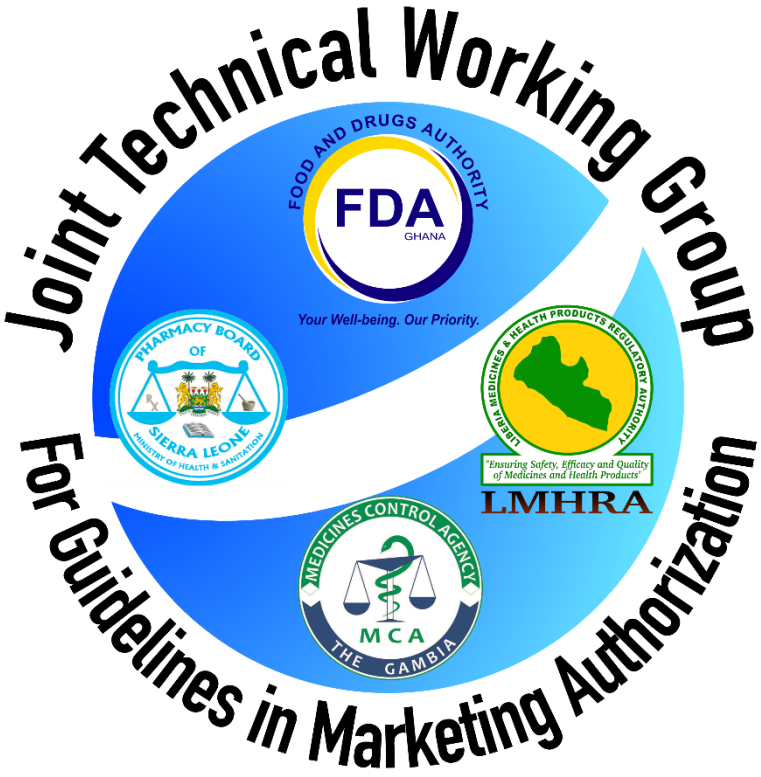

Guideline on Renewal

For the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia

Updated December 2, 2022

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NMRAs are welcome to download and use the following guideline if credit is given to the authors - all members of the Joint Technical Working Group for Development of Guidelines in Marketing Authorization (TWG-MAG):

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<02 December 2022>
Joint Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG):
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Medicines Control Agency (MCA, The Gambia)
Pharmacy Board of Sierra Leone (PBSL, Sierra Leone)
Global Health Protection Programme (GHPP-PharmTrain Project),
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Guideline on Renewal of Marketing Authorization, Version 1.0, Updated December 2, 2022

Draft written by PBSL	September 2021
Draft reviewed and agreed by TWG-MAG: LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	09 September 2022
Updated by LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	02 December 2022
Adopted by <Committee/Board> for release for consultation	<DD Month YYYY>[1]
Start of public consultation	<DD Month YYYY>[2]
End of consultation (deadline for comments)	<DD Month YYYY>[3]
Agreed by <Working group(s)/Department(s)>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date of coming into effect	<DD Month YYYY>[4]

This guideline replaces '<guideline>' (NMRA/…/…).[5]

Comments should be provided using the template for submission of comments. The completed comments form should be sent to <as appropriate (NMRA's Email)>.

Keywords	***medicinal products, bioequivalence, pharmacokinetics, biowaiver, in-vitro dissolution, generics, renewal***

[1]Last day of relevant Committee meeting.
[2]Date of publication on the <NMRA> public website/1st day of the month following adoption of the guideline.
[3]Last day of the month concerned.
[4]First day of coming into effect. Latest 3 months after adoption.
[5]If this supersedes a previous guideline – otherwise delete.

<Street of the NMRA> • <Region> • <City> • <Country>
Telephone < > **Facsimile** < >
Send a question via our website www.<NMRA>…
An agency of the <……>.

Country logo

Guideline on Renewal of Marketing Authorization, Version 1.0, Updated December 2, 2022

Table of contents

Style notes for this draft version:

[ ] Comments to be removed with finalization

< > Placeholder to be filled with specific information or to be decided if kept or deleted.

Acknowledgements

We duly thank the Food and Drugs Authority Rwanda, Food and Drugs Authority Ghana, European Medicines Agency for publishing their guidelines that contributed in several aspects relevantly to the development of this guideline.

Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January / February 2020 by GHPP-PharmTrain Project team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone), and The Gambia (MCA, Medicines Control Agency).

This document has been discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-PharmTrain project team from September 2021 to September 2022.

From January 2022 the Joint Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG), with the above-mentioned members, was established to continue the successful development of regulatory guidelines.

<This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance.>

1. Introduction (background)

Renewal of marketing authorization (MA) of medicinal products is required as specified in the legal provision <quote title of national medicines Act and section if applicable>.

This guideline applies to all medicinal products whose MA validity is before ninety (90) calendar days to expiration. It provides guidance to marketing authorization holders (MAH) on format and content of minimum documents and information required for renewal of authorization of medicinal products. It also guides the <NMRA> in managing applications for renewal of authorized medicinal products.

This guideline provides requirements to be fulfilled by MAH, including specific documents to be submitted for evaluation prior to renewal of medicinal products authorization. MAHs should read this guideline in conjunction with <quote title(s) of national GL(s) for authorization of medicinal products, if applicable>, along with other references provided in this document.

It should be noted that the <NMRA> has the right to request any further information or documents, with a commitment that such requests are justifiable, and will be for the purpose of ensuring quality, safety, and efficacy of the submitted product.

1.1. Objective

This guideline presents a common format for the preparation and submission of an application to the <NMRA> for the renewal of authorization of authorized medicinal products.

The objectives of this guideline includes the following:

- Ensure appropriate preparation of documentation for the renewal of all authorized medicinal products.
- Provide guidance on the technical and other general data requirements for the renewal of authorized medicinal products.
- Promote transparency and efficiency for the subsequent evaluation processes by the <NMRA>.

2. Scope

This guideline is developed in pursuance of the legal provision <quote title of national medicines Act and section if applicable> and shall apply to all authorized medicinal products, submitted to the <NMRA>.

The term “medicinal products” in the context of this guideline includes finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, in-vitro diagnostics, blood products and animal products, if not indicated otherwise. MAs approved under routine as well as non-routine are covered by this guideline.

This guideline is also made to provide guidance to MAHs on the organization of information to be presented when applying for the renewal of medicinal product authorization. Medicinal products in the context of these guidelines include finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, *in-vitro* diagnostics, blood products and animal products. MAHs are encouraged to familiarize themselves with this document and the above law before completing the application form for the renewal of authorization of medicinal products.

3. Legal basis

In pursuance of the legal provision <quote title of national medicines Act and section if applicable> this guideline is hereby promulgated for information, guidance and strict compliance by all concerned on the procedure and requirements for the renewal of authorization of medicinal products in <country>. In accordance with the above legal provision a MA valid for <three/five> years could be granted. In order for a MA to remain valid, a renewal is required every <three/five/NMRA specific exceptions added here> years after the granting of the MA/renewal (irrespective of whether the MA has been suspended during that period). The <three/five> years period will be counted from the date of notification of the <NMRA> to the MAH. The MA may be renewed upon application by the MAH least ninety (90) calendar days before its expiry. The renewal assessment must be based on a general re-evaluation of the benefit-risk balance of the product. It is the responsibility of the MAH to apply for renewal of the authorization of the medicinal product.

In the case where a MAH does not submit the renewal application, the MA will expire by law.

4. Timelines

In accordance with the <NMRA>'s laws and regulations in place, MAHs must apply for renewal of authorization to the <NMRA> at least ninety (90) calendar days before its expiry.

Application submission, validation and processing should be done at least 3 months before the expiration of the validity of a registered medicinal product. Following which, the new validity period of the renewed medicinal product would commence just before or at about the same time of the product's expiry.

The <NMRA> will perform the validation of the content of the application and may request supplementary information in order to finalize the validation. Upon receipt of a technically valid and complete application for renewal, <NMRA> will start the procedure and will inform the MAH of the outcome of the assessment. A renewal application will be processed within 3 months of receipt of the application.

For any question regarding the submission of the renewal application, the MAH can contact the <NMRA>.

5. General Requirements

The renewal constitutes a crucial step in the lifecycle of a medicinal product, where a re-evaluation of the benefit-risk balance of the medicinal product takes place. The documentation presented hereafter should be submitted within the renewal application.

5.1. Administrative requirements for submission of application

- The application should be submitted by the MAH directly to the <NMRA> or through the authorized local representative. A cover letter should be addressed as follows:

<Indicate the designation of the head of agency and official address>

- The application should be submitted in English. All submitted documents that are in any language other than English must be accompanied by a notarized English translation.
- Data should be presented in readable format, font size <xx>, <style (as per country's specific requirements>. Every page shall be numbered sequentially (x of y). Extension sheets, tables, diagrams, and other supporting documents shall, where possible, be of the same size, clear, well annotated, numbered, and appropriately cross-referenced.

[As soon as every partner NMRA has its own general guidance document on the submission of application (which would take into consideration administrative requirements, such as font style/size, pagination, sample submission, payment of application fee etc) this section needs to be revised, e.g. referring to the respective GL.]

- Required technical data: All required technical data shall be presented in the Common Technical Document (CTD) format.
- Two CD-ROMs or external data drives should be provided containing all information on quality of the product (where applicable).
- Evidence of payment of the non-refundable renewal fee at the time of submission should be submitted alongside the application for renewal. Note that any application not accompanied by the requisite proof of payment will not be given consideration. Also, the <NMRA> reserves the right to determine the correct interpretation of the fee payable based on the published fee schedule (which can be found on <NMRA> website).

5.2. Content of the application; technical data requirements

Applications for the renewal of authorized medicinal products shall be accompanied by the following data documentation/requirements:

- An application for the renewal of medicinal product authorization shall be made in writing via a cover letter and filled application form dated and signed by the MAH (find model application cover and application form in <Annex X> and <AnnexY>).
- List of all currently authorized pharmaceutical strengths, forms, and product presentations/pack sizes for which renewal is sought in tabular format. Certain pharmaceutical strengths, forms, and product presentations/pack sizes that the MAH does not wish to renew should be clearly indicated in the cover letter.
- List of all variations accepted by the <NMRA> over the authorization period of the product, where applicable.
- The MAH should provide a list of all countries where the product has been reviewed and approved over the registration period of the product, the registration numbers, and copies of registration certificates if available.
- The MAH should submit the required number of commercial samples (including patient information leaflet and copies of coloured mock up labels of the product as marketed in the NMRA countries) as specified in the sample schedule to the <NMRA> as part of the renewal application.
- Current versions of Summary of Product Characteristics (SmPC), inner and outer labelling, and Patient Information Leaflet (PIL) in line with the approved NRA templates should be submitted electronically in both Microsoft Word and PDF and should be clearly expressed in English.
- Any variation has to be approved prior to the submission of the renewal application and no variation can be applied for until renewal authorization.
- Risk Management Plan (RMP): The updated RMP and where relevant, the new RMP.

- Where there are no new data justifying changes to the latest approved RMP, the MAH should provide in the clinical overview declaration and confirm that the current approved RMP remain unchanged and applicable. Where there is no RMP for the medicinal product, this should be stated in the cover letter.

5.3. Quality Requirements

- The MAH should incorporate a signed declaration stating that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedures to take account of technical and scientific progress, and that the product conforms with current <NMRA> quality guidelines.

Active Pharmaceutical Ingredient(s) (API(s))

- 3.2.S.2 Names and complete addresses of all current suppliers of active pharmaceutical ingredient(s) along with manufacturing and current Good Manufacturing Practices (GMP) certificates of the active pharmaceutical ingredient(s) manufacturing site issued by the competent regulatory authorities and indicating the date, and, where applicable, inspection team and outcome.
- 3.2.S.4 Copy of current signed and dated specifications (with version number) along with change history, where applicable and analytical procedures used for testing of the API(s) by the finished product manufacturing site.

Finished Pharmaceutical Product (FPP)

- 3.2.P.1 Description of qualitative and quantitative composition of the unit dosage form and of the commercial batch size(s) as approved by the NMRA including excipients (where applicable) in a manner provided for in <quote title(s) of national GL(s) for authorization of medicinal products and respective section 3.2.P.1, if applicable>.
- 3.2.P.3.1 MAH should submit valid GMP certificate, for the finished product manufacturing site indicating the date, and, where applicable, inspection team and outcome.
- 1.3.2 The MAH should provide a valid Certificate of Pharmaceutical Product (CPP) with the importing country specified.
- 3.2.P.5.1-2 A copy of current signed, dated and version numbered release and shelf life specifications of the finished products along with change history, where applicable, and standard testing procedures.
- 3.2.P.8 Data on current long term stability of the finished product should be provided. Studies should be conducted according to requirements stipulated under section 3.2.P.8 of the main Guidelines for the authorization of medicinal products and specific guidelines on Stability Testing Requirements for Active Pharmaceutical Ingredients and Finished Pharmaceutical Products.

- 3.2.R A copy of batch manufacturing record (BMR) for the largest production batch manufactured within six months before the date of submission of the renewal application.
- 3.2.R Report on annual product quality review (APQR, see <Annex> for details) for all batches of the finished product manufactured in the past <36 months / 60 months> before the date of application of the renewal.
- 3.2.R Copies of Certificate of Analyses (CoAs) for the finished products batches submitted as samples
- 3.2.R Completed Quality Information Summary (QIS)

Definitions

Active Pharmaceutical Ingredient (API)

An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Composition

In relation to a medicinal product means an ingredient of which it consists, proportions, degree of strength, quality, and purity in which those ingredients are contained.

Excipient

Any constituent of a pharmaceutical form that is not an active pharmaceutical ingredient.

Finished Pharmaceutical Product (FPP)

Product that has undergone all stages of production, including packaging in its final container and labelling. An FPP may contain one or more active pharmaceutical ingredients.

Formulation

The process by which different chemical substances including the active pharmaceutical ingredient, are combined to produce a final pharmaceutical product.

Label

Is a descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a packaging of any medicinal product.

Marketing Authorization (MA)

Approval to market a medicinal product in the NMRA's country. MA is issued by the NMRA with a legal document for the purpose of marketing or distribution of a product within the country after evaluation for safety, efficacy and quality in the marketing authorization assessment process.

Marketing Authorization Holder (MAH)

A person or entity whose product has been authorized by a national medicines regulatory authority to be on the market.

Manufacture

Any total or partial operation of producing, preparing, formulating, treating, processing, filling, decanting, packaging, labelling and release of medicines and the related controls.

Manufacturer

Any person or entity with responsibility in manufacturing activities including implementation of oversight and controls over the manufacture of the medicinal product or active pharmaceutical ingredients or excipients to ensure quality.

Manufacturing site

The location where the manufacturing process of a medicinal product is undertaken.

Medicinal Product

Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings.

The term “medicinal products” in the context of these guidelines includes finished pharmaceutical products, biotherapeutics, and vaccines. Not included are medical devices, in-vitro diagnostics, blood products and animal products, if not indicated otherwise.

Renewal

The process of extending the validity of a marketing authorization based on an application by the marketing authorization holder when the validity of the current authorization is due to expire.

Specifications

A document describing in detail the requirements such as physical, chemical, biological and microbiological test requirements with which the products or materials used or obtained during manufacture have to conform.

Shelf life

The period of time during which a medicinal product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product; the shelf life is used to establish the expiry date of each batch.

Variation

A change to the terms of a marketing authorization. There are different types of variations with different regulatory requirements and procedures.

References

European Medicines Agency, Guidelines on the processing of renewals in the centralized procedure, July 2016, EMEA/CHMP/2990/00 Rev.5.

European Medicines Agency, Reflection Paper Criteria for requiring one additional five year renewal for Centrally Authorized Medical Products, November 2007.

Ghana FDA, Guidelines for registration of biosimilar products, March 2019, FDA/SMC/BPD/GL-RBS/2013/02.

Ghana FDA, Registration renewal application form for innovator biological products, March 2015, FDA/SMC/BPD/A-RBP/2016/02.

Rwanda FDA, Guidelines No. DHT/GDL/022 on submission of documentation for registration of Veterinary medicinal products.

Rwanda FDA, Guidelines No DHT/GDL/001 on submission of documentation for registration of human medicinal products.

Saudi Food and Drug Authority SFDA, Data Requirements for the Renewal of Marketing Authorizations for Herbal and Health Products; May 2012.

Tanzania Medicines and Medical Devices Authority TMDA, Guidelines on submission of documentation for renewal of registration of human and Veterinary Medicinal products, March 2020.

Uganda NDA, Guidelines for submission of renewal of registration of pharmaceutical product for human use, February 2020.

WHO, Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A manual for National Medicines Regulatory Authorities (NMRAs), 2011.

This guideline template is based on the structure of the Guideline on Guidelines V1, February 2021 developed by the joint working group of Food and Drugs Authority (<NMRA>, Ghana), Liberia Medicines & Health Products Regulatory Authority (LMHRA, Liberia), Medicines Control Agency (MCA, The Gambia), Pharmacy Board of Sierra Leone (PBSL, Sierra Leone), and the Global Health Protection Programme (GHPP) PharmTrain-Project of the Federal Institute for Drugs and Medical Devices (BfArM, Germany).

List of Annexes

Annex I_Model application cover letter for the renewal of authorization of medicinal product

Annex II_Application form for renewal of authorization of a medicinal product

Annex III_Content of the annual product quality review report

Annex I

Model application cover letter for the renewal of authorization of medicinal product

Dear Sir/Madam,

Subject: Submission of Application for the renewal of Marketing Authorization of…… <Product Name(s), [strength(s)] of active pharmaceutical ingredient(s) and dosage form(s)>

We are pleased to submit our upplication for the renewal of marketing authorization of the under mentioned authorized product.

Please find details below:

Name of the medicinal product(s): ……

Dosage form(s) and strength(s): ……..

INN/active Pharmaceutical ingredient(s): …….....

Manufacturer name and country of origin: ..……

NMRA marketing authorization No: ……

Please note that you will also find alongside this cover letter the following:

• Two CD-ROMs or external data drives: containing all information on quality of the product (where applicable)

• Evidence of payment of the renewal fee (s) as stipulated in the fee schedule

• A valid Certificate of cGMP compliance

• Commercial samples with batch certificates of analysis

I, the undersigned certify that all the information in this application and accompanying documentation is correct, complete and true to the best of my knowledge.

Yours sincerely,

<Signature>

<Name>

<Designation>

<Phone number(s)>

<Email address>

Annex II

Application form for renewal of authorization of a medicinal product

Registration Renewal Application Form For Medicinal Products
(To be submitted in duplicate electronic copies)

Cover letter addressed to:

<NMRA's address>

Note: Samples and electronic documents should be forwarded to the Authority through the local agent; customs duty and clearance are to be effected by the marketing authorization holder (MAH) in all instances.

Submission Should Always Be Done By A Competent Technical Officer

1. Product Details (Must Be Completed)
Existing NMRA Registration Number: Full Name of Product (proprietary name): Human or Veterinary (if veterinary, state target species):
International Non-Proprietary Name (INN): Is this biological product registered in other countries? If yes, list countries and registration numbers: WHO prequalification status (*please provide PQ date*):
Pharmacological classification: Pharmaceutical form: Formulation type: Mode of usage: Concentration/Strength: Formulation type: Appearance/Colour: Proposed use: Active constituent(s):
Category of distribution: Proposed distribution network:
Country of origin: Marketing authorization holder: Marketing authorization number & date (country of origin):

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Application tracking number:

Registration number:

First renewal:

Second renewal:

2. MAH Contact Information (Must Be Completed)

Full name of MAH (*must be a company*):

Manufacturing company registration certificate number (*including accessory companies):*

Name of contact person(s):

Title and / or designation:

Street address or physical address (MAH):

Postal address (MAH):

E-mail (MAH):

Telephone number (MAH):

Fax number (MAH):

3. Name And Contact Details Of The Qualified Person For Pharmacovigilance (QPPV) Responsible For The Finished Product In <Country>

Name:

Certificate Number:

Address:

Telephone:

E-Mail:

Signature:

4. Declaration (Must Be Completed)

Note: Only a body incorporated in <Country> can be appointed as a local agent for this application

Full name of local agent (*must be a registered company*):

Registrar general's registration number: Name of contact person: Title and /or designation:
Postal address (local agent):
Street or physical address (local agent):
E-mail (local agent): Telephone number (local agent): Fax number (local agent):
Full name of Superintendent Pharmacist: Registration number of Superintendent Pharmacist:
Correspondence about this application is to be addressed to: MAH or local agent
I declare that the information provided with this application is complete and correct. Signature (MUST be in ink): _____ Date: Official stamp: ***False declaration may lead to prosecution.***
5. Product Data
Data must be accompanied by a table of content, information shall be provided in soft copy-DUPLICATE (An electronic format saved on a CD).

Data may include, but not limited to the following:

- Supporting documentation for any variations since the biological product was last registered
- Certificate of analysis of the finished biological product
- Certificate of Pharmaceutical Product (**CoPP**) issued by the statutory national drug regulatory authority, in accordance with the World Health Organization (WHO) Certification Scheme for Pharmaceutical Products Moving in International Commerce
- Long-term/Real-time and real condition stability studies for three (3) production batches (protocol and report)
- Method of analysis (Protocol and Report)
- Analytical Method Validation (Protocol and Report)
- Evidence of Good Manufacturing Practice (**GMP**)
- Batch release documents
- Reference Standard/ Product
- Certificate of Analysis of the Reference Standard/Reference Product

Risk management plan and pharmacovigilance/data on post market surveillance (*refer to NMRAs homepage)*

6. Variation(S) Made To Packaging/Presentation/Formulation
Please list all variations made to the primary and/or secondary packaging/presentation/formulation since initial registration

7. List Of All Change(s) In The Conditions Of Use, Labelling Or Registration Conditions For The Biological Product

8. Distinct Prescribed Uses
List all proposed **distinct** uses (for veterinary, state target species and situation)

I declare that the provided formulation information is complete and correct.

Signature (MUST be in ink): _____Date:

False declaration may lead to prosecution.

9. Manufacturers' Details (Must Be Completed)

The manufacturer must be licensed to manufacture the product for which this registration application applies. Include the name and street address of all facilities involved in any step of manufacture, including packaging & labelling, contractors and analytical laboratories where applicable.

Company name	**Company's registration number**	**Street/physical address of manufacturing site**	**Extent/Stage of manufacture** (attach flow diagram)
1.			
2.			
3.			
4.			
5			

Provide details of responsible person performing 'Release for Supply':

Name of responsible person:

Position:

Title:

Company name:

Street address:

E-mail:

Telephone number:

Fax number:

10. Container And Pack Size Details (Must Be Completed)

Proposed pack size(s)	**Brief description of the packaging material, including that which is in direct contact with the product (*i.e.* primary and secondary packaging).**	**Method of label attachment**

Provide details of product presentation (e.g. single glass bottle inside individual cardboard carton with enclosed leaflet).

11. Storage Stability Details (Must Be Completed)	
The proposed shelf life from the date of manufacture.	
Proposed in-use shelf life:	
Proposed storage conditions: (e.g. between 2°C and 8°C. Refrigerate. Do not freeze).	
Submit a comprehensive stability study protocol, data and report on three (3) consecutive batches to support the storage stability of the product.	
For biological products in multiple dose containers: Submit an in-use stability study to support the in-use shelf life of the product.	
Submit a detailed storage temperature profile of the product (i.e transportation and excursions).	

12. MAH'S CHECKLIST (MUST BE COMPLETED)

Tick the appropriate boxes to verify that required documentation is attached:

 Application Overview completed including outline of exact purpose of application (and all relevant attachments)

 Appropriate fee

 Application form signed in ink and completed all relevant sections

 Completed batch release records, if applicable *(Refer to NMRA's Homepage for minimum batch release requirements for specific products)*

Attachments

Attachments (where applicable) should be indicated in the table of attachments and attached to this Application Form.

Table of attachments

Attachment	Attached?
Product label in appropriate format	
Product Data	
GMP certificates/documentation	
<NMRA> import permit	
Evidence of purchase of reference product (if applicable)	
Other (specify)	

Note: The entire application should be submitted with a table of contents. The total number of pages in the application, and total number of pages of attachments and appendices should be clearly stated.

Annex III

Content of the annual product quality review report

a) A review of starting and primary packaging materials used in the FPP, especially those from new sources,

b) A tabulated review of quality control and in-process control results,

c) A review of all batches that failed to meet established specification(s),

d) A review of all changes carried out to the processes or analytical methods,

e) A review of the results of the stability monitoring programme, and

f) A list of validated analytical and manufacturing procedures and their revalidation dates.