World Health Organization

Capacity Building within the Context of the WHO Prequalification Programme

International Conference Local Production and Access to Medicines: Discussion with Stakeholders from International Organizations, Donor Agencies, Pharmaceutical Producers and NGOs
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Prequalification programme – powerful engine for facilitating quality manufacture

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PREQUALIFICATION PROGRAMME
A United Nations Programme managed by WHO

Vision

Good quality medicines for everyone.

Mission

In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make quality priority medicines available for the benefit of those in need.

This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of quality medicines.

Strategy

- Apply unified standards of acceptable quality, safety and efficacy.
- Comprehensively evaluate the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing

LATEST NEWS

Micro Labs' paediatric lamivudine tablet prequalified

Newly prequalified APIs

New WHO Assessment Report published

Speeding up access to quality medicines in Africa

Prequalification of medicines saves lives

WHO experts give risk rating for urgently needed medicines

Generic antiretroviral therapy is safe and effective

PQP response to claims of sub-standard antimalarials

Medicines Prequalification Programme (mPQP)

- Covers the prequalification procedures for:
  - Finished pharmaceutical preparations
  - APIs
  - Quality Control Laboratories

Snapshot of 2012 activities (1)

- **FPPs**. In 2012, mPQP prequalified a total of 48 medicines, bringing the total number of medicines prequalified to 317 (410 to include also products that have been approved via the USFDA tentative approval process, the EMA Article 58 process and by Health Canada).
- Significant number of anti-TB (19) and anti-Malaria (10) products were prequalified including **dispersible** Artemether/Lumefantrine, and **dispersible** Efavirenz 100mg and Lamivudine 30mg tablets, plus the first Zn product
- **Prequalification of active pharmaceutical ingredients (APIs)** - 21 APIs were prequalified, bringing the total to 28 prequalified APIs.
- **Prequalification of quality control laboratories.** Four quality control laboratories were prequalified, bringing the total to 26. The four QCLs are the first prequalified QCLs of the following countries: China, Russia, Thailand and Belarus.

Snapshot of 2012 activities (2)

- **Inspections.** The programme conducted a total of 83 inspections. This included 11 contract research organizations (to inspect clinical studies), 39 active pharmaceutical ingredient manufacturers, 32 finished pharmaceutical product manufacturers and 7 quality control laboratories.
- **Capacity building.** The programme organized (alone or in collaboration with our partner organizations) 27 capacity building exercises that involved a total of 1561 staff from manufacturers, regulators and QCLs from 78 countries. In addition, it had 3 rotational fellows (each for three months).

Other topics to be focused

- Capacities of local manufacturers to produce at WHO prequalification standards
- Challenges and developments concerning quality standards of locally produced medicines from the WHO perspective
- Needs for capacity building and WHO procedures
- Cooperation with other stakeholders (incl. NGOs)

Common deficiencies for dossiers

Original Paper

Generic Medicines

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Deficiencies in generic product dossiers as submitted to the WHO Prequalification of Medicines Programme

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Abstract

This study was undertaken to determine the type and extent of deficiencies in generic product dossiers in the therapeutic areas of HIV/AIDS, tuberculosis, malaria and reproductive health, as submitted to the WHO Prequalification of Medicines Programme. There were considerably more quality-related deficiencies in tuberculosis, malaria and reproductive health dossiers compared to HIV dossiers, especially in the category specification of active pharmaceutical ingredients, development pharmaceutics, manufacturing method and finished pharmaceutical product specifications. The deficiencies related to the efficacy/safety portion of the dossiers displayed a trend similar to that observed in the quality portion in that the most critical deficiencies such as an incorrect study design, the use of an unacceptable comparator or the failure to include a study occurred considerably more frequently in the tuberculosis, malaria and reproductive health dossiers than in the HIV dossiers. The frequency of dossier-related deficiencies as determined on screening and assessment of the dossiers seemed to be inversely related to the number of product dossiers that had been prequalified by the end of 2010. The results of this study stress the need for continued capacity building of local generic manufacturers, further development of pharmacopoeial monographs by WHO (PhInt) and other pharmacopoeial commissions, not least to promote development of generic products, as well as development of new guidelines (WHO guidelines for development of generic and paediatric products and a technology transfer guidance document are currently being finalized). To our knowledge, this is the first comprehensive review of the quality and efficacy/safety portions of generic product dossiers, originating from pharmaceutical companies in emerging markets, and comparison of dossier deficiencies across four critically important therapeutic areas.

Quality part

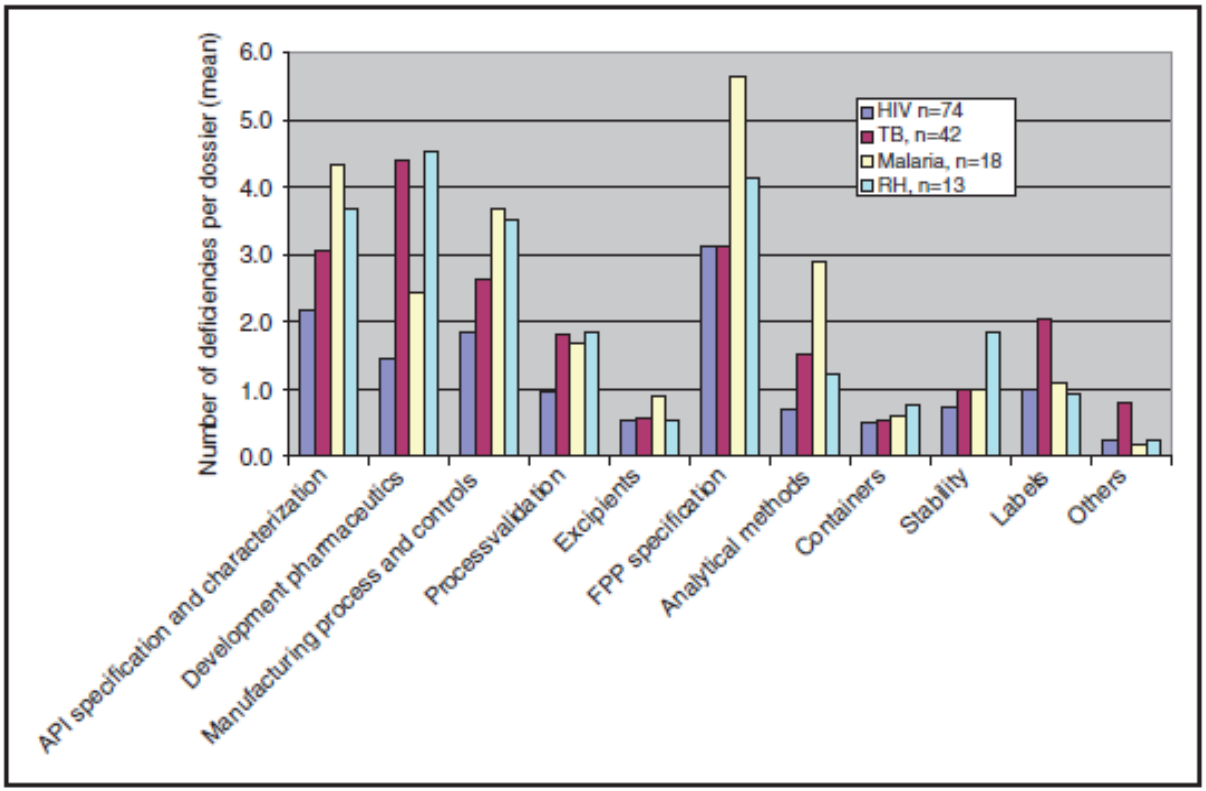

Figure 2. Deficiencies observed in generic product dossiers on the assessment of the quality (chemistry–pharmaceutical) part of the dossier, presented as the mean number of quality deficiencies per dossier and therapeutic area, by each of the 10 main categories.

Deficiencies are related to incomplete or incorrect information provided for the identified category.

HIV: human immunodeficiency virus; TB: tuberculosis; RH: reproductive health; API: active pharmaceutical ingredient; and FPP: finished pharmaceutical product.

Concluding remarks (1)

- Powerful engine to pull the quality medicines agenda Globally
- Ensures the quality during the whole life cycle of products (handling variations, also quality complaints)
- Has had since the beginning very strong capacity building component – for regulators and for local manufacturers
- Is involved with capacity building in cooperation with regulators – Nigeria example
- Involved in finding innovative regulatory solutions and publishing articles