



## Improving the Efficiency of Drug Product Registration

### BACKGROUND

Pharmaceuticals or drug products are regulated by the Food and Drug Administration. Specifically, its Center for Drug Regulation and Research (CDRR), through the Licensing and Registration Division (LRD), processes drug product registration. Drugs are then assessed for safety, efficacy, and quality.

### CURRENT ISSUES TO BE ADDRESSED

The current drug regulatory process and system demonstrate slow turnaround times on filing, processing, claiming of permits, and issuance of certificates of product registration, which in turn result in backlogs. Backlogs are due to applicants being unable to submit complete requirements for drug product registration and an inadequate number of evaluators. This inefficiency at the process level may present significant public health risks due to the possible increase of unregistered drug products in the black market.

### RECOMMENDATIONS

#### 1. Re-engineering of regulatory processes for drug products

This is intended to eliminate backlogs in applications and shorten turnaround times of the registration process. Process re-engineering involves the improvement in workflow design through the implementation of regulatory tools such as:

##### Risk-based evaluation scheme

Drug products are classified into risk categories and other criteria, such as the drug product's prequalification with the WHO, registration with a stringent regulatory authority, and public health urgency and importance. Shortened pathways will be applied to qualifying products to allow for faster review and shorter turnaround time.

##### Good review management and good submission practices

Good review management allows for the standardization of regulatory (clinical and non-clinical) evaluators, and addresses

ambiguities in the interpretation of standards among evaluators and applicants. On the other hand, good submission practices allows for quality improvement of dossier submissions of applicants. These practices act in synergy by reducing the administrative and technical burden brought about by poor submissions that negatively impact the efficiency of evaluation processes.

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##### Transparency measures

Transparency measures build trust between the regulatory agency and its stakeholders by making important information available to all. On the one hand, this allows for effective monitoring of the evaluation pathway, and, on another, builds a platform for inclusive dialogue in the development of regulatory policies.

##### Technological approaches

The information gathered, stored, and analyzed during dossier submission and evaluation are immense. The complexity introduced by evaluation pathways makes system design difficult. However, once bottlenecks are addressed, a digitized registration process should improve administrative feasibility and transparency in documentation and preserve the integrity of dossiers and worksheets.

## 2. Regulatory Collaboration

Regulatory collaboration aims to avoid duplication of work through information and work-sharing with other regulatory agencies, allowing for efficiency in resource use. Establishing such a reliable mechanism with other regulatory agencies should allow for expedited pathways.

There are three routes currently in practice on regulatory collaboration:

### Information-sharing

In the International Generic Drug Regulators Program, information is shared real-time by European Union (EU) authorities during the scientific assessment phase to participating non-EU regulatory agencies, such as Health Canada, SwissMedic, Taiwan FDA, and Australia Therapeutic Goods Administration. While non-EU authorities have simultaneous access to certain regulatory information, this does not preclude them from arriving at their own decisions in their assessments of drug products. Companies participating in this program also have the opportunity to obtain marketing authorizations in non-EU countries.

### Mutual recognition of assessment and inspection

In the ASEAN Sectoral Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) Inspection for Manufacturers of Medicinal Products, there is a mutual exchange and recognition of GMP reports and certificates. Member states benefit by facilitating market access through a reduction in inspections or audits that would have originally been conducted in the territories of the members of the MRA.

### Reliance

Reliance can be employed in a model wherein assessment reports generated by a stringent regulatory authority are recognized by a receiving regulatory authority. The receiving regulatory authority processes the reports through accelerated or abridged pathways, while taking into account country conditions.

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The **NHSM BRIEF** is a background document/reference material for discussion during the 3rd National Health Sector Meeting and prepared by the Health Policy Development and Planning Bureau in collaboration with the Health Regulation Team.

This Brief is written by Jon Martin de la Paz and Angelica Guinto, in consultation with Atty. Katherine Austria-Lock, edited by Dr. Gloria Nenita Velasco and Dr. Maria Iris Baltazar, designed by Jake Matthew Kho and Cherie Tan.