Update on PQ programme and regional harmonization of drug registration

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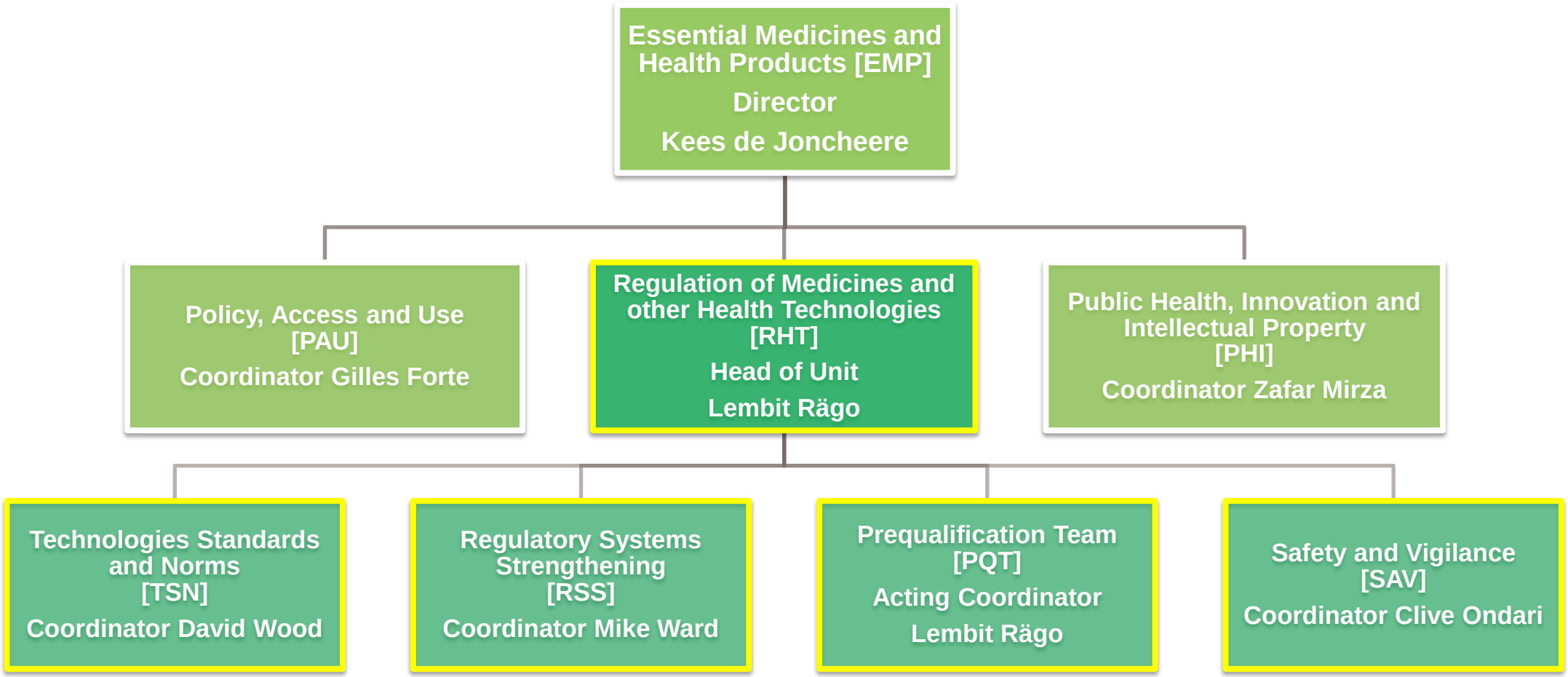
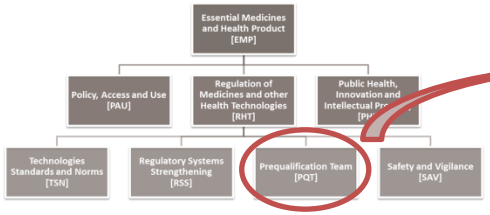
Overview

- Introduction
- Updates on PQ programme
- Collaborative procedure
- Regional harmonization initiatives for drug registration
- Concluding remarks

Structure of Department of Essential Medicines & Health Products: Regulation Unit (RHT)bringing together four teams dealing with regulatory issues



Structure of the Prequalification Team



Prequalification Team
Coordinator

Coordinator's office

Vaccines Assessment
Group Lead
Carmen Rodriguez Hernandez

Medicines Assessment
Group Lead
Matthias Stahl

Diagnostics Assessment
Group Lead
Irena Prat

Inspections
Group Lead
Deus Mubangizi

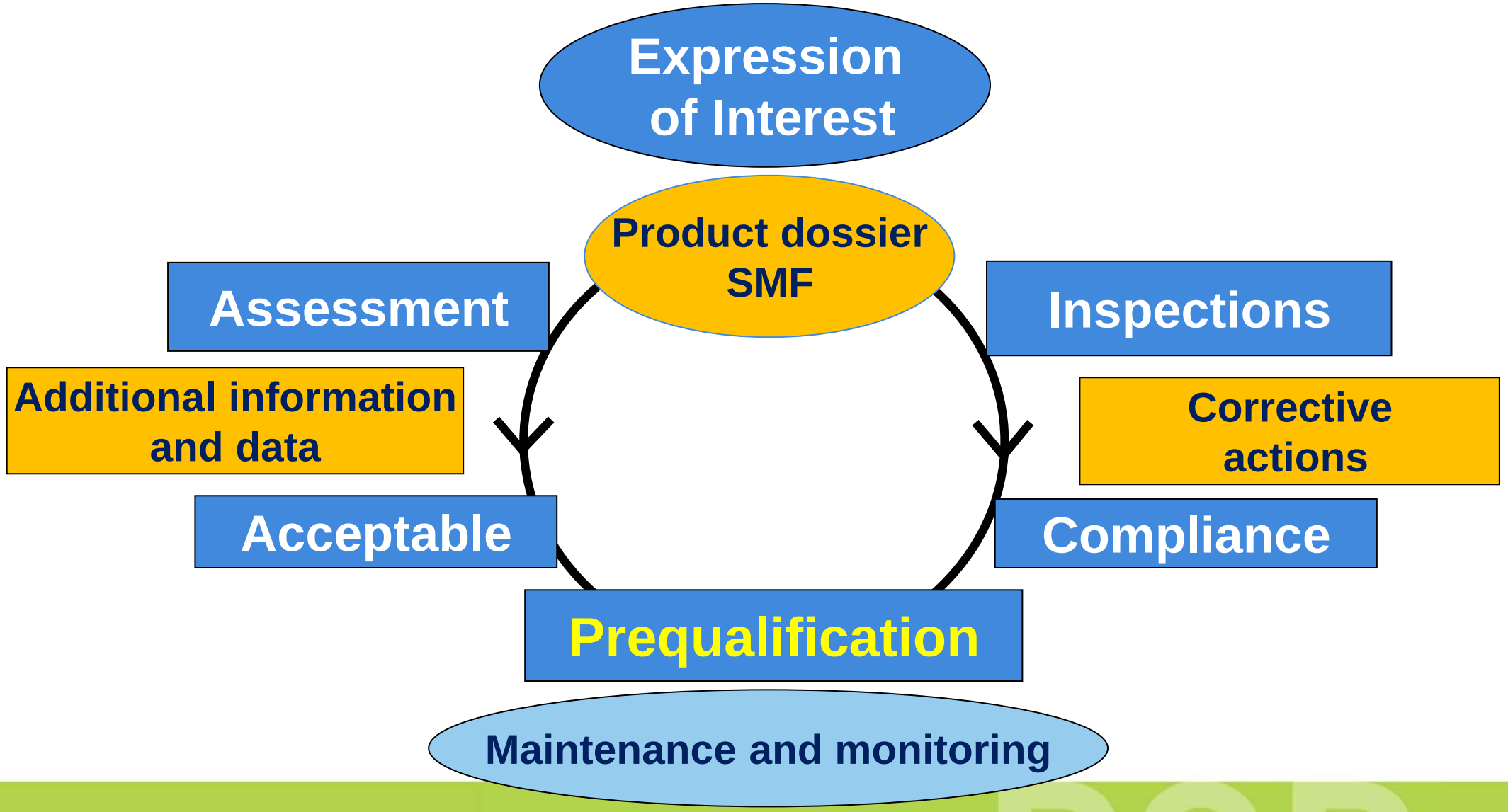
Technical Assistance/Labs
Group Lead
Milan Smid

Administrative team

The Prequalification of Medicines Programme (PQP)

- A United Nations Programme managed by WHO
- Started in March 2001 as a Pilot Project: Focus on HIV/AIDS
- Partners included WHO, UNICEF, UNFPA, UNAIDS and supported by World Bank
- Quickly expanded to include Tuberculosis, Malaria, Reproductive Health, Influenza and NTD products
- Alignment with WHO treatment guidelines and EML
- Funded mainly, but not exclusively, by donors – UNITAID and BMGF
- Fees introduced on 1 Sept 2013 (for new dossiers, major variations); the fee system will be modified soon

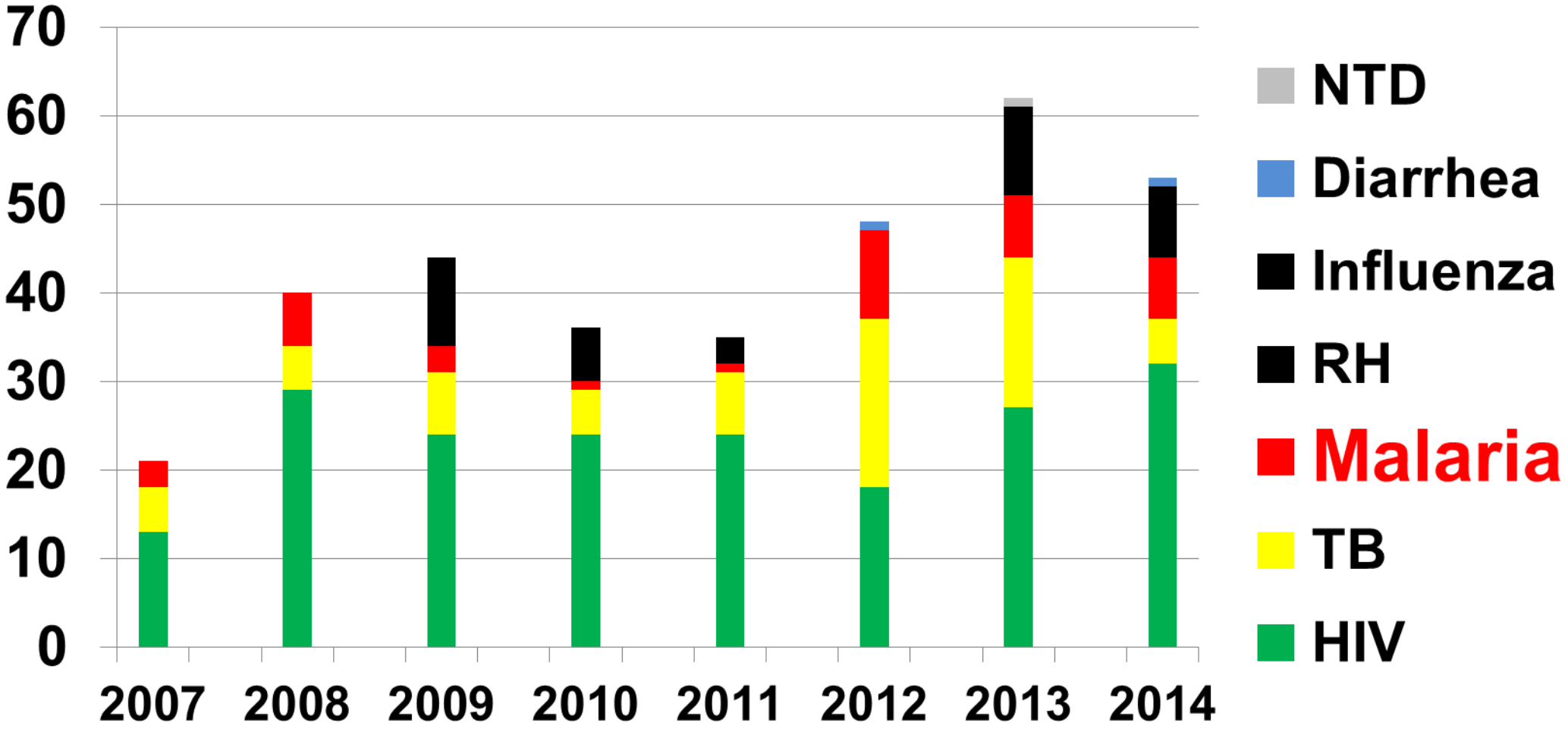
Prequalification process



Key outputs

- Published list of prequalified medicinal products (FPPs)
  - Used principally by UN agencies, including UNAIDS and UNICEF, and any other agency or organization involved in bulk purchasing of medicines, to guide their procurement decisions
- Published list of prequalified APIs
  - Can be used by FPP manufacturers to assure the quality of APIs
  - Can be used by NMRAs who wish to verify the standard of APIs that have been used to manufacture nationally registered medicines
- Published list of prequalified QC laboratories
  - The list may be used by any organization to ensure that testing for quality monitoring is done to an acceptable standard
- Advancing regulatory science - scientific articles, input to IGDRP
- Promoting collaboration – joint assessments, collaborative procedure

Products prequalified 2007- 2014



Current Prequalification Statistics

- Total of 417 products currently prequalified (12 March 2015). 53 prequalified in 2014: DI 1; HIV 32, IN 3, MA 7, RH 5 & TB 5
- Total listed as of 12 March 2015 (including those listed based on USFDA-PEPFAR/EMA Article 58/HC approvals): 513 products
- Majority of the prequalified products are for HIV/AIDS - 262 out of 417.
- 78 APIs currently prequalified (12 March 2015). 22 prequalified in 2014.
- 136 FPPs currently under assessment (12 March 2015)
- 62 APIs currently under assessment (12 March 2015)

Prequalification of APIs

Progress has exceeded expectations, due in part to the willingness of manufacturers previously involved with PQP to participate.

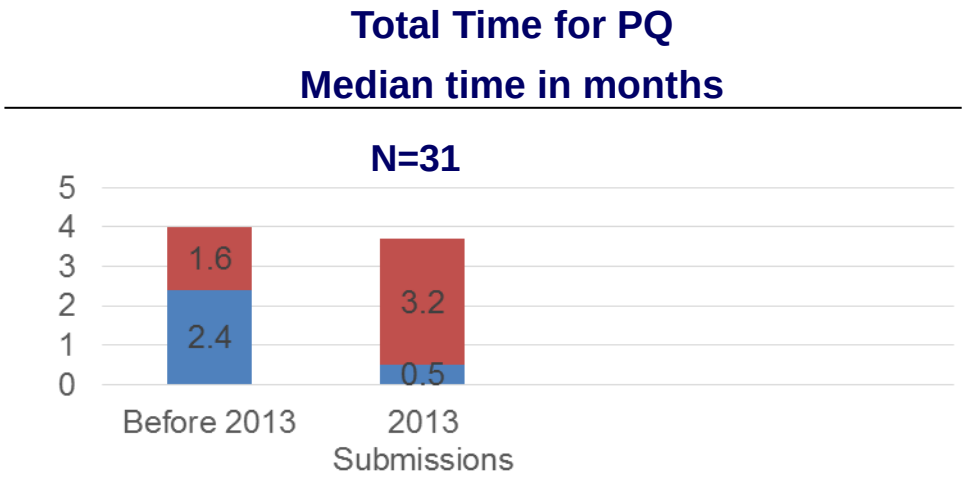
	Dec 2011	Dec 2012	Dec 2013	March 2015
Total number of applications (cumulative)	36	69	100	140
Number of PQ APIs (cumulative)	8	28	51	78

EFFICIENCY TREND IN WHO PQ TIMELINES - Medicines

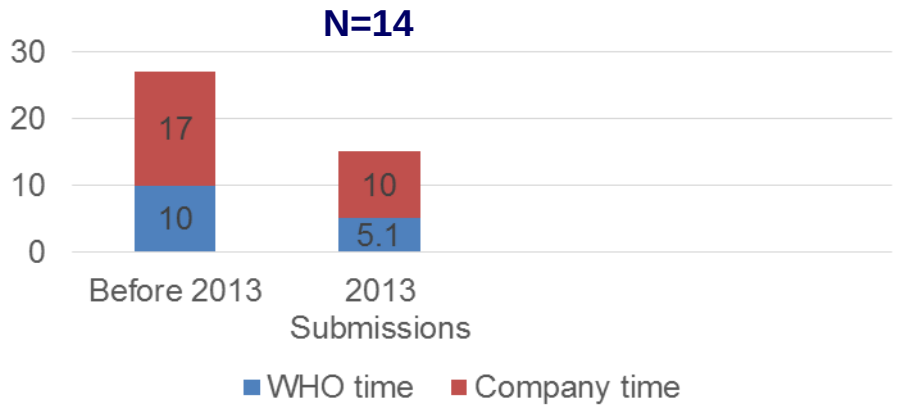
2013 Medicines Submission Cohort – Products Prequalified as of 31 December 2014

With Stringent Regulatory Authority approval[2]

(e.g. US FDA, EMA)



Without Stringent Regulatory Authority approval

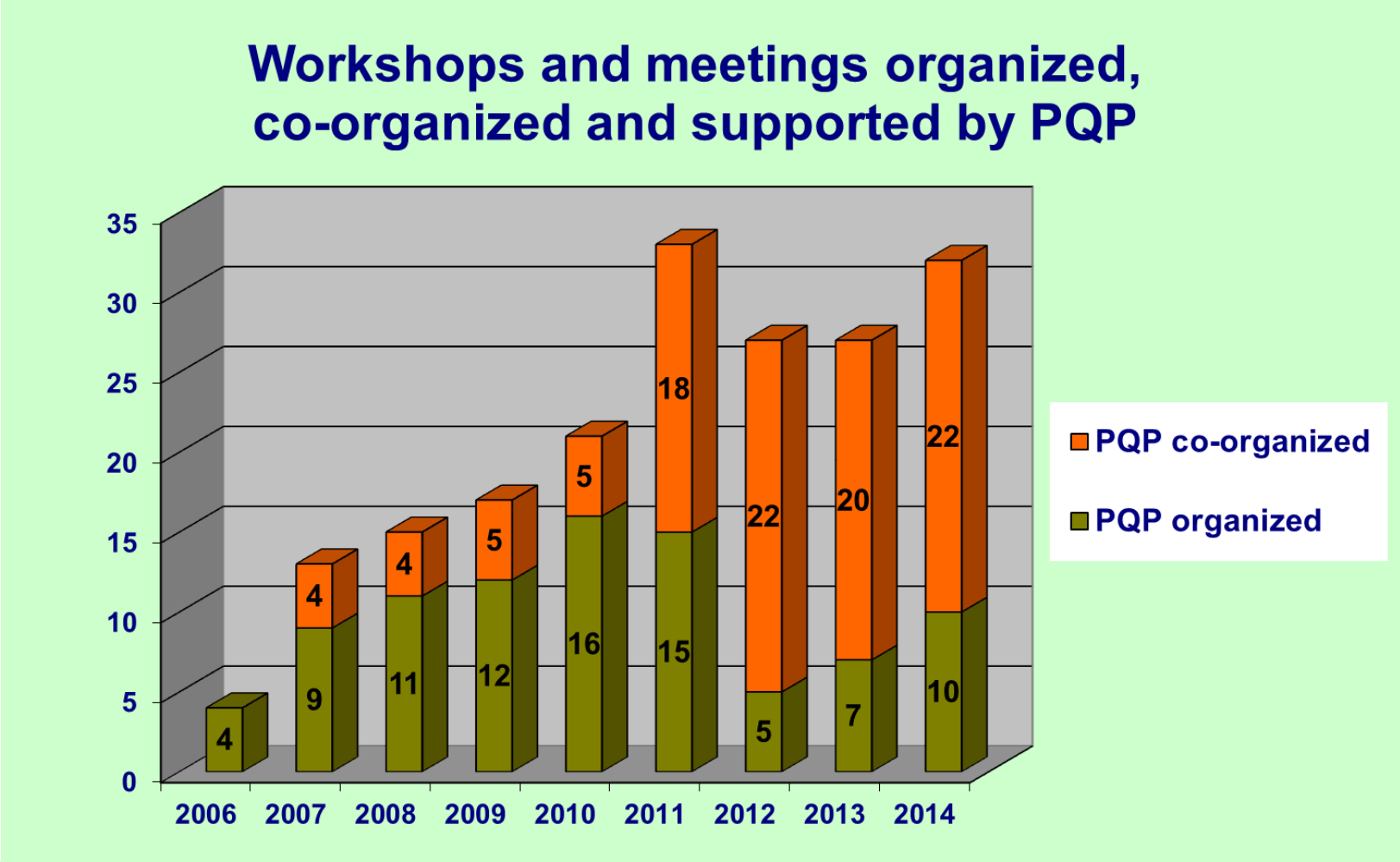


1. Factbase analysis; 2. Does not include US FDA PEPFAR or EU Art. 58 products (Automatically added to the PQ list)

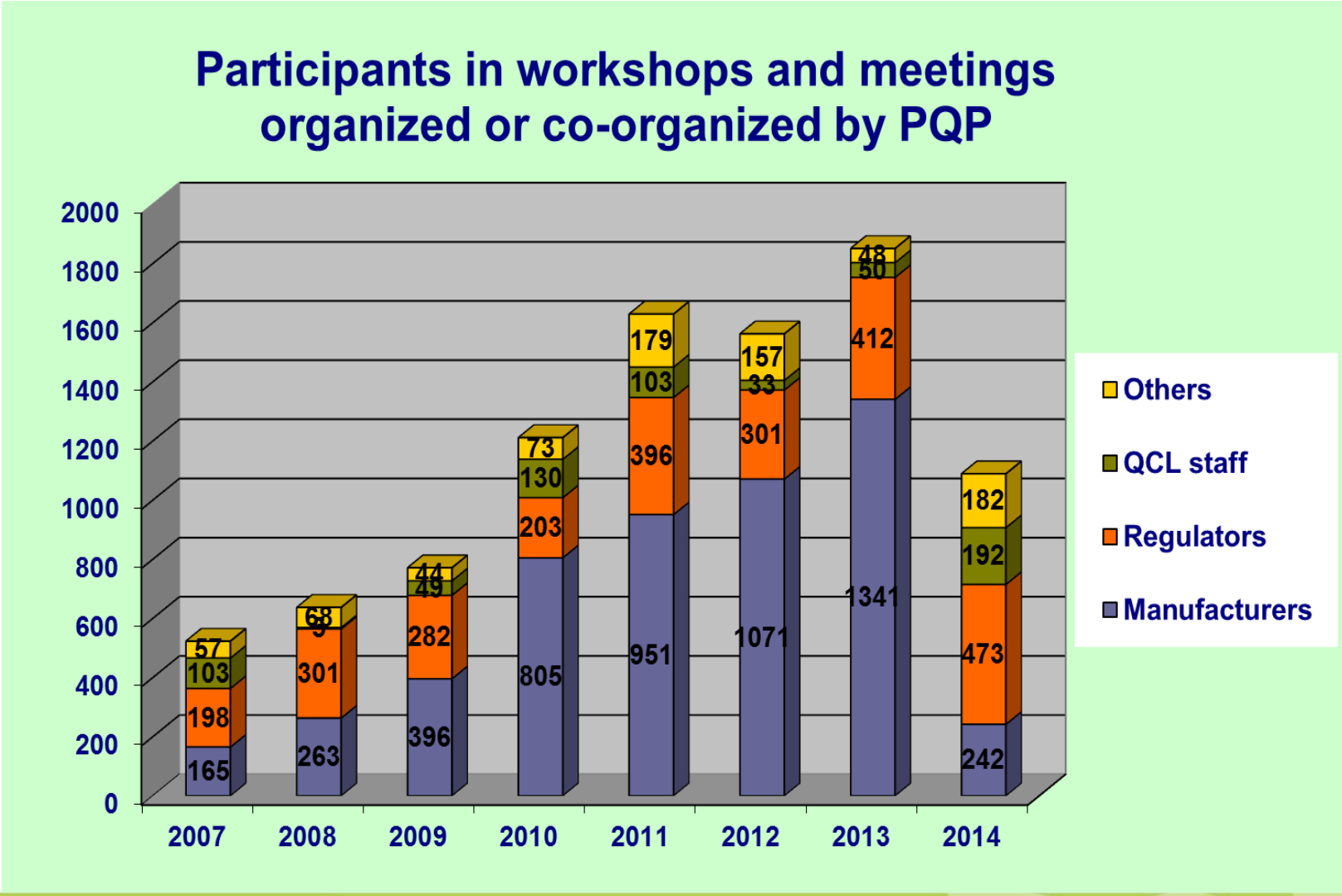
Capacity building

- **Seminars and workshops**
  - General – PQ procedures and WHO requirements
  - Annual PQ assessment training
  - Problem or product specific ; HIV/AIDS, TB, antimalarial or RH products
  - Pharmaceutical development/paediatric dosage forms
  - Training of NRA staff and manufacturers frequently combined
  - International experts frequently involved
  - Support is given to training organized by others
  - Focus on "training of trainers“
- **“Inclusive” (Assessments, Inspections), 3-4 month rotational post at WHO HQ; Zimbabwe, Uganda, Tanzania, Ethiopia, Kenya, Ukraine, Zambia, Botswana, Ghana, DR Congo, China, South Africa, Ghana, Nigeria etc.**
- **Within the assessment/inspection process, advisory meetings, review of protocols**
- **Technical assistance to eligible manufacturers**

Training workshops and meetings organized, co-organized or supported by PQT



Numbers of participants in trainings

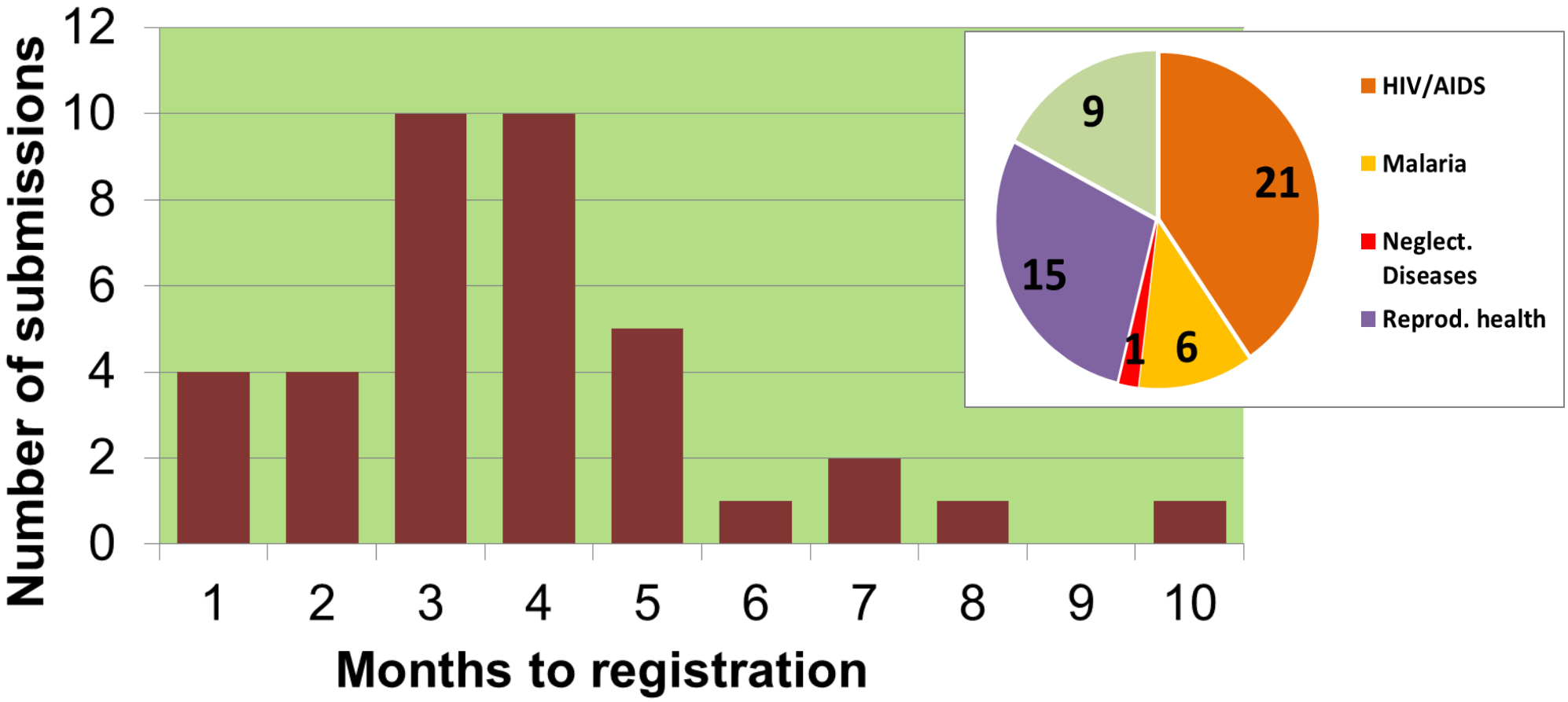


Regional harmonization of medicines registration to facilitate access to quality medicines

- African Medicines Registration Harmonization Initiative (AMRHI) – pilot in East Africa (EAC) – several partners, WHO providing technical support (assessments/ registration, GMP, IMS, QMS); extended to West-Africa next
- Joint assessment WHO PQT-EAC (Kenya, Tanzania, incl Zanzibar, Uganda, Rwanda and Burundi)
  - Prequalification and national registration as close as possible in time (successful pilot in 2010 with times to national registration reduced by 50% in EAC countries). Another round completed in 2014.
- Collaborative registration procedure (accelerated registration pilot project; started June 2012) – integrated as far as possible with AMRH activities
- Joint inspection (in EAC since 2010)
- Rotational fellowships continuing for assessors, new rotational positions for inspectors (Nigeria & China)

Collaborative procedure – timelines

74% approved within 4 months
47% approved within 3 months
Median time to registration is 93 days



web site: http://www.who.int/prequal/

Email: prequal@who.int

World Health Organization

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Dossier assessments
Prequalification of APIs
Inspections
Quality Control Laboratories
Quality Monitoring
Training material, workshops and meetings
Press and media

WHO - Health Systems and Services: Prequalification of Medicines Programme

:: Site Map

PREQUALIFICATION PROGRAMME
A United Nations Programme managed by WHO

Vision

Good quality medicines for everyone.

Mission

In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make quality priority medicines available for the benefit of those in need.

This is achieved through its evaluation and inspection activities, and by building national capacity for sustainable manufacturing and monitoring of quality medicines.

Strategy

- Apply unified standards of acceptable quality, safety and efficacy.
- Comprehensively evaluate the quality, safety and efficacy of medicinal products, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing and clinical sites.
- Prequalify sources of active pharmaceutical ingredients by comprehensively evaluating the quality of the API based on information submitted by the manufacturers, and inspection of the corresponding manufacturing sites.
- Prequalify quality control laboratories of pharmaceuticals.
- Build the capacity of staff from national regulatory authorities, quality control laboratories, and from manufacturers or other private companies, to ensure medicines quality.

Key output

LATEST NEWS

Current & Future Role of Generic Medicines in Increasing Access to Treatment: briefing (22 May 2013) during World Health Assembly

Acceptance of non-plant-derived-artemisinin

Information for manufacturers that experience delays in national registration of PQ'd medicines

Newly prequalified API

New PQP Variation Guidance - now effective

Guidance on BE studies for RH medicines

UNFPA 3rd invitation to manufacturers of Reproductive Health products

Collaboration with NMRAs to accelerate registration of PQ'd medicines

All News

QUICK LINKS

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Prequalified Medicines

Concluding remarks