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

6th TB Symposium - Ministry of Health of the Republic of Belarus, Republican Scientific and Practical Center for Pulmonology and Tuberculosis, and Médecins Sans Frontières

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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

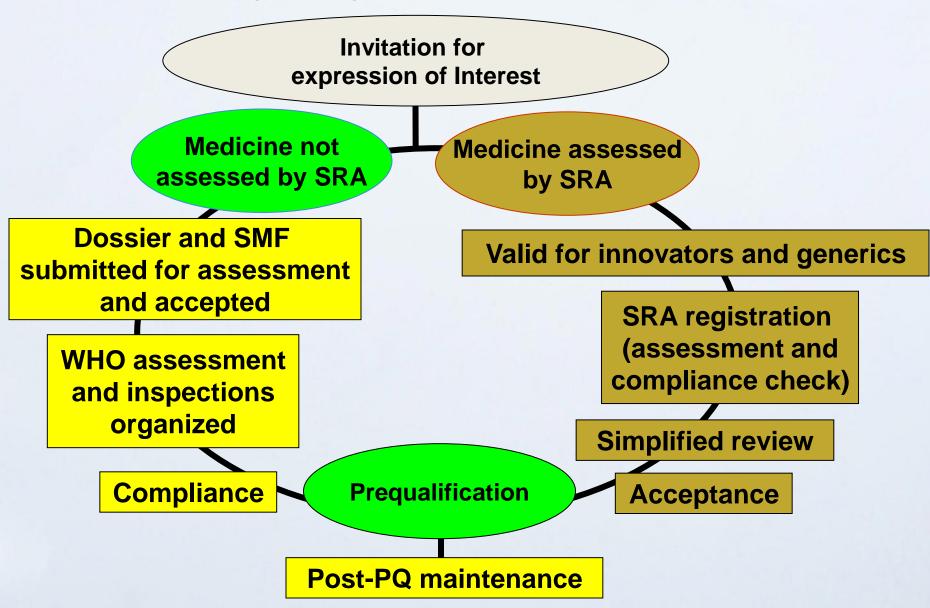
Objective:

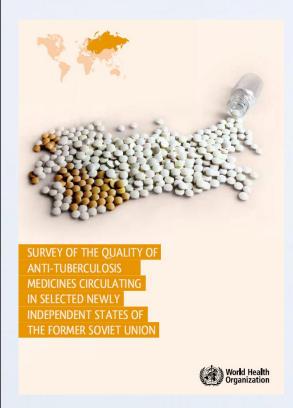
 To ensure quality, efficacy and safety of medicines procured using international funds (e.g. GFTAM, UNITAID) to serve patients in developing countries

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





Of the total of 291 samples, 38 (13%) were from WHO prequalified products.

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

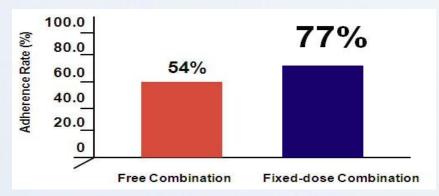
The samples were originating from 33 manufacturers from the following 12 countries: 10 from India, 5 each from Russia and from Ukraine, 3 from Kazakhstan, 2 each from Belarus and from China, and 1 each from Cyprus, France, Palestine, Syria, Turkey and Uzbekistan.

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

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%

Adherence



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



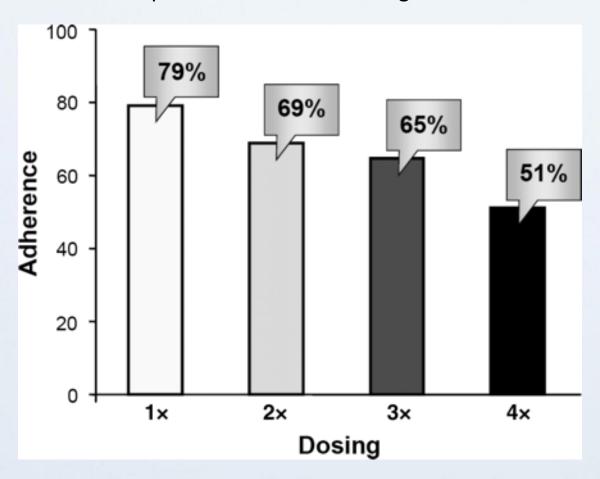
Even in high income settings with progressive health-care systems and patients who are well educated about health, adherence to treatment for diabetes is poor.

ENTRED study 2007 (France)

Good adherence	39%
Medium adherence	49%
Poor adherence	12%

Strategies to improve drug adherence

Ulrich Laufs, Volker Rettig-Ewen, Michael Böhm DOI: http://dx.doi.org/10.1093/eurheartj/ehq297 European Heart Journal 21 August 2010



Optimizing the adherence of medication administration may represent a powerful measure to reduce morbidity and mortality

WHO Prequalified FDCs

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

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Isoniazid/Rifampicin 75mg/150mg (5);
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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)/lsoniazid/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