Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG REGULATION AND RESEARCH

MONITORED RELEASE (MR)/ MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATION

Who May Avail : All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products

Fees to be Paid : **Initial**
Branded: PHP 3,000.00/year + PHP 500.00 (Brand Name Clearance) + 1% LRF
Unbranded: PHP 2,000.00/year + 1% LRF
The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997).
2-year validity:
Branded: PHP 6,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 6,500.00 + 1% LRF
Unbranded: PHP 4,000.00 + 1% LRF
5-year validity:
Branded: PHP 15,000.00 + PHP 500.00 (for Brand Name Clearance) = PHP 15,500.00 + 1% LRF
Unbranded: PHP 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS

NOTE: Submit the requirements for INITIAL REGISTRATION OF PRESCRIPTION GENERIC PHARMACEUTICAL PRODUCTS or INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS

Additional Requirements:

1. Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable), or proof of submission
2. Risk Management Plan (RMP)
3. Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)
4. For Vaccines and Biologicals: certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated.
5. For Vaccines: Adverse event following immunization report (summary of annual reports)

Note:
As per FDA Circular No. 2020-003, Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to:

- In response to a safety concern arising from a new route of administration;
- As a result of a new safety concern associated with a new indication that may require additional PV activities;

- If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.

END