Tuberculosis in 2017: Searching for new solutions in the face of new challenges

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Access to quality medicines in the region

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The reasons for the emergence of anti-microbial drug resistance:

• Health care providers – inadequate regimens

• Patients – inadequate drug intake, and

• Medicines - inadequate supply and quality
UN Prequalification Programme for Priority Essential Medicines

• Action plan of UN from 2001 for expanding access to selected priority medicines

• Objective:
  • To ensure quality, efficacy and safety of medicines procured using international funds (e.g. GFTAM, UNITAID) to serve patients in developing countries

• Components:
  • Evaluation of Quality, Safety and Efficacy of prioritized Essential medicines (FPPs and APIs), inspections of manufacturers and monitoring of the products after their prequalification.
  • Prequalification of quality control laboratories.
  • Building capacity of regulators, manufacturers and quality control laboratories.
Two prequalification routes

Invitation for expression of interest

- Medicine not assessed by SRA
  - Dossier and SMF submitted for assessment and accepted
    - WHO assessment and inspections organized
      - Compliance

- Medicine assessed by SRA
  - Valid for innovators and generics
    - SRA registration (assessment and compliance check)
    - Simplified review
    - Acceptance
  - Post-PQ maintenance
Of the total of 291 samples, 38 (13%) were from WHO prequalified products.

In total, 11% of samples failed in one or more tests.

The samples were originating from 33 manufacturers from the following 12 countries: 10 from India, 5 each from Russia and from Ukraine, 3 from Kazakhstan, 2 each from Belarus and from China, and 1 each from Cyprus, France, Palestine, Syria, Turkey and Uzbekistan.

The failure rate per product in the set of samples collected was the following:

- rifampicin capsules: 28,3%
- isoniazid tablets: 16,7%; isoniazid injection: 0%
- rifampicin/isoniazid tablets: 2,4%
- ofloxacin tablets: 15,8%; ofloxacin capsules and solution for infusion: 0%
- kanamycin powder for injection: 0%

http://apps.who.int/medicinedocs/documents/s19053en/s19053en.pdf?ua=1
Adherence

Comparison of adherence in free combination therapy and administration of fixed dose combination in diabetes treatment

Sanofi Diabetes

Even in high income settings with progressive health-care systems and patients who are well educated about health, adherence to treatment for diabetes is poor.

ENTRED study 2007 (France)

Good adherence 39%
Medium adherence 49%
Poor adherence 12%
Optimizing the adherence of medication administration may represent a powerful measure to reduce morbidity and mortality.
WHO Prequalified FDCs

Ethambutol (hydrochloride)/Isoniazid 400mg/150mg (2)

Isoniazid/Rifampicin 75mg/150mg (5);
30mg/60mg (1);
60mg/60mg (1);
150mg/300mg (2);
150mg/150mg (1)

Isoniazid/Pyrazinamide/Rifampicin 30mg/150mg/60mg (2)

Ethambutol (hydrochloride)/Isoniazid/Rifampicin 275mg/75mg/150mg (3)

Ethambutol (hydrochloride)/Isoniazid/Pyrazinamide/Rifampicin 275mg/75mg/400mg/150mg (6)
Quality Generic Drugs Save Lives

A quiet revolution in global public health: The World Health Organization’s Prequalification of Medicines Programme
‘t Hoen EFM, Hogerzeil HV, Quick JD, Sillo HB

THANK YOU