الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Data Requirements for the Renewal of Marketing Authorizations

(Herbal and Health Products)

Version 1.0

Date of implementation	01/05/2012

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Drug Sector
Saudi Food & Drug Authority
Kingdom of Saudi Arabia

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Document Control

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Renewal of Marketing Authorizations

Renewal is required for registered product which expired its registration certificate. 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.
- 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) [optional]

- The SPC should be written in English and have the same information as the ones approved in the country of origin if any.
- 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) [if applicable]

- 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.

1.3.5 Sample

One sample should be submitted and must represent the final finished product approved to be marketed in Saudi Arabia.

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 [if applicable]

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 Control of Drug Substance

3.2.S.2.1 Manufacturer(s)

The name, address, and responsibility of each manufacturer/supplier, including contractors, and each proposed production site or facility involved in production/collection and testing of the drug substance should be provided.

3.2. S.4.1 Specifications

Copies of the current raw materials 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 Control of Drug Product

3.2.P.1 Description and Composition of the Drug Product

A description of the product and its composition should be provided. The information provided should include, for example:

- Description of the dosage form;

- Composition, i.e.:
  - list of all components of the dosage form,
  - their amount on a per-unit basis (including overages, if any),
  - the function of the components, and
  - a reference to their quality standards (e.g., compendial monographs or manufacturer's specifications);
- Description of accompanying reconstitution diluent(s); and type of container and closure used for the dosage form and accompanying reconstitution diluent, if applicable

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)"*.