المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Baseline eCTD Submission Requirements

Version 1.1

Issue Date	7/2/2015
Implementation Date	Optional: 17/7/2016
	Mandatory: 1/1/2017

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Drug Sector
Saudi Food & Drug Authority
Kingdom of Saudi Arabia

Please visit SFDA's website at
http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx
for the latest update

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Drug Sector

Vision and Mission

Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

الرؤية

أن يكون قطاع الدواء رائداً إقليمياً في الرقابة على الأدوية ومستحضرات التجميل، ويقدم خدماته بمهنية متميزة تسهم في حماية وتعزيز الصحة في المملكة العربية السعودية.

Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system which is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

الرسالة

حماية الصحة العامة من خلال ضمان أمان وجودة وفعالية وتوفر الأدوية البشرية والبيطرية والمنتجات الحيوية وسلامة مواد التجميل عبر تطبيق نظام وطني للرقابة متوافق مع أفضل الممارسات الدولية وتقديم المعلومات الدوائية المبنية على أسس علمية للعامة والمهنيين الصحيين.

Document Control

Version	Author	Date	Comments
1.0	Regulatory Affairs	7/2/2015	Draft
1.1	Regulatory Affairs	29/6/2016	Update

Note: For most recent update please refer to annex 1.

Contents

Glossary

Applicant	The company or its representative.
Drug	An article intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease and which is intended to affect the structure or function of the body.
Common Technical Document (CTD)	An international harmonized format for submissions for approval of pharmaceuticals for human use. The CTD provides a standardization of the presentation of the content.
Drug Application	Drug application includes the application form, the product file and the drug samples.
Variation	A process of informing the authority of any minor or major changes in the drug product.
Renewal of marketing authorization	A process of renewing the marketing authorization license every five years.
Regulatory activity	A collection of sequences covering the start to the end of a specific business process.
Sequence	Electronic documents supplied at one particular time by the applicant as a part of, or the complete drug file.

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I. Introduction

According to the Drug sector's *eCTD implementation plan*, the eCTD is mandatory from the 3rd of January 2015. This applies only to human drug applications.

However, the Drug sector will show all the cases and scenarios of eCTD submissions especially the baseline eCTD submissions.

II. Technical Baseline Application and Timeline

A baseline submission is a compiled submission of the current status of the dossier, i.e. resubmission of currently valid documents that have already been provided to SFDA but in another format. Where an eCTD application is being used for the first time as variation or renewal application, applicants are obliged to submit a technical baseline for the product as this will greatly facilitate the review process.

It should be clearly stated in the **cover letter** of the "**baseline eCTD sequence**" that the content of the previously submitted dossier has not been changed, only the format. There is no need for the SFDA Drug sector to assess baseline submissions and hyperlinks between documents are not necessary. The submission unit '***reformat***' should be used in the envelope for the baseline sequence and submission type should be "none".

In **17th of July 2016**, the Baseline will be **optional** for products that finished all regulatory activities (initial registration, renewal or variation etc.).

In **1st of January 2017**, the baseline will be **mandatory** for any new regulatory activities (initial registration, renewal or variation etc.).

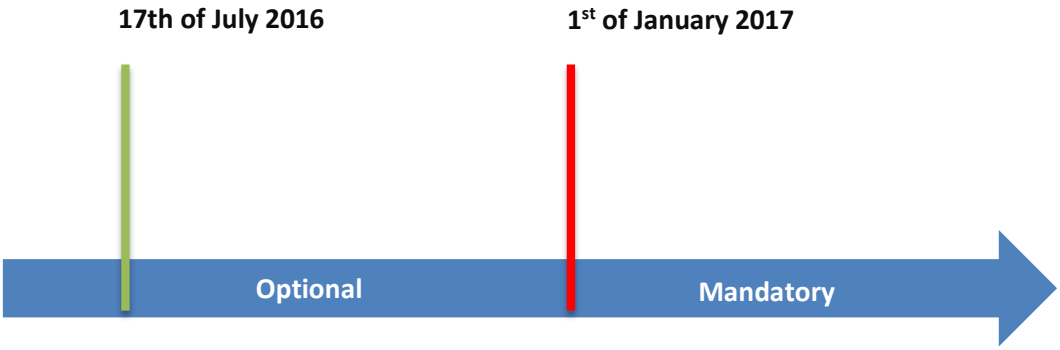

Figure1: Timeline for switching to eCTD baseline

III. Baseline eCTD Submission

One of the principles of eCTD is that with the use of the operation attributes, it is possible to manage the lifecycle of a product and generate a view of the "current dossier".

To convert from CTD or NeeS format to eCTD, a baseline needs to be submitted. A baseline submission is the resubmission of currently valid documents to start the eCTD life cycle.

An eCTD baseline should not contain any *new* information as it will not be subject to review by the Drug sector.

Submission of a baseline shall be after the *end* of a regulatory activity. i.e. the company will follow the same original submission for products under assessment until the end of the regulatory activity.

IV. Baseline Starting as Sequence 0000

For product files that are submitted as CTD or NeeS, the baseline submission should be submitted as sequence (0000). However, in some cases e.g. renewal and variation submitted as eCTD, the submission could continue to the next sequence of the submission life cycle. The baseline should always be a separate submission and should never include new applications.

V. Baseline Cases

1. For products submitted as NeeS/CTD:

If the product was submitted as NeeS/CTD and has no regulatory activity or complete regulatory activity, a baseline shall be submitted as sequence 0000. The first regulatory activity after baseline (for example a variation request) shall be submitted as sequence 0001. For the next submissions, the sequence number will advance, 0002, 0003, etc. See table below:

Sequence No.	Submission description	Submission type	Submission Unit	Related sequence
0005	Response to Question	NeeS/CTD	-	-
0000	Baseline submission	none	reformat	
0001	Variation	var-type2		
0002	Response to Questions	var-type2	response	0001

Table 1: Example for starting an eCTD with a baseline sequence

2. For products submitted as eCTD for renewal or variation:

Products submitted as eCTD submission, and are approved by SFDA with no ongoing regulatory activity, the baseline sequence may continue from the last one. Table 2 demonstrate more on this case.

Sequence No.	Submission description	Submission type	Submission Unit	Related sequence
0000	Renewal	renewal		
0001	Response to Questions	renewal		0000
0002	Response to Questions	renewal		0000
0003	Variation	var		
0004	Response to Questions	var		0003
0005	Baseline Submission	none	reformat	

Table 2: Example for starting a baseline with a regulatory activity

VI. Components of an eCTD Baseline Submission:

It is composed of the currently valid documents in an eCTD format. Refer to Appendix I for more details.

The cover letter should include **declaration** that indicates there is ***no new information***, only the format dossier has changed.

Notes:

- SFDA encourage applicants to move to a full eCTD (m1 to m5).
- The applicant has the right to upgrade to eCTD in which it requires the submission of a baseline. However, once eCTD is submitted going back to other format will not be accepted.
- For products that are registered through SDR system as eCTD, no need for a baseline.

VII. Appendix I:

Section	Requirements
Module 1	**Regional Administrative Information**
1.0	Cover letter
1.2	Application Form[1]
1.3	Product Information
1.3.1	Summary of Product Characteristics (SPC)
1.3.2	Labeling
1.3.3	Patient information leaflet (PIL)
1.3.3.1	Arabic leaflet
1.3.3.2	English leaflet
1.3.4	Artwork (Mock-ups)
1.7	Certificates and Documents
1.7.2	CPP or Free-sales
Module 3	Quality
3.2.S	Drug Substance
3.2.P	Drug Product
3.2.A	Appendices

[1] The application form submitted shall be the last valid application form

VIII. References

- Regulatory Framework for Drug Approvals.
- GCC Module 1 Specifications.
- Guidance for submission.
- EMA Reference Documents:
  Harmonised Technical Guidance for eCTD Submissions in the EU.

IX. Annex 1 Updates:

- **What's New in Baseline eCTD Submission Requirements (version 1.1)?**

The following table shows the update on the previous version 1.0:

Section	update
• Glossary	Added
• Technical Baseline	Add timeline of implementation
• Baseline Cases	Add examples of baselines submissions