VERSION 7.2.11

# CALYX RIM

## Data Migration Document

CALYX™

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# Contents

# Introduction

This document provides all migration requirements for the standard migration of Calyx RIM 7.2.10 to Calyx RIM 7.2.11.

# Data Administration Updates

## South Africa v3.1

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-3-1' 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 'ZA-3-1'. 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 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-3-1 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-3-1 | 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 |

Application Category!!

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-3-1 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 |
|---|---|---|---|
| A - NCE New Chemical Entity | ZA-3-1 | sub-type-1 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| D - New Generic Medicine | ZA-3-1 | sub-type-2 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Complementary Medicine - New | ZA-3-1 | sub-type-3 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| New Biological | ZA-3-1 | sub-type-4 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Biosimilar (na-bs) | ZA-3-1 | sub-type-5 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Clinical Trial Application | ZA-3-1 | sub-type-6 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| New Vaccines | ZA-3-1 | sub-type-7 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| I: Vaccine Antigen Master File | ZA-3-1 | sub-type-8 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| New SMF | ZA-3-1 | sub-type-9 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| New APIMF | ZA-3-1 | sub-type-10 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Plasma Master File (PMF) | ZA-3-1 | sub-type-11 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Line extension-New Strength | ZA-3-1 | sub-type-12 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Line extension-New Dosage Form | ZA-3-1 | sub-type-13 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Line extension-New Application | ZA-3-1 | sub-type-14 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Clone | ZA-3-1 | sub-type-15 | 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 |
|---|---|---|---|
| Replica-Same | ZA-3-1 | sub-type-16 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IA-Quality | ZA-3-1 | sub-type-17 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IAin-Clinical | ZA-3-1 | sub-type-18 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IAin-Quality | ZA-3-1 | sub-type-19 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IB-Clinical | ZA-3-1 | sub-type-20 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IB-Quality | ZA-3-1 | sub-type-21 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type I-Inspectorate | ZA-3-1 | sub-type-22 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type I-Other | ZA-3-1 | sub-type-23 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Safety (Clinical) | ZA-3-1 | sub-type-24 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II - Safety and Efficacy (Clinical) | ZA-3-1 | sub-type-25 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Quality | ZA-3-1 | sub-type-26 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Rescheduling | ZA-3-1 | sub-type-27 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Proprietary Name Change | ZA-3-1 | sub-type-28 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Change in Applicant-Relinquishing | ZA-3-1 | sub-type-29 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type II-Change in Applicant-Acquiring | ZA-3-1 | sub-type-30 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Baseline | ZA-3-1 | sub-type-31 | 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 |
|---|---|---|---|
| z-Code-Quality | ZA-3-1 | sub-type-32 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Pharmacovigilance | ZA-3-1 | sub-type-33 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| USRN-Clinical and Pharmacovigilance | ZA-3-1 | sub-type-34 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Application Withdrawal/Cancellation | ZA-3-1 | sub-type-35 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Renewal Filing | ZA-3-1 | sub-type-36 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Undefined Regulatory Activity* | ZA-3-1 | sub-type-37 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type lB-Related Clinical | ZA-3-1 | sub-type-38 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type lB-Related Quality | ZA-3-1 | sub-type-39 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type lB-Related Inspectorate | ZA-3-1 | sub-type-40 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type IA-Clinical | ZA-3-1 | sub-type-41 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type ll-Related Clinical | ZA-3-1 | sub-type-42 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type ll-Related Quality | ZA-3-1 | sub-type-43 | ZA-NP, AMAP, JR, WHO-PQ, WHO-CRP, CH-GHP, EU-M4ALL, CTA, NDA |
| Type ll-Related Inspectorate | ZA-3-1 | sub-type-44 | 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-3-1 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 | ZA-3-1 | 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*, Type lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 (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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 (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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 (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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 (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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-Related Inspectorate |

| Sub Filing Type (Display Name) | Applicable DTD/Schema | eCTD Code | Available for Filing Type |
|---|---|---|---|
| Response-Renewals | 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, 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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-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 (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 lB-Related Clinical, Type lB-Related Quality, Type lB-Related Inspectorate, Type IA-Clinical, Type ll-Related Clinical, Type ll-Related Quality, Type ll-Related Inspectorate |

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-3-1 | 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 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-3-1 | eval-path-1 | Priority |
| South Africa | ZA-3-1 | eval-path-2 | Full Evaluation |
| South Africa | ZA-3-1 | eval-path-3 | Abridged Evaluation |
| South Africa | ZA-3-1 | eval-path-4 | Rolling Review |
| South Africa | ZA-3-1 | 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-3-1' 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*
  - Type lB-Related Clinical
  - Type lB-Related Quality
  - Type lB-Related Inspectorate
  - Type IA-Clinical
  - Type ll-Related Clinical
  - Type ll-Related Quality
  - Type ll-Related Inspectorate
- 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