Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Pre-Authorization Approval of Medicines

Version Number	3	
Issued Date	17.12.2024	
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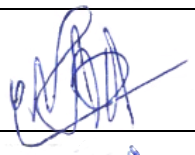
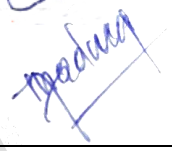
Approved By	Aishath Mohamed, Pharmaceutical Specialist	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

Summary of Changes

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	09.08.2022	-	Creation of the document	Fathimath Azuma, Pharmaceutical Officer
2	08.10.2023	Overall Document	Changes to the validity of Pre-authorization approval, submission of PSUR	Fathimath Azla, Pharmaceutical Officer
3	17.12.2024	Clause 6	Changes to the application pathways	Fathimath Azla, Pharmaceutical Officer

CONTENTS

ABBREVIATIONS

GMP	Good Manufacturing Practices
CoPP	Ceritificate of Pharmaceutical Product
COA	Certificate of Analysis
MFDA	Maldives Food and Drug Authority
MTG	Medicine and Therapeutics Goods Division
PA	Pre-Authorization
ADL	Approved Drugs List
HPA	Health Protection Agency
WHO	World Health Organization

Definitions

Applicant	The person or Company who submits an application of a product to the Authority and is responsible for the product information, recall etc., availability.
Importer	Company/sole proprietorship/partnerships registered as an importer in MFDA with a valid Importers Permit. Preauthorisation approval can be only requested by a registered importer.
Manufacturer of the Product	A company that carries out all the operations of production, packaging, labeling and quality assurance of the products.
Product Label	Includes all the written, printed or graphic material of the primary and secondary packaging of the product, excluding any outer shipping container.
Evaluation	Refers to a comprehensive safety, efficacy and quality analysis of the submitted product for registration.
Good Manufacturing Practices (GMP)	Refers to a system which ensures that products are consistently produced and controlled according to quality standards (WHO).
Approved Drug List (ADL)	A list of all medicinal products approved for import and use in Maldives.
Batch	A defined quantity of product processed in a single process or series of processes and therefore expected to be homogeneous. In continuous manufacture, the batch must correspond to a defined fraction of production, characterized by its intended homogeneity. Source: World Health Organization WHO Technical Report Series, No. 863, 1996
Post market surveillance	Post market surveillance, is the practice of monitoring the safety of a medicine after it has been released on the market and is an important part of the science of pharmacovigilance. Since these medicines are approved on the basis of registration, post-market surveillance can further evaluate the safety of a medicine after it is used in the general population by large numbers of people who have a wide variety of medical conditions.

1 INTRODUCTION

Maldives is a 100% importing country for medicines. Due to the small market and due to low volume of critically required medicines, importers are unable to get the required documentation from manufacturers for registration of these products.

Hence, MFDA has set up a criterion for ensuring availability of these medicines through reliance pathways by ensuring the quality, safety and efficacy of medicines. The procedure is established to ensure uninterrupted supply of essential medicines in Maldives which are critical to health care system.

This approval is only given for essential medicines and those medicines that are critically required for the healthcare system. The main purpose of this approval is to ensure availability and accessibility of these essential medicines including critical and emergency medicines antidotes. The Reliance approach is utilized for this process due to consistent quality issues which has been identified in the previous pre authorization criteria. The reliance approach is more simplified here than the product registration procedure.

In the Approved Drug List, products eligible for this approval is categorized as “Pre-Authorization required before import” (highlighted in green).

As this is a Pre-Authorization, (Not a Post Authorization), the products which are already imported will not be included for this approval.

2 PURPOSE

This guideline has been developed as a guidance for all medicines importers on preauthorization application and approval process.

3 STAKEHOLDERS

Medicine importers responsible for taking PA before import	Only registered medicine importer can apply for a PA
Health Protection Agency (HPA)	An approval is given for National immunization program conducted by HPA
World Health Organization (WHO)	An approval is given for Donation medicines
Pharmacists/Pharmacy owners	Inform any product safety issues and corporate any recall issues.
Consumers	Main users of medicine.

4 Requirements for Applications

4.1 The applicant shall be registered as an authorized medicine importer under the authority as per the criteria of Medicine Regulation R-46/2014 & R-49/2016 with valid importers permit from MTG/MFDA.

4.2 The importer shall have an established system for reporting and handling adverse drug reaction (ADR). Evidence of this shall be submitted when registering as an authorized medicine importer.

4.3 All electronic documents submitted shall be signed and endorsed by the concerned regulatory authorities. If the submitted documents are not signed and endorsed it can be accepted only if it can be verified from the relevant regulatory authorities.

4.4 All documents submitted shall be in English language.

4.5 MTG/MFDA shall reject the applications which does not fulfill the required criteria as mentioned above.

4.6 For all the pediatric oral formulations including cough, cold and paracetamol formulations, the certificate of analysis (COA) shall be submitted for all the excipients used, specifically if glycerin or glycerol or propylene glycol (sorbitol) is used, verifying that it does not contain the impurities diethylene glycol (DEG) and ethylene glycol (EG).

4.7 Manufacture validation protocols of the excipients shall be submitted specifically those that are at a risk for diethylene glycol (DEG) and ethylene glycol (EG) contamination. For such excipients each container of the excipients shall be tested for purity and validity and evidence documents shall be submitted.

4.8 Nitrosamine impurities are compounds containing a nitroso group at the dialkyl-substituted amine group. In RANITIDINE, Valsartan, Losartan, and Irbesartan substances, these impurities result from the reaction of solvent impurities (used for synthesis) and nitrite ions in the acidic environment. NDMA contamination poses a potential carcinogenic risk. The product shall be tested for purity and validity and evidence documents shall be submitted during import for the specific batch imported at that time.

5 How to Apply

5.1 Application shall be submitted online via MFDA's Dhirithi portal (https://dhirithi.egov.mv).

5.2 In order to do so, the importer shall first register as a user in Dhirithi portal using the form available on the MOH website and in Dhrithi portal under "Publications".

5.3 The product applied for must be a product that has been previously not approved for PA and categorized as a PA required product in the most recent version of ADL.

5.4 Control medicines and hospital use products can only be requested by MTG/MFDA designated importers.

5.5 If all requirements are met PA is issued for a duration of 3 years.

6 Documents and information required for Pre-Authorization

6.1 Table 1 below details the documents and information required for pre authorization approval.

6.2 Applicants can select either option 1 or option 2 from point A, as a reliance pathway. To provide the documents for the selected option is mandatory in addition to the information in B, C and D in the table below.

6.3 **Table 1: Requirements for pre-authorization**

REQUIREMENTS FOR PRE-AUTHORIZATION APPROVAL	
Option 1: A. Approved **in a Reference NRA**	
1.	Evidence of approval from the reference organization (in one or several documents, e.g. evidence of MA, public[1]evaluation reports or CoPP). This shall be submitted as a separate attachment.
OR	
Option 2: A. Manufacturing site certified by PIC/S member NRA	
1.	Evidence of PIC/S-GMP compliance for the site where the finished dosage form is manufactured and batch release takes place.
2.	Evidence of approval by the NRA of the country where the finished dosage form is manufactured, and batch release takes place. For this, a link should be provided to trace the evidence or registration or marketing authorization certificate.
3.	Verifiable declaration of approval by any other NRA/NRAs. For this, a link should be provided to trace the evidence or registration or marketing authorization certificate. (NRA website shall verify that the product is registered there even though CoPP is provided)
B. Manufacturer information	
1.	Name(s) and complete address(es) (including specific unit/blocks) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)] or biological drug products(s) (DP(s)), including the final product release if different from the manufacturer:
2.	Name and complete address (including specific unit/blocks) of the API/drug substance manufacturer(s):
3.	Provide a valid GMP certificate or incorporate the information in this sheet as per the mentioned information below, if providing a certificate, it must be attached separately. cGMP certificate information, including: o certificate number

	o applicable standards o site name o site address o issue date and validity o Scope: product o Scope: Manufacturing operations
C. Product information	
1.	Proprietary product name /Brand Name:
2.	International Nonproprietary Name (INN) of the active pharmaceutical /Generic Name:
3.	Composition:

Component and quality standard	Function of the component in the formulation	Quantity per unit (mg)	%
Eg: Paracetamol (BP/USP)	*Eg: Active Pharmaceutical Ingredient (API)*	*Eg: 500*	*Eg: 83.33%*
Eg: Microcrystalline Cellulose (BP/USP)	*Diluent/Binding Agent*	*80*	*13.33%*
		Total	*100%*

4.	Strength:
5.	Pharmaceutical form (Dosage form):
6.	Indication or Use of the product:
7.	Storage conditions:
8.	Shelf life of the product:
9.	WHO ATCC code:
10.	Dispensing Category:
11.	Pack size / Volume:
12.	Attach Detailed description of the primary and secondary packing including pack size or volume
13.	Attach Product information for healthcare professionals (SMPC)
14.	Attach Public[2] evaluation reports (for new medicines[3] only)
15.	Product artwork, labels from all sides
D. Additional information	
1	Attach Declaration of sameness of the product (The product registered in the reference NRA /PICs certified manufactured is same as that of the product submitted for pre authorization).
2	Attach detailed Description (visual appearance) of the finished pharmaceutical product (eg: tablet, syrup etc)
3	Cost and propose retail price:

1 Unredacted assessment reports are also evidence of approval, but are generally not accessible publicly. The sharing of such document would usually require a Memorandum of Understanding and/or a Confidential Disclosure Agreement

2 Unredacted assessment reports would be ideal but they are generally not accessible publicly. The sharing of such document would usually require a Memorandum of Understanding and/or a Confidential Disclosure Agreement.

3 In the context of this document, new medicines/vaccines refer to either a substance, association of substances, pharmaceutical form, dosage, indication, or posology which has never been granted a marketing authorization in the country.

7 Application Processing

7.1 Once the applicant requests, it will be checked for document completion and legibility. If all the requirements as per the acceptance criteria is fulfilled, the request will be accepted within 10 working days.

7.2 MFDA has the right to reject incomplete applications and hence it's the applicant's responsibility to ensure that all are in accordance with the requirements.

7.3 If all the requirements are complete, the request will be accepted while requests that require further clarification will be put to "Need clarification" status on Dhirithi portal. The clarification requested by the authority shall be resolved within 10 working days by the applicant, otherwise the request will be rejected.

7.4 In the case of a rejection, the reason for the rejection will be specified.

7.5 An Invoice will be generated with a fee of 7710/- MVR (Seven Thousand Seven Hundred and Ten Maldivian Rufiyaa) which shall be paid via Bandeyri Pay within 5 working days from the time of status change to "verified" in Dhirithi portal. If the payment is not made within the given 5 days, the request will be rejected. This fee is non-refundable.

7.6 All financial transactions will be processed through Bandeyri Pay and MTG/MFDA will not request for or accept any other methods of payment.

7.7 The PA approval process may be prolonged due to the time taken by the applicant to respond to the authority's request to provide additional information or further clarification.

8 Issuing the PA permit

8.1 Once the payment is made the request will be approved and status will be updated from Dhirithi portal as “Approved”.

8.2 Once the request is approved, a signed copy of the PA permit will be uploaded to Dhirithi portal within 2 working days from the date of Approval.

8.3 The product can only be imported, distributed and sold in the country once the pre-authorization approval has been issued and permit has been uploaded to Dhirithi portal.

8.4 A format of the permit is in the Annex 1.

9 Authorizations for National Programs, and Donations.

9.1 Health Protection Agency (HPA) is the responsible body for ensuring the availability of National program Medicines for the Maldives.

9.2 The product shall be a WHO pre-qualified product and shall apply with a proof the product is WHO pre-qualified.

9.3 If 9.2 is unavailable, Option 1 or option 2 of A in table 1 shall be followed.

9.3.1 Product label shall contain the following information;

9.3.2 Brand name, Generic name, strength and dosage form

9.3.3 Full manufacturing site address of the product.

9.3.4 Shall be in English language.

9.4 A permit is not required for the products already mentioned in the Approved Drug List.

9.5 If the brand name, strength, dosage form or the manufacturer is different than section 9.1.6, a permit is required as of section 9.1.2.

9.6 A format of the permit is in the Annex 2.

10 Responsibilities of Importers with PA Approvals

10.1 The importer shall take full responsibility of the medicine that is going to be in the market, which includes, informing the authority of any variations in the product after issuance of PA, recalling the medicine (PA taken and imported) if required.

10.2 If any quality issue of the product imported is identified, MTG/MFDA has the right to revoke the permit at any time. In addition, the product and the manufacturer will be on hold for further imports until the investigation is completed.

10.3 If there is any recall notification from MTG/MFDA, the importer shall take the responsibility to recall the product from the market and proceed with disposal as per the instruction of the MFDA.

11 Registration process of a pharmaceutical product

11.1 Once the 3-year duration of PA permit is complete, the same product cannot be given PA approval for a second time. The product has to be registered as per the registration criteria as mentioned "Guideline for Product Registration and Emergency Approvals" (MTG/RE-RP/GLN-TE 001)

11.2 All pre authorizations permits issued previously shall also undergo the registration procedure as per the "Guideline for Product Registration and Emergency Approvals" (MTG/RE-RP/GLN-TE 001)

12 Rejection, Cancellation or Suspension of PA approval

12.1 The Maldives Food and Drug Authority reserves the right to reject, cancel or suspend the approval of any product if:

a. There are deficiencies in safety, quality, or efficacy of the product

b. Failure to comply with conditions of Approval.

c. Any report on adverse drug reactions of serious nature has been received from national or international sources.

d. Failure to submit the mandatory documents.

13 Pre market and Post Market Testing

13.1 Once the product is PA approved, imported and introduced to the market, the product shall be on surveillance as to ensure that the same product PA taken is in the market.

13.2 National Health Laboratory (NHL) is the designated national laboratory for testing pharmaceuticals.

13.3 Once a PA product is imported and introduced to the market, as part of the post market surveillance, samples will be collected from the market and tested from NHL as well as the designated laboratory from abroad and these results will be published.

13.4 MFDA will put the company on surveillance for any recalls or alerts of any products manufactured by that company.

14 Legal basis

1. Medicine Regulation R-46 (2014)
2. Medicine Regulation Amendment R-49 (2016)
3. Health Service Act (29/2015)

15 Annex

Annex 1: Pre-Authorization Approval

Annex 2: Authorization permit for National Programs

Annex-1

[illegible]

MTG/RE-2023/AP-PM/**** [illegible]

[illegible]

Name of the Company [illegible]

Company registration / NID No. [illegible]

Address [illegible]

7655080 [illegible]

Manufacturing site change [illegible]

No	Generic Name	Brand Name	Strength/Volume	Dosage Form	Manufacturer
1					

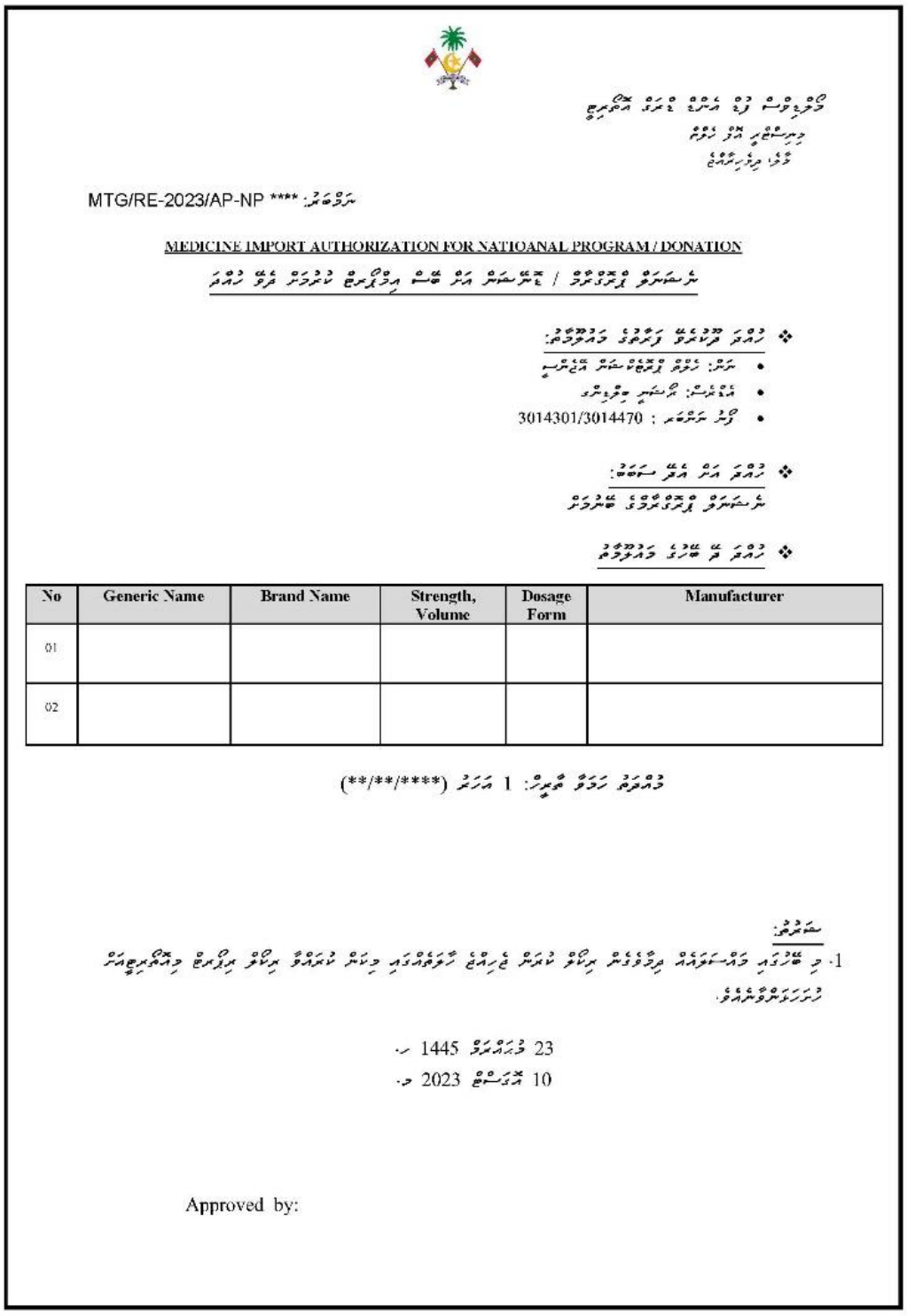
Expiry Date:

[illegible]

25 July 2023

Aishath Mohamed
Pharmaceutical Specialist

Annex-2



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MTG/RE-2023/AP-NP **** :ނަންބަރ

MEDICINE IMPORT AUTHORIZATION FOR NATIOANAL PROGRAM / DONATION

ބަލަހައްޓާ ފަރާތުން ގެނެވޭ ބޭސް ބޭނުންކުރާ / ޚައިރާތުގެ ގޮތުގައި ލިބޭ ބޭސް ބޭނުންކުރާ ތަކެއް ގެނައުން

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- ފޯން ނަންބަރ : 3014301/3014470

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ބަލަހައްޓާ ފަރާތުގެ ނަން

❖ **ގެނެވޭ ތަކެއްގެ ތަފްޞީލް**

No	Generic Name	Brand Name	Strength, Volume	Dosage Form	Manufacturer
01					
02					

ގެނެވޭ ތަކެއް ލިބޭނެ ތާރީޚް: 1 ވަނަ (/**/****)**

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Approved by: