



LNCT
Learning Network for
Countries in Transition

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Sourcing Quality Assured Vaccines

Introduction

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Objectives of this session

- To present developments and challenges on vaccine quality regulation, *and*
- To review common issues with sourcing quality vaccines

Potential questions and challenges

- Are we sourcing safe and effective vaccines – from local manufacturers, global manufacturers, and/or UNICEF SD?
- Does registration, inspection, surveillance, etc. differ for locally-sourced and imported products?
- Do we have the structures, knowledge and capacities to undertake vaccine quality assurance activities?
- Do we have a functional NRA? How can we ensure our NRA is fulfilling its functions?
- Are we complying with WHO norms, standards and requirements?
- Are we assuring the quality of vaccines from the point of import and production till the point of administration?
- How many vaccines are PQ by WHO? Is this fully reliable?
- What roles are played by the UN agencies compared to countries on vaccine quality assurance?
- How should we approach quality assurance with non-PQ vaccines?
- Are there vaccines being considered that are not available through UNICEF? Are they of assured quality?
- Could we rely on Market Authorization delivered by neighboring countries?
- Could we collaborate at regional or sub-regional level on vaccine quality? What are the current experiences and initiatives within the region?
- How are partners supporting capacity building in participating countries and in the region?

Access to Safe, Effective, Quality and Affordable Medical Products

Legal framework mandate and enforcement power

Norms and standards

Leadership, coordination & Strategic Planning

Quality Management /Risk Management System

Resources HR, FR, IMS, Infrastructure



Good Regulatory Practices (GRP)

NRA functions depending on source of vaccines

Vaccine-specific NRA functions needed	Areas of activity by NRA (or WHO) depending on source of vaccines		
	Vaccine procured by United Nations agency	Vaccine procured by NRA	Vaccine manufactured in country
FUNCTION 1 Marketing authorization and licensing activities	✓	✓	✓
FUNCTION 2 AEFI surveillance	✓	✓	✓
FUNCTION 3 NRA lot release	NRA functions undertaken by WHO on behalf of United Nations agencies or producing countries.	✓	✓
FUNCTION 4 Laboratory access		✓	✓
FUNCTION 5 Regulatory inspections		NRA functions undertaken by producing country.	✓
FUNCTION 6 Oversight of clinical trials			✓

Source: World Health Organization

Session agenda



