



**SAHPRA za-envelope-XML Form Instructions
(Creating the Trigger file)**

12 March 2024, v1.1

Table of Contents

1. Introduction.....	3
2. SAHPRA za-envelope.XML Form	3
2.1. Multiple Entries	4
2.2. Controlled Vocabulary Items	5
2.2.1. Application Types	5
2.2.2. Application ID and Application Number.....	6
2.2.3. Submission Type, Evaluation Pathway and Submission Lead	6
2.2.3.1. More than one Submission Type in a Submission	9
2.2.3.2. More than one (1) Submission Number submitted within one (1) Submission Type 9	
2.2.4. Sequence Types.....	10
2.3. Sequence Numbers	11
2.4. Contact Information.....	12
3. Creating the envelope.xml file	13
4. Change control.....	15
5. Version History	15

Table of Tables

Table 1: Guidance on Application Types	6
Table 2: Guidance on Submission Types	7
Table 3: Guidance on Sequence Types	11

Table of Figures

<i>Figure 1: Submission Types as per defined list matrix.....</i>	<i>7</i>
<i>Figure 2: Evaluation Path as per defined list matrix.....</i>	<i>7</i>
<i>Figure 3: Submission Lead as per defined list matrix.</i>	<i>7</i>
<i>Figure 4: Submission Lead as per defined list matrix.</i>	<i>11</i>
<i>Figure 5: Contact Type as per defined list matrix</i>	<i>12</i>

1. Introduction

As SAHPRA moves towards automating its processes for accepting and processing applications, information provided in the eCTD envelope is required. Automation will enable increased efficiencies and improve communication and information on applications received and processed.

The information contained in the envelope is also linked to many validation criteria which increases transparency of content and format required to improve the evaluation and avoid delays due to missing content for a submission or due to qualitative issues with the files provided.

Applicants are encouraged to make themselves familiar with the ZA-SAHPRA eCTD Specifications, and particularly the section pertaining to the Envelope.

To facilitate the creating of the envelope.xml file, SAHPRA has provided an Excel form which will auto create the required content, if filled in correctly. Please note that this is meant to be an interim option until sequences are uploaded to the portal.



This does NOT replace the za-regional.xml located in Module 1.

2. SAHPRA za-envelope.XML Form

Open the za-envelope.XML.xlsx file downloaded from [SAHPRA's website](#).

ZA Envelope					envelop.xml - COPY ENTIRE CONTENTS BELOW	
Occurrence	Constraint	Description	List Code			
Single	Mandatory	CIPC Number				<sahpra>
Single	Mandatory	Applicant				<za-company>
Single	Mandatory	Submitted by				<cipc-number></cipc-number>
						<applicant></applicant>
						<submitted-by></submitted-by>
						</za-company>
Single	Mandatory	ZA-Envelope Version	3.0			<za-envelope za-spec-version="3.0">
Single	Mandatory	Application Type	1.0			#N/A
Single	Mandatory	Application ID				<application-id></application-id>
Unique	Mandatory	Application Number				<application-number></application-number>
Unique	Mandatory	Proprietary Name				<proprietary-name></proprietary-name>
Single	Mandatory	Dosage Form				<dosage-form></dosage-form>
Unique	Mandatory	INN				<inn></inn>
Unique	Mandatory	INN				<inn></inn>
Unique	Optional	APIMF Number				<apimf-number></apimf-number>
Unique	Optional	PMF Number				<pmf-number></pmf-number>
Unique	Optional	VAMP Number				<vamf-number></vamf-number>
Unique	Mandatory	SMF Number				<smf-number></smf-number>
						</application>
Single	Mandatory	Submission Type	1.0			#N/A
Single	Mandatory	Evaluation Path	1.0			#N/A
Single	Mandatory	Submission Lead	1.1			#N/A
Single	Mandatory	Submission Number(s)				<submission-number></submission-number>
						</submission>
						</sequence>
Unique	Mandatory	Sequence Type	1.0			#N/A
Single	Mandatory	Sequence Description				<sequence-description></sequence-description>
Single	Mandatory	Sequence Date				<sequence-date>1900-01-00</sequence-date>
Single	Mandatory	Sequence Number				<sequence-number></sequence-number>
Single	Mandatory	Related Sequence Number				<related-sequence-number></related-sequence-number>
				Proprietary Name	Application Number	</sequence>
Multiple	Optional	Multiple Applications				
Single	Mandatory	Contact Code	1.0			<contact code-version="1.0" code="">
Single	Mandatory	Contact Name				<contact-name></contact-name>
Single	Mandatory	Contact Email(s)				<email></email>
						</contact>
						</za-envelope>
						</sahpra>

ZA-Envelope Form v1.0

User-friendly form

XML content preview

The form has two main components, a user-friendly form with controlled vocabulary on the left, and a preview of the xml content. The xml content section (indicated in blue) is to be copied to notepad after the form has been completed. See [section 3.0](#).

The mandatory content in the form is indicated through the column listing the constraint consistent with SAHPRA's eCTD specification and ZA validation criteria. The fields that must be filled in for the mandatory content are also shaded **red** to clearly point out information that must still be entered. Optional content is shaded **green** to clearly point out that these fields do not require any information and can be left blank.

Please refer to the [ZA-SAHPRA eCTD specification](#) for further clarification on each of the items listed. Enter the values in each of the fields as they are defined e.g. Application Number as assigned by SAHPRA.

2.1. Multiple Entries

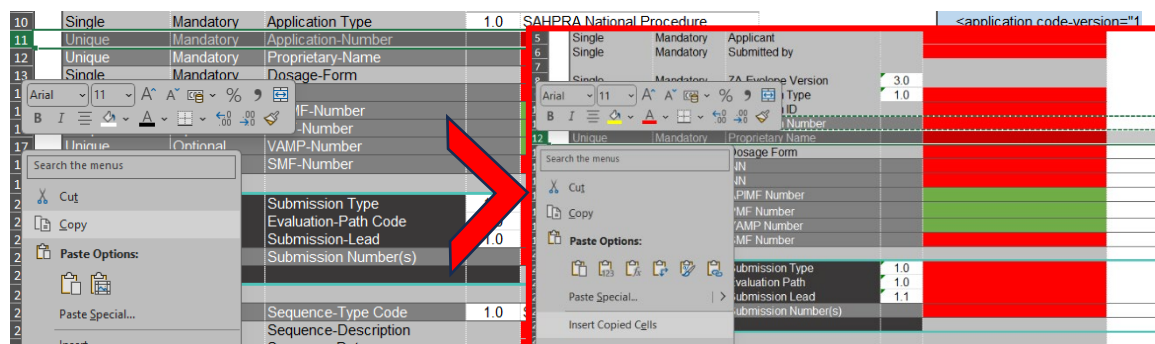
Many items in the form allow multiple occurrences e.g. Proprietary Name, Application Number, INN, APIMF Number, PMF Number, VAMP Number, SMF Number, Submission Number and Multiple Applications. Multiple values should **not be** placed in a single field, rather the entire row for those fields should be copied and inserted directly after the first field provided. For rows indicated in **dark grey**, only the **single line** should be copied and may be copied multiple times for multiple entries, e.g., if an application has 3 strengths, the application number line should be copied for each of the application numbers correlating with each strength. Apply the same principal for proprietary name for each strength.

ZA Envelope				envelop.xml - COPY ENTIRE CONTENTS BELOW	
Occurrence	Constraint	Description	List Code		
Unique	Mandatory	Application-Number	123456	<saupra>	<application-number> 123456</application-number>
Unique	Mandatory	Application-Number	123457	</saupra>	<application-number> 123457</application-number>
Unique	Mandatory	Application-Number	123458		<application-number> 123458</application-number>
Unique	Mandatory	Proprietary-Name	AfriCapsule 100 mg		<proprietary-name> AfriCapsule 100 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name	AfriCapsule 200 mg		<proprietary-name> AfriCapsule 200 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name	AfriCapsule 300 mg		<proprietary-name> AfriCapsule 300 mg</proprietary-name>
Unique	Mandatory	Application-Number	123458		<application-number> 123458</application-number>
Unique	Mandatory	Proprietary-Name	AfriCapsule 100 mg		<proprietary-name> AfriCapsule 100 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name	AfriCapsule 200 mg		<proprietary-name> AfriCapsule 200 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name	AfriCapsule 300 mg		<proprietary-name> AfriCapsule 300 mg</proprietary-name>
Single	Mandatory	Dosage-Form	Capsule		<dosage-form> Capsule</dosage-form>
Unique	Mandatory	INN	Ibuprofen		<inn> Ibuprofen</inn>
Unique	Mandatory	INN	Paracetamol		<inn> Paracetamol</inn>
Unique	Optional	APIMF Number	SAHPRA APIMF 1234		<apimf-number> SAHPRA APIMF 1234</apimf-number>
Unique	Optional	APIMF Number	SAHPRA APIMF 4567		<apimf-number> SAHPRA APIMF 4567</apimf-number>
Unique	Optional	PMF Number			<pmf-number> </pmf-number>
Unique	Optional	VAMP Number			<vamp-number> </vamp-number>
Unique	Mandatory	SMF Number	L0387		<smf-number> L0387</smf-number>
Unique	Mandatory	SMF Number	P3455		<smf-number> P3455</smf-number>
Single	Mandatory	Submission Type	10 Type IA - Quality		<submission-code-version="1.0" code="sub-type-17">
Single	Mandatory	Evaluation Path	10 Full Evaluation		<evaluation-path code-version="1.0" code="Full Evaluation"/>
Single	Mandatory	Submission Lead	10 Orthodox		<submission-lead code-version="1.0" code="Orthodox"/>
Unique	Mandatory	Submission Number(s)	24041550		<submission-number> 24041550</submission-number>
Unique	Mandatory	Submission Number(s)	24041551		<submission-number> 24041551</submission-number>
Unique	Mandatory	Submission Number(s)	24041552		<submission-number> 24041552</submission-number>
Single	Mandatory	Submission Type	10 Type IAIN - Quality		<submission-code-version="1.0" code="sub-type-19">
Single	Mandatory	Evaluation Path	10 Full Evaluation		<evaluation-path code-version="1.0" code="Full Evaluation"/>
Single	Mandatory	Submission Lead	10 Orthodox		<submission-lead code-version="1.0" code="Orthodox"/>
Unique	Mandatory	Submission Number(s)	24041556		<submission-number> 24041556</submission-number>
Unique	Mandatory	Submission Number(s)	24041557		<submission-number> 24041557</submission-number>
Unique	Mandatory	Sequence Type	Supplementary Information		<sequence>
Single	Mandatory	Sequence Description	Specification update API, Specification update FP, Change analytical procedures		<sequence-description> Specification update API, Specification update FP, Change analytical procedures</sequence-description>
Single	Mandatory	Sequence Date	20240930		<sequence-date> 45538</sequence-date>
Single	Mandatory	Sequence Number	0004		<sequence-number> 0004</sequence-number>
Single	Mandatory	Related Sequence Number	0004		<related-sequence-number> 0004</related-sequence-number>
Multiple	Optional	Multiple Applications	IncredPill 100 mg	Application Number	</sequence>
Multiple	Optional	Multiple Applications	IncredPill 200 mg	123453.6	<multiple-applications proprietary-names="IncredPill 100 mg" application-numbers="123453.6"/>
Multiple	Optional	Multiple Applications	IncredPill 300 mg	123460.7	<multiple-applications proprietary-names="IncredPill 200 mg" application-numbers="123460.7"/>
Single	Mandatory	Contact Type	10 Local Applicant		<contact code-version="1.0" code=""/>
Single	Mandatory	Contact Name	Jane Doe		<contact-name> Jane Doe</contact-name>
Single	Mandatory	Contact Email(s)	Jane.doe@examplepharma.co.za		<email> Jane.doe@examplepharma.co.za</email>
					</contact>
					</sa-envelope>
					</saupra>



The entire row must be copied to ensure entries for each field also appear in the envelope preview window and can be copied once the form is complete.

Select relevant row > Right click > Copy > Right click on row below copied area > Insert Copied Cells



As many copies of the rows can be created as needed. If a copy is created of a row that has occurrences defined as single, the row will be marked red. If the row is not removed, your envelope.xml file will not pass validation.

2.2. Controlled Vocabulary Items

Five (5) items have controlled vocabulary from lists managed on the [SAHPRA website](#): Application Type, Submission Type, Evaluation Path, Submission Lead, and Sequence Type. A dropdown menu has been provided to ensure accurate entry of these values. Select the appropriate value.

2.2.1. Application Types

The lists on the website are updated periodically. Changes are versioned and version numbers are indicated on the online list. Select the version number from the drop down for List Version.

Single	Mandatory	ZA-Evelope Version	3.0	
Single	Mandatory	Application Type	1.0	SAHPRA National Procedure
Single	Mandatory	Application ID	1.0	
Unique	Mandatory	Application Number		
Unique	Mandatory	Proprietary Name		

Thereafter choose the appropriate value corresponding to your submission.

Single	Mandatory	ZA-Envelope Version	3.0	
Single	Mandatory	Application Type	1.0	SAHPRA National Procedure
Single	Mandatory	Application ID		SAHPRA National Procedure
Unique	Mandatory	Application Number		AMA Procedure
Unique	Mandatory	Proprietary Name		ZAZIBONA Joint Review
Single	Mandatory	Dosage Form		WHO-PQ
Unique	Mandatory	INN		WHO SRA CRP
Unique	Optional	APIMF Number		Swissmedic MAGHP
Unique	Optional	PMF Number		EU M4ALL
Unique	Optional	VAMP Number		

Table 1: Guidance on Application Types

Application Type	
List Value	Comment
SAHPRA National Procedure	For all application types not covered under collaborative review
AMA Procedure	For collaborative review only
ZAZIBONA Joint Review	
WHO-PQ	
WHO SRA CRP	
Swissmedic MAGHP	
EU M4ALL	

2.2.2. Application ID and Application Number

The Application ID is the current Application Folder Name, this will be auto generated by the Portal from Jul 2024.

Application Number is the current Application Number/Process, this will be auto generated by the Portal from July 2024.

Single	Mandatory	Application Type	1.0	SAHPRA National Procedure
Single	Mandatory	Application ID		AfriCapsule-123456-8
Unique	Mandatory	Application Number		123456
Unique	Mandatory	Application Number		123457
Unique	Mandatory	Application Number		123458
Unique	Mandatory	Proprietary Name		AfriCapsule 100 mg
Unique	Mandatory	Proprietary Name		AfriCapsule 200 mg
Unique	Mandatory	Proprietary Name		AfriCapsule 300 mg

2.2.3. Submission Type, Evaluation Pathway and Submission Lead

The Submission Type, Evaluation Pathway and Submission Lead must be given. Choose the version of the list and the appropriate value corresponding to your submission.

Single	Mandatory	Submission Type	1.0	
Single	Mandatory	Evaluation Path	1.0	
Single	Mandatory	Submission Lead	1.1	
Unique	Mandatory	Submission Number(s)		
Unique	Mandatory	Sequence Type	1.0	
Single	Mandatory	Sequence Description		
Single	Mandatory	Sequence Date		
Single	Mandatory	Sequence Number		
Single	Mandatory	Related Sequence Number		
Multiple	Optional	Multiple Applications		
Single	Mandatory	Contact Code	1.0	
Single	Mandatory	Contact Name		

Figure 1: Submission Types as per defined list matrix.

Mandatory	Submission Type	1.0	
Mandatory	Evaluation Path	1.0	
Mandatory	Submission Lead	1.1	
Mandatory	Submission Number(s)		
Mandatory	Sequence Type	1.0	
Mandatory	Sequence Description		

Figure 2: Evaluation Path as per defined list matrix.

Mandatory	Submission Type	1.0	
Mandatory	Evaluation Path	1.0	
Mandatory	Submission Lead	1.1	
Mandatory	Submission Number(s)		
Mandatory	Sequence Type	1.0	
Mandatory	Sequence Description		
Mandatory	Sequence Date		
Mandatory	Sequence Number		

Figure 3: Submission Lead as per defined list matrix.

Table 2: Guidance on Submission Types

Submission Type	
List Value	Comment
New Chemical Entity	New applications
New Generic (Multi-source)	
New Complementary	
New Biological	
New Biosimilar	
New Clinical Trial Application	

New Vaccines	
New VAMF	Vaccine Master File
New SMF	Site Master File
New APIMF	Active Pharmaceutical Ingredient Master File
New PMF	Plasma Master File
Line extension - New Strength	Additional sequence to an existing eCTD
Line extension - New Dosage Form	A Line Extension resulting in the first Sequence of a New eCTD Application
Line extension - New Application	A Line Extension resulting in the first Sequence of a New eCTD Application
Clone	Additional sequence to an existing eCTD
Replica - Same	Additional sequence to an existing eCTD
Type IA - Quality	See SAHPRA Variations Addendum
Type IAin - Clinical	See SAHPRA Variations Addendum
Type IAin - Quality	See SAHPRA Variations Addendum
Type IB - Clinical	See SAHPRA Variations Addendum
Type IB - Quality	See SAHPRA Variations Addendum
Type I - Inspectorate	See SAHPRA Variations Addendum
Type I - Other	See SAHPRA Variations Addendum
Type II - Safety (Clinical)	See SAHPRA Variations Addendum
Type II - Safety and Efficacy (Clinical)	See SAHPRA Variations Addendum
Type II - Quality	See SAHPRA Variations Addendum
Type II - Rescheduling	See SAHPRA Variations Addendum
Type II - Proprietary Name Change	See SAHPRA Variations Addendum
Type II - Change in Applicant - Relinquishing	See eCTD Guidance for more information
Type II - Change in Applicant - Acquiring	See eCTD Guidance for more information
Baseline	First sequence of an Application already submitted using another format
z-Code - Quality	Only use if advised by SAHPRA, for Variations not covered by the SAHPRA Variations Addendum
Pharmacovigilance	PSUR/PBRER, RMP Reports
USRN - Clinical & Pharmacovigilance	Urgent Safety Restriction Notification
Application Withdrawal/Cancellation	Withdrawal of Pre-Reg, Cancellation of Registered Product

Renewal	See Renewal Guidance for more information
Undefined Regulatory Activity	Only use if advised by SAHPRA to use

2.2.3.1. More than one Submission Type in a Submission

In cases where more than one submission type is submitted within a sequence (please refer to [submission matrix](#) for allowed grouping of submissions), select all of the rows indicated in charcoal and grouped within a teal outline area to copy and insert directly behind. Complete section as required.



Select relevant rows > Right click > Copy > Right click on row below copied area > Insert Copied Cells

Example:

Single	Mandatory	Submission Type	1.0	Type IA - Quality	<submission code-version="1.0" code="sub-type-17">
Single	Mandatory	Evaluation Path	1.0	Full Evaluation	<evaluation-path code-version="1.0" code="Full Evaluation"/>
Single	Mandatory	Submission Lead	1.1	Orthodox	<submission-lead code-version="1.1" code="Orthodox"/>
Unique	Mandatory	Submission Number(s)		24041550	<submission-number>24041550</submission-number>
Unique	Mandatory	Submission Number(s)		24041551	<submission-number>24041551</submission-number>
Unique	Mandatory	Submission Number(s)		24041552	<submission-number>24041552</submission-number>
					</submission>
Single	Mandatory	Submission Type	1.0	Type IAIN - Quality	<submission code-version="1.0" code="sub-type-19">
Single	Mandatory	Evaluation Path	1.0	Full Evaluation	<evaluation-path code-version="1.0" code="Full Evaluation"/>
Single	Mandatory	Submission Lead	1.1	Orthodox	<submission-lead code-version="1.1" code="Orthodox"/>
Unique	Mandatory	Submission Number(s)		24041556	<submission-number>24041556</submission-number>
Unique	Mandatory	Submission Number(s)		24041557	<submission-number>24041557</submission-number>
					</submission>

2.2.3.2. More than one (1) Submission Number submitted within one (1) Submission Type

For information on the Submission Number, please refer to the ZA-SAHPRRA eCTD Specifications, this will be auto generated by the Portal from July 2024. In cases where there

is only one (1) Submission Type (e.g. Type IA), and multiple submissions are bundled into the same submission each of the assigned Submission Numbers should be included in the xml. Thus, within the section indicated in **charcoal** ONLY the row of the Submission Number should be copied within the section.

Submission Type	Evaluation Path	Submission Lead	Submission Number(s)
Single	Mandatory	1.0	New Chemical Entity
Single	Mandatory	1.0	
Single	Mandatory	1.0	
Unique	Mandatory		

118



Select relevant row > Right click > Copy > Right click on row below copied area > Insert Copied Cells

From April to June 2024, **Submission Numbers** to be generated by the Applicant as follows:

- 24041550=YYMDDmi (24=Year; 04=Month; 15=Day; 50=minutes)

Example:

Single	Mandatory	Submission Type	1.0	Type IA - Quality
Single	Mandatory	Evaluation Path	1.0	Full Evaluation
Single	Mandatory	Submission Lead	1.1	Orthodox
Unique	Mandatory	Submission Number(s)		24041550
Unique	Mandatory	Submission Number(s)		24041551
Unique	Mandatory	Submission Number(s)		24041552

2.2.4. Sequence Types

The sequence type must be provided. Once the sequence type has been selected a sequence description should be provided. Please refer to ZA-SAHPRa eCTD Specifications for guidance on Sequence Descriptions.

Unique	Mandatory	Sequence Type	1.0	
Single	Mandatory	Sequence Description		Initial
Single	Mandatory	Sequence Date		Supplementary Information
Single	Mandatory	Sequence Number		Response - Clinical
Single	Mandatory	Related Sequence Number		Response - Quality
Multiple	Optional	Multiple Applications		Response - Inspectorate
Single	Mandatory	Contact Type	1.0	Response - N&S
Single	Mandatory	Contact Name		Closing Information
Single	Mandatory	Contact Email(s)		Work Grouping Partial Withdrawal
				Submission Withdrawal

Figure 4: Submission Lead as per defined list matrix.

Table 3: Guidance on Sequence Types

Sequence Type	
List Value	Comment
Initial	The first sequence of a Submission
Supplementary Information	Additional information being provided not prompted by recommendations
Response - Clinical	Response to Clinical Recommendations
Response - Quality	Response to Quality Recommendations
Response - Inspectorate	Response to Inspectorate Recommendations
Response - N&S	Response to N&S Recommendations
Closing Information	Only use for "Approval Pending" or transfer of content e.g., PI/PIL/Labels from Clean to Approved.
Work Grouping Partial Withdrawal	Only use to withdraw a Submission from a bundle of work grouping
Submission Withdrawal	Withdrawal of a Submission (Post Reg)

2.2.5. Sequence Numbers & Sequence Date

Enter a four (4) digit number for the sequence number and related sequence number. Each sequence should be submitted sequentially using the next available number for the product application. The related sequence number should indicate the first sequence of a submission. ZA-SAHPRAs eCTD specifications 3.0 states that a sequence not relating to any previous sequences, should relate to itself, e.g., 0004 post-reg variation which is submitted as the initial sequence of a submission (not a follow-up), should relate to itself - thus 0004 (and not "none" as previously used). Please refer to ZA-SAHPRAs eCTD Specifications.

The sequence date should be entered starting with the date, however, if the format was entered incorrectly, the file will autocorrect it to the correct format.

2	Single	Mandatory	Sequence Description	analytical procedures	procedures</sequence-description>
3	Single	Mandatory	Sequence Date	2024/09/03	<sequence-date>2024-09-03</sequence-date>

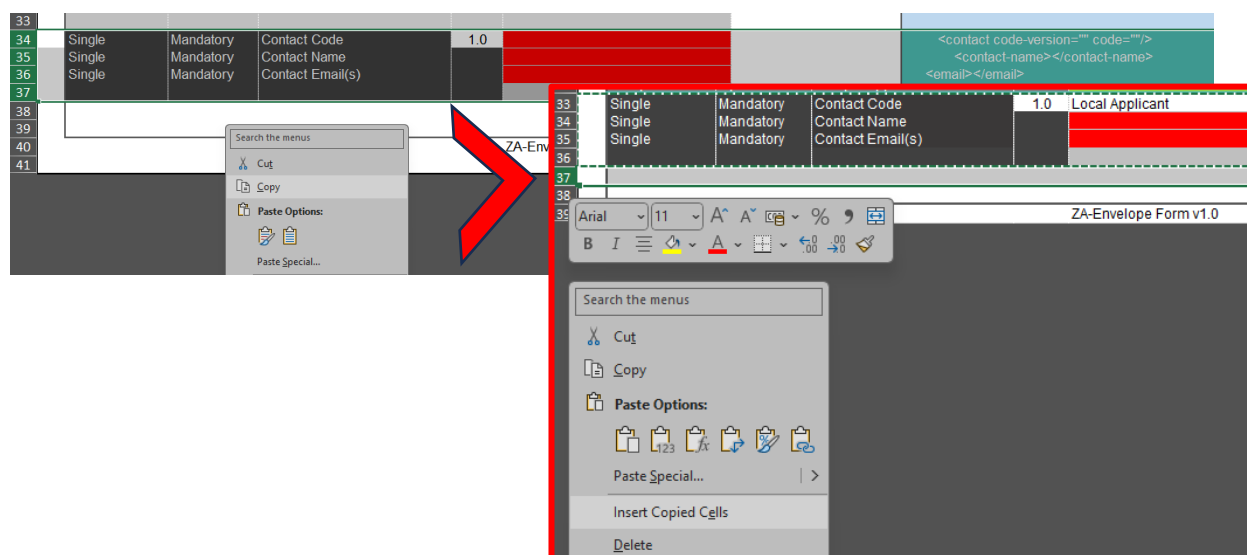
Figure 5: Example of sequence date auto-correction.

2.3. Contact Information

A dropdown menu is provided for the Contact Type. The relevant information to be completed as required. This section can be copied for multiple contacts. All the rows in the area indicated in charcoal and grouped within a teal outline area to copy and insert directly behind.

Multiple	Optional	Multiple Applications		
Single	Mandatory	Contact Type	1.0	Local Applicant
Single	Mandatory	Contact Name		Local Applicant
Single	Mandatory	Contact Email(s)		Regulatory
				Technical
				Product Information
				General

Figure 6: Contact Type as per defined list matrix



160



Select relevant rows > Right click > Copy > Right click on row below copied area > Insert Copied Cells

3. Creating the envelope.xml file

Once all of the sections have been filled in and form is complete, the envelope.xml file can be created. The file can be created using Notepad, Notepad++ or any XML Editing software. The examples shown here have been done using Notepad and Notepad++ as these are readily available and either included in most computer setups or available for download from open source for free.

- Select the entire content shaded in blue in the envelope.xml preview window and copy.
- Open Notepad and paste the content.
- Save the file with the filename as sequence-envelope.xml and file type All Files.

ZA Envelope

Occurrence	Constraint	Description	List Code	Value
Single	Mandatory	CIPC Number		2024/123/2009
Single	Mandatory	Applicant		Example Pharma
Single	Mandatory	Submitted by		Jane Doe
Single	Mandatory	ZA-Envelope Version	3.0	
Single	Mandatory	Application Type	10	SAHPRA National Procedure
Single	Mandatory	Application ID		123456-8
Unique	Mandatory	Application Number		123456
Unique	Mandatory	Application Number		123457
Unique	Mandatory	Application Number		123458
Unique	Mandatory	Proprietary Name		AfriCapsule 100 mg
Unique	Mandatory	Proprietary Name		AfriCapsule 200 mg
Unique	Mandatory	Proprietary Name		AfriCapsule 300 mg
Single	Mandatory	Dosage-Form		Capsule
Unique	Mandatory	INN		Ibuprofen
Unique	Mandatory	INN		Paracetamol
Unique	Optional	APMF Number		SAHPRA APMF 1234
Unique	Optional	APMF Number		SAHPRA APMF 4567
Unique	Optional	PMF Number		
Unique	Optional	VAMP Number		
Unique	Mandatory	SMF Number		L0987
Unique	Mandatory	SMF Number		P3455
Single	Mandatory	Submission Type	1.0	Type IA - Quality
Single	Mandatory	Evaluation Path	1.0	Full Evaluation
Single	Mandatory	Submission Lead	1.1	Orthodox
Unique	Mandatory	Submission Number(s)		24041550
Unique	Mandatory	Submission Number(s)		24041551
Unique	Mandatory	Submission Number(s)		24041552
Single	Mandatory	Submission Type	1.0	Type IAIN - Quality
Single	Mandatory	Evaluation Path	1.0	Full Evaluation
Single	Mandatory	Submission Lead	1.1	Orthodox
Unique	Mandatory	Submission Number(s)		24041556
Unique	Mandatory	Submission Number(s)		24041557
Unique	Mandatory	Sequence Type		Supplementary Information
Single	Mandatory	Sequence Description		Specification update API, Specification update FP, Change analytical procedures
Single	Mandatory	Sequence Date		2024/09/03
Single	Mandatory	Sequence Number		0004
Single	Mandatory	Related Sequence Number		0004
Multiple	Optional	Multiple Applications		IncrediPill 100 mg
Multiple	Optional	Multiple Applications		IncrediPill 200 mg
Multiple	Optional	Multiple Applications		IncrediPill 300 mg
Single	Mandatory	Contact Code	1.0	Local Applicant
Single	Mandatory	Contact Name		Jane Doe
Single	Mandatory	Contact Email(s)		Jane.doe@examplepharma.co.za

envelope.xml - COPY ENTIRE CONTENTS BELOW

```

<?xml version="1.0" encoding="UTF-8" standalone="yes">
<sahpra>
  <za-company>
    <cipc-number>2024/123/2009</cipc-number>
    <applicant>Example Pharma</applicant>
    <submitted-by>Jane Doe</submitted-by>
  </za-company>
  <za-envelope za-spec-version="3.0">
    <application>
      <app>
        <app-number>123456</app-number>
        <app-name>AfriCapsule 100 mg</app-name>
        <app-dosage-form>Capsule</app-dosage-form>
        <app-inn>Ibuprofen</app-inn>
        <app-apmf-number>SAHPRA APMF 1234</app-apmf-number>
        <app-pmf-number></app-pmf-number>
        <app-vamp-number></app-vamp-number>
        <app-smf-number>L0987</app-smf-number>
      </app>
      <app>
        <app-number>123457</app-number>
        <app-name>AfriCapsule 200 mg</app-name>
        <app-dosage-form>Capsule</app-dosage-form>
        <app-inn>Paracetamol</app-inn>
        <app-apmf-number>SAHPRA APMF 4567</app-apmf-number>
        <app-pmf-number></app-pmf-number>
        <app-vamp-number></app-vamp-number>
        <app-smf-number></app-smf-number>
      </app>
    </application>
    <submission>
      <sub>
        <sub-type>1.0</sub-type>
        <sub-eval-path>1.0</sub-eval-path>
        <sub-submission-lead>1.1</sub-submission-lead>
        <sub-submission-number>24041550</sub-submission-number>
        <sub-submission-number>24041551</sub-submission-number>
        <sub-submission-number>24041552</sub-submission-number>
      </sub>
      <sub>
        <sub-type>1.0</sub-type>
        <sub-eval-path>1.0</sub-eval-path>
        <sub-submission-lead>1.1</sub-submission-lead>
        <sub-submission-number>24041556</sub-submission-number>
        <sub-submission-number>24041557</sub-submission-number>
      </sub>
    </submission>
    <sequence>
      <seq-type>Supplementary Information</seq-type>
      <seq-description>Specification update API, Specification update FP, Change analytical procedures</seq-description>
      <seq-date>2024/09/03</seq-date>
      <seq-number>0004</seq-number>
      <seq-related-number>0004</seq-related-number>
    </sequence>
    <multiple-applications>
      <app>IncrediPill 100 mg</app>
      <app>IncrediPill 200 mg</app>
      <app>IncrediPill 300 mg</app>
    </multiple-applications>
  </za-envelope>
</sahpra>
  
```

0004-envelope.xml

File Edit View

Save as

File name: 0004-envelope.xml

Save as type: All files

Ln 56, Col 1 2 845 characters 100% Windows (CRLF) UTF-8

- When opened in Notepad++ or an xml editor, the components of the xml are visible through colour coding. The empty lines can be removed but this is not required.

```
CAUsers\Public\Documents\123456-8\0004-envelope.xml - Notepad++
File Edit Search View Encoding Language Settings Tools Macro Run Plugins Window ?
0004-envelope.xml
7 <za-envelope za-spec-version="3.0">
8   <application code-version="1.0" code="app-type-1"/>
9     <application-id>123456-8</application-id>
10    <application-number>123456</application-number>
11    <application-number>123457</application-number>
12    <application-number>123458</application-number>
13    <proprietary-name>AfriCapsule 100 mg</proprietary-name>
14    <proprietary-name>AfriCapsule 200 mg</proprietary-name>
15    <proprietary-name>AfriCapsule 300 mg</proprietary-name>
16    <dosage-form>Capsule</dosage-form>
17    <inn>Ibuprofen</inn>
18    <inn>Paracetamol</inn>
19    <apimf-number>SAHPRA APIMF 1234</apimf-number>
20    <apimf-number>SAHPRA APIMF 4567</apimf-number>
21    <pmf-number></pmf-number>
22    <vamf-number></vamf-number>
23    <smf-number>L0987</smf-number>
24    <smf-number>P3455</smf-number>
25  </application>
26  <submission code-version="1.0" code="sub-type-17">
27    <evaluation-path code-version="1.0" code="Full Evaluation"/>
28    <submission-lead code-version="1.0" code="Orthodox"/>
29    <submission-number>24041550</submission-number>
30    <submission-number>24041551</submission-number>
31    <submission-number>24041552</submission-number>
32  </submission>
33  <submission code-version="1.0" code="sub-type-19">
34    <evaluation-path code-version="1.0" code="Full Evaluation"/>
35    <submission-lead code-version="1.0" code="Orthodox"/>
36    <submission-number>24041556</submission-number>
37    <submission-number>24041557</submission-number>
38  </submission>
39  </sequence>
40    <sequence-type code-version="" code="">
41    <sequence-description>Specification update API, Specification update FP, Change analytical procedures</sequence-description>
42    <sequence-date>45538</sequence-date>
43    <sequence-number>0004</sequence-number>
44    <related-sequence-number>0004</related-sequence-number>
45  </sequence>
46  <multiple-applications proprietary-names="IncrediFill 100 mg" application-numbers="123459.6"/>
47  <multiple-applications proprietary-names="IncrediFill 200 mg" application-numbers="123460.7"/>
48  <multiple-applications proprietary-names="IncrediFill 300 mg" application-numbers="123461.8"/>
49
50  <contact code-version="" code="">
51    <contact-name>Jane Doe</contact-name>
52    <email>Jane.doe@examplepharma.co.za</email>
53  </contact>
54 </za-envelope>
55 </sahpra>
```

The saved .xml file (trigger file) should be included in your main application folder of the sequence, outside of the eCTD application (where you would save your working documents folder). This does NOT replace the za-regional.xml located in Module 1. The saved .xml file (trigger file) should only be added to the Application folder when the Applicant has completed the upload and has Quality Controlled the upload, and is ready to submit.

Name	Date modified	Type	Size
0004	2024/03/11 16:09	File folder	
0004-working documents	2024/03/11 16:10	File folder	
0004-envelope	2024/03/11 15:58	XML File	3 KB

4. Change control

The following documents were referenced during the creation of this document:

- [ZA-SAHPRA eCTD Specification](#)
- [Defined list and codes for Application Type, Submission Type, Submission Lead, Evaluation Pathway, Sequence Type, Contact Type](#)
- [Submission Type Matrix](#)
- [ZA-envelope-XML Envelope Form v1.0 March 2024](#)

Factors that could affect the content of this guidance include, but are not limited to:

- change in the content of the Module 1 for the CTD
- update of standards that are already in use within the eCTD
- new functional requirements
- experience with using eCTD, in particular the envelope
- process changes within SAHPRA.

We will:

- provide a practical timeframe for future changes to minimize impact on industry.
- introduce changes at scheduled intervals to allow stability.

5. Version History

Date	Version	Description of Change	Effective Date
March 2024	1.0 Mar 24	Initial version	March 2024
April 2024	1.1 Apr 24	Minor typographical update, information on sequence date added. Text highlighted for clarity.	April 2024