



Regulatory requirements

New developments and challenges on vaccine regulation



Program of the day

S1

- Title: Intro to vaccine procurement and regulatory issues
- Objective: understanding regulatory challenges and constrains

S2

- Title: Focused country exchange on vaccine regulatory issues
- Objective: Mapping major country regulatory requirements

S3

- Title: Introduction to vaccine registration processes and issues
- Objective: Knowing regulatory pathways and Good Regulatory Practices

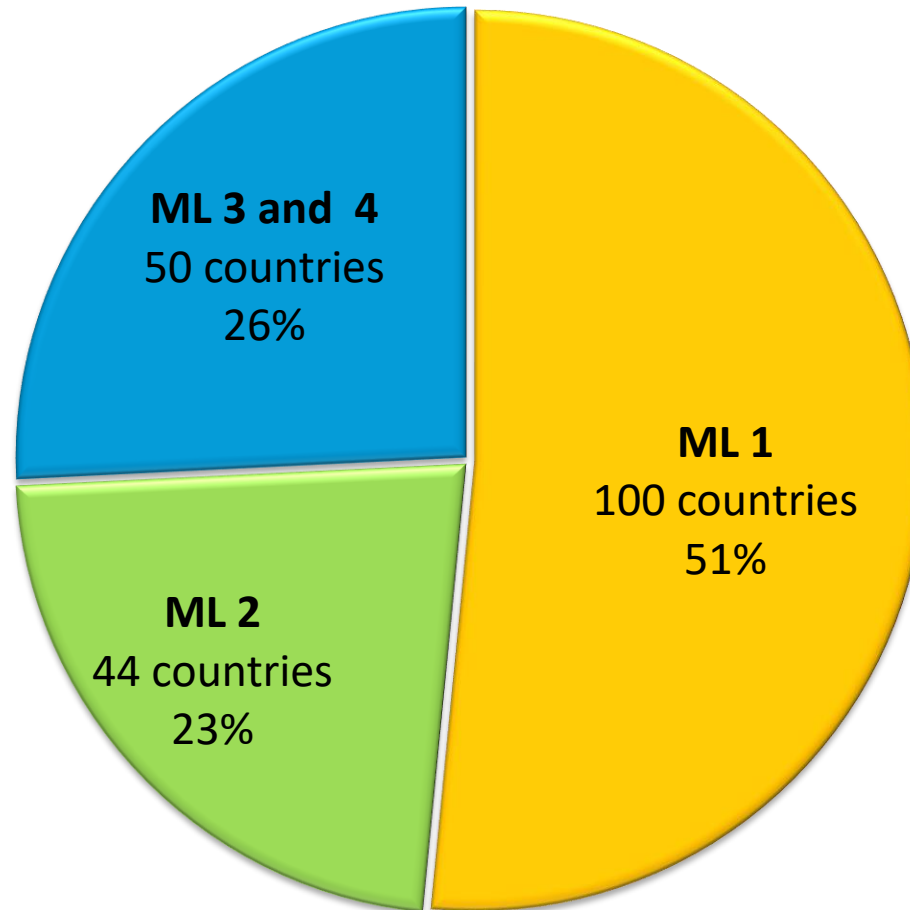
S4

- Title: Focused country exchange on vaccine registration processes and issues
- Objective: Develop a plan to address regulatory challenges

Outline

- Global NRA status
- Global context: SDG and WHA Resolution for Regulatory System Strengthening
- WHO Regulatory System Capacity Building Model
- WHO Global Benchmarking Tool
- Measuring performance of regulatory systems
- Global overview

Overall regulatory systems' maturity level of WHO Member States



(Updated 8 Feb 2019)
WHO MVP/RSS/CRS



SUSTAINABLE DEVELOPMENT GOALS



1 NO POVERTY 	2 NO HUNGER 	3 GOOD HEALTH 	4 QUALITY EDUCATION 	5 GENDER EQUALITY 	6 CLEAN WATER AND SANITATION
7 RENEWABLE ENERGY 	8 GOOD JOBS AND ECONOMIC GROWTH 	9 INNOVATION AND INFRASTRUCTURE 	10 REDUCED INEQUALITIES 	11 SUSTAINABLE CITIES AND COMMUNITIES 	12 RESPONSIBLE CONSUMPTION
13 CLIMATE ACTION 	14 OCEANS AND UNDERSEA ECOSYSTEMS 	15 LIFE ON LAND 	16 PEACE AND JUSTICE 	17 PARTNERSHIPS 	18 DISASTERS AND CLIMATE RESILIENCE

SDG 3 – Target 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

WHA Resolution 67.20

What WHO should do



To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

Evaluate

Evaluate national regulatory systems

Tools

Apply WHO evaluation tools

Performance

Generate and analyze evidence of regulatory system performance

IDPs

Facilitate the formulation and implementation of institutional development plans

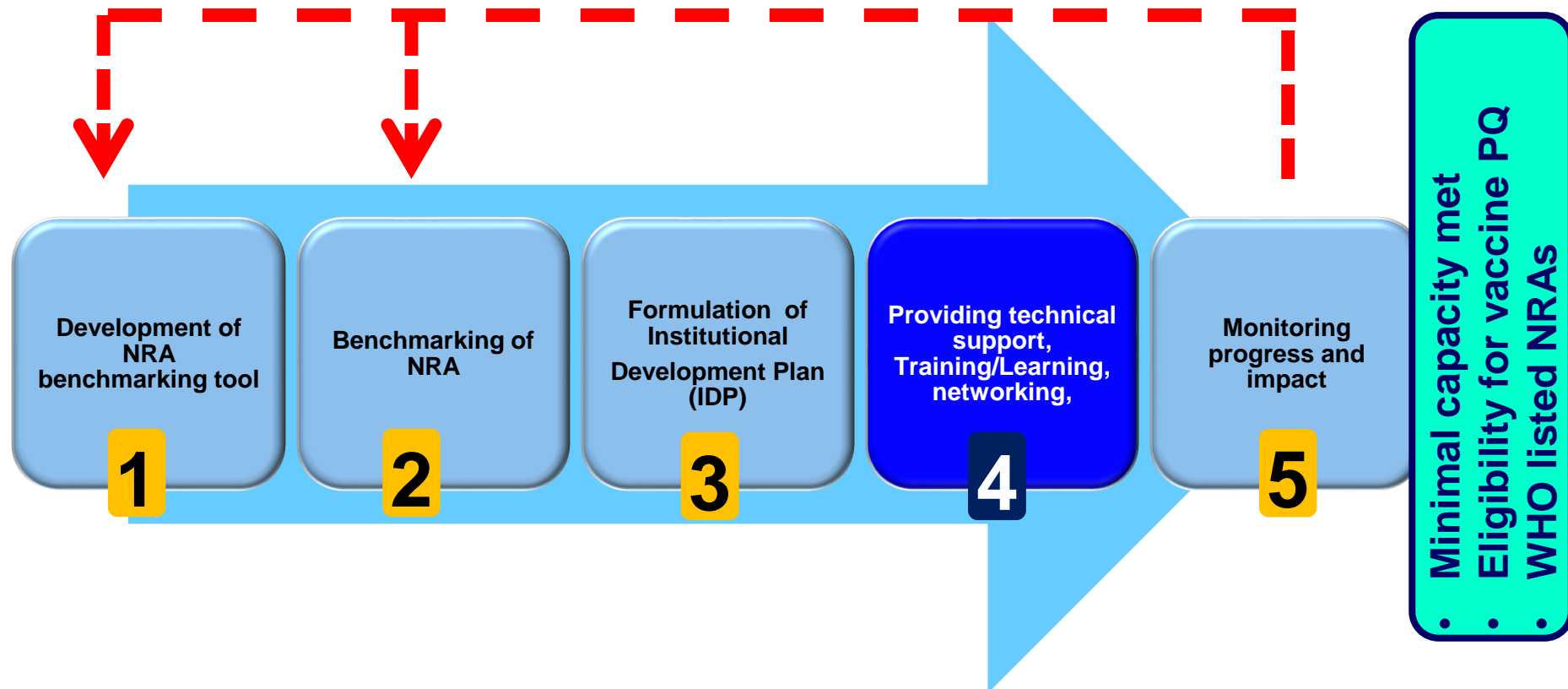
Technical support

Provide technical support to national regulatory authorities and governments

WHO capacity building model



WHO NRA 5 step capacity building



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

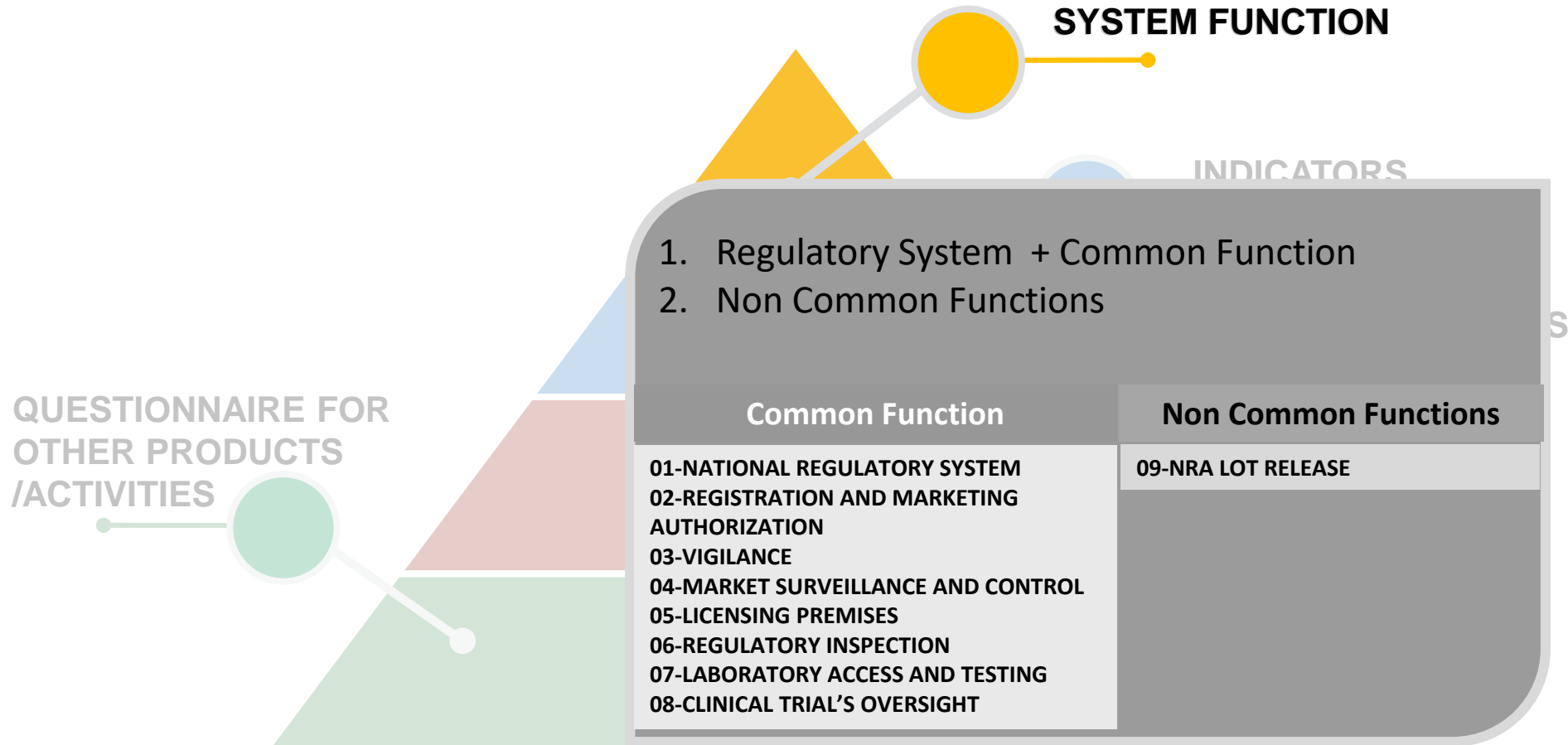


Good Regulatory Practices (GRP)

WHO Global Benchmarking Tool

Structure/Hierarchy

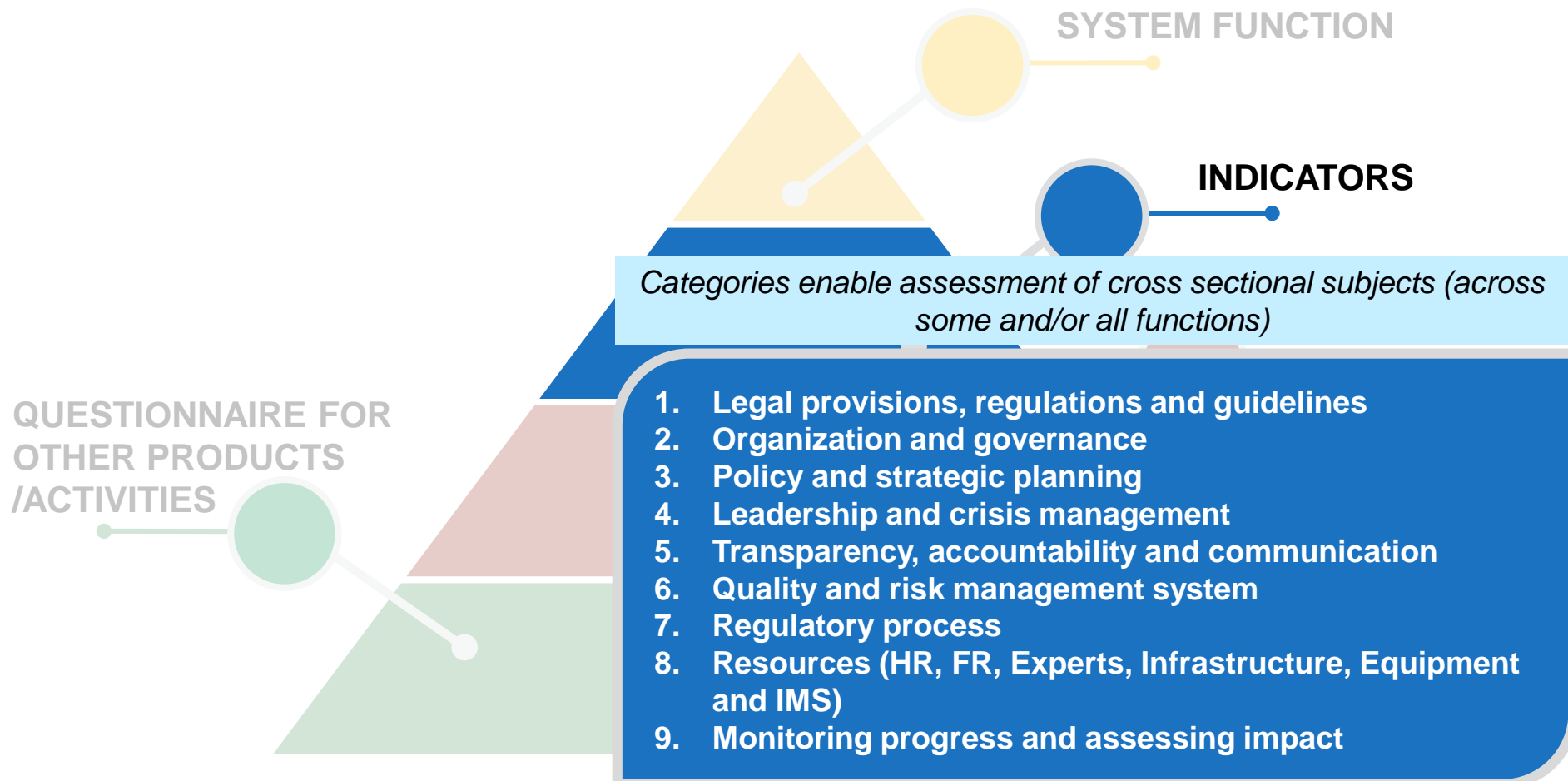
National Regulatory System (NRS) and Functions (NRF)



WHO Global Benchmarking Tool

Structure/Hierarchy

Indicators Categorization (cross cutting subjects)



Essential medicines and health products

[Medicines and health products](#)[About us](#)[Access and innovation](#)[Regulation](#)[Publication](#)[News](#)[Contacts](#)

WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems

Regulatory systems play a key role in assuring the quality, safety, and efficacy of medical products. Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation.



Related links

[National Regulatory Systems](#)

WHO Global Benchmarking Tool (GBT) Rev VI

https://www.who.int/medicines/regulation/benchmarking_tool/en/

The development of the current GBT Revision VI takes into consideration input received from two international consultations with Member States in 2015, a public consultation in early 2018 and a series of meetings involving experts from regulatory authorities from different parts of the world.

The GBT Revision VI replaces all tools previously used by WHO, representing the first truly "global" tool for benchmarking regulatory systems. The GBT is designed to evaluate the overarching regulatory framework and the component regulatory functions (e.g. clinical trial oversight) through a series of sub-indicators that may also be grouped and examined according to nine cross-cutting categories or themes, for example, quality and risk management system. Fact sheets have been developed for

[sheet](#)
pdf, 1.03Mb[Laboratory Testing \(LT\) fact sheet](#)
pdf, 1.02Mb[Clinical Trials Oversight \(CT\) fact sheet](#)
pdf, 1.03Mb[NRA Lot Release \(LR\) factsheet](#)
pdf, 0.11kb

WHO GBT Performance Maturity Levels

ISO 9004



No formal approach



Reactive approach



Stable formal system approach



Continual improvement emphasized

WHO GBT

Some elements of regulatory system exist

Evolving national regulatory system that partially performs essential regulatory functions

Stable, well-functioning and integrated regulatory system

Regulatory system operating at advanced level of performance and continuous improvement

Can ensure the quality of products if rely on ML 3/ ML 4 regulatory systems

Target of WHA Resolution 67.20

Advanced and well resourced regulatory systems

100 Countries

44 Countries

50 Countries

China: The Success Story

1st PQ vaccine



World Health Organization

statistics Media centre Publications Countries Programmes and projects

Newly accessible Japanese encephalitis vaccine will make saving children easier in developing countries

First vaccine from China to be prequalified by WHO

9 OCTOBER 2013 | GENEVA - A newly accessible vaccine against Japanese encephalitis is going to make the protection of more children in developing countries easier. The vaccine, manufactured in China, only needs to be given in one dose, it can be used for infants, and it is less expensive than other Japanese encephalitis vaccines.

NRA Benchmarking

NRA Re-Assessment

Functional NRA, after benchmarking in Dec 2010

More vaccine submitted for PQ

IDP

IDP

2005

Mar/2011

Oct/2013

Q2/2014

Fact and figures
GLOBAL OVERVIEW



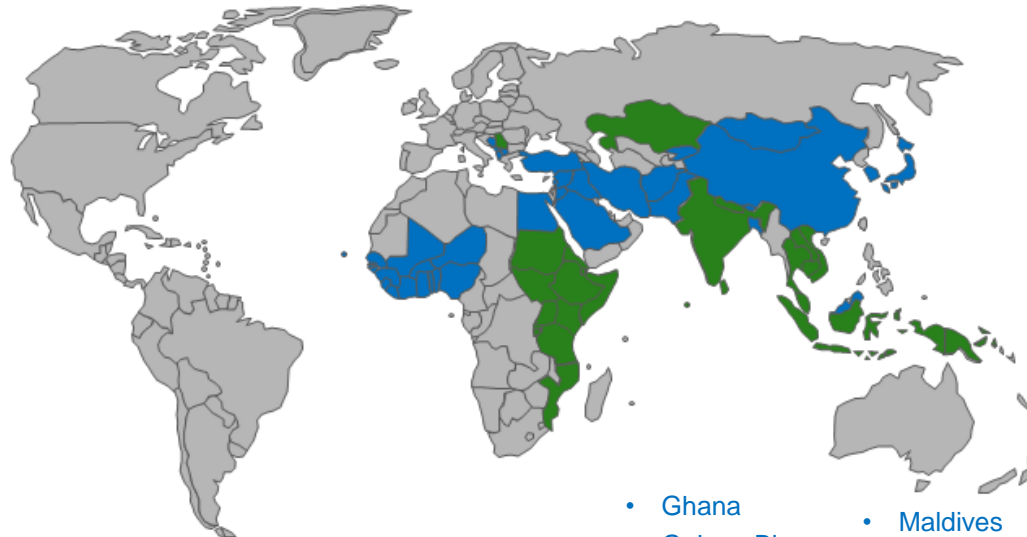
Countries/areas targeted for WHO Regulatory System Strengthening Program and benchmarked against GBT indicators between 2016- Feb 2019



Formal Benchmarking

- India
- Papua new guinea
- Timor-Leste
- Tanzania
- Burundi
- Ethiopia
- Mozambique
- Kenya
- Djibouti
- Eritrea
- Sudan
- South Sudan
- Somalia
- Uganda
- Serbia
- Cambodia
- Lao PDR
- Thailand
- Indonesia
- Kazakhstan
- Vietnam
- Rwanda

(Updated 15 Feb 2019)



Self Benchmarking

- Afghanistan
 - Pakistan
 - Malaysia
 - Japan
 - Iraq
 - Jordan
 - Lebanon
 - Mongolia
 - Kyrgyzstan
 - Korea
 - Bangladesh
 - Iran
 - Syria
 - Egypt
 - Saudi Arabia
 - Gambia
 - Benin
 - Burkina Faso
 - Guinea
 - Sierra Leone
 - Montenegro
 - Bosnia and Herzegovina
 - Macedonia
 - Albania
 - Kosovo area*
- Ghana
 - Guinea Bissau
 - Liberia
 - Niger
 - Cape Verde
 - Nigeria
 - Turkey
 - China
 - Maldives
 - Nepal
 - Sri Lanka
 - Cote d'Ivoire
 - Bhutan
 - Senegal
 - Togo
 - Mali

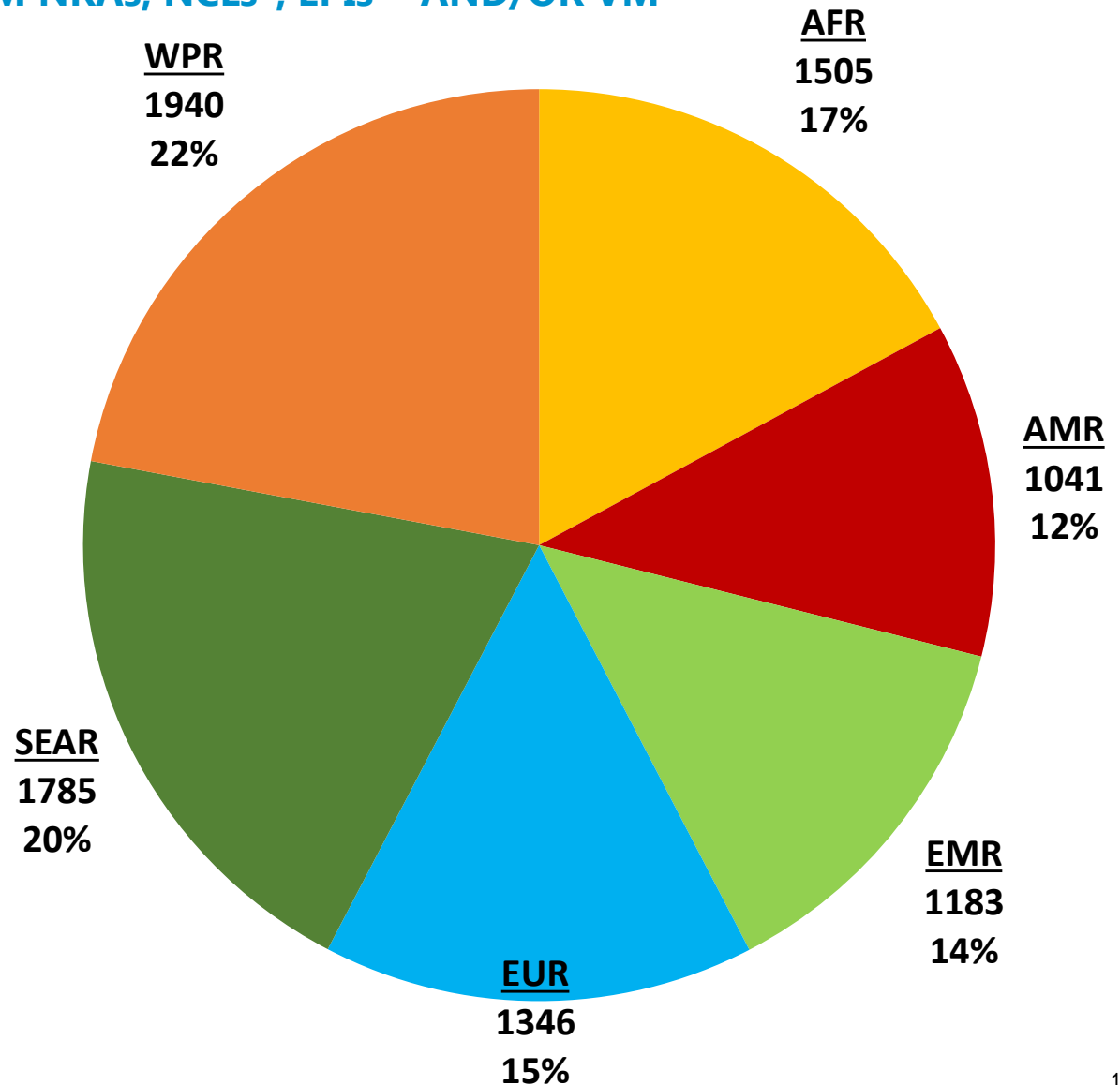
** in accordance with United Nations Security Council resolution 1244 (1999)*
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on map represent approximate border lines for which there may be not yet be full agreement.

STRENGTHENING NATIONAL REGULATORY AUTHORITY (NRA) TRAINING CONDUCTED 1996-2018



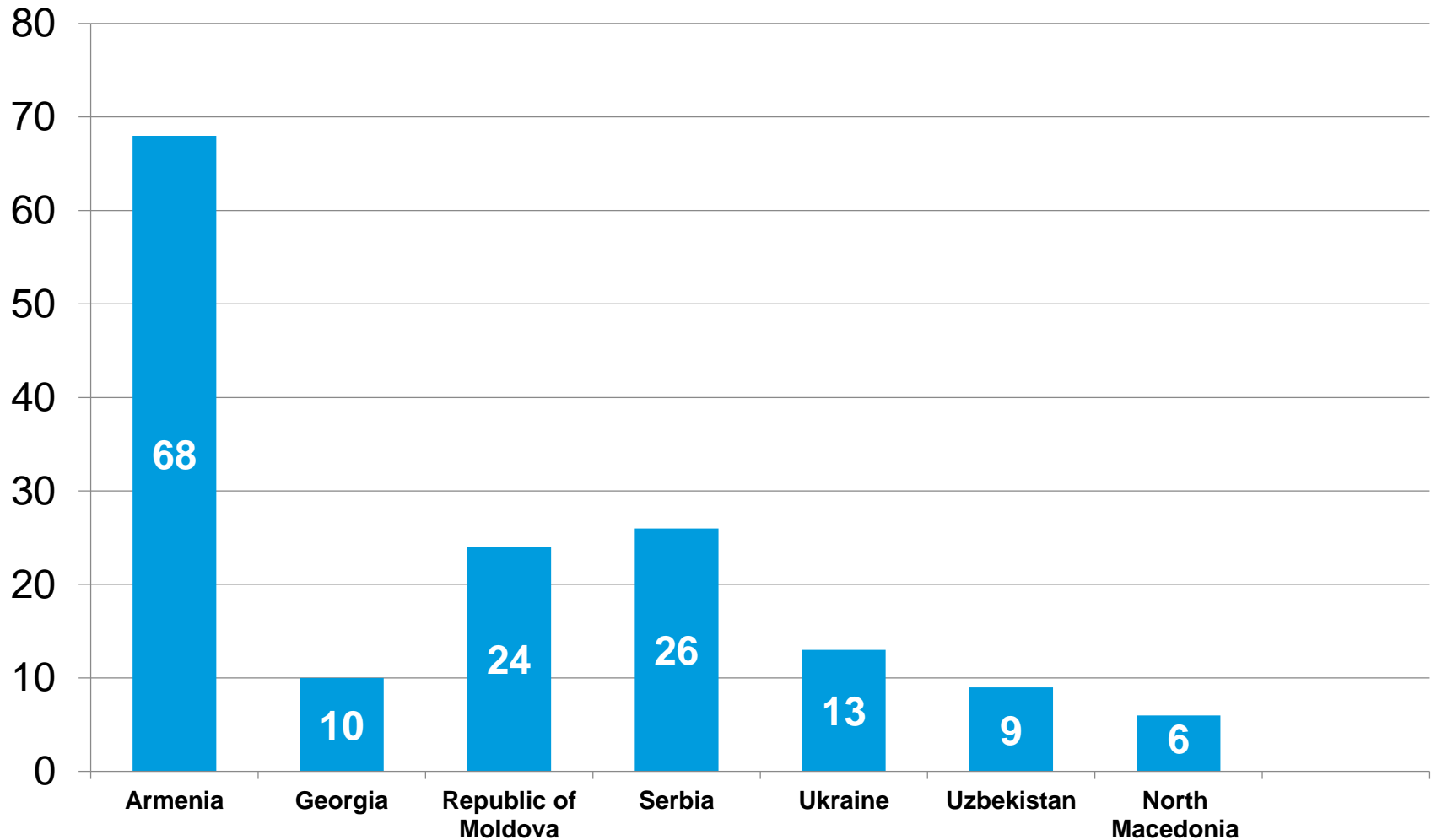
8800 PARTICIPANTS FROM NRAs, NCLs*, EPIs** AND/OR VM***

8800 head counts
have been trained
by WHO between
1996 till Dec 2018



* National Control Laboratory
** Expanded Programme on Immunization
*** Vaccine Manufacture
Source: WHO/ EMP

Number of trainees per country 1996-2018



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Important Links

Go to our Regulatory system strengthening website



Go to the Global Benchmarking Tool



Go to SharePoint site



Go to GBT online training



Thank you



World Health
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Regulatory Systems Strengthening (RSS)

Regulation of Medicines and Other Health Technologies (RHT)

World Health Organization (Geneva, Switzerland)