



مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

GCC Data Requirements for the Renewal of Marketing Authorizations

Version 1.2

Date of implementation	01/01/2014
------------------------	------------



Document Control

Version	Date	Author(s)	Comments
1.0	10/12/2011	Executive Directorate of Product Evaluation and Standards Setting	Final
1.1	24/2/2013	Executive Directorate of Product Evaluation and Standards Setting	Updated
1.2	26/5/2013	Executive Directorate of Product Evaluation and Standards Setting	Updated

Note: For most recent update please refer to annex 2.



Table of Contents

Module 1:	4
1.0 Cover letter	4
1.1 Comprehensive table of content	4
1.2 Application Form	4
1.3 Product Information:	5
1.3.1 Summary of Product Characteristics (SPC)	5
1.3.2 Labeling	5
1.3.3 Patient information leaflet (PIL)	5
1.3.4 Artwork (Mock-ups)	5
1.7 Certificates and Documents	6
1.7.2 CPP or Free-sales	6
1.7.7 Certificate of suitability for TSE	6
1.8 Pricing	6
1.8.1 Price list	6
Module 3:	6
3.2.S Drug Substance	6
3.2.S.4 Control of Drug Substance	7
3.2.S.4.1 Specifications	7
3.2.P.5 Control of Drug Product	7
3.2.P.5.1 Specifications	7
3.2.P.8 Stability	7
Annex 1	8
Annex 2	9



Renewal of Marketing Authorizations

Renewal applications have to contain a consolidated version of the file, containing at least the documents listed below. They should be presented in accordance with the appropriate headings and numbering of the CTD format:

Module 1:

1.0 Cover letter

1.1 Comprehensive table of content

1.2 Application Form

This section should contain the renewal application form with the following annexes:

- A list of all authorized drug product presentations for which renewal is required.
- The contact details for the qualified person(s) for both quality and pharmacovigilance with their qualifications.
- Status of the drug product in other countries where the product is on the market:
 - A List of countries where the drug product is authorized for marketing.
- Chronological list of all approved variations since grant of the Marketing Authorization or last renewal. For each change, the date of approval (if approved) and brief description of the change should be provided.
- Revised list of all remaining follow-up measures/post-authorization commitments (*where applicable*).
- In case of contract manufacturing, please list any changes in the technical contract.



1.3 Product Information:

1.3.1 Summary of Product Characteristics (SPC)

- If there are any change(s) in the previously approved SPC, a revised copy for the SPC should be submitted highlighting the proposed change(s).
- The layout of the SPC must be in accordance with the “GCC Guidance for Presenting the SPC, PIL and Labeling Information”.

1.3.2 Labeling

- The inner and outer label should be submitted.
- If there are any change(s) in the previously approved label, a revised copy for the label should be submitted highlighting the proposed change(s).
- The layout of the label must be in accordance with the “GCC Guidance for Presenting the SPC, PIL and Labeling Information”.

1.3.3 Patient information leaflet (PIL)

- The English and Arabic PIL should be submitted.
- If there are any change(s) in the previously approved PIL, a revised copy for the PIL should be submitted highlighting the proposed change(s).
- The layout of the PIL must be in accordance with the “GCC Guidance for Presenting the SPC, PIL and Labeling Information”.

1.3.4 Artwork (Mock-ups)

- One or more mock-ups of the currently marketed outer and immediate packaging for each pharmaceutical form should be submitted.



1.7 Certificates and Documents

1.7.2 CPP or Free-sales

- Original Certificate of Pharmaceutical Product (CPP) or free sale certificate from the country of origin.

1.7.7 Certificate of suitability for TSE

- List of all materials derived from animal origin used in the finished product. In addition, the source of the material should be indicated and any relevant certificate(s) should be submitted.

1.8 Pricing

1.8.1 Price list

- A price list shall include the price of the drug product in countries listed in the Price Certificate Form (Form 30).

Module 3:

3.2. S Drug Substance

The drug substance information should be submitted in one of the following options:

1. Complete section 3.2.S, or
2. Drug Master File (DMF), or
3. Certificate of suitability (CEP) with the followings sections; 3.2.S.1.3 (General properties), 3.2.S.3.1 (Elucidation of structure and other characteristics), 3.2.S.4.2 (Analytical procedures), 3.2.S.4.3 (validation of analytical procedures) and 3.2.S.6 (Container closure system)

In case the finished product contains plasma derivatives, submit a complete Plasma Master File (PMF) or a commitment letter from the manufacturer showing that the source of plasma did not changed from the previously approved source.



3.2. S.4 Control of Drug Substance

3.2. S.4.1 Specifications

- Copies of the current API specifications, duly signed and dated, should be provided, including the test methods. The specifications should indicate the reference number, version number, effective date and change history if any.

3.2. P.5 Control of Drug Product

3.2. P.5.1 Specifications

- Copies of the current drug product specifications, duly signed and dated, should be provided, including the test methods. The specifications should indicate the reference number, version number, effective date and change history if any.

3.2. P.8 Stability

Stability data on two production batches in accordance with the “GCC Guidelines for Stability Testing of Active Pharmaceutical Ingredients (APIs) and Finished Pharmaceutical Products (FPPs)”. The stability study should be conducted on at least two Production batches Manufactured recently within the last five Years.



Annex 1:

What's New in Data Requirements for the Renewal of Marketing Authorizations (version 1.1)?

The following table shows statement which replaced to the past version 1.0 December 10, 2011:

Section	Old Statement	New statement
<i>Section 3.2.P.8 stability</i>	The stability study should be recent (within the previous five years) performed on at least two production batches.	The stability study should be recent conducted during the last five years on at least two production batches and covers the claimed shelf-life.



Annex 2:

What's New in Data Requirements for the Renewal of Marketing Authorizations (version 1.2)?

The following table shows statement which deleted from the past version 1.1 February 24, 2013:

Section	Deleted statement
<i>1.3 Product Information:</i> <i>1.3.1 Summary of Product Characteristics (SPC)</i>	The SPC should be written in English and have the same information as the ones approved in the country of origin.