**Maldives Food and Drug Authority**
Ministry of Health
Male'
Republic of Maldives

## Reference country categorization for pharmaceutical product registration

**A) Category 1**: Includes countries having stringent/strong regulatory authorities as declared by WHO and expert consultant to MFDA

| # | Regulatory Authority | Country |
|---|---|---|
| 1 | United states Food and Drug Administration (US FDA) | United states Of America |
| 2 | European Medicines Agency (EMA) | European Union |
| 3 | Health Canada | Canada |
| 4 | Therapeutic Goods Administration (TGA) | Australia |
| 5 | Ministry of Health, Labor and Welfare | Japan |
| 6 | Icelandic Medicines Agency | Iceland |
| 7 | Medicines and Medical Devices Safety Authority ( MEDSAFE) | New Zealand |
| 8 | Health Science Authority (HSA) | Singapore |
| 9 | Argentinean Health Authority | Argentina |
| 10 | Medicines and Medical Devices Regulatory Authority | South Africa |
| 11 | Swissmedic | Switzerland |
| 12 | The National Agency of Drug and Food Control | Indonesia |
| 13 | National Pharmaceutical Regulatory Agency | Malaysia |
| 14 | Ministry of Health | Israel |
| 15 | Norwegian Medicines Agency | Norway |
| 16 | The National Health Surveillance Agency or ANVISA | Brazil |
| 17 | Ministry of Food and Drug Safety (MFDS) | South Korea |
| 18 | Ministry of Public Health | Qatar |

1. Medicines manufactured and registered in **Category 1** country:

1.1 Products manufactured from countries in category 1 and regulated by the respective authorities in the country of manufacture, shall submit the following documents only for the registration:

1.1.1 Good Manufacturing Practice (GMP) of the manufacturing site of the product

1.1.2 Certificate of pharmaceutical product (COPP) certificate from the regulatory authority in the manufacturing country

1.1.3 Stability tested reports of the product

1.1.4 Finished product specification

1.1.5 Product and company details (as specified in Guideline on Product Registration and Approval of Medicines) including the cost price and proposed retail price of the product, product label and product sample.

1.1.6 1.1.6. Second country registration certificate is not required for this category.

1.2 Multinational companies where the parent company is from category 1 countries, second country registration in category 1 is not required. However, supporting documents from the parent company is required regarding the product to be registered in addition to the documents as mentioned in 1.1.1 to 1.1.4. Supporting documents shall include but not limited to:

1.2.1 A document from the parent company stating the product manufactured from the proposed site is up to the standard of the parent company OR a recent audit or assessment report of the site by the parent company etc.

**B) Category 2**: Includes regulatory authorities recognized nationally, based on the reviews of the regulatory systems of these countries.

| # | Regulatory Authority | Country |
|---|---|---|
| 1 | National Medicines Regulatory Authority (NMRA) | Srilanka |
| 2 | Food and Drug Administration (Thai FDA) | Thailand |
| 3 | Food and Drug Administration | Philippines |
| 6 | The Central Drugs Standard Control Organization (CDSCO) | India |
| 7 | Directorate General of Drug Administration (DGDA) | Bangladesh |
| 8 | Drug Regulatory Authority of Pakistan (DRAP) | Pakistan |

2. Medicines manufactured and registered in **Category 2** country:

2.1 Products manufactured from countries in category 2 and regulated by the respective authorities in the country of manufacture, shall submit:

2.1.1 Full dossier of the product as per the Guideline on Product Registration and Approval of Medicines.

2.1.2 Second country registration certificate in any of the countries in Category 1 **OR** MFDA to conduct GMP inspection of the manufacturing facility **OR** to submit analysis report of 3 batches of the product tested form a WHO collaborating center/**OR** to submit batch certificates for individual batches imported during import.

**C) Category 3**: Include all other countries other than those mentioned in Category 1 and 2.

3. Medicines manufactured and registered in **Category 3** country:
   3.1 Second country registration certificate from Category 1 is required with full dossier.

**D)** Products **prequalified under WHO Prequalification scheme** do not require full dossier for registration. However, supporting documents shall be submitted as per the Guideline on Product Registration and Approval of Medicines)

**Important notes to consider:**

- *This criterion will be effective from 15 November 2021, for all products for registration.*
- *The products manufactured from facilities not fitting the above criteria and have been registered before and has been in market for more than 5 years without any issues of quality, safety and efficacy, the products manufactured from the same site can be accepted with the criteria as mentioned in 2.1*
- *Products registered under this criterion will not get exclusive market for that particular product. The product is open for registration to other parties provided all the required documents are submitted.*
- *For the products mentioned in point 2 .1.2 above:*
    1) *Registration with second country registration certificate will be for 3 years provided periodic safety updates, market safety data shall be submitted*
    2) *Registration with GMP inspection will be for 2 years and the periodic safety updates, market safety data, post market surveillance data has to be submitted on yearly basis.*
    3) *Registration with batch analysis reports will be for 1 year and periodic safety updates, market safety data and yearly batch analysis reports shall be submitted.*
- *The registration periods as mentioned here in 2.1.2 will be extended to 5 years provided all the required information is submitted and the assurances that the product will be in the market with no stock outs.*
- *The products in ADL which has already been given exclusivity will be kept exclusive for further 3 months only, from the date of implementation of this criteria, and after that the same product is open to other parties for registration and import.*

- *A grace period of 3 years is given for the existing products which are registered and approved, to comply with these criteria.*
- *Within these 3 years, the products in ADL shall be registered and importers can only import those medicines which they have registered only.*

***For further reference and detail, refer to "GUIDELINEFOR PRODUCT REGISTERATION AND APPROVAL OF MEDICINE (Document number: MTG/RE-RP/GLN-TC 001)" published in Ministry of Health Website / Dhirithi Portal***