

Strengthening developing countries regulatory systems

15th DCVMN Annual Meeting 27-29

October 2014

New Delhi, India

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EMP restructuring process

- The quality, safety and standards team (QSS) from the Immunization, Vaccines and Biologicals (IVB) Department was transferred to the Essential Medicines and Health Products Department (EMP) in November 2012
- Subsequently, EMP was restructured. The objective of this process was to align policies, objectives, strategies and procedures for strengthening regulatory capacity for all medical products and health technologies.

EMP in the WHO hierarchy

HIS: Health systems and Innovation

EMP: Essential Medicines and Health Products

RHT: Regulation of Medicines and other Health Technologies

PAU: Policy, Access and Use

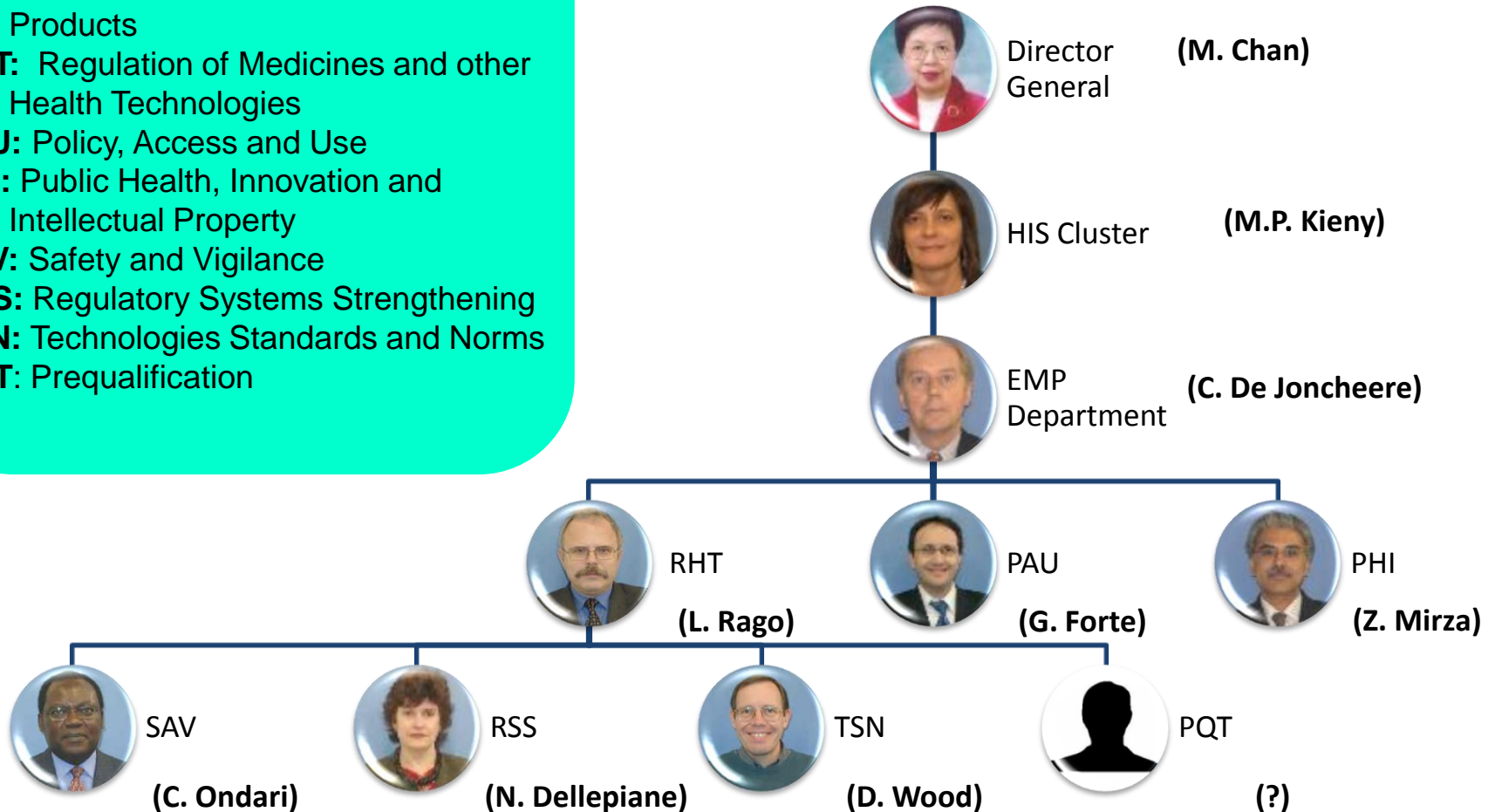
PHI: Public Health, Innovation and Intellectual Property

SAV: Safety and Vigilance

RSS: Regulatory Systems Strengthening

TSN: Technologies Standards and Norms

PQT: Prequalification



Strategic Objectives of RSS

1. Functional national regulatory systems developed and sustained
2. Regional regulatory systems developed and converged and regulatory requirements harmonized.
3. Regulatory networks developed and sustained
4. Accelerate access to products of public health interest through support to countries to ensure appropriate regulatory oversight of such products

WHA 67.20 resolution

- A WHA resolution on regulatory systems strengthening endorsed in May 2014 re-enforces WHO and member state commitment to strengthen regulatory systems.
 - It mandates that more human and financial resources are required to foster regulatory systems in countries in need to foster networking, convergence and collaboration

Addressing WHA resolution mandate

Process launched to ensure that WHO NRA policy, assessment process and assessment tool used in the WHO global programme for strengthening NRAs are updated as needed to seek integration and convergence for all product categories and that strengthening efforts are aligned across WHO (HQ, ROs and COs) to better serve the needs of member states.

Strategic Objective1- Functional national regulatory systems developed and sustained

Policy related aspects

- ☐ Develop a WHO-wide policy for strengthening regulatory capacity
 - Functionality requirement across all PQ programmes?
 - Use of 5-steps capacity building model across all product categories?
 - How to prioritize efforts? Which countries? Which functions?

Process related aspects

- ☐ Revise the assessment process to meet current needs
 - All steps from planning to outcome

Tool related aspects

- ☐ Combine all existing tools into a single NRA assessment tool to be used for all needs and product categories and revise the indicators

Process for policy development and tool and assessment process revision

HIS
Reorganisation &
Move of QSS
team from IVB
to EMP
Sept.2012

EMP
reorganised &
New teams
established
Dec.2013

Revised tools
Published for
comments
May 2014

Coordination
With PAHO
June 2014

Invitation to
Request
expert
designations
from ROS &
NRAs,
Aug.2014

Online mtg
2-4 Dec
2014
HQ F to F
Meeting
Jan 13 to 15
2015

Planning &
concept paper
for
international
consultation
shared with all
ROs, June
2014

Working
Groups
sessions
Oct-Nov

Harmonization of medicines, PAHO, diagnostics, medical devices , & vaccines tools

2012-2013

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2014



**World Health
Organization** 2015

Strategic Objective 2

Regional regulatory systems developed and converged and regulatory requirements harmonized.

- Focus efforts on regional economic blocks or other regional efforts for regulatory convergence and harmonization (i.e. EAC, ASEAN, etc)

Strategic Objective 3

Regulatory networks developed and sustained

1. Support to global networks, such as the Developing country vaccine regulators network
2. Collaborate as resource members with the Developing country vaccine manufacturers network
3. Support to regional networks, such as the Regional Alliance , for NRAs in the Western Pacific Region, African Vaccine Regulatory Forum, PANDRH, SEARO Network of National Control Laboratories, etc as needed



Strategic Objective 4

Accelerate access to products of public health interest through support to countries to ensure appropriate regulatory oversight of such products

1. Pandemic Influenza preparedness project with focus on 15 countries (majority in Africa)
2. Local Production and Access to Medicines and other Health Technologies (WHO/EC project)
 1. Capacity building and technical assistance for local production of selected essential medical products for both regulatory authorities and manufacturers
3. Assist countries to use resources effectively to implement the necessary regulatory functions (e.g. facilitated registration of PQd products, information sharing instead of duplicating efforts, focus on PMS, etc)
4. Assist countries to establish regulatory pathways for registration of medical products for emergency use (fast track procedures, waivers, other)

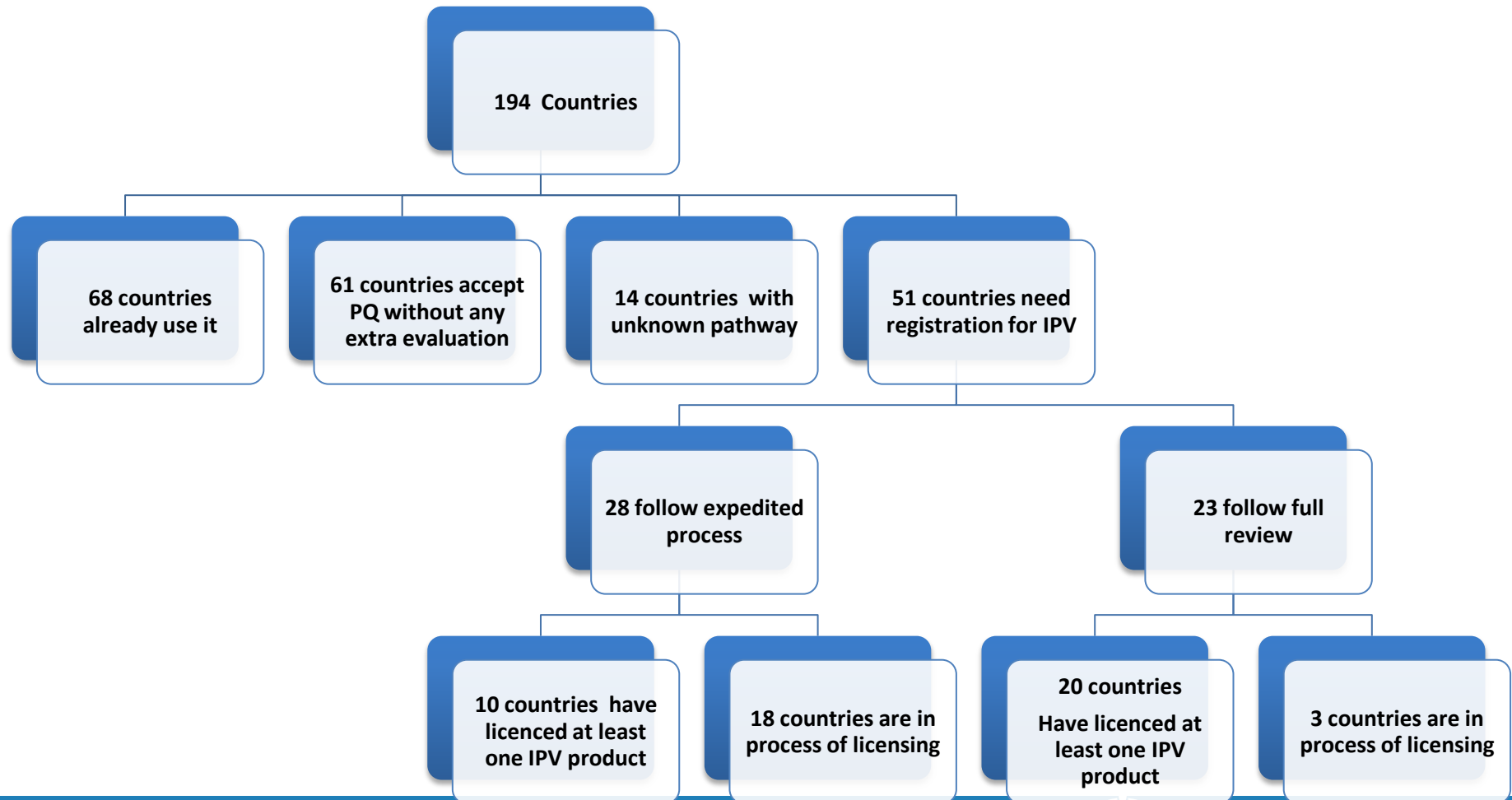


Support to countries for registration of IPV in the context of the polio eradication end game

Three possible regulatory pathways:

- I. Recognition of prequalification status without further action: Registration waiver
- II. Recognition of prequalification status as the basis for country registration: Expedited review procedure
- III. Full review procedure independent from prequalification

IPV licencing status



Support to countries for registration of IPV following full review procedure

- Joint review meeting in Morocco from 20 to 24 October 2014 to assist 6 countries in EMRO that follow pathway III for facilitated registration of two IPV products with support from NRAs from country of origin
- Joint review meetings in Turkey to assist African countries (francophone and anglophone) that follow pathway II for facilitated registration (Collaborative agreement procedure) of two IPV products based on the review of prequalification reports.

Support to countries for the continued regulatory oversight of IPV

- Monitor progress with registration of IPV (meeting end 2014 deadline)
- Assisting countries as required for the review and approval of variations
- Assist countries with PMS

Registration of bOPV for introduction in countries for routine use

WHO/PQ will review data for label change for use of bOPV in routine (once change is approved by NRAs of record). WHO proposed option to facilitate timely introduction of bOPV in the routine programme

- Seek a WHA resolution in 2015 WHA that would recommend that “in the unique context of Polio as a public health emergency, all countries are requested to accept bOPV for use in their routine immunization programme on the basis of the prequalification granted by WHO” and that
- "Countries are encouraged to start their own national registration process for bOPV, if required, as soon as the vaccine is prequalified and without delaying the introduction of this vaccine".



Addressing regulatory challenges

- Some countries require performance of domestic clinical trials for the registration of imported vaccines
- Some countries require performance of domestic clinical trials for approval of major variations (e.g. new building)
- It is unclear whether regulations in some developing countries include provisions for approval and use of medicines including vaccines in case of emergency
- A survey will be conducted to better understand current regulations and requirements in countries
 - Based on outcome, guidance document to be developed to inform countries on possible changes to current regulatory framework
 - Support the implementation of changes
 - Propose global mechanism to support registration/conditional approval of products for emergency use



Thank you



PHOTO. Massimiliano Pugliese

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