

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

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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:

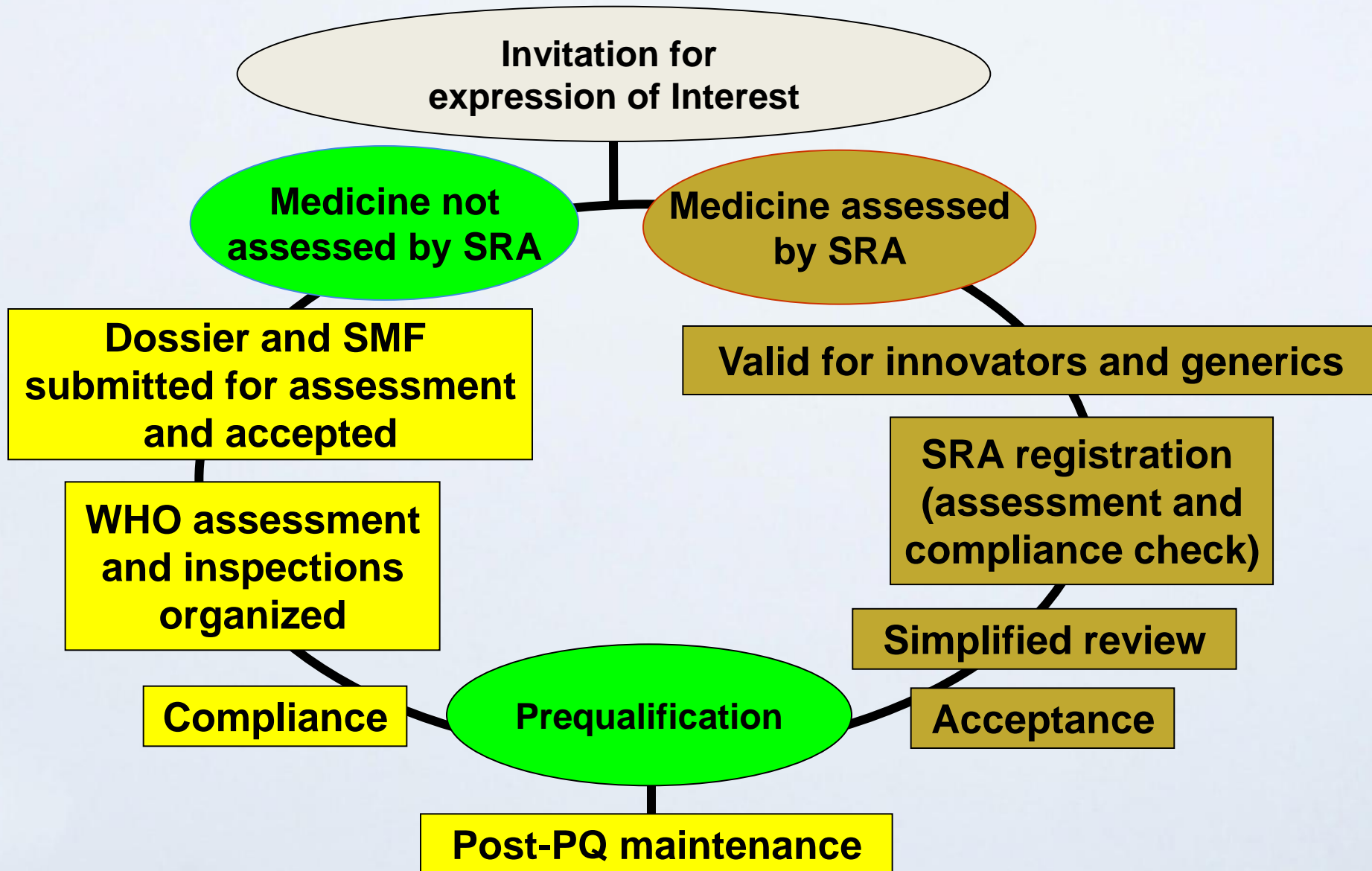
- Health care providers – inadequate regimens
- Patients – **inadequate drug intake**, and
- Medicines - inadequate supply and **quality**

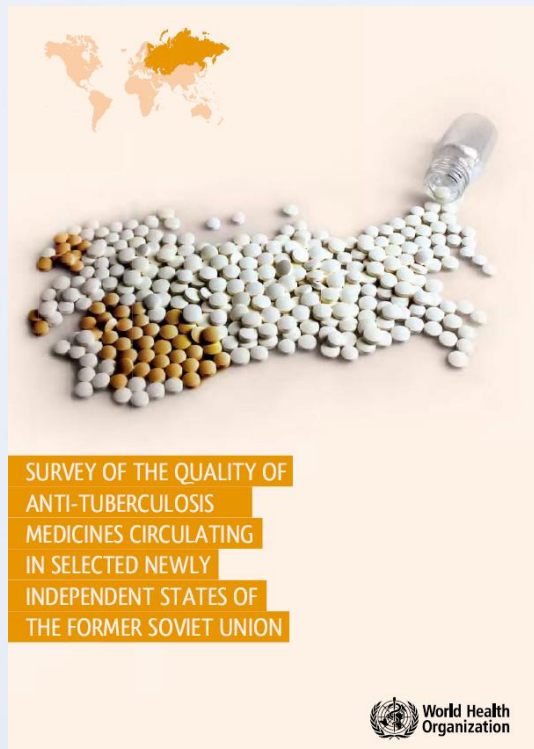


UN Prequalification Programme for Priority Essential Medicines

- 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.

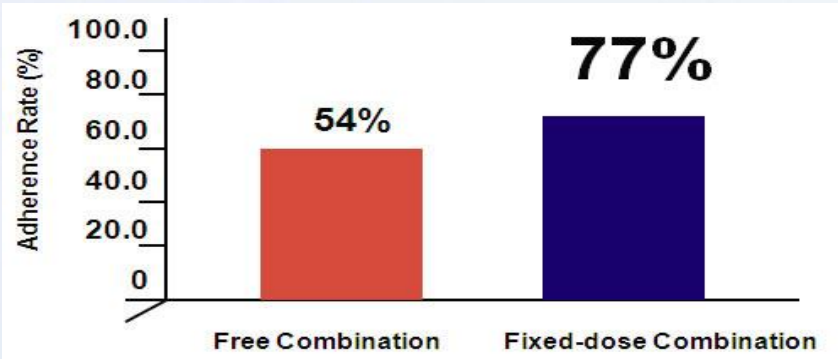
The samples were originating from 33 manufacturers from the following 12 countries: 10 from India, 5 each from Russia and from Ukraine, 3 from Kazakhstan, 2 each from Belarus and from China, and 1 each from Cyprus, France, Palestine, Syria, Turkey and Uzbekistan.

<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)

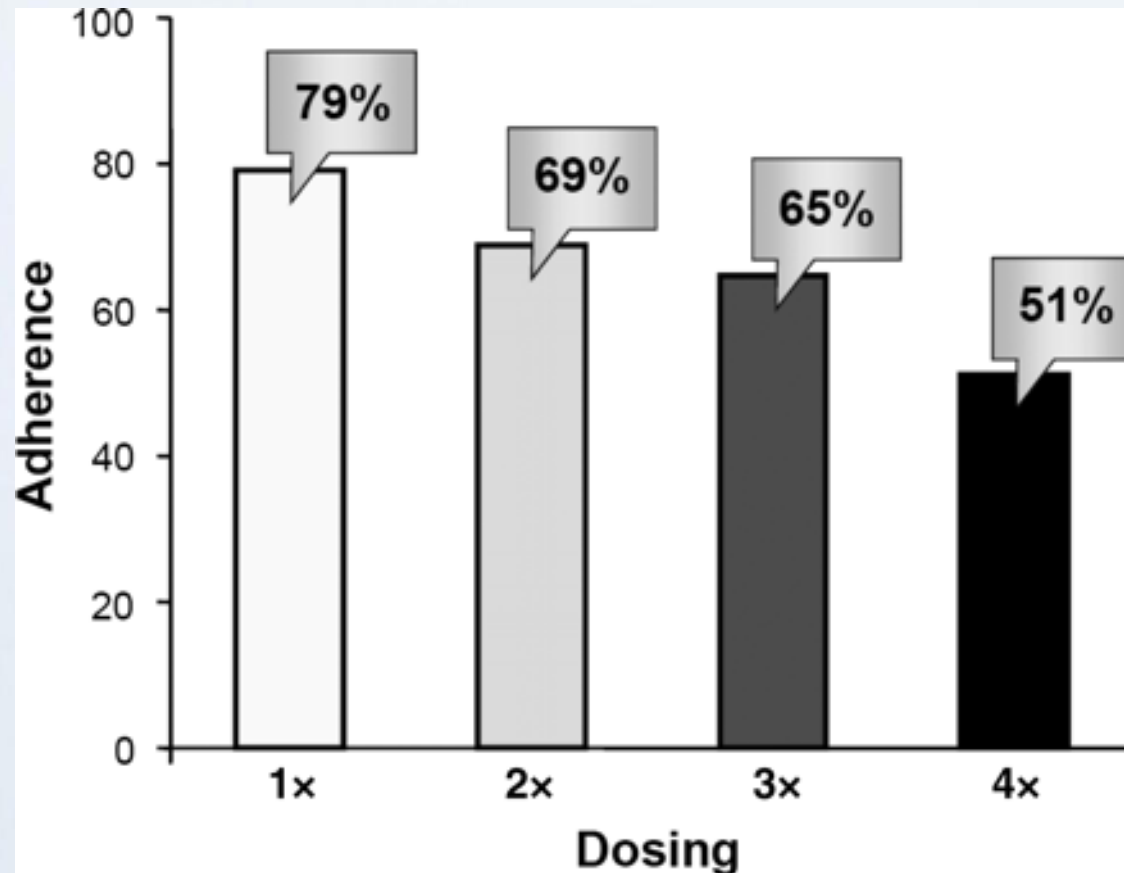
Good adherence	39%
Medium adherence	49%
Poor adherence	12%

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)/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