



PQP
QUALITY MEDICINES FOR EVERYONE

PREQUALIFICATION OF
MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME
MANAGED BY WHO



WHO PREQUALIFICATION OF MEDICINES PROGRAMME GLOBAL MEETING WITH MANUFACTURERS

THEME: WHO MEDICINES PREQUALIFICATION IN A NEW DECADE

WHERE? Copenhagen, Denmark

WHEN? 26 and 27 July 2010

VENUE? Conference Hall 1, WHO Regional Office for Europe

WHO SHOULD COME?

- ✓ Manufacturers interested in participating in the WHO Prequalification of Medicines Programme (PQP)
- ✓ Manufacturers currently participating in PQP

The meeting will be held immediately after the bi-monthly dossier assessment session and will be an opportunity to hear about common dossier and GMP deficiencies, and new or revised WHO guidelines, from expert assessors, inspectors and other manufacturers. There will also be an opportunity to discuss your experiences with the WHO prequalification programme and help identifying possible opportunities for improvement. The focus of the meeting will be on multisource (generic) medicines as innovative medicines are mostly prequalified relying on the scientific assessments carried out by stringent regulatory authorities. An interactive style of meeting is proposed, with presentations, panel discussions and workshops.

TENTATIVE PROGRAM:

DAY 1

- Introduction
- Common deficiencies with dossiers and how to address them
- Update on new or revised procedures and guidelines, including re-qualification
- Panel discussion on dossier assessment
 - API quality assessment
 - Finished dosage form quality assessment
 - Bioequivalence assessment



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World Health
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- Common GMP deficiencies and how to address them
- Update on new or revised GMP guidelines
- PQP support to manufacturers
- Panel discussion on GMP

DAY 2

- Report on the results of the Survey of Manufacturers (soon to be sent to manufacturers to obtain feedback about PQP)
- Overview of quality policies implemented by different "buyers" (GFTAM, WB, PEPFAR, GDF etc.)
- Manufacturers experiences with WHO prequalification
- Procurement experiences with manufacturers and PQP
- Panel discussion (or workshops?) on the outcome of the manufacturer survey with the view to identifying incentives and disincentives for manufacturers and improvements that could be made to PQP

Manufacturers are invited to suggest additional topics for discussion and to indicate interest in the meeting, including an indication of the number of possible participants, by email to prequal@who.int before 31 March 2010.