

Pharmaceutical Product Regulation



Medicine Renewal Guideline

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Version 2.2



NHRA CEO Approval:

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Document Control

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Summary of Changes:

No.	Section	Description of Change
2	2.3 Assessment & Queries	Addition of the assessment of the application is expected to be completed by the designated NHRA staff within 25 working days.

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1. Introduction

Guideline documents are meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. Guideline documents also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

The purpose of this guideline is to provide clear instruction on the NHRA procedure for renewal of a marketing authorization (MA) once every 5 years from the date of first licensing of a medicine in the Kingdom of Bahrain.

The renewal process is designed to provide for a periodic review by the NHRA of all available data to support an existing MA and therefore to ensure that the benefits of medicines holding MAs issued by the NHRA continue to outweigh any known risks.

Renewal applications should be submitted 3 months prior to the expiry date of the MA to ensure that the assessment can be carried out before the date of expiry. In addition, renewal applications should contain all the data/documentation as outlined in this guideline to facilitate efficient and timely assessment. Suspended Products are not allowed to be submitted for the renewal until the suspension is lifted.

As per Bahrain pharmacy Law 18 of 1997 and amendment by royal decree #20 of 2015, all products should have a valid medicine license for importation and distribution in the Kingdom of Bahrain. Thus, product with expired license shall not be allowed for importation or distribution by NHRA.

It should be noted that the NHRA has the right to request any information and data within the context of this guidance in order to assess adequately the safety, efficacy, and quality of any medicines at the time of renewal. The NHRA is committed to ensuring that such requests are justifiable, and decisions are clearly documented.

NHRA, has the right to review the price of the medicine upon renewal.

Approval of a renewal by NHRA should be consistent with the NHRA requirement that the interest of consumers and users of approved medicines are protected, notably in the following areas:

- A pharmaceutical product should be of appropriate quality such that its contents and its pharmaceutical performance should conform to acceptable standards.
- The risk of using the product should be acceptable and reasonable, taking into account that the use of any medicine carries a risk, which should be considered in the light of the likely benefit.
- There should be a demonstrable benefit for pharmaceutical products. If a medicinal claim is made, the consumer is entitled to expect a benefit.

This document should be read in conjunction with other applicable guideline documents.

2. License Renewal Procedure

2.1 Before Submission

Applicants should prepare a renewal application (in eCTD format) including all documents listed in medicine renewal checklist; the medicine renewal form must be filled and signed by the MAH Company for all renewals applications.

Please note that for each application the most up to date version of these forms should be downloaded directly from NHRA website.

Compounding variation applications with renewal applications is not accepted. The variation and renewal applications can be submitted at the same time.

NHRA manufacturing site registration certificate must be valid before submitting renewal application.

2.1.1 Fees

As per resolution 17 of 2016, license fees are chargeable for each medicine renewal application submitted to NHRA. The applicant must refer to the latest fee structure from NHRA website.

2.1.2 Data Requirements

All required data should be in accordance with ICH Common Technical Document (CTD) in eCTD format.

Module 1 is region specific. Specific details to eCTD submission are mentioned in Annex I.

Module 1 Requirements:

- A. Cover letter: Original company paper signed, and dated, the cover letter should include a declaration that indicates there is no new information or changes from the previously submitted documents.
- B. Application form: Complete application form must be included in this section. The latest version of the Medicine renewal application form must be filled, signed, and stamped with date by the MAH Company.



C. Product Information

1. Summary of product characteristics (SmPC): In addition to the SmPC, a declaration from the MAH that the SmPC submitted is correct and similar to the one approved in COO is included in this section (if there are any differences the company shall declare it).
2. Label text (immediate and secondary packaging).
3. NHRA last approved package leaflet (bilingual English/Arabic).
4. NHRA last approved Artwork (outer pack, inner label, and package leaflet).

D. Certificates and Documents

1. Copy of valid Good Manufacturing Practice (GMP) certificates or proof of inspection by a recognized health authority for all finished product manufacturer(s) including bulk manufacturer, primary packager, and secondary packager.
2. Copy of valid Good Manufacturing Practices (GMP) of each API.
3. Certificate of Pharmaceutical Product (CPP) according to WHO format; legalized and issued from the (batch releaser country or the MAH country), electronic CPPs are exempted from legalization.
4. NHRA Price Certificate Form.
5. Certificate of analysis for the drug substance from the API supplier. (Issued in the last 5 years).
6. Certificate of analysis for the finished product. (Issued in the last 3 years).
7. Certificate of suitability for TSE/BSE.
8. Certificate of suitability (CEP) if available, the last approved version by PPR-NHRA.

E. Additional Data

1. Contact details for the Marketing Authorization Holder responsible person for communication with the NHRA on quality issues.
2. Worldwide registration status (registered, marketed (date), under registration and rejected).
3. Manufacturer registration certificate in Bahrain (batch releaser).
4. Manufacturer registration certificate in Bahrain (bulk) for sterile products only.
5. NHRA Product License copy.



Note:

1. Above listed documents are to be part of module1.
2. The submitted documents should be according to the latest approved information of the product in PPR-NHRA, any changes to this information must be submitted as a separate variation application.
3. One sample to be submitted along with the application, pharmaceutical product of biological origin, vaccines, cytotoxic, radiopharmaceuticals, contrast media and controlled medicines are exempted from submitting the sample.
4. The submitted Stability Study should be according to the latest GHC Guidelines.

2.2 Submission

Renewal applications must be submitted through the NHRA online system “Adweya”. The applicant is required to prepare and upload all the necessary documents along with the eCTD sequence directly into the Adweya system.

2.3 Assessment & Queries

Each application is assessed in accordance with NHRA standard operating procedures and relevant technical guidelines and, where queries arise, a request for further information will be sent to the MAH via respective agent through the Adweya portal. The assessment of the application is expected to be completed by the designated NHRA staff within 25 working days.

Note: Incomplete/invalid responses to queries sent shall not be entertained. Information request will be sent three times only. If the queries are not satisfactorily addressed, the application will be closed following which the application has to be re-submitted upon rectification.

2.4 Approval

A renewal certificate will be issued upon payment.

3. Post Approval Changes

Any change to the approved medicine information must be approved by NHRA. Please refer to NHRA variation guideline for more information.

Annex I

Electronic Common Technical Document (eCTD)

I. Introduction

According to NHRA's eCTD implementation plan, the renewal submission in eCTD format is mandatory from the 2nd of May 2017. This applies only to human medicine applications.

The ICH M4 Expert Working Group (EWG) has defined the Common Technical Document (CTD). The ICH M2 EWG has defined, in the current document, the specification for the Electronic Common Technical Document (eCTD). The eCTD is defined as an interface for industry to agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, life cycle management and archiving of the electronic submission.

The CTD as defined by the M4 EWG does not cover the full submission that is to be made in a region. It describes only modules 2 to 5, which are common across all regions. The regional Administrative Information and Prescribing Information is described in Module 1. The CTD does not describe the content of module 1 because it is regional specific, nor does it describe documents that can be submitted as amendments or variations to the initial application. Module 1 Specifications of the electronic Common Technical Document (eCTD) for Gulf Health Council (GHC) are described in "GCC module 1 specifications."

This document should be read together with ICH eCTD specifications and with GCC module 1 specifications to prepare a valid eCTD submission to NHRA. The latest version of the ICH eCTD Specification can be found at: <http://estri.ich.org> and of GCC module 1 specification can be found at: <http://www.sfda.gov.sa>

NHRA will show all the cases and scenarios of eCTD submissions especially the baseline eCTD submissions.

II. Technical Baseline Application

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 NHRA 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 NHRA 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".

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 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 NHRA.

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, 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

For products submitted as CTD:

If the product was submitted as 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	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.



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:

1. NHRA encourage applicants to move to a full eCTD (m1 to m5) at least full M1 and M3 should be submitted.
2. The applicant can submit the eCTD dossier for currently registered product in which it requires the submission of a baseline. However, once eCTD is submitted going back to other format will not be accepted.

Appendix I: Components of an eCTD Baseline Submission

Section	Requirements
Module 1	Regional Administrative Information
1.0	Cover letter
1.2	Application Form
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
1.7	Certificates and Documents
1.7.1	GMP Certificate
1.7.2	CPP
Module 3	Quality
3.2.S	Drug Substance
3.2.P	Drug Product
3.2.A	Appendices

Annex II

Medicine Renewal Checklist

Product Name	Strength	Form	Pack Size
Drug Registration Number			
Active Substance			
MAH Name & Address			
Local Agent			
First Renewal Yes <input type="checkbox"/> No <input type="checkbox"/> specify date of last renewal:			
Module 1	<i>Administration information to be submitted in addition to eCTD on EURSNext</i>		
1.	Cover letter (original, company paper signed and dated).		<input type="checkbox"/>
2.	Legalized CPP (in WHO format) from the COO (batch releaser/MAH).		<input type="checkbox"/>
3.	Finished product sample- 1nos		<input type="checkbox"/>
4.	eCTD (Modules 1 and 3).		<input type="checkbox"/>

I declare that all the documents which refer to in this check list are attached.

Date:

Name & Signature of Responsible Person:

Signature: _____

Annex III

Medicine Renewal Application Form

Product Name		Strength	Form	Pack Size
Active Substance				
MAH Name & address			Drug Registration Number	
Invoicing company Name & Country			ATC Code	
First Renewal	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Specify the date of last renewal:	
Shelf Life				
Storage Conditions				
Primary Packaging Material				
Method of Sale				
Leaflet Revision Date				
Manufacturer Responsible for	Site Name		Site Address	
Bulk Manufacturing				
Primary Packaging				
Secondary Packaging				
Batch Releasing				
Active Pharmaceutical Ingredient (API)				
Name of API	Site Name		Site Address	
Has the product market authorization withdrawn during last 5 years from any country where it was marketed? Yes <input type="checkbox"/> No <input type="checkbox"/>				
If yes, please clarify:				
<i>I/we apply for a medicine license Renewal in respect of the product for which details are provided above. It is hereby confirmed that all information relevant to the product have been supplied in the file as appropriate and they are all correct (must be filled by the MAH).</i>				
Name of signatory			Signature	
State capacity in which signed			Date	



References:

1. Decree-Law No. (18) of 1997 With Respect to the Practice of Pharmacists and Pharmaceutical Centers_
2. Decree-Law No. (20) of 2015 Amending Decree-Law No. (18) of 1997 on the Organization of the Pharmacy Profession and Pharmaceutical Centers
3. Decree No. (17) of 2016 on NHRA Application Fees
4. Resolution No. (63) of 2019 on Requirements and Procedures for Practicing Pharmacy Professions and Licensing of Pharmaceutical Facilities
5. Gulf Health Council, <http://ghc.sa/en-us/Pages/Home.aspx#>
6. The International Council for Harmonization (ICH) - Electronic Standards (ESTRI)
<https://www.ich.org/page/electronic-standards-estri>