WHO Medicines Prequalification: What is it and why is it important?

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Mission of WHO medicines prequalification: ensure timely availability of quality-assured health products for priority diseases and reproductive health in low- and middle-income countries

Goal

- Make quality priority products available in a consistent and timely manner
- Ensure sustainable supply of quality-assured products
- Create national capacity to evaluate and monitor ongoing quality of products

Strategy

- Apply and promote unified quality, safety and efficacy/performance standards, for comprehensive evaluation of health products
- Build capacity of staff of regulatory authorities, quality control laboratories and manufacturers

Key outputs

- Lists of prequalified products and QCLs
- WHO public assessment/ inspection reports
- Accelerated national registration of prequalified products
- Increased regulatory capacity at national level
- Improved good manufacturing practice

Medicines prequalification: assessment of quality, safety, efficacy / performance, with focus on specific needs of resource-limited settings

- **As well as strengthening** manufacturers' and national regulatory **capacity**
- **Programmatic suitability**: specific emphasis on issues of particular relevance to resource-limited settings, such as:
  - ✓ Stability of products (heat conditions)
  - ✓ Adapted: appropriate formulation
- **Life cycle management** of products

WHO medicines prequalification: benefits for stakeholders (1)

Patients

- ✓ Access to quality-assured products, adapted to their specific needs
- ✓ Appropriate and effective treatment

WHO Member States & NRAs

- ✓ Reduced burden of regulatory approval
- ✓ Increased regulatory capacity & harmonization of regulatory practices in countries
- ✓ Implementation of specifically developed and road-tested international guidelines
- ✓ Access to quality-assured products

Donors, procurers and UN agencies

- ✓ List of prequalified products and laboratories
- ✓ Increased availability of quality-assured products
- ✓ Monitoring quality of prequalified products
- ✓ Diversity and affordability of products → healthier markets

WHO medicines prequalification: benefits for stakeholders (2)

Manufacturers

- ✓ Access to donor-sponsored tenders
- ✓ Faster regulatory approval
- ✓ Timely assessment of variations and changes
- ✓ International quality-assured product status (improved image)
- ✓ Recognition of GMP status, beyond prequalified products
- ✓ Increased capacity in quality management systems
- ✓ Target product profiles
- ✓ Harmonization of regulatory practices within WHO Member States
- ✓ Reduced operating and manufacturing costs

QC labs

- ✓ International recognition of prequalified QCLs
- ✓ Technical assistance and scientific advice

Medicines PQ = a global public good

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A quiet revolution in global public health: The World Health Organization's Prequalification of Medicines Programme

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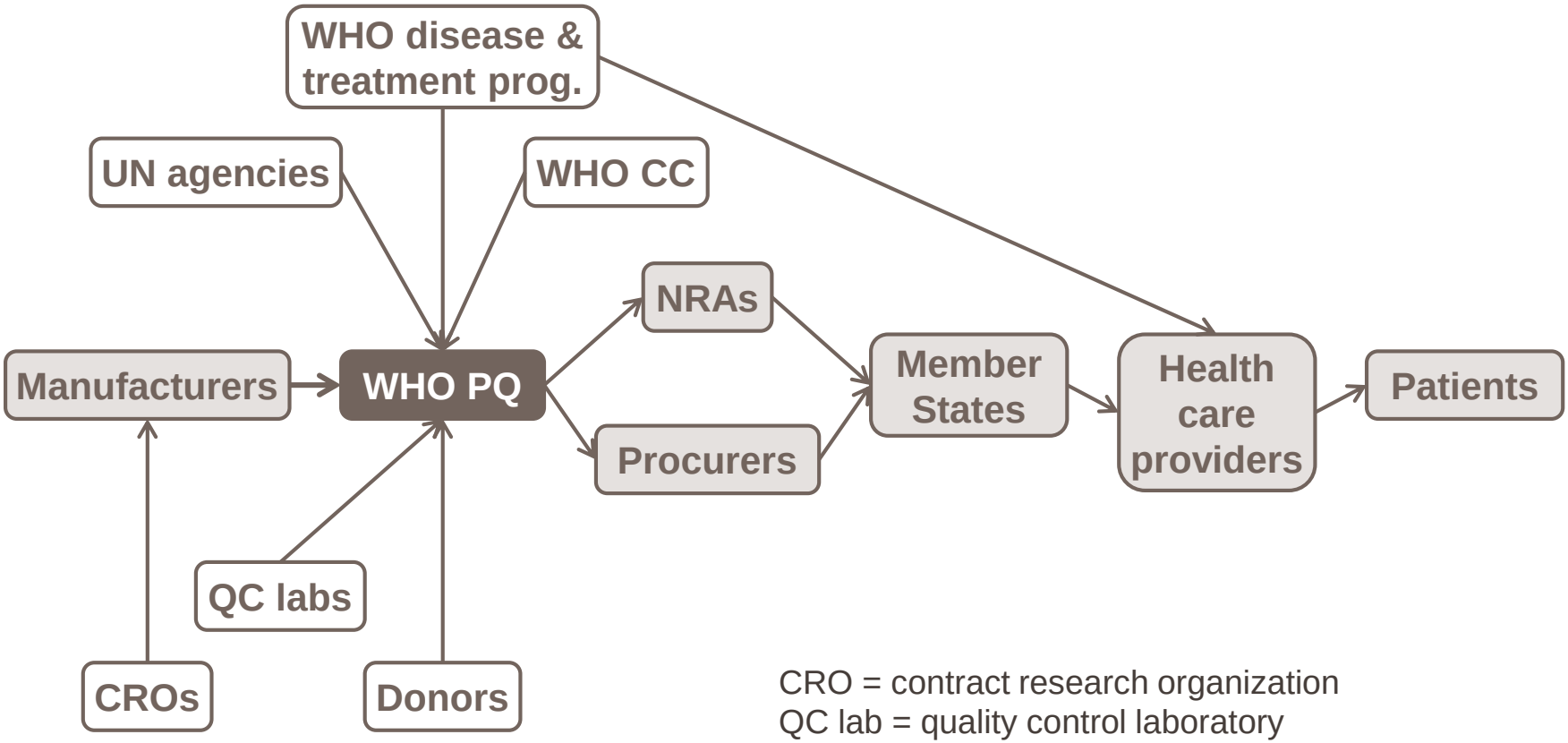
"The prequalification programme could continue for a long time, with a slowly changing range of essential medicines of great public interest, each in its own market development cycle…The WHO PQP has become a global public good that has helped save millions of lives…It is the strongest mechanism currently in place to create sustainable regulatory systems in low- and middle-income countries. This alone justifies investment in WHO PQP."

…but not all by itself



CRO = contract research organization
QC lab = quality control laboratory
WHO CC = WHO collaborating centre

However…less prequalification success with reproductive health medicines

- Too much focus on price
- For manufacturers: not enough evidence that quality pays
- Regulatory expense
- Technically difficult (oxytocin, DMPA, misoprostol)
- Low demand (magnesium sulphate)

► Too few quality-assured products

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015
Accepted for Assessment	10	4	7	7	3	3	14	5	6
Cum. total	10	14	21	28	31	34	48	53	59
In total **73** applications were submitted to PQP									
Prequalified	-	-	**3**	**5**	**3**	-	**10**	**5**	**2**
Cum. total	-	-	**3**	**8**	**11**	**11**	**21**	**26**	27
In total **28** products were prequalified by WHO-PQT + **1** listed based on EMA Art 58 approval									

Applications accepted 2007–2015, at 9 Sept 2015

What would make a difference?

Procurers:

- ✓ Forecasting information?????
- ✓ Harmonized standards for international/national procurement of quality-assured products?????

Regulators & manufacturers:

- ✓ More sharing of assessment and inspection reports/use of collaborative procedure for accelerated registration

WHO prequalification:

- ✓ Continued and sustained outreach to manufacturers pre-application
- ✓ Improved accessibility of information about prequalification.

Thank you for your attention