WHO Prequalification of Medicines Programme (WHO-PQP): Ensuring quality medicines

Dr Lembit Rägo
Essential Medicines and Health Products
World Health Organization
Geneva
Switzerland
ragol@who.int
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• WHO Medicines Prequalification Programme – what it does?
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• The **Millennium Development Goals** (MDGs):
  - Eight international development goals that 192 United Nations member states and at least 23 international organizations have agreed to achieve by the year 2015
  - New aspirations – health for all and NCD agenda – both heavily depend on availability and accessibility of good quality safe EM
Is quality of medicines still a big problem?

World Health Organization


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Information Exchange System

Alert No. 125

Contaminated Isotab® (isosorbide mononitrate) incident in Lahore Pakistan

Increased vigilance is requested for batch/lot number J093 of Isotab® 20 mg (isosorbide mononitrate) labeled as being manufactured by Efroz, Karachi, Pakistan.

A serious incident occurred in Lahore (Punjab, Pakistan) involving the deaths of 107 patients with serious adverse reactions in more than 450 patients. The incident is currently being investigated.

At the request of the Department of Health Government Punjab, samples of the suspected tainted medicines were sent to different laboratories for testing in Pakistan and abroad, including two European laboratories of national regulatory authorities.

The results of those tests are being communicated, both to the Punjab Health Authority and to WHO. The analysis from the first of those tests are now available. The Punjab Health Authority and WHO have been informed that one of the medicines tested, an antianginal medicine (isosorbide mononitrate) contained pyrimethamine in quantities large enough to cause a severe adverse reaction...
Common deficiencies observed: quality

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.
Quality monitoring projects (1)

- Quality survey of antimalarials Africa
  - Cooperation with NDRAs in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, Tanzania
  - ACTs and sulfadoxine-pyrimethamine
  - 935 samples collected and screened by Minilab, 306 tested in laboratory
Technical work areas of WHO supporting medicines prequalification programme

• International Nonproprietary Names (INNs)
• Norms and standards
• Quality Assurance, including blood products
• Safety/Pharmacovigilance
• Regulatory support
• Anti SFFC (anticounterfeiting)
Prequalification of Medicines Programme

Since 2001 the UN Prequalification Programme managed by WHO is ensuring that medicines procured with international funds are of assessed and inspected for *quality, efficacy and safety*, involves

- Prequalification programme for medicines (finished dosage forms)
- Prequalification of active pharmaceutical ingredients (APIs)
- Prequalification of quality control (QC) laboratories

The Prequalification Programme is an action plan for expanding access to priority essential medicines in the following four areas:

- HIV/AIDS
- Tuberculosis
- Malaria
- Reproductive Health
- Selected individual products for other diseases (Flu, Zinc sulphate)
Medicines Prequalification Process

Expression of Interest

Product dossier SMF

Assessment
Additional information and data
Compliance

Inspections
Corrective actions
Compliance

Prequalification
Handling of complaints
Monitoring
Dossier maintenance (variations)
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 and clinical sites.

- Prequalify sources of active pharmaceutical ingredients by comprehensively evaluating the quality of the API based on information submitted by the manufacturers, and inspection of the corresponding manufacturing sites.

- Prequalify quality control laboratories of pharmaceuticals.

- Build the capacity of staff from national regulatory authorities, quality control laboratories, and from manufacturers or other private companies, to ensure medicines quality.

Key output
The list of prequalified medicinal products used for HIV/AIDS, malaria, tuberculosis and for reproductive health.
Extensive collaboration: working with regulators … for regulators

• Not duplicating work done be stringent regulatory authorities
  – SRA approval of new and generic products – abridged procedure
  – US FDA tentative approvals – based on confidentiality agreement including in the PQ products list
  – European Medicines Agency (EMA) – Art 58 … and beyond
  – Collaboration with EDQM, in particular in the area of APIs (confidentiality agreements with US FDA, EDQM, EMA …)

• Active participation and involvement of
  – Regulatory authority experts from well resourced and less resourced settings
Key achievements

• Contribution to increased access to quality medicines, for example:
  – in 2012, 8 million people living with HIV and in need of treatment were receiving treatment, around 6.5 million of whom were taking WHO-prequalified antiretrovirals (ARVs);
  – and sales of WHO-prequalified artemisinin-based combination antimalarials exceeded 180 million individual treatment courses in 2010

PQP achievements 2009–2012:

- In addition:
  - prequalification of **28 active pharmaceutical ingredients** (APIs), all of which can be used for manufacturer of UNITAID priority products
  - prequalification of **19 medicines quality control laboratories** (QCLs), so that prequalified QCLs can now be found in all six WHO regions
Capacity building provided a core value of the programme. Participants in various capacity building workshops organized or co-organized by PQP during 2007–2012.
What PQ can offer to the regulators and industries in the regions?

• Regulators
  – Capacity building/training – improved technical knowledge and skills
  – Practice and experience for collaboration and cooperation
  – Offers a lot of practical tools and guidelines
  – Helps to build more credible regulatory systems
  – Save resources

• Industries
  – Access to international funds
  – Better quality production/products/regulatory knowledge – better access to markets
  – Better image, more trust from procurement and regulators
Conclusions

• PQP is a powerful and effective mechanism to promote access to quality medicines
• PQP saves lives
• PQP is not a replacement for national regulatory systems but a (time limited) mechanism to promote access to quality medicines
• PQP is a major proactive contributor to capacity building both for regulators and local manufacturers
• PQP promotes collaboration and cooperation among regulators, including relying on each others work and reducing duplications
The time of poor quality medicines for poor people should be over

Poor people also deserve good quality medicines