



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

28 May 2024, v2.0

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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 Trigger File				envelope.xml v2.0- COPY ENTIRE CONTENTS OF COLUMN L BELOW, EXCLUDING ROW 1	
Occurrence	Constraint	Description	List Code		
Single	Mandatory	CI/PC Number			<sa-hpra-trigger-file-version="2.0">
Single	Mandatory	Applicant			<za-company>
Single	Mandatory	Submitted by			<applicant></applicant>
Single	Mandatory	ZA-Trigger File Version	3.0	Version used for Trigger File, does not have to be the same as the regional.xml version	<submitted-by></submitted-by>
Single	Mandatory	Application Type	1.0		<za-company>
Single	Mandatory	Application ID			<sa-envelope-za-spec-version="3.0">
Unique	Mandatory	Application Number			<application-code-version="1.0" code="MISSING-CODE">
Unique	Mandatory	Proprietary Name			<application-id></application-id>
Single	Mandatory	Dosage Form			<application-number></application-number>
Unique	Mandatory	INN			<proprietary-name></proprietary-name>
Unique	Optional	APMF Number			<dosage-form></dosage-form>
Unique	Optional	PMF Number			<inn></inn>
Unique	Optional	VAMP Number			<smf-number></smf-number>
Unique	Mandatory	SMF Number			</application>
Single	Mandatory	Submission Type	2.0		<submission-code-version="2.0" code="MISSING-CODE">
Single	Mandatory	Evaluation Path	1.0		<evaluation-path-code-version="1.0" code="MISSING-CODE">
Single	Mandatory	Submission Lead	1.1		<submission-lead-code-version="1.1" code="MISSING-CODE">
Unique	Mandatory	Submission Number(s)			<submission-number></submission-number>
Unique	Mandatory	Sequence Type	1.0		</submission>
Single	Mandatory	Sequence Description		LIMIT 80 CHARACTERS	<sequence-type-code-version="1.0" code="MISSING-CODE">
Single	Mandatory	Sequence Date			<sequence>
Single	Mandatory	Related Sequence Number			<sequence-description></sequence-description>
Multiple	Optional	Multiple Applications			<sequence-date>1500-01-00</sequence-date>
Single	Mandatory	Contact Code	1.0		<sequence-number></sequence-number>
Single	Mandatory	Contact Name			<related-sequence-number></related-sequence-number>
Single	Mandatory	Contact Email(s)			</sequence>
					<sequence-type></sequence-type>
					<sequence-date></sequence-date>
					<sequence-number></sequence-number>
					<related-sequence-number></related-sequence-number>
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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.

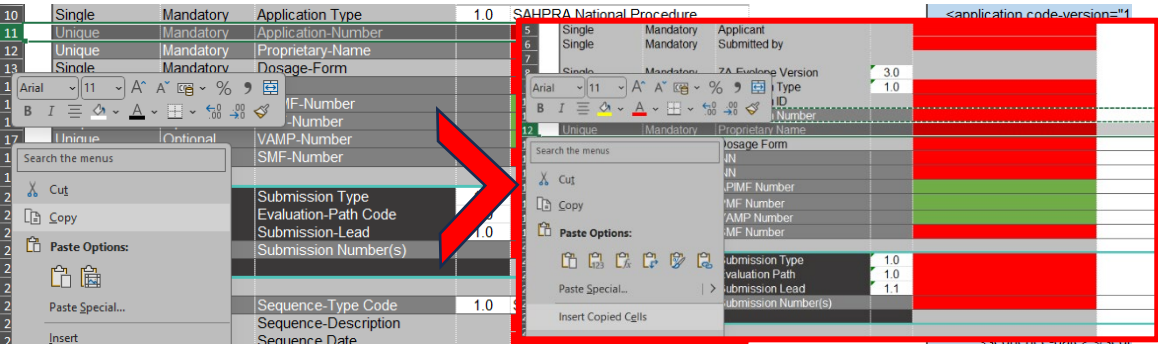
2.1. Multiple Entries

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 Trigger File					envelope.xml v2.0- COPY ENTIRE CONTENTS BELOW
Occurrence	Constraint	Description	List Code		(sahpra-trigger-file-version="2.0") (<sa-environment>
Unique	Mandatory	Application-Number		123456	<application-number> 123456</application-number>
Unique	Mandatory	Application-Number		123457	<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		123456	<application-number> 123456</application-number>
Unique	Mandatory	Proprietary-Name		IncredPill 100 mg	<proprietary-name> IncredPill 100 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name		IncredPill 200 mg	<proprietary-name> IncredPill 200 mg</proprietary-name>
Unique	Mandatory	Proprietary-Name		IncredPill 300 mg	<proprietary-name> IncredPill 300 mg</proprietary-name>
Single	Mandatory	Dosage-Form		Film coated tablets	<dosage-form> Film coated tablets</dosage-form>
Unique	Mandatory	INN		Ibuprofen	<inn> Ibuprofen</inn>
Unique	Mandatory	INN		paracetamol	<inn> paracetamol</inn>
Unique	Optional	APIMF Number		APIMF 123	<apimf-number> APIMF 123</apimf-number>
Unique	Optional	APIMF Number		APIMF 123	<apimf-number> APIMF 123</apimf-number>
Unique	Optional	PMF Number			
Unique	Optional	VAMP Number		S205	<smf-number> S205</smf-number>
Unique	Mandatory	SMF Number		D356	<smf-number> D356</smf-number>
Unique	Mandatory	SMF Number		G123	<smf-number> G123</smf-number>
Single	Mandatory	Submission Type	2.0	Renewal	<(application)>
Single	Mandatory	Evaluation Path	1.0	Full Evaluation	<(evaluation-path code-version="1.0" code="eval-path-2")>
Single	Mandatory	Submission Lead	1.1	Orthodox	<(submission-lead code-version="1.1" code="sub-lead-4")>
Unique	Mandatory	Submission Number(s)		24050206	<(submission-number) 24050206</submission-number>
Unique	Mandatory	Sequence Type	1.0	Response - Renewals	<(sequence)>
Single	Mandatory	Sequence Description		Renewal	<(sequence-type code-version="1.0" code="seq-type-6")>
Single	Mandatory	Sequence Date		02/05/2024	<(sequence-description) Renewal</sequence-description>
Single	Mandatory	Sequence Number		0004	<(sequence-date) 02/05/2024</sequence-date>
Single	Mandatory	Related Sequence Number		0003	<(sequence-number) 0004</sequence-number>
Multiple	Optional	Multiple Applications		Proprietary Name	<(related-sequence-number) 0003</related-sequence-number>
Multiple	Optional	Multiple Applications		AfriCapsule 100 mg	<(sequence)>
Multiple	Optional	Multiple Applications		AfriCapsule 200 mg	<(multiple-applications proprietary-names="AfriCapsule 100 mg" application-numbers="123453 456")>
Multiple	Optional	Multiple Applications		AfriCapsule 300 mg	<(multiple-applications proprietary-names="AfriCapsule 200 mg" application-numbers="123460 457")>
Single	Mandatory	Contact Code	1.0	Local Applicant	<(multiple-applications proprietary-names="AfriCapsule 300 mg" application-numbers="123461 458")>
Single	Mandatory	Contact Name		Jane Doe	<(contact code-version="1.0" code="contact-type-1")>
Single	Mandatory	Contact Email(s)		jane.doe@pharmadexsample.co.za	<(contact-name) Jane Doe</contact-name>
Single	Mandatory	Contact Code	1.0	Technical	<(contact-email) jane.doe@pharmadexsample.co.za</contact-email>
Single	Mandatory	Contact Name		John Smith	<(contact code-version="1.0" code="contact-type-3")>
Single	Mandatory	Contact Email(s)		john.smith@pharmadexsample.co.za	<(contact-name) John Smith</contact-name>
					<(contact-email) john.smith@pharmadexsample.co.za</contact-email>
					</sa-environment>

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



Application Type	Application Number	Proprietary Name	Dosage Form	Submission Type
Single	Mandatory	SAHPRA National Procedure	1.0	SAHPRA National Procedure
Unique	Mandatory	Application Number	1.0	SAHPRA National Procedure
Unique	Mandatory	Proprietary Name	1.0	SAHPRA National Procedure
Single	Mandatory	Dosage Form	1.0	SAHPRA National Procedure
Unique	Mandatory	Submission Type	1.0	SAHPRA National Procedure
Unique	Mandatory	Evaluation-Path Code	1.0	SAHPRA National Procedure
Unique	Mandatory	Submission-Lead	1.0	SAHPRA National Procedure
Unique	Mandatory	Submission Number(s)	1.0	SAHPRA National Procedure
Unique	Mandatory	Sequence-Type Code	1.0	SAHPRA National Procedure
Unique	Mandatory	Sequence-Description	1.0	SAHPRA National Procedure
Unique	Mandatory	Sequence Date	1.0	SAHPRA National Procedure

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-Envelope 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 ID	123456
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

2.2.3. Submission Type, Evaluation Pathway and Submission Lead

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

Single	Mandatory	Submission Type	1.0	
Single	Mandatory	Evaluation Path	1.0	New Chemical Entity
Single	Mandatory	Submission Lead	1.1	New Generic (Multi-source)
Unique	Mandatory	Submission Number(s)		New Complementary
				New Biological
				New Biosimilar
Unique	Mandatory	Sequence Type	1.0	New Clinical Trial Application
Single	Mandatory	Sequence Description		New Vaccines
Single	Mandatory	Sequence Date		New VAMF
Single	Mandatory	Sequence Number		New SMF
Single	Mandatory	Related Sequence Number		New APIMF
Multiple	Optional	Multiple Applications		New PMF
Single	Mandatory	Contact Code	1.0	Line extension - New Strength
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	Priority
Mandatory	Submission Number(s)		Full Evaluation
			Abridged Evaluation
			Rolling Review
Mandatory	Sequence Type	1.0	Section 21
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)		Biologicals
			Complementary
			Master Files
Mandatory	Sequence Type	1.0	Orthodox
Mandatory	Sequence Description		Pharmacovigilance
Mandatory	Sequence Date		Veterinary
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

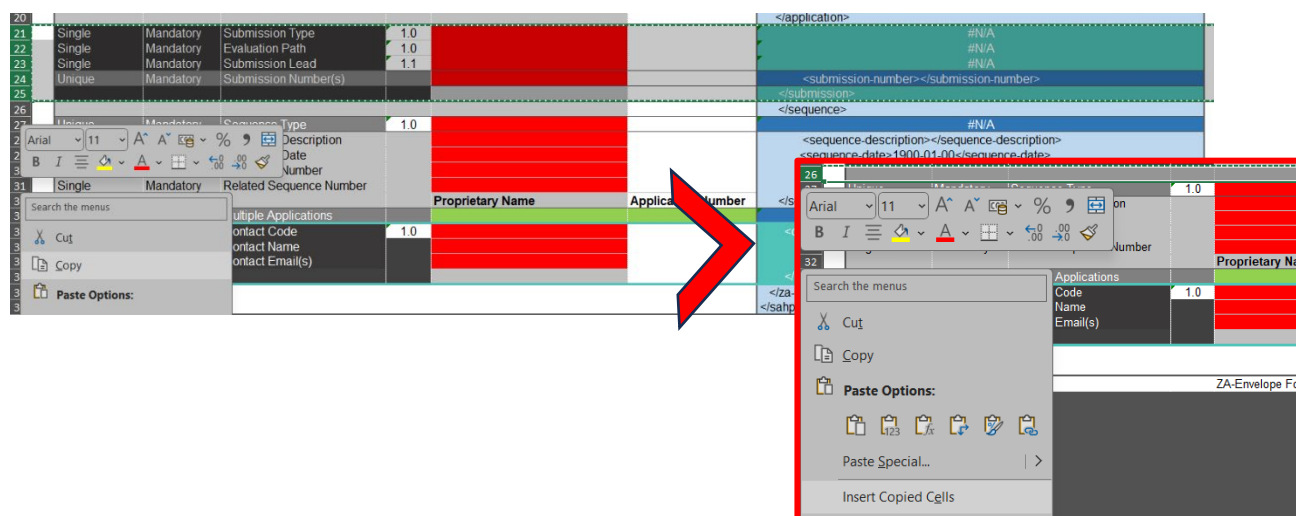
Line extension - New Application	A Line Extension resulting in the first Sequence of a New eCTD Application
Clone	Additional sequence to an existing eCTD
Replica - Same	Additional sequence to an existing eCTD
Type IA - Quality	See SAHPRA Variations Addendum
Type IAin - Clinical	See SAHPRA Variations Addendum
Type IA - 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

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89 **2.2.3.1. More than one Submission Type in a Submission**

90 In cases where more than one submission type is submitted within a sequence (please refer
 91 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.



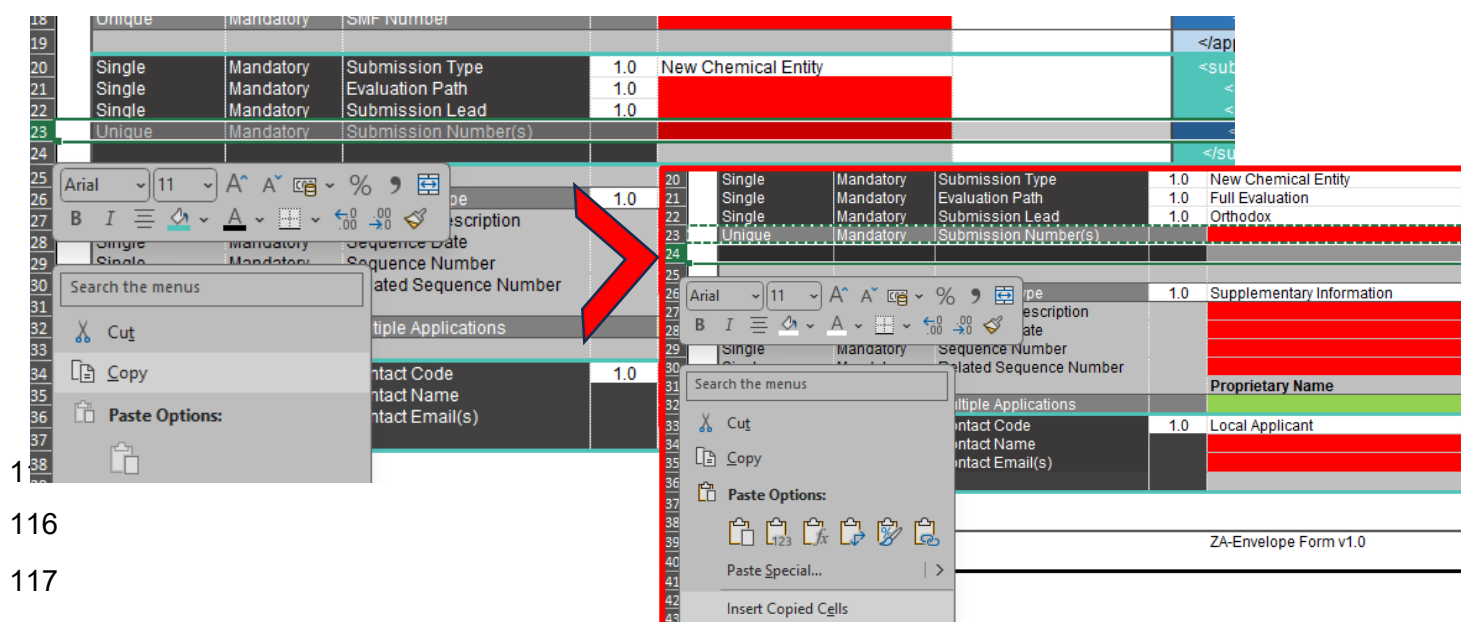
i Select relevant rows > Right click > Copy > Right click on row below copied area > Insert Copied Cells

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.



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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-SAHPR eCTD Specifications for guidance on Sequence Descriptions.

Unique	Mandatory	Sequence Type	1.0	Initial
Single	Mandatory	Sequence Description		Supplementary Information
Single	Mandatory	Sequence Date		Response - Clinical
Single	Mandatory	Sequence Number		Response - Quality
Single	Mandatory	Related Sequence Number		Response - Inspectorate
Multiple	Optional	Multiple Applications		Response - N&S
Single	Mandatory	Contact Type	1.0	Closing Information
Single	Mandatory	Contact Name		Work Grouping Partial Withdrawal
Single	Mandatory	Contact Email(s)		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 Description – this should be brief, precise, and not more than 80 characters e.g. Change in API Manufacturer.

2.2.6. 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>
4	Single	Mandatory	Sequence Number	0004	<sequence-number>0004</sequence-number>

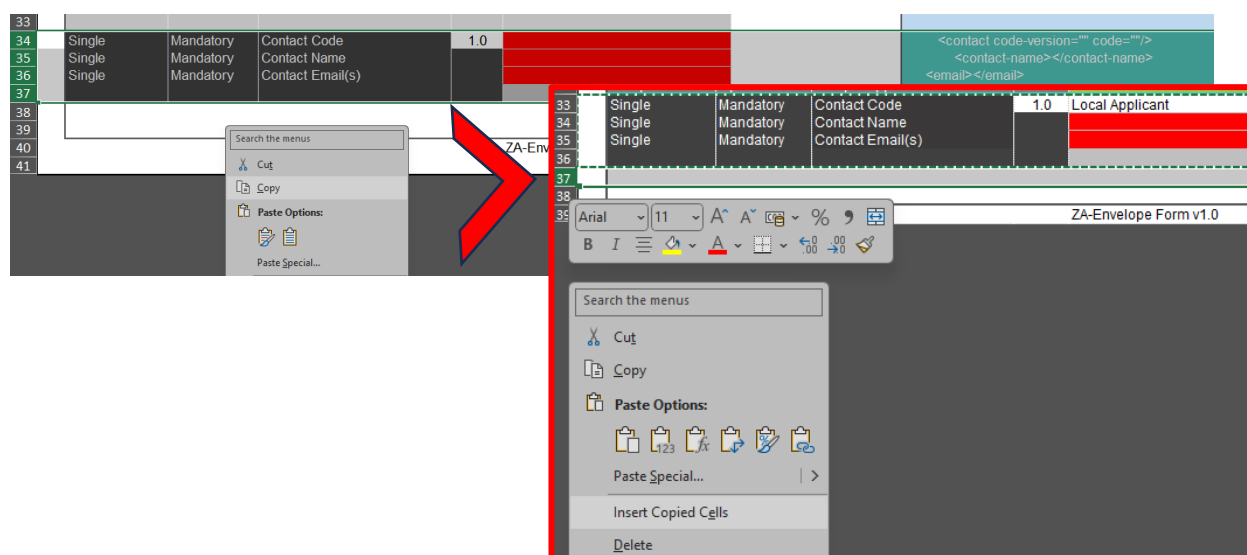
Figure 5: Example of sequence date auto-correction.

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



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

3. Creating the envelope.xml file

Note that mandatory code fields are highlighted red if not completed in column L which is copied to create the XML Trigger File. i.e. all fields MUST be blue/teal before copying.

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	
Single	Mandatory	OIPC 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	1.0	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	APIMF Number		SAHPRA APIMF 1234
Unique	Optional	APIMF Number		SAHPRA APIMF 4567
Unique	Optional	APIMF 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
				Specification update API, Change analytical procedures
Single	Mandatory	Sequence Description		2024/09/03
Single	Mandatory	Sequence Number		0004
Single	Mandatory	Related Sequence Number		0004
				Proprietary Name Application Number
Multiple	Optional	Multiple Applications		IncrediPill 100 mg 123456.8
Multiple	Optional	Multiple Applications		IncrediPill 200 mg 123456.7
Multiple	Optional	Multiple Applications		IncrediPill 300 mg 123456.8
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>
          <app>
            <pro>
              <pro>
                <inn>
                  <inn>
                    <api>
                      <api>
                        <smf>
                          <smf>
                            <smf>
                              <smf>
                                <smf>
                                  <smf>
                                </smf>
                              </smf>
                            </smf>
                          </smf>
                        </api>
                      </api>
                    </inn>
                  </inn>
                </pro>
              </pro>
            </app>
          </app>
        </app>
      </application>
      <submission>
        <eva>
          <sub>
            <sub>
              <sub>
                <sub>
                  <sub>
                    <sub>
                      <sub>
                        <sub>
                          <sub>
                        </sub>
                      </sub>
                    </sub>
                  </sub>
                </sub>
              </sub>
            </sub>
          </eva>
        </submission>
        <submission>
          <eva>
            <sub>
              <sub>
                <sub>
                  <sub>
                    <sub>
                      <sub>
                        <sub>
                          <sub>
                        </sub>
                      </sub>
                    </sub>
                  </sub>
                </sub>
              </sub>
            </eva>
          </submission>
          <sequence>
            <sequence-type code-version="" code="">
            <sequence-description>Specification update API, Specification update FP, Change analytical procedures</sequence-description>
            <sequence-data>4553R</sequence-data>
          </sequence>
        </submission>
      </za-envelope>
    </sahpra>
```

- 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="1.0" code="Full Evaluation"/>
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  </contact code-version="1.0" code="Full Evaluation"/>
50  <contact-name>Jane Doe</contact-name>
51  <email>Jane.doe@examplepharma.co.za</email>
52  </contact>
53  </za-envelope>
54  </sahpra>
55
```

The saved .xml file (trigger file) should be included in your root application folder (please see below) 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
0001	2024/04/30 13:05	File folder	
0001-working documents	2024/05/30 11:18	File folder	
0001-envelope.xml	2024/04/30 13:21	XML File	2 KB

3.1. Root folder naming convention:

For upload to the FTP – please ONLY use the application number of the first strength as naming convention for the root folder. Please DO NOT use hyphens (-), registration numbers, full stops (.), or any other naming conventions (previously communicated in the FTP naming convention guideline) as your application will be rejected.

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
April 2024	1.2 Apr 24	Inclusion of naming convention of root folder for upload to FTP	April 2024