Central Administration of Pharmaceutical Products
General Administration For Human Pharmaceuticals Registration

Central Administration for Biologics, Innovative Products, and Clinical Studies
General Administration of Biological Products
General Administration of Innovative Products

Guideline

EG Module 1 eCTD Specification

Year 2026

Code:

Version No: 1.0

Issue Date: --/--/----

Effective date: --/--/----

Draft

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Glossary of Terms

Term	Definition
Applicant	The authorized person or company who submits an application for marketing authorization of a new medical product, an update to an existing marketing authorization or a variation to an existing marketing authorization.
Applicant's Information	Regulatory information submitted by an ***applicant*** for, or to maintain, a marketing authorisation that falls within the scope of this guidance document.
DTD	A set of rules that defines the structure, elements, and attributes allowed in an XML file. In eCTD, XML files describe the organization, metadata, and relationships of submission documents. The DTD acts like a blueprint, telling both the applicant's publishing tool and the regulatory authority's receiving system exactly how the XML must be formatted and what elements are valid.
eCTD application or also known as a dossier	A collection of electronic documents compiled by a pharmaceutical company or its agent in compliance with Egyptian legislation and guidelines in order to seek marketing authorisation or any amendments thereof. An ***eCTD application*** may comprise a large number of ***regulatory activities***. For products with different dosage forms and strengths are submitted under separate applications.
Envelope	Part of the eg-regional.xml file containing high-level metadata about the submission package. See section Envelope
High Level Number	**Submission Number** This number represents the high-level procedure number related to the regulatory activity in case of submissions of grouped variations if multiple products are concerned. Samples are provided in the EG M1 Specification. Note: not required in case

	only one product is concerned. Issued by EDA through the portal.
Procedure Tracking Number	Unique identifier assigned to the application procedure. Issued through the EDA portal
Regulatory Activity	A ***single sequence or a collection of sequences*** covering the start to the end of a specific business process, e.g. an MA application or variation. To allow a more precise handling, the regulatory activity will be classified using a controlled vocabulary (submission type or regulatory activity type) and a free text field for a short narrative description.
Sequence	A single set of information and / or electronic documents submitted at a specific time by the applicant as a part of, or the complete application. Any collection of content assembled in accordance with the eCTD specification (ICH and EG) will be described using metadata as defined by the EG envelope. Sequences may be related to one another within one regulatory activity. The related sequence number should always be stated. In case of activities with only one sequence the same sequence number will be used.
Submission Type	The submission type describes the ***regulatory activity*** to which the content will be submitted.
Submission Unit Type	The submission unit type element of the envelope metadata set describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity such as the initial submission, the applicant response to validation issues or list of questions or any other additional information.
Working Documents	working-documents folder can be added to a submission for documents requested by the authority these documents should be placed outside the eCTD structure and named for example 0000-workingdocuments. The working document folder can be

	included in the zip file at the top-level structure for example 0000 and 0000-workingdocuments would be the two folders in the zip file.

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Introduction

This document specifies Module 1 of the electronic Common Technical Document (eCTD) for the Egyptian Drug Authority ("EDA") in Egypt ("EG").

This document should be read together with the ICH eCTD Specification to prepare a valid eCTD submission for EDA. The latest version of the ICH eCTD Specification can be found at: https://www.ich.org/page/electronic-standards-estri.

Regional File Formats

Module 1

Generally, the recommended file format for content documents is PDF. All PDF files included in an eCTD (irrespective of the module) should be versions 1.4, 1.5, 1.6, 1.7, PDF/A-1 and PDF/A-2 except where there is an agency-specific requirement for a later version (e.g. for an application form).

For the latest acceptable file formats list, please refer to the document "EG Accepted File Formats for eCTD". Other formats (not specified in the document) for Module 1 content provided outside of the eCTD in the working-documents folder should be used as required by EDA.

For data requested by EDA which needs to be provided in any other format than specified above, please follow the instructions given by requestor.

Handling of Empty or Missing eCTD Sections

Placeholder documents highlighting 'no relevant content' should not be included in the eCTD. These files would create a document lifecycle for non-existent documents, and unnecessary complication and maintenance of the eCTD lifecycle. So, sections without information should be left empty and justified in the respective Module 2 document, as relevant.

"Not Applicable" Module 1 documents should not be included in the eCTD unless requested by EDA. However, when a justification for the absence of a certain document in Module 1 is required, such justification should be provided in its corresponding section in the eCTD structure.

The EG Module 1 is provided with a standard style sheet that can be used to view the content. Note that the style sheet has been designed to display the complete Module 1 table of contents (i.e. all the sections), irrespective of whether files are present in those sections or not.

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Updating backbone attributes/metadata

It is not possible to update XML backbone attributes such as 'manufacturer' during the eCTD lifecycle, nor is it necessary to attempt workarounds such as deleting existing documents and resubmitting them with new attributes. The recommendation is to retain the obsolete entry and to rely on the document content to explain the current details unless otherwise requested by EDA.

Whilst the need for a change to the set of EG Module 1 XML attributes/metadata in the middle of the procedure is deemed to be very rare, it is recommended to contact EDA whether such change could be done during the procedure, along with other changes, or as part of an eCTD "reformat" submission.

General Architecture of Module 1

EG Module 1 architecture is similar to that of Modules 2 to 5 of the eCTD, comprising a directory structure and a backbone with leaves. The backbone must be a valid XML document according to the EG Regional Document Type Definition (DTD). The backbone instance (the "eg-regional.xml" file) contains meta-data for the leaves, including pointers to the files in the directory structure. In addition,

the EG Regional DTD defines meta-data at the submission level in the form of an envelope. The root element is "eg-backbone" and contains two elements: "eg-envelope" and "m1-eg".

The EG Regional DTD is modularised, i.e. the envelope and leaves are referenced from the main part of the DTD as external entities called respectively "**eg-envelope.mod**" and "**eg-leaf.mod** ". The EG "leaf" is identical to the leaf element described in the ICH eCTD DTD; reference is made to Table 6-8 of the ICH eCTD Specification.

Examples of XML coding for a simple new application, specific regulatory activities are provided as an appendix to this specification. Examples of XML coding that support the variation regulation are provided as well in Appendix 1: The EG Module 1 XML Submission and Appendix 2: Directory / File Structure for Module 1.

Files can be referred to across modules (e.g. from Module 1 to Module 2) or across sequences within the same eCTD application; note however that it is not possible to refer to files in sequences in other eCTD applications.

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When referring to files across modules or across sequences, the reference must always be relative, starting from the location of the XML file. For instance, a reference from within Module 1 of Sequence 0003 (e.g. 0003/m1/eg/eg-regional.xml) to a file located in Module 2 of Sequence 0000 (e.g. file "introduction.pdf" in folder 0000/m2/22-intro), would be encoded in the EG Module 1 as "../../../0000/m2/22-intro/introduction.pdf". (This example is not business-specific – it merely serves to demonstrate the principle).

While submitting future sequences during the Lifecycle management of the product, any file(s)/document(s) already submitted in previous sequences should not be added again in eCTD, to avoid complication and extra maintenance. Applicants are encouraged to provide cross reference/hyperlink across sequences to facilitate the dossier review.

Envelope

The "eg-envelope" element is designed to be used for all types of submissions (MAAs, variations, renewals, etc.) for a given medicinal product and will mainly be used for the first simple processing at EDA level. The envelope provides meta-data at the eCTD application and sequence level. A short description of each "envelope" element is provided in Appendix 1 of this specification.

The envelope element submission 'mode' should only be used in variation regulatory activities, and the value can be set to: 'single', 'grouping', 'parallel-single' or 'parallel-grouping' (see examples in Appendix 1.1). An additional high-level submission number should also be provided in the envelope under the following circumstance:

- For submissions of grouped variations that affect multiple marketing authorisations Here, the submission 'mode' will be 'grouping' and the high-level number applied is generated from the EDA portal. Please refer the appendix 1.1 and associated technical guidance for eCTD submissions Egypt for further details for this high-level number

Such a high-level number, if appropriate, should be provided in addition to the usual product-specific procedure tracking numbers. The relevant number can be generated using the online portal and placed in the envelope.

m-1-eg

The "m1-eg" element of the EG regional DTD is based on the same conceptual approach as the common part of the ICH eCTD DTD. It provides an XML catalogue with meta-data at the leaf level including pointers to the location of files in a directory structure. As for the ICH eCTD DTD, the "m1-eg" element maps to the directory structure. A tabular overview of the directory structure explaining where to place country and language-specific files is provided in Appendix 2 of this specification.

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Directory / File Structure

The EG Module 1 Specification provides a directory and file structure that is strongly recommended:

- The same high-level directory structure is used for all types of submission to EDA.
- Country directories are named according to Appendix 2.1.
- Language directories are named according to Appendix 2.2.
- The recommended directory structure for the use of country and language identifiers is described in Appendix 2.
    - In Module 1.3.1, every document should be placed in an appropriately named language subdirectory, which has the appropriate language identifier.

Node Extensions

Node extensions are a way of providing extra organisational information to the eCTD. The node extension should be visualised as an extra heading in the CTD structure and should be displayed as such when the XML backbone is viewed.

However, the **use of node extensions should be limited to those areas where it is critical**. Consideration should be given regarding the impact of the view for the reviewer since the inconsistent use of node extensions can lead to unanticipated effects in the cumulative view of a submission.

The following rules govern the use of node extensions for EDA:

- Node extensions must not be used where ICH-specified sub-headings already exist (e.g. indication, manufacturer, drug substance and drug product are all-ICH specified node extensions).
- Node extensions must only be used at the lowest level of the eCTD structure (e.g. a node extension can be used at the level 5.3.5.1 but must not be used at the level 5.3).
- Node extensions are mainly to be used to group together documents made up of multiple leaf elements (e.g. a clinical study made up of separate files for the synopsis, main body and individual appendices could be grouped together under a node extension with the Study Identifier as its Title attribute).
- Node extensions must be maintained over the entire life of the eCTD lifecycle (e.g. if a node extension is used in Sequence 0000 to group files for a study report in Module 5.3.5.1, then any files submitted in a later sequence must also be placed under a node extension, even if only one file is submitted).
- Node extensions may be nested as this is allowed by the eCTD DTD. However, as noted in Bullet 2, the first node extension must be at the lowest level in the eCTD structure (e.g. in Module 5.3.7 a node extension may be added to group together files with the Study Identifier as Title attribute). Further node extensions may be added as children of the Study Identifier node, separating CRFs from individual patient listings.

The content associated with a node extension can be placed in a separate sub folder in the submission; this is recommended for studies in Module 5 where study reports are provided as multiple files. However, there is no specific requirement for an additional subfolder in other modules.

To help in the management of responses over the lifecycle of the eCTD, the responses relating to a particular regulatory activity should be grouped under a node-extension in the eg-regional.xml file. The title of the node extension should identify the regulatory activity (e.g. Responses to Questions for the Initial Application, Responses to Questions for Variation 028, etc.). It is recommended that the applicant provides a full copy of the list of questions received from the authority as the first leaf in this section.

It is recommended to use the variable component of the filename and the leaf title, to present the information clearly to the assessor. The response files should preferably be named as:

responses-<regulatory activity type identifier>-<response number>-<content identifier>.pdf, using the -var component of the filename to define the content. See Technical Guidance for eCTD Submissions in Egypt for additional information.

File Naming Convention

File names have the general structure FIXED-VAR.EXT, where FIXED is a defined component of the filename based on the CTD section and VAR is an additional optional variable component. EXT represents the file extension. Components are separated by a hyphen (except the dot for the file extension). No spaces should be used within each component, but hyphens can be used in the variable part to separate several words.

Fixed components are highly recommended. The variable component is optional and should be used as appropriate to further define these files. The variable component, if used, should be a meaningful concatenation of words with the option of hyphens for separators and should be kept as brief and descriptive as possible to avoid exceeding the maximum path length. File extensions in line with this specification should be applied as applicable.

The first should be the document type code, as per Appendix 2 and 2.3. The second component if necessary, should be the variable component. In cases where differentiation is needed (e.g. between 1.5mg and 15mg) the word 'point' written in full (i.e. ‘1point5mg’) or a hyphen can be used (i.e.’1-5mg’).

There are no recommendations for variable components in this specification. The format of the file is indicated by the file extension. File names should always be in lowercase, in line with the ICH eCTD specification.

Examples:

cover.pdf
form-eaf.pdf
form-annex-01.pdf
outer-tablet10mg.pdf
combined-tablet1-5mg.pdf
combined-tablet10mgannotated.pdf nongmo.pdf

In m1-responses, the recommendation is to use responses-<regulatory activity type identifier>-<response number>-<content identifier>.pdf, using the -var component of the filename to define the content. It is recommended to use the variable component of the filename and the leaf title, to present the information clearly to the assessor.

Examples:

Suggested Filename	Suggested Leaf Title
responses-maa-clin.pdf	Clinical Responses, MAA
responses-maa-2nd-clin.pdf	2nd Clinical Responses, MAA
responses-maa-3rd-clin.pdf	3rd Clinical Responses, MAA
responses-maa-3rd-clinq4.pdf	3rd Clinical Response Question 4, MAA
responses-maa-3rd-clinq7.pdf	3rd Clinical Response Question 7, MAA
responses-var03-clin.pdf	Clinical Responses, Var03
responses-var03-2nd-clin.pdf	2nd Clinical Responses, Var03
responses-maa-qual.pdf	Quality Responses, MAA

Folder and File Name Path Length

The overall folder and file name path length starting from the sequence number should not exceed 180 characters, for any file in any module. This is an EG regional requirement, and it is acknowledged that this is less than the ICH agreed overall path length.

Universal Unique Identifier (UUID)

For EDA, although the eCTD envelope contains several pieces of information about the eCTD application that the sequence belongs to, such as the procedure number and the trade name, there have been instances when an eCTD sequence has been loaded into the wrong application by the receiving agency. For this reason, all eCTD sequences built in accordance with this specification must contain a UUID, linking the sequence to the eCTD application to which it belongs.

The UUID is used by the EDA to facilitate archiving the sequence with the correct eCTD lifecycle and also used for automated sorting of incoming eCTD submissions to the correct eCTD lifecycle. It is important that the UUID is unique for each eCTD lifecycle and should therefore always be machine generated, i.e. be created by the eCTD building tool or, if not possible, by using an online UUID generator. Creating the UUID with uppercases or lowercases is not restricted but needs to be kept as chosen during the full lifecycle.

The applicant should generate a UUID based on ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. It is a hexadecimal number in the form of xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx, showing 32 digits and 4 hyphens. The 'x' will be replaced by a number or a letter. It is recommended to use randomly generated sections (version 4 of UUID types). Such UUID would for example look like 4cc86cf0-9088-4a3c-9526-fa6320f4c469.

This structure guarantees uniqueness across applicants and applications. The UUID will be generated for the first time when creating the first sequence following the implementation of the UUID requirement in the specification and will be provided in the eCTD envelope. All subsequent sequences for that same eCTD lifecycle should contain the same UUID. In this way, sequences can be allocated automatically to the correct eCTD lifecycle by EDA and it is therefore important that the UUID is kept for the eCTD for its entire lifecycle.

Besides the technical validation checking the correct UUID, EDA can also check that the UUID is not the same as in another already existing eCTD lifecycle in EDA's eCTD repository. Although extremely unlikely, this has been experienced, probably by copying a UUID from an example given somewhere or from another eCTD. Since the UUID is used by some authorities in the automatic processing of eCTD sequences, it is important that each UUID in the eCTD repository is unique.

Therefore, even if this is not part of the eCTD technical validation criteria, in such cases, the EDA will contact the applicant/MAH and request an updated eCTD sequence with a new UUID.

The updated eCTD sequence should be submitted with a new UUID to EDA using the same sequence number. A comment should be included in the application form that the eCTD is a technically corrected sequence (corrected UUID) that is re-sent.

Change Control

The EG Module 1 specification is likely to change with time. Factors that could affect the content of the specification include, but are not limited to:

- Change in the content of Module 1 for the CTD, either through the amendment of information, at the same level of detail, or by provision of more detailed definition of content and structure
- Change to the regional requirements for applications that are outside the scope of the CTD
- Update of standards that are already in use within the eCTD
- Identification of new standards that provide additional value for the creation and/or usage of the eCTD
- Identification of new functional requirements
- Experience of use of the eCTD by all parties, in particular Module 1.

For any proposed changes to the eCTD v3.2.2 specification or the related validation rules, please raise a support ticket via the online form in the portal.

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Appendix 1: The EG Module 1 XML Submission

The EG Module 1 XML Submission contains an element for each document in Module 1 as per Appendix 2: Directory / File Structure for Module 1. The following sections describe information that is captured within Module 1 XML submission in an eCTD.

Appendix 1.1: Envelope Element Description

The "eg-envelope" element is the root element that defines meta-data of the submission.

The list of elements is provided in the Controlled Vocabulary (CV) Lists. The following table indicates a subset of data elements taken from different controlled vocabulary lists and describes the only allowed terms for usage in eCTD submissions.

Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
eg-envelope		Root element that provides meta-data for the submission.	N/A	**Mandatory**	**Unique**
envelope		Parent element for the submission meta-data.	N/A	**Mandatory**	**Repeatable**
	country	The country is EGYPT (EG).	**eg**	**Mandatory**	**Unique**
identifier		A UUID as specified by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. The same UUID will be used for all sequences of an eCTD application.	25635f23-a3a4-c4e0- b994-99c5f074960f	**Mandatory**	**Unique**
submission		Provides administrative information associated with the submission.	N/A	**Mandatory**	**Unique**
	type	The type of regulatory activity to which the content will be submitted. The list is available in the Submission Type CV. **N.B.** Officially, Roman numerals are used for variations, e.g. Type VAR PAC-II – the elements must remain Arabic, however.	**maa**	**Mandatory**	**Unique**

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Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
	mode	The high-level handling of the information submitted as part of variation(s) The mode should only be used in variation regulatory activities and must be included in every sequence of that activity. The list is available in the submission mode CV-list: ▪ *single* = a single regulatory activity (e.g. a Type II variation) ▪ *grouping* = Several variations grouped to a single submission for a single product for Human Pharmaceuticals = For Biological and Innovative Products: - Several variations grouped to a single submission for a single product Or - Several variations grouped into a single submission for multiple products Or - Single variation submitted for multiple products ▪ *parallel-single* = Parallel Assessment. Imported Products, evaluation of the procedure at the same time with the authority of the country of origin. ▪ *parallel grouping* = Parallel Assessment. Imported Products, evaluation of the procedure at the same time with the authority of the country of origin.		**Optional** *(note that this element must be populated for sequences in variations)*	**Unique**

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Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
number		This is the high-level submission number, to be used when grouping variations for multiple marketing authorisations. In case of a grouping concerning only one single marketing authorisation this number field should be left empty. In case of grouped variations applying to more than one MA, a separate eCTD submission must be built for each MA covered by the variation. In the envelope of each of the eCTD submissions, the high-level submission number will be the same, but the individual tracking numbers listed here should be specific to the MA in question. Please ensure that these grouping numbers are always mentioned in the case of additional information otherwise the Agency might not be able to process your submission correctly. (**Note** that for submissions affecting multiple MAs, the 'xxxx' used in the submission number is a sequential number) This number is issued through the online form on the EDA portal.	**B-GV-xxxx** **or** **B-PGV-xxxx** **or** **I-GV-xxxx**	**Optional**	**Unique**

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Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
procedure-tracking		Provides administrative information to track the submission.	N/A	**Mandatory**	**Unique**
	number	This is any number used by the EDA or the applicant to track the submission, in any procedure, in relation to a particular product. This could be one or more of the following: • P-VAR-PAC-N-0002 • I-IPV-PU-0001 There must be at least one tracking number identified from EDA and, in addition, the applicant can choose to include an internal tracking number. This procedure tracking number is issued through the EDA portal. In case grouped variations applying to more than one MA, a separate eCTD submission must be built for each MA covered by the variation. In the envelope of each of the eCTD submissions, the high-level submission number will be the same, but the individual tracking numbers listed here should be specific to the MA in question. For more information see Technical Guidance Document Please ensure that these grouping numbers are always mentioned in the case of additional information or	For example, see bullet points in the column on the left-hand side	**Mandatory**	**Repeatable**

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Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
		corrigendum otherwise EDA might not be able to process your submission correctly.			
submission-unit		Provides administrative information associated with the submission unit.	N/A	**Mandatory**	**Unique**
	type	Submission unit type describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity. The list is available in the Submission Unit CV.	**response**	**Mandatory**	**Unique**
applicant		The name of the company submitting the eCTD.	**Pharma Company Ltd.**	**Mandatory**	**Unique**
agency		Parent element for the identification of the receiving agency.	N/A	**Mandatory**	**Unique**
	code	The identification of the receiving agency EDA (see Appendix 2.4).	**EG-EDA**	**Mandatory**	**Unique**
invented-name		The name of the medicinal product (should not be repeated for EDA submission.)	**WonderPill**	**Mandatory**	**Repeatable**
registration		Provides information associated with the registration of the product.	**N/A**	**Mandatory**	**Unique**
	type	Registration type of the product, e.g. Imported Finished or Imported Bulk. The list is available in the Registration Type CV.	**local**	**Mandatory**	**Unique**

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Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
marketing		Provides information associated with the marketing of the product in Egypt.	**N/A**	**Mandatory**	**Unique**
	type	Marketing type of the product, e.g. Local or Tender and Export. The list is available in Marketing Type CV.	**local**	**Mandatory**	**Unique**
inn		International Non-proprietary Name, used to identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A non-proprietary name is also known as a generic name.	**Pioglitazone hydrochloride**	**Optional**	**Repeatable**
sequence		This is the sequence number of the submission – this should start at 0000 for the initial submission, and then increase incrementally with each subsequent submission related to the same product e.g. 0000, 0001, 0002, 0003 etc.	**0000**	**Mandatory**	**Unique**
related-sequence		This is the sequence number of previous submission(s) to which this submission relates e.g. the responses to questions to a particular variation. In the case of submission unit types 'initial' and 'reformat', the related sequence is identical to the sequence number.	**0001** See appendix 1.1.	**Mandatory**	**Repeatable**
submission-description		This element is used to provide a free text description of the submission. The list below provides additional examples for such a field:	**Response to LOQ**	**Mandatory**	**Unique**

Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
		▪ For an MAA: Original MAA Application for <Product X> ▪ For a variation: Please quote the scope of variation from the Application Form ▪ For responses: Response to validation questions / Response to Questions ▪ For supplementary information: Providing supplementary information regarding xx			

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Example of the use of the Related Sequence and the Submission Unit type elements

The related-sequence element is used to identify sequences belonging to the same 'regulatory activity'. A 'regulatory activity' is a logical unit of submission activity (e.g., MAA, Variation, Renewal) with a defined start and end point (e.g. initial submission to final approval). In eCTD, this will consist of all the sequences that together make up the lifecycle of that particular 'regulatory activity'. The Submission Unit type element describes the stage within the regulatory activity, such as initial, response.

For new regulatory activities ("initial") and for "reformat", the related-sequence attribute should always be equal to the sequence number. When submitting lifecycle sequences within an existing activity, the related-sequence attribute should be populated with the sequence number the regulatory activity has been started with.

Therefore, when submission unit = initial or submission_unit = reformat, then the related sequence number is always = sequence number and vice versa, when the submission unit ≠ initial or the submission_unit ≠ reformat, the related sequence is always < sequence number. See below for some illustrative examples.
The submission unit type should be populated with the respective term describing the content of the sequence to be filed at that point in time. See below for some illustrative examples.

It is generally expected that there is usually just one related sequence, but there are occasions where more than one related sequence should be provided: e.g. there are two post authorisation measures (sequence 0050 and sequence 0060) and a single response (sequence 0070) is produced that relates to both post authorisation measures. If more than one different category of activities (submission types) is referred to (as related sequence), then the "highest category" should be used in the envelope attributes. If any of the related variations were grouped, then 'grouping' should be used. For any of the submission types (regulatory activities), an initial and any of the additional submission unit types can be used, e.g. 'response' in case of responses to list of questions or out-standing list of issues. The post authorisation measure may have an initial and additional-info submission unit type. The submission description may describe details if this content is related to e.g. an earlier defined obligation.

Special attention should be paid to the correct use of the related-sequence element when the regulatory activity is a variation that covers more than one Marketing Authorisation. An example is given in the Appendix.

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Sequence	Submission description	Submission type	Related sequence	Submission unit type	Comment
0000	Original MAA application	maa	0000	initial	This is the beginning of a new regulatory activity and so the submission unit type is 'initial'. The related sequence will be identical with the sequence number (i.e. 0000 in this example).
0001	Responses to questions on the original application	maa	0000	response	This is a continuation of the regulatory activity 'maa' initiated in 0000 and so the related sequence points to the beginning of that activity. The submission unit type describes the actual contribution 'response' being submitted within maa regulatory activity
0002	Further Responses to further questions on the original application	maa	0000	response	This is a continuation of the regulatory activity 'maa' initiated in 0000 and so the related sequence points to the beginning of that activity The submission unit type describes the actual contribution 'response' being submitted within maa regulatory activity
0003	Letter of Undertaking (submission unit type: additional info)	maa	0000	additional-info	This is a continuation of the regulatory activity initiated in 0000 and so the related sequence points to the beginning of that activity. The submission unit describes the actual contribution 'additional-info' being submitted within maa regulatory activity

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0004	Type VAR PAC-II variation for 'Treatment of Pain' indication	Var PAC-II	0004	initial	This is the beginning of a new regulatory activity, Var PAC-II' and so the submission unit is "initial". The related sequence will be identical with the sequence number 0004.
0005	Type VAR PAC-II variation for a change in manufacturing site (Westferry)	Var PAC-II	0005	initial	This is the beginning of another new regulatory activity, Var PAC-II' and so the submission unit is "initial". Again, the related sequence will be identical with the sequence number 0005.
0006	Responses to questions on Type II variation for 'Treatment of Pain' indication	Var PAC-II	0004	response	This is a continuation of the regulatory activity initiated in 0004 and so the related sequence points to the beginning of that activity. The submission unit type 'response' indicates that this is a response to questions.
0007	Responses to questions on Type II variation for change in manufacturing site (Westferry)	Var PAC-II	0005	response	As above, but this is a continuation of the regulatory activity initiated in 0005
0008	Updated, agreed, product information taking into account new indication (Treatment of Pain')	Var PAC-II	0004	response	This is the completion of the new indication ('Treatment of Pain') activity, the related sequence points to the sequence which was 'initial' for this activity, and submission unit indicates that this is a response to questions.

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For a new regulatory activity, the appropriate submission type should be used. Applicants should refer to the submission type descriptions in the eCTD EG Technical Guidance or CV Lists. For the submission unit type that initiates a regulatory activity the term 'initial' should always be used. For subsequent sequences within that regulatory activity the respective terms should be selected from the submission unit type values in the submission unit type CV list. The related sequence will be maintained as another way to describe relationships and will be especially meaningful in case of parallel variations.

Table 1: Example of a MAA

Sequence number	Submission Description	Submission Type	Related Sequence	Submission Unit Type
0000	MAA	maa	0000	initial
0001	Validation update	maa	0000	validation-response
0002	Responses	maa	0000	response
0003	Responses	maa	0000	response
0004	Agreed English product information	maa	0000	response

Table 2: Example of a Variation

Sequence number	Submission Description	Submission Type	Related Sequence	Submission Unit Type
0008	Variation for new indication of COPD	Var PAC-II	0008	initial
0009	Validation update	Var PAC-II	0008	validation-response
0010	Responses to questions	Var PAC-II	0008	response

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Table 3: Example of the use of the submission unit type 'reformat'

The submission unit type 'reformat' should be used for each baseline submission. Related sequence should be equal to the sequence number' Baseline for all modules need to be submitted in one submission.

Sequence number	Submission Description	Submission Type	Related Sequence	Submission Unit Type
0000	Baseline of M1 – M5	none	0000	reformat
0001	Variation for a new indication of COPD	Var PAC-II	0001	initial
0002	Responses to questions	Var PAC-II	0001	response

Table 4: Example of how to indicate the withdrawal of a single regulatory activity

If a regulatory activity (e.g. variation) needs to be withdrawn or was rejected by agency, the sequence needs to re-establish the previous status of the dossier. Submitted documents justifying the regulatory activity (e.g. variation) need to be deleted or replaced by the previous version of a document. The submission unit type of that sequence is 'Response'.

The submission description should include some text to identify the sequence as a consolidation sequence after rejection/withdrawal of the regulatory activity (e.g. variation) number (sequence 0005 from first example above).

Sequence number	Submission Description	Submission Type	Related Sequence	Submission Unit Type
0006	Withdrawal of variation to change manufacturing site 'Westferry'	Var PAC-II	0005	responses
0007	Variation for new indication of back pain	Var PAC-II	0007	initial
0008	Response to clinical questions	Var PAC-II	0007	response

Table 5: Example of how to withdraw of MA application

In case of withdrawing the entire MA application or the already authorised product (i.e. the full eCTD dossier) the withdrawal submission sequence needs to state this in a simple way (using submission description text field). This is considered as a regulatory activity, the submission type is 'withdrawal', the submission unit type 'initial' and the related sequence will be identical with the sequence number.

Sequence number	Submission Description	Submission Type	Related Sequence	Submission Unit Type
0016	Withdrawal of the MA application (entirely)	Withdrawal	0016	initial

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Appendix 1.2: Product Information Element Description

The "m1-3-1-spc-label-pl". can have multiple child "pi-doc" elements that allow identification of product information language, document type and applicable country as described below.

Element	Attribute	Description/Instructions	Example	Constraint	Occurrence
pi-doc		Parent element for identification of the type, language and country of one or more product information documents.	N/A	Mandatory	Repeatable
	xml:lang	The language that the product information is written in (see Appendix 2.2 for allowable values).	ar	Mandatory	Unique
	type	The type of product information document (see Appendix 2.3 for allowable values).	combined	Mandatory	Unique
	country	The receiving country for the product information (see Appendix 2.1 for full list of allowable values)	eg	Mandatory	Unique

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Appendix 2: Directory / File Structure for Module 1

The directory / file structure is defined in this appendix as a table containing the following information:

Sequential number		Each item in the table has a unique sequentially assigned reference number. These reference numbers can change with each version of this appendix.
	Number	CTD section number
	Title	CTD title
	Element	Element name in the EG Backbone
	File/Directory	File/Directory name from m1/eg – should be relative path from m1/eg/ e.g. 12-form/121-af/form-af.pdf. This is consistent with ICH standards. The file extension corresponds to the file type, i.e. the "pdf" extension is only illustrative.
	Comment	Comments

Where the following conventions are used:

Codes*	**Definition**
CC	Country Code, also referred to as the destination code as per Appendix 2.1
LL	Local Language code as per Appendix 2.2
EXT	File extension.
PIDOC	Product Information Document identifier as per Appendix 2.3
VAR	Variable component of the filename.
DDDD	A sequence number made of 4 digits (e.g. 0000)

* = The names of the actual files and directories used should be presented in lower case in accordance with the eCTD specification. The use of upper case for codes is for illustrative purposes only to show differentiation between the variable parts and the fixed part of the name.

1	Number	
	Title	EG Module 1
	Element	m1-eg
	Directory	m1/eg
	Comment	Top level directory for the EG Module 1 as per ICH eCTD Specification.
2	Number	
	Title	
	Element	
	File	m1/eg/eg-regional.xml
	Comment	The EG Regional XML instance including envelope information. Note that the operation attribute for the eg.regional.xml should always be set to ‘new’.
3	Number	1.0
	Title	Cover Letter
	Element	m1-0-cover
	Directory	m1/eg/10-cover
	Comment	
4	Number	
	Title	
	Element	
	File	m1/eg/10-cover/cover-VAR.EXT
	Comment	Filename for the Cover Letter composed of a fixed component “cover” and an optional variable component

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5	Number	
	Title	
	Element	
	File	m1/eg/10-cover/tracking-VAR.EXT
	Comment	A tracking table should always be included in addition to the cover letter for submissions within all procedures The file should be named tracking-var.pdf ('var' for the variable part) and be placed in /XXXX/m1/eg/10-cover
6	Number	1.2
	Title	Application Forms
	Element	m1-2-form
	Directory	m1/eg/12-form
	Comment	General placeholder for forms and annexes
7	Number	1.2.1
	Title	Application Form
	Element	m1-2-1-af
	Directory	m1/eg/12-form/121-af/
	Comment	
8	Number	
	Title	
	Element	
	File	m1/eg/12-form/121-af/form-af-VAR.EXT
	Comment	Filename for the Application Form composed of a fixed component 'form-af' and an optional variable component to be used if required (e.g. form-af-tablet.pdf)

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9	Number	1.2.2
	Title	Legal Documents
	Element	m1-2-2-legal
	Directory	m1/eg/12-form/122-legal
	Comment	
10	Number	1.2.2.1
	Title	Letter of Attorney for Company Representative
	Element	m1-2-2-1-loattor
	Directory	m1/eg/12-form/122-legal/1221-loattor
	Comment	
11	Number	1.2.2.2
	Title	Manufacturing License and IDA License
	Element	m1-2-2-2-manlic
	Directory	m1/eg/12-form/122-legal/1222-manlic
	Comment	
12	Number	1.2.2.3
	Title	GMP Certificate(s) / Alternative Documents
	Element	m1-2-2-3-gmpcert
	Directory	m1/eg/12-form/122-legal/1223-gmpcert
	Comment	
13	Number	1.2.2.4
	Title	The Register of Trade
	Element	m1-2-2-4-trade

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	Directory	m1/eg/12-form/122-legal/1224-trade
	Comment	
14	Number	1.2.2.5
	Title	Toll Manufacturer License
	Element	m1-2-2-5-toll
	Directory	m1/eg/12-form/122-legal/1225-toll
	Comment	
15	Number	1.2.2.6
	Title	Scientific Office License
	Element	m1-2-2-6-sol
	Directory	m1/eg/12-form/122-legal/1226-sol
	Comment	
16	Number	1.2.2.7
	Title	Importers Register License
	Element	m1-2-2-7-import
	Directory	m1/eg/12-form/122-legal/1227-import
	Comment	
17	Number	1.2.2.8
	Title	Store License
	Element	m1-2-2-8-storelic
	Directory	m1/eg/12-form/122-legal/1228-storelic
	Comment	

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18	Number	1.2.2.9
	Title	Authorisation Letter / Agency Agreement
	Element	m1-2-2-9-authlet
	Directory	m1/eg/12-form/122-legal/1229-authlet
	Comment	
19	Number	1.2.2.10
	Title	Manufacturing Agreement
	Element	m1-2-2-10-managre
	Directory	m1/eg/12-form/122-legal/12210-managre
	Comment	
20	Number	1.2.2.11
	Title	Packaging Agreement
	Element	m1-2-2-11-pacagre
	Directory	m1/eg/12-form/122-legal/12211-pacagre
	Comment	
21	Number	1.2.2.12
	Title	Storage Agreement
	Element	m1-2-2-12-storeagre
	Directory	m1/eg/12-form/122-legal/12212-storeagre
	Comment	
22	Number	1.2.2.13
	Title	Other Agreements
	Element	m1-2-2-13-othagre

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	Directory	m1/eg/12-form/122-legal/12213-othagre
	Comment	
23	Number	1.2.2.14
	Title	Termination / Waiver
	Element	m1-2-2-14-term
	Directory	m1/eg/12-form/122-legal/12214-term
	Comment	
24	Number	1.2.2.15
	Title	Tax Card
	Element	m1-2-2-15-tax
	Directory	m1/eg/12-form/122-legal/12215-tax
	Comment	
25	Number	1.2.2.16
	Title	List of Distributors
	Element	m1-2-2-16-distribut
	Directory	m1/eg/12-form/122-legal/12216-distribut
	Comment	
26	Number	1.2.2.17
	Title	IP Protection Law No. 82 of 2002 Commitment
	Element	m1-2-2-17-ipp
	Directory	m1/eg/12-form/122-legal/12217-ipp
	Comment	

27	Number	1.2.2.18
	Title	NEW local MA legal Agreement
	Element	m1-2-2-18-newlegag
	Directory	m1/eg/12-form/122-legal/12218-newlegag
	Comment	
28	Number	1.2.2.19
	Title	Letter of Authorisation for a new Applicant in Egypt
	Element	m1-2-2-19-loauth
	Directory	m1/eg/12-form/122-legal/12219-loauth
	Comment	
29	Number	1.2.2.20
	Title	PV Agreement between the MAH & the Service Provider
	Element	m1-2-2-20-pvagre
	Directory	m1/eg/12-form/122-legal/12220-pvagre
	Comment	
30	Number	1.2.2.21
	Title	GMP Certificate
	Element	m1-2-2-21-gmpcert2
	Directory	m1/eg/12-form/122-legal/12221-gmpcert2
	Comment	
31	Number	1.2.3
	Title	EDA Approvals
	Element	m1-2-3-edaapp

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	Directory	m1/eg/12-form/123-edaapp
	Comment	
32	Number	1.2.3.1
	Title	Registration Request Approval
	Element	m1-2-3-1-regreq
	Directory	m1/eg/12-form/123-edaapp/1231-regreq
	Comment	
33	Number	1.2.3.2
	Title	Inquiry Approval
	Element	m1-2-3-2-inqapp
	Directory	m1/eg/12-form/123-edaapp/1232-inqapp
	Comment	
34	Number	1.2.3.3
	Title	Name Approval
	Element	m1-2-3-3-nameapp
	Directory	m1/eg/12-form/123-edaapp/1233-nameapp
	Comment	
35	Number	1.2.3.4
	Title	Registration License
	Element	m1-2-3-4-reglic
	Directory	m1/eg/12-form/123-edaapp/1234-reglic
	Comment	

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36	Number	1.2.3.5
	Title	Preliminary Approval
	Element	m1-2-3-5-prelimapp
	Directory	m1/eg/12-form/123-edaapp/1235-prelimapp
	Comment	
37	Number	1.2.3.6
	Title	Non-Reference Approval
	Element	m1-2-3-6-nonrefapp
	Directory	m1/eg/12-form/123-edaapp/1236-nonrefapp
	Comment	
38	Number	1.2.3.7
	Title	Exemption Approval
	Element	m1-2-3-7-exemptapp
	Directory	m1/eg/12-form/123-edaapp/1237-exemptapp
	Comment	
39	Number	1.2.3.8
	Title	Pricing Certificate
	Element	m1-2-3-8-price
	Directory	m1/eg/12-form/123-edaapp/1238-price
	Comment	
40	Number	1.2.3.9
	Title	Pharmacovigilance Approval
	Element	m1-2-3-9-pvapp

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	Directory	m1/eg/12-form/123-edaapp/1239-pvapp
	Comment	
41	Number	1.2.3.10
	Title	Inspection Report
	Element	m1-2-3-10-insprep
	Directory	m1/eg/12-form/123-edaapp/12310-insprep
	Comment	
42	Number	1.2.3.11
	Title	Importation Approval for each API
	Element	m1-2-3-11-importapp
	Directory	m1/eg/12-form/123-edaapp/12311-importapp
	Comment	
43	Number	1.2.3.12
	Title	CADC Report
	Element	m1-2-3-12-cadcrep
	Directory	m1/eg/12-form/123-edaapp/12312-cadcrep
	Comment	
44	Number	1.2.3.13
	Title	Stability Study Approval
	Element	m1-2-3-13-stabstud
	Directory	m1/eg/12-form/123-edaapp/12313-stabstud
	Comment	

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45	Number	1.2.3.14
	Title	Stability Protocol Approval
	Element	m1-2-3-14-stabprot
	Directory	m1/eg/12-form/123-edaapp/12314-stabprot
	Comment	
46	Number	1.2.3.15
	Title	Module 3 Approval
	Element	m1-2-3-15-m3app
	Directory	m1/eg/12-form/123-edaapp/12315-m3app
	Comment	
47	Number	1.2.3.16
	Title	Module 5 Approval
	Element	m1-2-3-16-m5app
	Directory	m1/eg/12-form/123-edaapp/12316-m5app
	Comment	
48	Number	1.2.3.17
	Title	Pre-approved letters from EDA concerning the product
	Element	m1-2-3-17-preapplet
	Directory	m1/eg/12-form/123-edaapp/12317-preapplet
	Comment	
49	Number	1.2.3.18
	Title	Variation Approvals
	Element	m1-2-3-18-varapp

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	Directory	m1/eg/12-form/123-edaapp/12318-varapp
	Comment	
50	Number	1.2.3.19
	Title	Innovative Products Scientific Committee Approval
	Element	m1-2-3-19-ipsca
	Directory	m1/eg/12-form/123-edaapp/12319-ipsca
	Comment	
51	Number	1.2.3.20
	Title	Registration License for the Solvent
	Element	m1-2-3-20-reglicsolv
	Directory	m1/eg/12-form/123-edaapp/12320-reglicsolv
	Comment	
52	Number	1.2.4
	Title	Declarations
	Element	m1-2-4-declar
	Directory	m1/eg/12-form/124-declar
	Comment	

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53	Number	1.2.4.1
	Title	Declaration Letter stating the list of Registered & Under-Registration Products owned by the Toll Company
	Element	m1-2-4-1-regprod
	Directory	m1/eg/12-form/124-declar/1241-regprod
	Comment	
54	Number	1.2.4.2
	Title	Declaration Letter from the License Holder specifying the API Manufacturers
	Element	m1-2-4-2-apiman
	Directory	m1/eg/12-form/124-declar/1242-apiman
	Comment	
55	Number	1.2.4.3
	Title	Declaration letter from the license holder specifying approved pack in Egypt
	Element	m1-2-4-3-liceholdpac
	Directory	m1/eg/12-form/124-declar/1243-liceholdpac
	Comment	
56	Number	1.2.4.4
	Title	Declaration Letter from the License Holder stating the Form of Bulk (Strips, Capsules, etc.)
	Element	m1-2-4-4-liceholdbulk
	Directory	m1/eg/12-form/124-declar/1244-liceholdbulk
	Comment	

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57	Number	1.2.4.5
	Title	Declaration Letter from the Manufacturer of the Active Substance to inform the Applicant in case of Modification of the manufacturing Process or Specifications
	Element	m1-2-4-5-apimanappl
	Directory	m1/eg/12-form/124-declar/1245-apimanappl
	Comment	
58	Number	1.2.4.6
	Title	Declaration Letter from API Supplier
	Element	m1-2-4-6-apisupp
	Directory	m1/eg/12-form/124-declar/1246-apisupp
	Comment	
59	Number	1.2.4.7
	Title	Declaration Letter for Site Addition
	Element	m1-2-4-7-siteadd
	Directory	m1/eg/12-form/124-declar/1247-siteadd
	Comment	
60	Number	1.2.4.8
	Title	Declaration Letter Form LH stating all Variations & Justification for the Change
	Element	m1-2-4-8-allvar
	Directory	m1/eg/12-form/124-declar/1248-allvar
	Comment	

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61	Number	1.2.4.9
	Title	Other declarations requested by Egyptian Drug Authority
	Element	m1-2-4-9-decother
	Directory	m1/eg/12-form/124-declar/1249-decother
	Comment	
62	Number	1.2.4.10
	Title	List of the Countries where the Product is registered & marketed
	Element	m1-2-4-10-countries
	Directory	m1/eg/12-form/124-declar/12410-countries
	Comment	
63	Number	1.2.4.11
	Title	Ph. Eur. Certificate(s) of Suitability for TSE
	Element	m1-2-4-11-tse
	Directory	m1/eg/12-form/124-declar/12411-tse
	Comment	
64	Number	1.2.4.12
	Title	TSE/BSE Supplier Safety Declaration (if CEP not available)
	Element	m1-2-4-12-bsesafdec
	Directory	m1/eg/12-form/124-declar/12412-bsesafdec
	Comment	
65	Number	1.2.4.13
	Title	Raw Materials Storage Responsibility Declaration (for local Products)

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	Element	m1-2-4-13-rawmat
	Directory	m1/eg/12-form/124-declar/12413-rawmat
	Comment	
66	Number	1.2.4.14
	Title	Excipient/s Supplier Name & Origin
	Element	m1-2-4-14-exipsup
	Directory	m1/eg/12-form/124-declar/12414-exipsup
	Comment	
67	Number	1.2.4.15
	Title	Trade Name of the Albumin used as Stabilizer
	Element	m1-2-4-15-albtraden
	Directory	m1/eg/12-form/124-declar/12415-albtraden
	Comment	
68	Number	1.2.4.16
	Title	Albumin as Stabilizer Batch Release Certificate
	Element	m1-2-4-16-albstabil
	Directory	m1/eg/12-form/124-declar/12416-albstabil
	Comment	
69	Number	1.2.4.17
	Title	Plasma Derivative Supplier Safety and Efficacy Commitment
	Element	m1-2-4-17-plasdersub
	Directory	m1/eg/12-form/124-declar/12417-plasdersub
	Comment	

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70	Number	1.2.4.18
	Title	No Change in physical Address and Product related Processes Declaration
	Element	m1-2-4-18-nochaadd
	Directory	m1/eg/12-form/124-declar/12418-nochaadd
	Comment	
71	Number	1.2.4.19
	Title	Pack Type Declaration
	Element	m1-2-4-19-pactype
	Directory	m1/eg/12-form/124-declar/12419-pactype
	Comment	
72	Number	1.2.4.20
	Title	Insert Declaration Letter
	Element	m1-2-4-20-insdeclet
	Directory	m1/eg/12-form/124-declar/12420-insdeclet
	Comment	
73	Number	1.2.4.21
	Title	Site Master File Declaration
	Element	m1-2-4-21-sitemfdec
	Directory	m1/eg/12-form/124-declar/12421-sitemfdec
	Comment	
74	Number	1.2.4.22
	Title	Storage Temperature at 25 °C Declaration

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	Element	m1-2-4-22-storetemp
	Directory	m1/eg/12-form/124-declar/12422-storetemp
	Comment	
75	Number	1.2.5
	Title	Reference Product Document / Compendial
	Element	m1-2-5-refprod
	Directory	m1/eg/12-form/125-refprod
	Comment	
76	Number	1.2.5.1
	Title	The Reference Product Documents
	Element	m1-2-5-1-refproddoc
	Directory	m1/eg/12-form/125-refprod/1251-refproddoc
	Comment	
77	Number	1.2.5.2
	Title	Scientific Reference (Trials & Literature)
	Element	m1-2-5-2-sciref
	Directory	m1/eg/12-form/125-refprod/1252-sciref
	Comment	
78	Number	1.2.5.3
	Title	Reference for the trade name change
	Element	m1-2-5-3-reftradn
	Directory	m1/eg/12-form/125-refprod/1253-reftradn
	Comment	

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79	Number	1.2.5.4
	Title	The latest recent Pharmacopeia
	Element	m1-2-5-4-recph
	Directory	m1/eg/12-form/125-refprod/1254-recph
	Comment	
80	Number	1.2.6
	Title	Imported Products Documents
	Element	m1-2-6-importdoc
	Directory	m1/eg/12-form/126-importdoc
	Comment	
81	Number	1.2.6.1
	Title	Certificate of Pharmaceutical Product (CPP)
	Element	m1-2-6-1-cpp
	Directory	m1/eg/12-form/126-importdoc/1261-cpp
	Comment	
82	Number	1.2.6.2
	Title	List of Affiliates / Subsidiaries
	Element	m1-2-6-2-loaff
	Directory	m1/eg/12-form/126-importdoc/1262-loaff
	Comment	
83	Number	1.2.7
	Title	Reliance Documents
	Element	m1-2-7-reliance

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	Directory	m1/eg/12-form/127-reliance
	Comment	
84	Number	1.2.7.1
	Title	Sameness Letter
	Element	m1-2-7-1-sameness
	Directory	m1/eg/12-form/127-reliance/1271-sameness
	Comment	
85	Number	1.2.7.2
	Title	Unredacted Assessment Report
	Element	m1-2-7-2-unredact
	Directory	m1/eg/12-form/127-reliance/1272-unredact
	Comment	
86	Number	1.2.7.3
	Title	RRA Variation Application with Annexes
	Element	m1-2-7-3-rravar
	Directory	m1/eg/12-form/127-reliance/1273-rravar
	Comment	
87	Number	1.2.7.4
	Title	Correspondences between the Applicant and the Reference Agency
	Element	m1-2-7-4-correspond
	Directory	m1/eg/12-form/127-reliance/1274-correspond
	Comment	

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88	Number	1.2.7.5
	Title	List of Changes after first MA issued from EMA or FDA
	Element	m1-2-7-5-lofchange
	Directory	m1/eg/12-form/127-reliance/1275-lofchange
	Comment	
89	Number	1.2.7.6
	Title	Rejection or Amendment Reporting Commitment
	Element	m1-2-7-6-reject
	Directory	m1/eg/12-form/127-reliance/1276-reject
	Comment	
90	Number	1.2.8
	Title	Composition Documents
	Element	m1-2-8-composit
	Directory	m1/eg/12-form/128-composit
	Comment	
91	Number	1.2.8.1
	Title	Composition Certificate
	Element	m1-2-8-1-compositcert
	Directory	m1/eg/12-form/128-composit/1281-compositcert
	Comment	
92	Number	1.2.8.2
	Title	Specifications
	Element	m1-2-8-2-spec

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	Directory	m1/eg/12-form/128-composit/1282-spec
	Comment	
93	Number	1.2.8.3
	Title	Any Composition Calculations
	Element	m1-2-8-3-compcalc
	Directory	m1/eg/12-form/128-composit/1283-compcalc
	Comment	
94	Number	1.2.8.4
	Title	Pellets / Premix Composition and Certificates
	Element	m1-2-8-4-pelletcomp
	Directory	m1/eg/12-form/128-composit/1284-pelletcomp
	Comment	
95	Number	1.2.8.5
	Title	Opadry / Coating Premix Composition
	Element	m1-2-8-5-opadry
	Directory	m1/eg/12-form/128-composit/1285-opadry
	Comment	
96	Number	1.2.8.6
	Title	Capsule Shell Composition
	Element	m1-2-8-6-capshell
	Directory	m1/eg/12-form/128-composit/1286-capshell
	Comment	

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97	Number	1.2.8.7
	Title	Synonyms Evidence
	Element	m1-2-8-7-synonyms
	Directory	m1/eg/12-form/128-composit/1287-synonyms
	Comment	
98	Number	1.2.9
	Title	Certificate of Analysis
	Element	m1-2-9-coa
	Directory	m1/eg/12-form/129-coa
	Comment	
99	Number	1.2.10
	Title	Post Approval Changes Requirements
	Element	m1-2-10-postappch
	Directory	m1/eg/12-form/1210-postappch
	Comment	
100	Number	1.2.10.1
	Title	PAC Approval from the COO (Imported Products)
	Element	m1-2-10-1-pacapp
	Directory	m1/eg/12-form/1210-postappch/12101-pacapp
	Comment	
101	Number	1.2.10.2
	Title	Summary of Change for Variation
	Element	m1-2-10-2-sumcavar

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	Directory	m1/eg/12-form/1210-postappch/12102-sumcavar
	Comment	
102	Number	1.2.10.3
	Title	Justification of the proposed Post Approval Change
	Element	m1-2-10-3-justpoc
	Directory	m1/eg/12-form/1210-postappch/12103-justpoc
	Comment	
103	Number	1.2.10.4
	Title	Any additional Documents relevant to Variations
	Element	m1-2-10-4-anydoc
	Directory	m1/eg/12-form/1210-postappch/12104-anydoc
	Comment	
104	Number	1.2.11
	Title	Proof of Payment
	Element	m1-2-11-pop
	Directory	m1/eg/12-form/1211-pop
	Comment	
105	Number	1.2.12
	Title	Analysis Requirements Documentation (for Biological Products only)
	Element	m1-2-12-analysreq
	Directory	m1/eg/12-form/1212-analysreq
	Comment	

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106	Number	1.2.12.1
	Title	Detailed Standard Operating Procedures (SOP)
	Element	m1-2-12-1-sop
	Directory	m1/eg/12-form/1212-analysreq/12121-sop
	Comment	
107	Number	1.2.12.2
	Title	Summary Protocol for Vaccines and Plasma derived Medicinal Products
	Element	m1-2-12-2-sumvacc
	Directory	m1/eg/12-form/1212-analysreq/12122-sumvacc
	Comment	
108	Number	1.2.13
	Title	For Plasma derived Medicinal Products
	Element	m1-2-13-plasma
	Directory	m1/eg/12-form/1213-plasma
	Comment	
109	Number	1.2.13.1
	Title	Plasma Master File
	Element	m1-2-13-1-pmf
	Directory	m1/eg/12-form/1213-plasma/12131-pmf
	Comment	
110	Number	1.2.13.2
	Title	Certificate of Plasma Batch Release from Health Authority

	Element	m1-2-13-2-plasbatch
	Directory	m1/eg/12-form/1213-plasma/12132-plasbatch
	Comment	
111	Number	1.2.13.3
	Title	PMF Approval from Country of Origin
	Element	m1-2-13-3-pmfapp
	Directory	m1/eg/12-form/1213-plasma/12133-pmfapp/
	Comment	
112	Number	1.2.14
	Title	Scientific Advice Report
	Element	m1-2-14-scienadv
	Directory	m1/eg/12-form/1214-scienadv/
	Comment	
113	Number	1.2.15
	Title	Documents related PV
	Element	m1-2-15-relpv
	Directory	m1/eg/12-form/1215-relpv/
	Comment	
114	Number	1.2.15.1
	Title	Latest valid PSMF Assessment Report / Confirmation E-mail of PSMF Document(s) Receival
	Element	m1-2-15-1-valpsmfas
	Directory	m1/eg/12-form/1215-relpv/12151-valpsmfas/

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	Comment	
115	Number	1.2.15.2
	Title	Updated Version of Summary of PSMF(s) / PSSF
	Element	m1-2-15-2-updpsmf
	Directory	m1/eg/12-form/1215-relpv/12152-updpsmf/
	Comment	
116	Number	1.2.15.3
	Title	The latest PSUR(s) (or the ACO in Case of Renewal)
	Element	m1-2-15-3-latpsur
	Directory	m1/eg/12-form/1215-relpv/12153-latpsur
	Comment	
117	Number	1.2.15.4
	Title	The most updated EU/Global/Core-Risk Management Plan (RMP)
	Element	m1-2-15-4-updrmp
	Directory	m1/eg/12-form/1215-relpv/12154-updrmp
	Comment	
118	Number	1.2.15.5
	Title	The Egyptian Display of EU-RMP / Global-RMP
	Element	m1-2-15-5-egrmp
	Directory	m1/eg/12-form/1215-relpv/12155-egrmp
	Comment	
119	Number	1.2.16
	Title	Documents related Inspection

	Element	m1-2-16-relinsp
	Directory	m1/eg/12-form/1216-relinsp
	Comment	
120	Number	1.2.16.1
	Title	Site Master File for all Manufacturers
	Element	m1-2-16-1-smfall
	Directory	m1/eg/12-form/1216-relinsp/12161-smfall
	Comment	
121	Number	1.2.16.2
	Title	Latest Full Inspection Report(s) by SRA (past 3 Years)
	Element	m1-2-16-2-fullinsprep
	Directory	m1/eg/12-form/1216-relinsp/12162-fullinsprep/
	Comment	
122	Number	1.2.16.3
	Title	One completed Batch Manufacturing and Packaging Record
	Element	m1-2-16-3-batchrep
	Directory	m1/eg/12-form/1216-relinsp/12163-batchrep
	Comment	
123	Number	1.2.16.4
	Title	List of any Recalls with Quality Defects (past 3 Years) (if found)
	Element	m1-2-16-4-recalls
	Directory	m1/eg/12-form/1216-relinsp/12164-recalls
	Comment	

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124	Number	1.2.16.5
	Title	Any Warning Letter or equivalent regulatory Action (Production-line specific) (if found)
	Element	m1-2-16-5-warnlet
	Directory	m1/eg/12-form/1216-relinsp/12165-warnlet
	Comment	
125	Number	1.2.16.6
	Title	Last Annual Product Quality Review
	Element	m1-2-16-6-annualrev
	Directory	m1/eg/12-form/1216-relinsp/12166-annualrev
	Comment	
126	Number	1.2.16.7
	Title	Cold Chain Storage & Transportation Procedures including Excursion allowed
	Element	m1-2-16-7-coldchain
	Directory	m1/eg/12-form/1216-relinsp/12167-coldchain
	Comment	
127	Number	1.3
	Title	Product Information
	Element	m1-3-pi
	Directory	m1/eg/13-pi
	Comment	General placeholder for Product Information.
128	Number	1.3.1
	Title	SmPC, Labelling and Package Leaflet

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	Element	m1-3-1-spc-label-pl
	Directory	m1/eg/13-pi/131-spclabelpl
	Comment	General placeholder for SmPC, Package Leaflet.
129	Number	
	Element	
	Directory	m1/eg/13-pi/131-spclabelpl/*LL*
	Comment	Always use a language directory at this level during the lifecycle of the submission (Arabic or English).
130	Number	
	Title	
	Element	
	File	m1/eg/13-pi/131-spclabelpl/*LL*/*PIDOC-VAR.EXT*
	Comment	Filename for the spc-label-pl document composed of a fixed component “PIDOC” as per table of Appendix 2.3 and an optional variable component to be used if needed (e.g. m1/eg/13-pi/131-spclabelpl/ar/spc-tablet10mgar.pdf). Summary of Product Characteristics "spc" & Package Leaflet "pl" are required by EDA
131	Number	1.3.2
	Title	Mock-up
	Element	m1-3-2-mockup
	Directory	m1/eg/13-pi/132-mockup
	Comment	

132	Number	
	Title	
	Element	
	File	m1/eg/13-pi/132-mockup/mockup-*VAR.EXT*
	Comment	Filename for the mock-up document composed of a fixed component "mockup" and an optional variable component to be used if needed (e.g. mockup-tablet10mgouter.pdf).
133	Number	1.3.3
	Title	Specimen
	Element	m1-3-3-specimen
	Directory	m1/eg/13-pi/133-specimen
	Comment	
134	Number	
	Title	
	Element	
	File	m1/eg/13-pi/133-specimen/specimen-*VAR.EXT*
	Comment	Filename for the list of physical specimens provided with the submission composed of a fixed component "specimen" and an optional variable component to be used if needed (e.g. specimen.pdf).
135	Number	1.3.4
	Title	Consultation with Target Patient Groups
	Element	m1-3-4-consultation

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	Directory	m1/eg/13-pi/134-consultation
	Comment	
136	Number	
	Title	
	Element	
	File	m1/eg/13-pi/134-consultation/consultation-*VAR.EXT*
	Comment	Filename for the results of assessments carried out in cooperation with target patient groups on the package leaflet, composed of a fixed component "consultation" and an optional variable component to be used if needed (e.g. consultation-tablet10mgpl.pdf).
137	Number	1.3.5
	Title	Product Information already approved in the Member States
	Element	m1-3-5-approved
	Directory	m1/eg/13-pi/135-approved
	Comment	
138	Number	
	Title	
	Element	
	File	m1/eg/13-pi/135-approved/approved-*VAR.EXT*
	Comment	Filename for the approved Product Information document composed of a fixed component "approved" and an optional variable component to be used if needed.
139	Number	1.3.6

	Title	Braille
	Element	m1-3-6-braille
	Directory	m1/eg/13-pi/136-braille
	Comment	
140	Number	
	Title	
	Element	
	File	m1/eg/13-pi/136-braille/braille-*VAR.EXT*
	Comment	Filename for the Braille information is composed of a fixed component "braille" and an optional variable component to be used if needed. (e.g. braille.pdf).
141	Number	1.4
	Title	Information about the Experts
	Element	m1-4-expert
	Directory	m1/eg/14-expert
	Comment	General placeholder for Expert Information.
142	Number	1.4.1
	Title	Quality
	Element	m1-4-1-quality
	Directory	m1/eg/14-expert/141-quality
	Comment	General placeholder for quality information.
143	Number	

	Title	
	Element	
	File	m1/eg/14-expert/141-quality/quality-*VAR.EXT*
	Comment	Filename for the quality expert document composed of a fixed component "quality" and an optional variable component to be used if needed (e.g. quality.pdf).
144	Number	1.4.2
	Title	Non-Clinical
	Element	m1-4-2-non-clinical
	Directory	m1/eg/14-expert/142-nonclinical
	Comment	General placeholder for non-clinical information.
145	Number	
	Title	
	Element	
	File	m1/eg/14-expert/142-nonclinical/nonclinical-*VAR.EXT*
	Comment	Filename for the non-clinical expert document composed of a fixed component "nonclinical" and an optional variable component to be used if needed (e.g. nonclinical.pdf).
144	Number	1.4.3
	Title	Clinical
	Element	m1-4-3-clinical

Draft

	Directory	m1/eg/14-expert/143-clinical
	Comment	General placeholder for clinical information.
145	Number	
	Title	
	Element	
	File	m1/eg/14-expert/143-clinical/clinical-*VAR.EXT*
	Comment	Filename for the clinical expert document composed of a fixed component "clinical" and an optional variable component to be used if needed (e.g. clinical.pdf).
146	Number	1.5
	Title	Specific Requirements for Different Types of Applications
	Element	m1-5-specific
	Directory	m1/eg/15-specific
	Comment	General placeholder for Specific Information.
147	Number	1.5.1
	Title	Information for Bibliographical Applications
	Element	m1-5-1-bibliographic
	Directory	m1/eg/15-specific/151-bibliographic

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	Comment	General placeholder for bibliographical applications.
148	Number	
	Title	
	Element	
	File	m1/eg/15-specific/151-bibliographic/bibliographic-*VAR.EXT*
	Comment	Filename for the specific bibliographic submission information composed of a fixed component "bibliographic" and an optional variable component to be used if needed (e.g. bibliographic.pdf).
149	Number	1.5.2
	Title	Information for Generic, Hybrid' or Bio-similar Applications
	Element	m1-5-2-generic-hybrid-bio-similar
	Directory	m1/eg/15-specific/152-generic-hybrid-bio-similar
	Comment	General placeholder for generic, hybrid' or bio-similar applications.
150	Number	
	Title	
	Element	
	File	m1/eg/15-specific/152-generic-hybrid-bio-similar/generic-*VAR.EXT* or m1/eg/15-specific/152-generic-hybrid-bio-similar/hybrid-*VAR.EXT* or m1/eg/15-specific/152-generic-hybrid-bio-similar/biosimilar-*VAR.EXT*
	Comment	Filename for the specific generic, hybrid or bio-similar submission

		information composed of a fixed component "generic" or "hybrid" or "biosimilar", and an optional variable component to be used if needed (e.g. generic.pdf).
151	Number	1.5.3
	Title	(Extended) Data/Market Exclusivity
	Element	m1-5-3-data-market-exclusivity
	Directory	m1/eg/15-specific/153-data-market-exclusivity
	Comment	General placeholder for (extended) data/market exclusivity.
152	Number	
	Title	
	Element	
	File	m1/eg/15-specific/153-data-market-exclusivity/datamarketexclusivity-*VAR.EXT*
	Comment	Filename for the data / market exclusivity composed of a fixed component "datamarketexclusivity" and an optional variable component to be used if needed (e.g. datamarketexclusivity.pdf).

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153	Number	1.5.4
	Title	Exceptional Circumstances
	Element	m1-5-4-exceptional-circumstances
	Directory	m1/eg/15-specific/154-exceptional
	Comment	General placeholder for marketing authorisation granted under exceptional circumstances.
154	Number	
	Title	
	Element	
	File	m1/eg/15-specific/154-exceptional/exceptional-*VAR.EXT*
	Comment	Filename for marketing authorisation granted under exceptional circumstances, composed of a fixed component "exceptional" and an optional variable component to be used if needed (e.g. exceptional.pdf).
155	Number	1.5.5
	Title	Conditional Marketing Authorisation
	Element	m1-5-5-conditional-ma
	Directory	m1/eg/15-specific/155-conditional-ma
	Comment	General placeholder for conditional marketing authorisation.

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156	Number	
	Title	
	Element	
	File	m1/eg/15-specific/155-conditional-ma/conditionalma-*VAR.EXT*
	Comment	Filename for conditional marketing authorisation, composed of a fixed component "conditionalma" and an optional variable component to be used if needed (e.g. conditionalma.pdf).
157	Number	1.6
	Title	Environmental Risk Assessment
	Element	m1-6-environrisk
	Directory	m1/eg/16-environrisk
	Comment	General placeholder for Environmental Risk Assessment.
158	Number	1.6.1
	Title	Non-GMO
	Element	m1-6-1-non-gmo
	Directory	m1/eg/16-environrisk/161-nongmo
	Comment	General placeholder for non-GMO.

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159	Number	
	Title	
	Element	
	File	m1/eg/16-environrisk/161-nongmo/nongmo-*VAR.EXT*
	Comment	Filename for the environmental risk assessment non-GMO composed of a fixed component "nongmo" and an optional variable component to be used if needed (e.g. nongmo.pdf).
		Only one of the 2 folders 1.6.1 or 1.6.2 can have content when sending a sequence.
160	Number	1.6.2
	Title	GMO
	Element	m1-6-2-gmo
	Directory	m1/eg/16-environrisk/162-gmo
	Comment	General placeholder for GMO.

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161	Number	
	Title	
	Element	
	File	m1/eg/16-environrisk/162-gmo/gmo-*VAR.EXT*
	Comment	Filename for the environmental risk assessment GMO-composed of a fixed component "gmo" and an optional variable component to be used if needed (e.g. gmo.pdf).
		Only one of the 2 folders 1.6.1 or 1.6.2 can have content when sending a sequence.
162	Number	1.7
	Title	Information relating to Orphan Market Exclusivity
	Element	m1-7-orphan
	Directory	m1/eg/17-orphan
	Comment	General placeholder for Orphan Market Exclusivity information.
163	Number	1.7.1
	Title	Similarity
	Element	m1-7-1-similarity
	Directory	m1/eg/17-orphan/171-similarity
	Comment	General placeholder for information on similarity with authorised orphan product.

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164	Number	
	Title	
	Element	
	File	m1/eg/17-orphan/171-similarity/similarity-*VAR.EXT*
	Comment	Filename for the information on similarity composed of a fixed component "similarity" and an optional variable component to be used if needed.
165	Number	1.7.2
	Title	Market Exclusivity
	Element	m1-7-2-market-exclusivity
	Directory	m1/eg/17-orphan/172-market-exclusivity
	Comment	General placeholder for information on market exclusivity.

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166	Number	
	Title	
	Element	
	File	m1/eg/17-orphan/172-market-exclusivity/marketexclusivity-*VAR.EXT*
	Comment	Filename for information on market exclusivity composed of a fixed component "marketexclusivity" and an optional variable component to be used if needed.
167	Number	1.8
	Title	Information relating to Pharmacovigilance
	Element	m1-8-pharmacovigilance
	Directory	m1/eg/18-pharmacovigilance
	Comment	General placeholder for information on pharmacovigilance.
168	Number	1.8.1
	Title	Pharmacovigilance System
	Element	m1-8-1-pharmacovigilance-system
	Directory	m1/eg/18-pharmacovigilance/181-phvig-system
	Comment	General placeholder for information on pharmacovigilance system.

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169	Number	
	Title	
	Element	
	File	m1/eg/18-pharmacovigilance/181-phvig-system/phvigsystem-*VAR.EXT*
	Comment	Filename for information on pharmacovigilance system composed of a fixed component "phvigsystem" and an optional variable component to be used if needed.
170	Number	1.8.2
	Title	Risk-management System
	Element	m1-8-2-risk-management-system
	Directory	m1/eg/18-pharmacovigilance/182-riskmgt-system
	Comment	General placeholder for information on risk management system.
171	Number	
	Title	
	Element	
	File	m1/eg/18-pharmacovigilance/182-riskmgt-system/riskmgtsystem-*VAR.EXT*
	Comment	Filename for information on pharmacovigilance system composed of a fixed component "riskmgtsystem" and an optional variable component to be used if needed.

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172	Number	1.9
	Title	Information relating to Clinical Trials
	Element	m1-9-clinical-trials
	Directory	m1/eg/19-clinical-trials
	Comment	General placeholder for information on clinical trials.
173	Number	
	Title	
	Element	
	File	m1/eg/19-clinical-trials/clinicaltrials-*VAR.EXT*
	Comment	Filename for information on clinical trials composed of a fixed component "clinicaltrials" and an optional variable component to be used if needed.
174	Number	1.10
	Title	Information relating to Paediatrics
	Element	m1-10-paediatrics
	Directory	m1/eg/110-paediatrics
	Comment	General placeholder for information on paediatrics.

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175	Number	
	Title	
	Element	
	File	m1/eg/110-paediatrics/paediatrics-*VAR.EXT*
	Comment	Filename for information on paediatrics composed of a fixed component "paediatrics" and an optional variable component to be used if needed.
176	Number	
	Title	Responses to Questions
	Element	m1-responses
	Directory	m1/eg/responses
	Comment	

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177	Number	
	Title	
	Element	
	Directory	m1/eg/responses
	File	m1/eg/responses/responses-*VAR.EXT*
	Comment	Placeholder for responses document. For file name of the response document please see section Node Extensions
178	Number	
	Title	Additional Data
	Element	m1-additional-data
	Directory	m1/eg/additional-data
	Comment	The section 'Additional Data' should only be used for required information that is not currently included in the EG eCTD M1 Specification. Supportive documents, which are not part of any M2-5 section or Response to Questions, should be placed here. Any updates to documents originating from M2-5 should replace the outdated version in its original location in M2-5. Supportive documents submitted as answers to questions should be placed in Module 1 Responses to Questions.
		This section is not intended for including already submitted documents. Any information/file which was already submitted in a previous sequence should **not** be submitted again in eCTD. For already submitted documents, a reference/hyperlink/cross-link to the existing file should be created. This helps to avoid multiple lifecycles and repetitions of the files.

179	Number	
	Title	
	Element	
	File	m1/eg/additional-data/additionaldata-*VAR.EXT*
	Comment	Filename for additional information requested composed of a fixed component “additionaldata” and an optional variable component to be used if needed (e.g. additionaldata-yellowpink.pdf)."
180	Number	
	Title	
	Element	
	Directory	m1/eg/util
	Comment	Additional folder to hold utility files used in EG
181	Number	
	Title	
	Element	
	Directory	m1/eg/util/dtd
	Comment	Additional folder to hold DTD files used in EG.

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182	Number	
	Title	
	Element	
	Directory	util/dtd
	Comment	ICH specified location for eCTD DTD files.
183	Number	
	Title	
	Element	
	Directory	util/style
	Comment	ICH specified location for eCTD style-sheet files. The style-sheet to be used should be the most recent version, which is always published as part of the specification package for download.
		Note that the XML instance can only point to one style-sheet and that referencing a customised style-sheet will effectively prevent the EDA using the official one. It is therefore recommended not to submit customised style-sheets.

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Appendix 2.1: Destination Codes

In most cases the destination code is an ISO-3166-1-alpha-2 code usually called "country code" or "*CC*" in this specification.

Code	Destination	Comment
eg	Egypt	ISO-3166-1-alpha-2 code

Appendix 2.2: Language Codes

Code	Language
ar	Arabic
en	English

Appendix 2.3: SPC, Labelling and Package Leaflet File Name Identifiers

PI DOC	Description
spc	Summary of Product Characteristics
pl	Package Leaflet

* = When labelling documents (Outer and Immediate Packaging) are submitted as a single file, the type 'interpack' should be used

Appendix 2.4: Agency Codes and Names

The table below provides the Agency Code for the Egyptian Drug Authority. The Agency Code is the value to use from within the EG Module 1 XML file.

Country	Agency Code	Agency Name
Egypt	EG-EDA	Egyptian Drug Authority

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343 **History Table**

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Summary of Changes	Issue date	Version No.
New Issue		**1.0**

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