



FOOD AND DRUG ADMINISTRATION



Ensuring Safety, Efficacy, and Quality of Drug Products

National Medicines Regulatory Authority

- Number of WHO prequalified medicines registered by the collaborative registration process: **22 products**
- Number of applications pending in the process: **4 applications**

PFDA Local Experience

➤ Local applicant:

- S.M.H.P. Marketing & Consultancy
 - 22 products that have been issued MA
- Hetero Philippines Inc.
 - 4 products with pending applications

➤ PQ Holders:

- Macleods Pharmaceuticals Limited, India
- Hetero Laboratories Limited, India

Document and Compliance with the Procedure

- FDA accepts registration applications filed following the ASEAN and ICH CTD format (flexibility to the WHO/PQP Dossier)
- For the 22 products approved via the CRP, essential data is the same as the WHO prequalified products
 - Local administrative requirements, representative samples, RMP+PSUR (for new drugs) were submitted by the local applicant

Document Sharing

➤ PQT assessment reports

- Play a significant role for the FDA Philippines to facilitate the review of CRP applications

➤ Inspection reports

- Local applicants of pharmaceutical products manufactured abroad must secure first a Foreign GMP Clearance prior to application
- Part and parcel of desktop review for Foreign GMP Clearance issuance

Compatibility of CRP with National Registration Process

- CRP applications are prioritized
- Pre-evaluation
 - Check for completeness
 - Verify if the local submission is the same as the WHO prequalified product
 - Additional requirements [e.g. country-specific requirements, RMP+PSUR (for new drugs/monitored release)]
- Facilitated review
 - Process is significantly abbreviated (due to the reliable information and data provided/shared online via MedNet)

Drawback of the Process

- Proper coordination between the local applicant (importer) and the Prequalification Holder (foreign manufacturer) to ensure that the local applicant has first filed the application for marketing authorization with the NMRA before the NMRA accepts the procedure.

Proposed Improvements

- Although we earlier proposed stop clock for FDA Philippines following the need for the local applicants to comply with certain country-specific requirements, FDA Philippines have come up with the ff. strategies instead:
 - Ensure that the application of the local applicant is the same as the WHO prequalified product in terms of content (quality and clinical aspects)
 - Ensure that local applicant submits the complete administrative requirements (e.g., labeling following the AO 2016-08, representative sample, RMP+PSUR for new drugs following FC 2013-004).

Proposed Improvements

- Only when the 2 prior-mentioned conditions have been fulfilled will FDA Philippines formally accept the procedure for the product application concerned, and this will be considered as “Day 0” of the assessment process.
 - The 22 product applications that FDA Philippines have processed so far following the CRP has fulfilled the 90-day assessment period.

Way Forward

- Adoption of the Expedited Review of the WHO Prequalified Drug Products
 - Administrative Order (Legal Basis)
 - For approval of the Ministry of Health
- With the official adoption of the CRP,
 1. The registration process for WHO prequalified products will be significantly abbreviated due to the reliable information and data provided/shared online;
 2. Reduced regulatory burden as reliable quality and clinical assessment reports are readily available online via MedNet; and,
 3. Drug products will be readily available to the market.



Salamat Po!