

Medical Products Manufactured Data Submission Format

Please find the attached Excel **document** for the submission of **Products Manufactured Data** related to **Medicines, Medical Devices, Borderline Products, and Cosmetics**.

All required data shall be provided **using only this Excel format** and completed **in accordance with the instructions below**.

General Instructions

- The attached Excel template shall be used **as provided**, without altering the format.
- Please ensure that a **hard copy** of the email sent regarding the import details should be **attached to the renewal application (Do not attached the excel sheet)**.
- Use **separate Excel sheets** for **medicines, medical devices, borderline products, and cosmetics**.
- The manufactured data of **all registered products** of your company **for each quarter** should be submitted in a **single Excel sheet**.
- All entries must be completed in **English only**.
- **No cells should be left blank**. If a field is not applicable, enter “N/A”.
- Ensure correct spelling of the product names and all reference details.
- Data shall be entered **strictly in the same column order** as shown in the Excel sheet.
- Do not merge cells, add additional columns, or apply special formatting.
- All numerical values (dates, quantities, pack sizes) must be accurate and consistent.
- The **year of manufactured** should be mentioned at the top of the Excel sheet.
- **Manufactured data shall be submitted quarterly (Once in every three months)**.
 - 1st Quarter – January 1st to March 31st
 - 2nd Quarter – April 1st to June 30th
 - 3rd Quarter - July 1st to September 30th
 - 4th Quarter - October 1st to December 31st
- If **no manufacturing occurred during the reporting period**, mention it as “**Not manufactured during this period**” with a **valid reason** in the **Remarks** column and submit the Excel file.

Completion Guidance

- **Date of Consignment Release**
 - Date of consignment/batch release to the market.
 - Format: **DD/MM/YYYY**
- **Name of the Manufacturer**
 - Enter the **name** as per the manufacturing registration.
- **Generic Name of the product**
 - State the **generic or product name**.
- **Brand Name of the product**
 - Enter the **brand name**.
- **Product Category**
 - Select one: **Medicine / Medical Device / Borderline / Cosmetic**
- **Pharmacological Classifications of Medicines / ATC Code**
 - Specify ATC code for medicines.
 - Enter “**N/A**” if not applicable (Medical Devices, Borderline Products, and Cosmetics).
- **Dosage form**
 - Specify the dosage form.
 - As examples; Medicines: Tablet, Syrup, Injection, etc.
- **Name of the local manufacturer**
 - Use official registered manufacturer name

- **Manufacturing site address**
 - Include complete site address.
- **Manufacturing Date**
 - Enter the manufacturing date in the format: DD/MM/YYYY
- **Expiry Date**
 - Enter the **expiry date** in the format: DD/MM/YYYY.
- **Batch NO**
 - Enter the **batch number** as mentioned on the product label.
- **Commercial Invoice No**
 - Provide the **invoice number** issued for market.
- **Manufacturing License No**
 - Enter the official manufacturing license number issued.
- **Certificate of Registration No**
 - As per product registration with NMRA.
- **Pack type**
 - Enter the packaging type
- **Pack size**
 - State the quantity per pack
- **Number of commercial packs**
 - Enter the total number of packs imported.
- **Total Quantity (total number of units)**
 - Enter the total number of individual usable units (e.g., tablets, bottles, syringes).
 - This must reflect the actual end-use quantity, not only the number of packs.

Examples:

$(10 \times 10 \text{ tablets}) \times 500 \text{ packs} = \mathbf{50,000}$

100 bottles of 200 ml = **100**

- **Market**
 - Whether consignment supply to government tenders or private market.
 - Select one: Government/ Private
- **Unit Price**
 - NMRA approved price.
- **Remarks**
 - Use to explain additional information regarding relevant consignment details.
 - If you are not manufacturing in a particular quarter, indicate it as "**Not manufactured during this period**" and also state the **reason** for not manufacturing.

Submission Method

- Submit the **completed Excel documents** via email to: mcimport@nmra.gov.lk
- Ensure that you use the official company email address and mention it in the manufacturing license renewal application accordingly.
- Ensure the file is complete and accurate before submission.

Assistance & Clarifications

- Market Surveillance and Control Division - National Medicines Regulatory Authority (NMRA)
- mcimport@nmra.gov.lk