-5	Pharmacovigilance
South Africa	ZA-3-0	sub-lead-6	Veterinary

Evaluation Pathway Values will be added to the Submission Maintenance – Evaluation Pathway 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
South Africa	ZA-3-0	eval-path-1	Priority

Region	Applicable DTD/Schema	eCTD Code	Regulatory Activity Lead
South Africa	ZA-3-0	eval-path-2	Full Evaluation
South Africa	ZA-3-0	eval-path-3	Abridged Evaluation
South Africa	ZA-3-0	eval-path-4	Rolling Review
South Africa	ZA-3-0	eval-path-5	Section 21

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	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

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

- Updates ZA region to have the code value ‘ZA’ 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.
- Adds the ‘ZA-3-0’ assembly DTD type in the **Assembly - Assembly DTD/Schema Types** section in Data Administration, if it does not already exist.
- Adds or updates ‘National ZA’ Procedure Type in the Application Maintenance - Procedure Type values section in Data Administration, to make it activated (if inactive) and updates to have the eCTD code value ‘national’.

- Updates **Application Maintenance – Application type Values** with following values and assigns corresponding eCTD codes:
 - SAHPRA National Procedure
 - AMA Procedure
 - ZAZIBONA Joint Review
 - WHO-PQ
 - WHO SRA CRP
 - Swissmedic MAGHP
 - EU M4ALL
- Updates **Sequence Maintenance – Filing Type Values** with following values and assigns corresponding eCTD codes:
 - 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
 - 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*
- Updates **Submission Maintenance – Sub Filing Type Values** with following values and assigns corresponding eCTD codes:
 - 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 following values and assigns corresponding eCTD codes:
 - Biologicals
 - Complimentary
 - Master Files
 - Orthodox
 - Pharmacovigilance
 - Veterinary
- Updates **Submission Maintenance – Evaluation Pathway Values** with following values and assigns corresponding eCTD codes:
 - Priority
 - Full Evaluation
 - Abridged Evaluation
 - Rolling Review
 - Section 21
- Updates **Submission Maintenance – Applicant Contact Type Values** with following values and assigns corresponding eCTD codes for South Africa:
 - Local Applicant
 - Regulatory
 - Technical
 - Product Information
 - General

