Stakeholders Workshop on Pilot of the Collaborative Registration Procedure (CRP) of Vector Control Products

Cotonou, Benin
28 -29 September 2023

Overview of the workshop objectives, agenda and approach

Marie Valentin
Team Lead
WHO

World Health Organization

Objective of the meeting

Identify **needs and challenges for facilitated product introductions of prequalified vector control products.**

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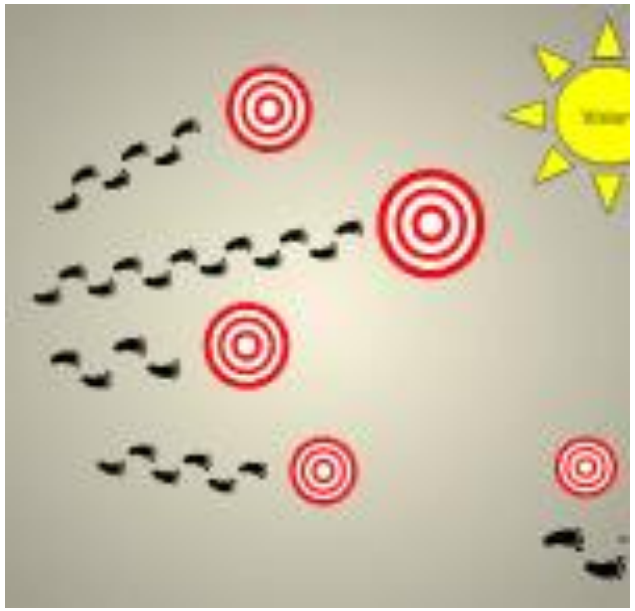
Specific objectives



To share experience and strategize on how address to improve access to WHO-prequalified vector control products,

To discuss ways to facilitate registration of Vector Control products through reliance mechanisms;

To discuss and agree on criteria for participating in the pilot CRP for VCP (identify countries and products);

To agree on action points (short-term, midterm and long-term) towards implementation of the prospective CRP for VCP.

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AGENDA - Day 1

Day 1	**Moderator:** AFRO	
08:30 - 9:00	Registration	*All*
09:00 – 09:20	Welcoming and opening remarks Introductions	*Angus Spiers, Director, I2I* *WHO AFRO or Marie Valentin, WHO/REG/FPI*
09:20 – 09:30	Overview of the workshop objectives, agenda and approach *(10 minutes presentation)*	*Marie Valentin, WHO/REG/FPI*
09:30 – 10:00	Fighting vector-borne diseases by optimizing vector control tools *(20 minutes presentation and 10 minutes of discussion)*	*Angus Spiers, Director, I2I*
10:00 – 10:30	Coffee break	*All*
10:30 – 11:15	Overview of Facilitated Product Introduction pathways *(30 minutes presentation and 10 minutes of discussion)*	*Agnes Sitta Kijo, WHO/REG/FPI*
11:15 – 12:00	Collaborative Registration Procedure: overview, mechanisms, tools, achievements *(30 minutes presentation and 10 minutes of discussion)*	*Sunday Kisoma, WHO/REG/FPI*
12:00 – 12:30	Reliance and collaborative approaches on in country registration of vector control products *(20 minutes presentation and 10 minutes of discussion)*	*Angus Spiers, Director, I2I*
12:30 – 13:30	Lunch Break	*All*
13:30 -14:30	Overview of WHO Prequalification and Vector Control Prequalification Stream • Product Assessment; • Site Inspections; • Prequalification output and life cycle maintenance. *(45 minutes presentation and 15 minutes of discussion)*	*Dominic Schuler, WHO/PQ/VCT*
14:30 – 15:00	Coffee Break	
15:00 – 16:00	Panel Discussion: Country approaches and methods to vector-borne diseases control and status of VCP regulation. *(60 minutes of Q&A))*	*Panel discussion* *Moderator: Marie Valentin, WHO/REG/FPI* *Panelists:* • *Kenya* • *Uganda* • *Tanzania* • *Nigeria* • *Burkina Faso* • *Rwanda* • *Democratic Republic of Congo (DRC)* • *Ethiopia*
16:00	***End of day one***	

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AGENDA - Day 2

Day 2	***Moderator:*** *Angus Spiers, Director, I2I*	
09:00 – 10:30	WHO Prequalification of vector control products: Manufacturer's perspectives and envisaged support to CRP - VCP *(60 minutes presentations (20 minutes each) and 30minutes of discussion)*	*Panel discussion* *Moderator: Dominic Schuler WHO/PQ/VCT* *Panelists:* • *Manufacturer of PQed VCPs* • *Manufacturers of VCP under PQ* • *Vector Control Development Partner*
10:30 – 11:00	Coffee break	*All*
11:00 – 13:00	Collaborative registration procedure for WHO prequalified vector control products (CRP – VCP): *Proposed* Pilot incl tools and sources of information to support CRP-VCP *(60minutes presentation)* Reflections, Questions and Answers • reflections in line with existing registration framework; • what could work; • challenges foreseen; • solutions and what could be achieved; • readiness for participating in the pilot; signing of CRP agreements for pilot phase *(60 minutes discussion)*	*Agnes Sitta Kiio, WHO/REG/FPI* *Ana Rita Nogueira WHO/REG/FPI*
13:00 – 14:00	Lunch break	*All*
14:00 – 14:30	Summary of discussions and next steps	*Marie Valentin, WHO/REG/FPI* *Ana Rita Nogueira WHO/REG/FPI*
14:30 – 15:00	Coffee /discussion	*All*
15:30 – 16:00	Closing	*Angus Spiers, Director, I2I*
16:00	**End of day two and adjourn**	

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Thank you for your attention!

For more information, please contact:
Marie Valentin
valentinm@who.int

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Overview of the Vector Control Landscape

Case for change in the adoption of new tools

Draft

Introductions | Innovation to Impact

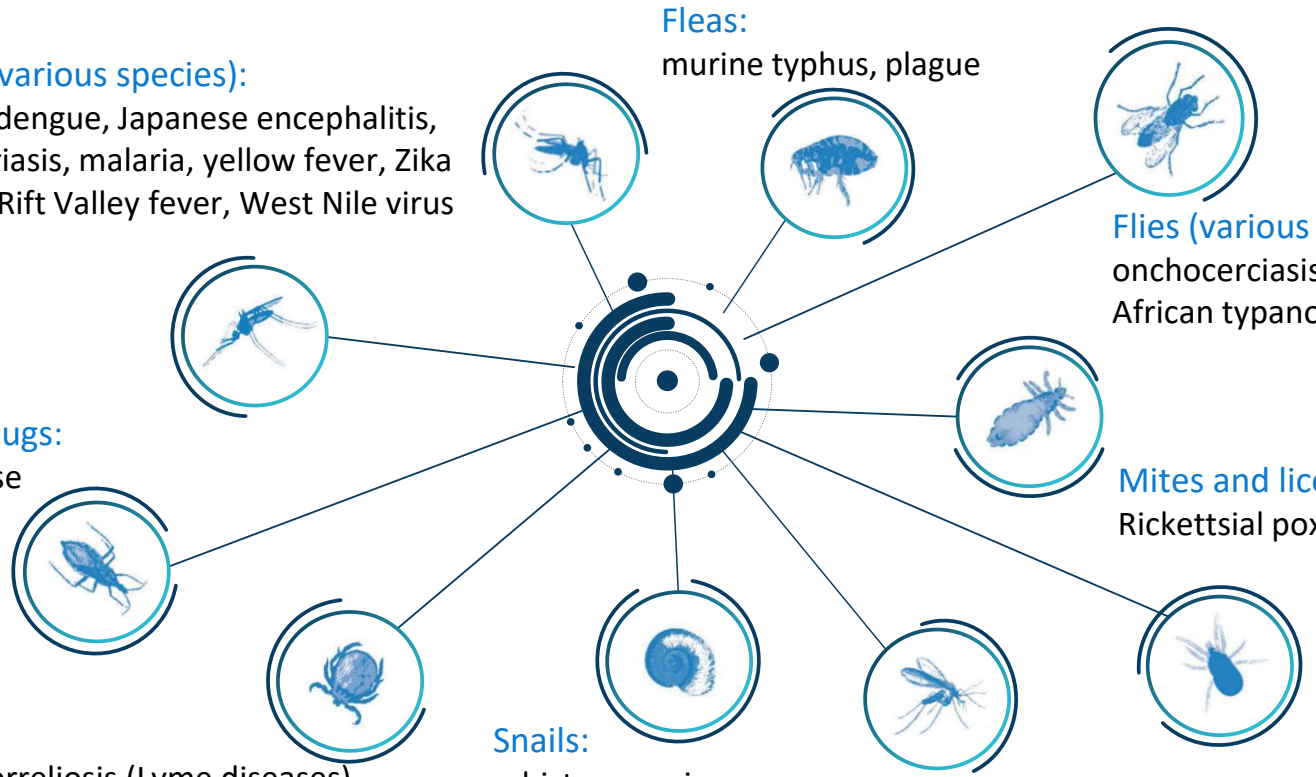
Mission

To promote innovation, efficiency and quality in vector control product development by working together with all the stakeholders involved in developing and bringing new vector control tools to market, identifying shared obstacles & catalyzing solutions

Vision

A product development environment conducive to innovation and investment which efficiently delivers a steady stream of new, quality vector control tools to those who need them most, then safeguards their continued effectiveness

Vector-borne diseases are varied and disproportionately affect sub-Saharan Africa



Risk

80% of the world's population is at risk of one or more vector-borne disease

Mortality

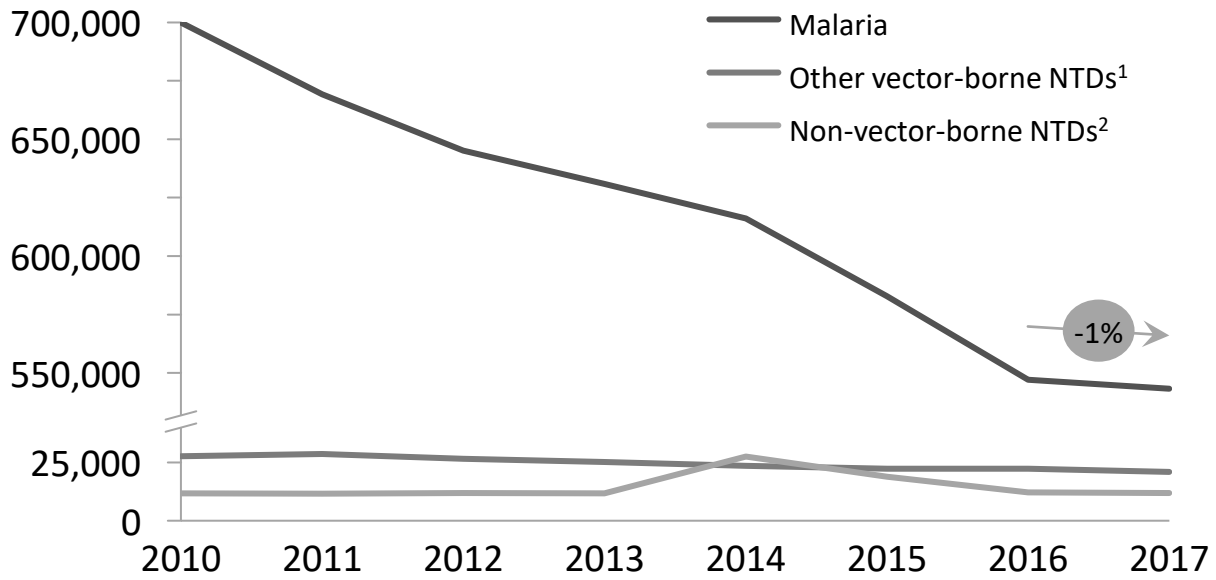
Over 700,000 deaths are caused by vector-borne diseases annually, 80% of which are in sub-Saharan Africa

Sources: WHO Global Health Observatory & Global Health Estimates; Global vector control response 2017-2030

Despite strong progress, vector-borne diseases & NTDs continue to impose a significant challenge on African development

Significant progress made against malaria pre-2016, but limited progress for other NTDs & stalling momentum…

Number of deaths in Sub-Saharan Africa



…with continued, significant social & economic cost

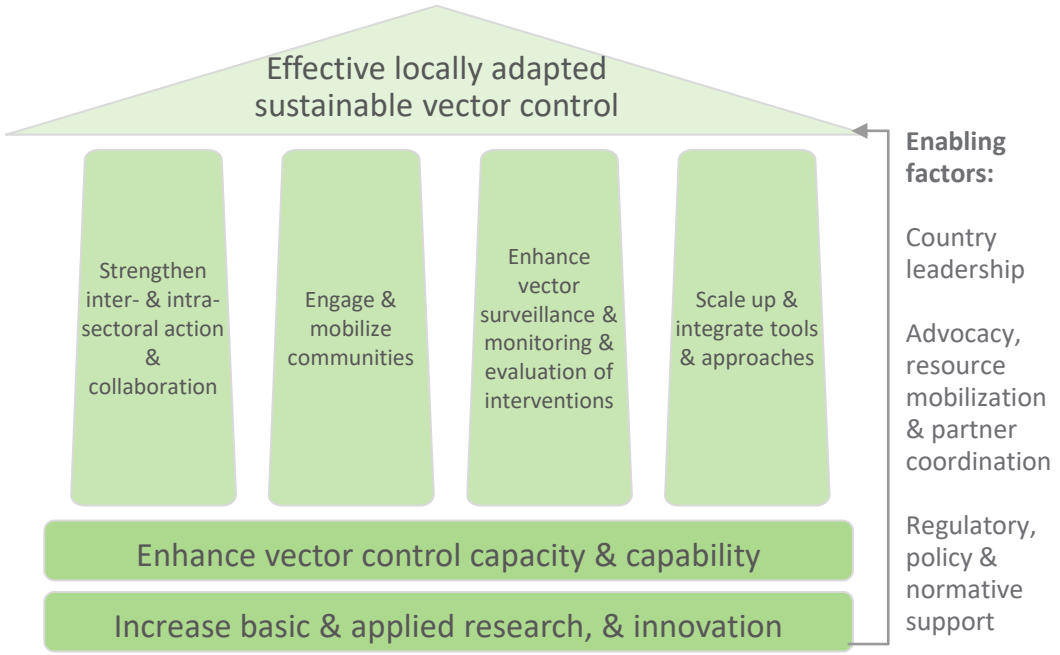
Example impacts of disease prevalence

- Malaria continues to slow economic growth by 0.25-1.3% per year and strains public health systems, accounting for up to 40% of spending in high-transmission settings
- The daily economic burden for a dengue illness infection can be 0.7 – 5X an individual's average daily income[3]
- 10% increase in malaria incidence correlates to 0.1 years of schooling missed and literacy reduction of 1-2 percentage points

1. African trypanosomiasis, Ascariasis, Cystic echinococcosis, Cysticercosis, Dengue, Hookworm disease, Leishmaniasis, Thricuriasis, Schistosomiasis, Yellow fever; 2. Ebola, Rabies, Food-borne trematodiases, leprosy, podoconiasis, arthropod-borne viral infections, bacterial relapsing fevers, unspecified protozoan diseases and helminthic diseases for which data is available; 3. Uses the average daily cost of dengue illness in Burkina Faso and Kenya divided by the average daily income in those countries, respectively. Sources: WHO Global Health Observatory & Global Health Estimates; IHME Global Burden of Disease Study 2017; RBM Action and Investment to Defeat Malaria 2016-2030; Lee J-S, Mogasale et al. (2019) A multi-country study of the economic burden of dengue fever based on patient-specific field surveys in Burkina Faso, Kenya, and Cambodia. PLoS Negl Trop Dis 13(2)

Eliminating vector-borne and other Neglected Tropical Diseases is a global agenda

The WHO has developed an integrated strategy to reduce the burden of vector-borne diseases: Global Vector Control Response 2017-2030



The African Union has also highlighted a focus on the prevention of malaria & Neglected Tropical Diseases (NTDs)

One of AU's key health objectives is the continent-wide elimination of malaria by 2030[1]

The AU also created the Africa Center for Disease Control and Prevention in 2017; one strategic objective is to support health systems strengthening by addressing NTDs

AFRICA CDC

Finally, AU launched the Zero Malaria Starts with Me campaign in 2018, with the goal of building country ownership, awareness and political commitment to malaria elimination

1. Agenda 2063, Catalytic Framework to End AIDS, TB and Eliminate Malaria by 2030
Source: WHO Global vector control response 2017–2030 (GVCR)

Vector control products are key in the fight against vector-borne diseases through prevention of new cases

Sample vector control products and impacts on malaria

Insecticide treated bed nets (ITN)

Single most important contributor to decline of malaria cases between 2000 and 2015, responsible for 451 million averted cases

Half of people at risk in Africa are estimated to be sleeping under an ITN at a median cost as low as $2.20 per person per year

Indoor residual sprays (IRS)

Depending on location, malaria infections have been reduced from between 30% and 90% by deploying IRS products; between 2000 and 2015 IRS are responsible for 66 million averted cases

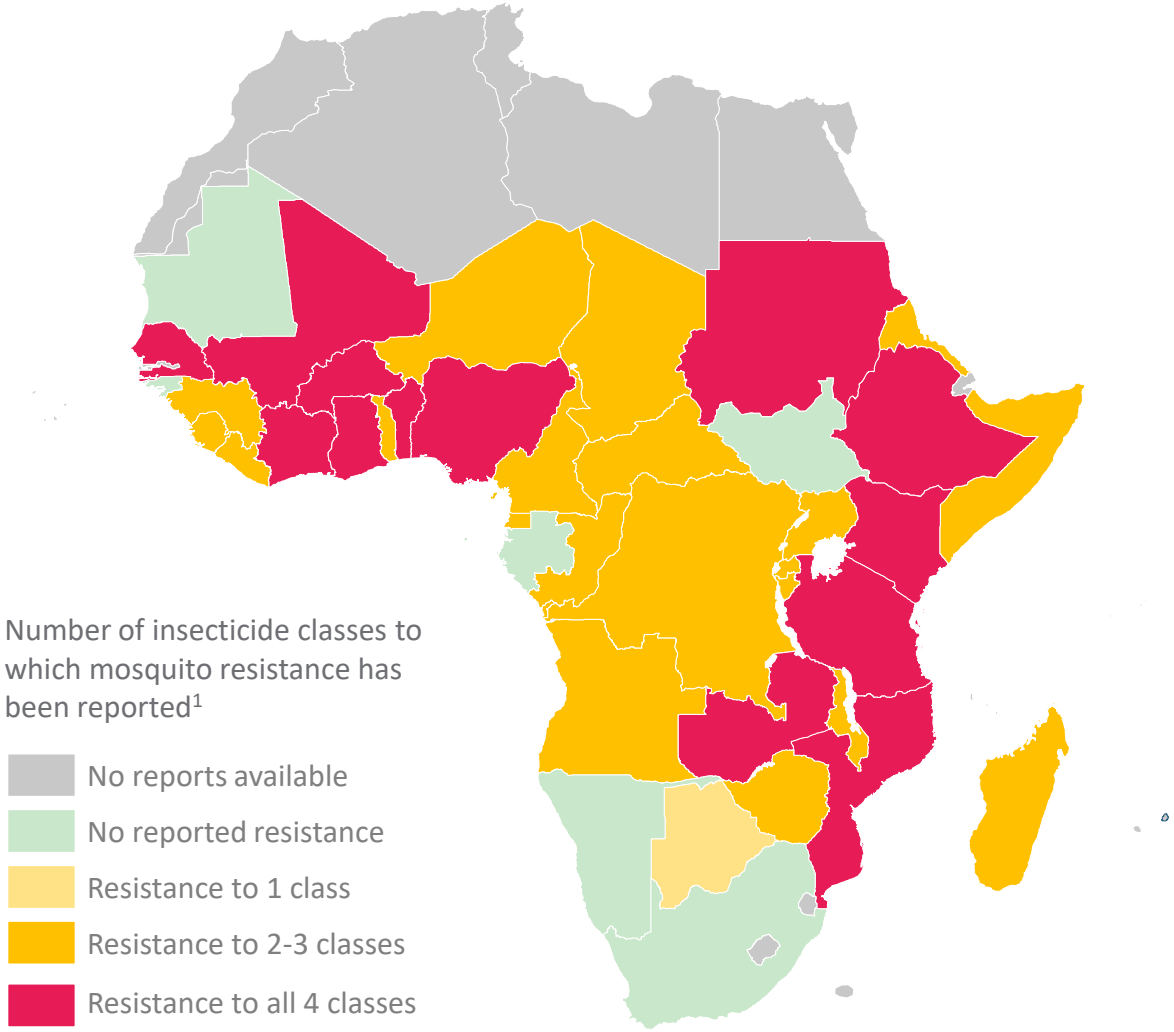
An estimated 3% of African population at risk is protected by IRS at a median cost of $6.70 per person per year

Both nets and sprays are also used to effectively control other vector-borne illnesses

Sources: WHO World Malaria Report 2018; WHO Global Insecticide Use for Vector-Borne Disease Control 2000-2009, The effect of malaria control on Plasmodium falciparum in Africa between 2000 and 2015, Nature 526, 207-211 (2015); Costs and cost-effectiveness of malaria control interventions - a systematic review. Malar JJ 10:337 (2011)

However, resistance to insecticides used in vector control products has been steadily increasing

…leading to a risk for resurgence of disease

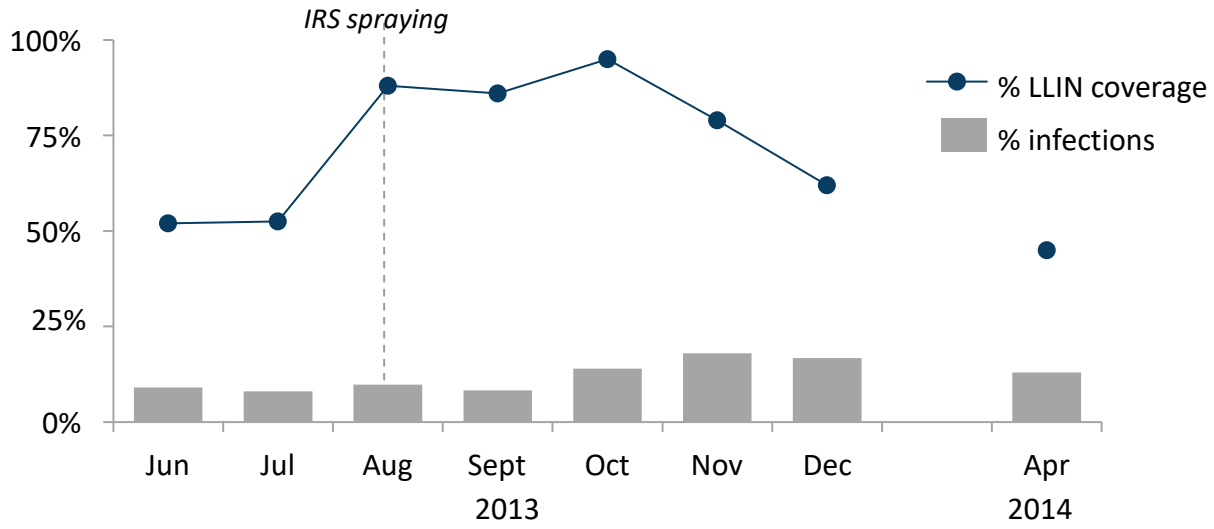


1. Four major classes are Pyrethroids, Organochlorines, Organophosphates & Carbamates
Source WHO Global report on insecticide resistance in malaria vectors 2010-2016

Furthermore, existing VC products are insufficient to eliminate the deadliest vector-borne disease: Malaria

Despite high coverage of control interventions, residual malaria transmission can still be prominent…

Infection rates in The Gambia despite mass distribution of LLINs and annual IRS spraying with DDT



… meaning further tools are required to achieve elimination

Reasons for residual transmission

- Avoidance of treated indoor surfaces
- Feeding on unprotected humans outdoors

Some strategies for tackling residual transmission

- Provide indoor protection to individuals who are not sleeping under nets
- Provide outdoor protection to humans
- Modify mosquito population genome to affect fertility / ability to transmit

Sources: Mwesigwa J, Achan J, Di Tanna GL, Affara M, Jawara M, Worwui A, et al. (2017) Residual malaria transmission dynamics varies across The Gambia despite high coverage of control interventions; Characterizing, controlling and eliminating residual malaria transmission, Malaria Journal 2014 13:330; Guidance note on the control of residual malaria parasite transmission, WHO 2014

A new generation of products is being developed…

Examples of novel VC product groups

Novel pesticides

New chemical combinations to which vectors are not yet resistant

Attractive targeted sugar baits

A sugary and scented substance that attracts mosquitoes, ticks and other vectors and poisons them

Passive Emanators

Products that emanate repellent insecticides to deter mosquitoes

Endectocides

Drugs, such as Ivermectin, that have the potential to kill mosquitoes when taken preventatively in humans

…but timely access will be crucial to address these issues

Questions regulators are asking

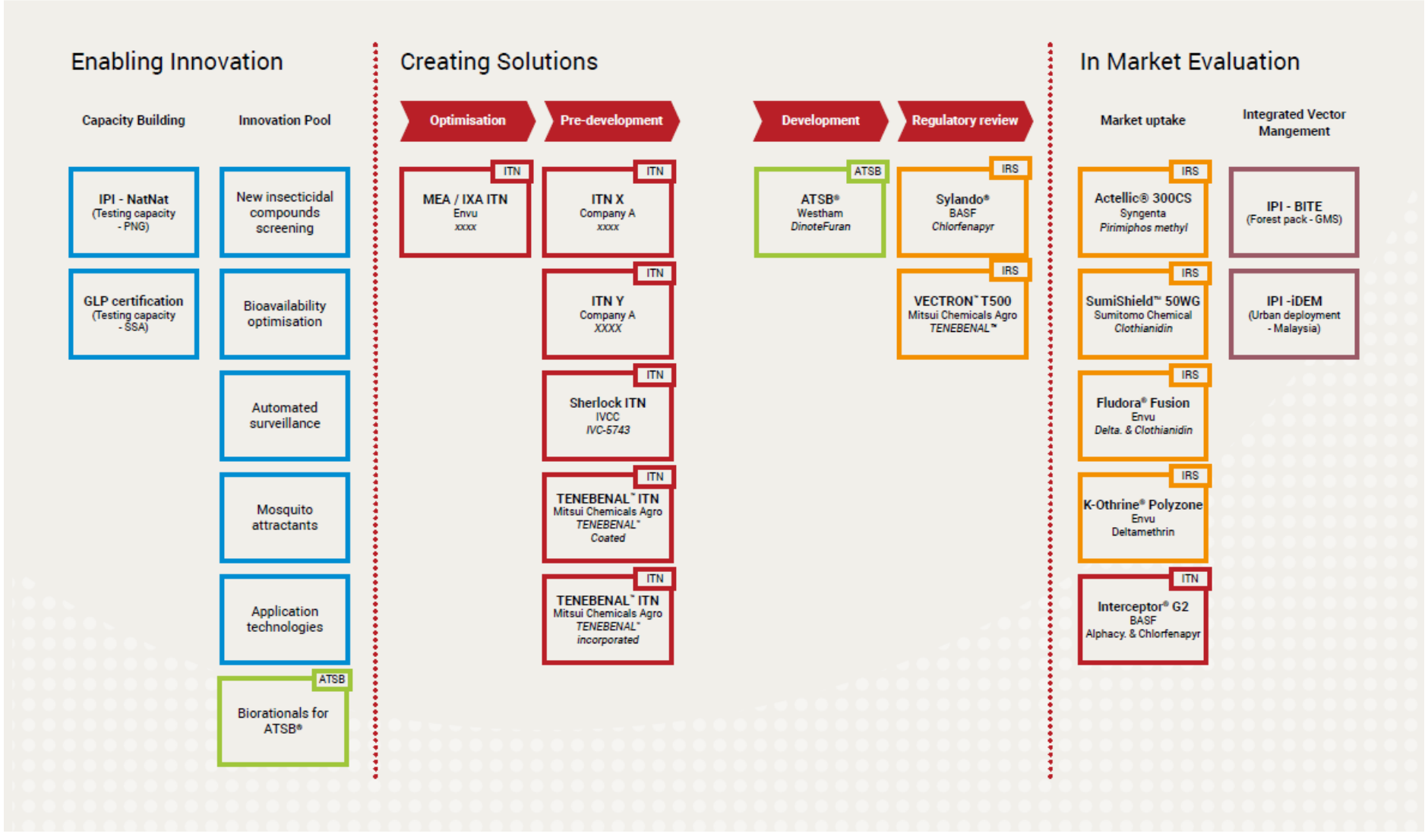
Which bodies/ministries should assess novel products?

Which standards should be used for these novel products?

How do we deal with **cross-border impact** of these novel products?

IVCC Development Portfolio

IVCC Product Development Portfolio



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We have heard interest from all types of stakeholders to see increased collaboration for Vector Control regulation

Regulators

We don't know what's on the cutting edge for vector control. We need standard guidelines and want to learn from more experienced regulators and authorities.

I see great benefits in terms of time and quality with a regional system, where certain activities like inspections and safety evaluations are done jointly.

Industry

We could get products to market much quicker if countries across the continent had standardized requirements and procedures for vector control.

We spend a lot of time while regulators review findings already approved by the WHO PQ process. We could speed up the process greatly if they could collaborate.

Procurers

We rely on WHO PQT-VC to indicate what to buy, and it would be fantastic if country regulators could leverage those assessments.

There is a great opportunity for regional and global stakeholders to help grow vector control expertise and streamlined processes at the country level.

The WHO Prequalification process is a rigorous VC product evaluation system, offering a significant opportunity for regulators

WHO prequalification team (PQT) was set up to evaluate VC products…

- PQT-VC replaced WHOPES as the WHO evaluation process for VC products
- PQT-VC assesses product dossiers, inspects manufacturing sites and supports quality-control
- The WHO PQT-VC publishes a list of (a) prequalified VC products and (b) manufacturing sites for public health pesticidal active ingredients

… that could help increase both speed and quality of decision-making at country level

Can lower burden on regulatory authorities through information and analysis sharing

Can enable capacity building through exchanges between vector control experts

Can work with stakeholders to set standards for a new generation of vector control products

Partnerships in other areas have already demonstrated high impact and addressed similar challenges

WHO Collaborative Registration Procedure (CRP)

Allows regulators to leverage WHO assessments, and has reduced median registration time for in-scope medicines from >1 year to <3 months for 25 African member states

Comité permanent inter-État de lutte contre la sécheresse au Sahel[1] (CILSS/COAHP)

Enables manufacturers to register pesticide products in 12 member states through a single, 2-3 month joint review process

EAC Medicines Regulatory Harmonization (MRH)

Builds regulator capacity and reduces assessment duplication via joint review process, with a reduced lead time from application to decision from 2-4 years to 225 days

This is a critical moment in the fight against vector-borne diseases

We need to engage now to seize this opportunity and access new, effective tools

Thank you

Stakeholders Workshop on Pilot of the Collaborative Registration Procedure (CRP) of Vector Control Products
Region/Countries: WHO AFRO region
Venue: Azalai Hotel, Cotonou, Benin
Dates: 28-29 September 2023

Introduction to Facilitated Registration Pathways and Collaborative Registration Procedure (CRP)

Agnes Sitta Kijo
Technical Officer, Facilitated Product Introduction
Regulation and Prequalification Department
WHO

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Facilitated Regulatory Pathways (FRP) as a solution to NRAs

When timely access to quality-assured products is compromised…

NRAs carry great responsibilities in ensuring timely access to quality assured products to their population

Internal factors: low maturity of many regulatory systems, lack of resources and expertise in-house, and ack of collaboration between countries

External factors: increasing complexity of supply chains and global challenges, such as health emergencies

- Overwhelm NRAs - lengthy regulatory approvals of much needed medical products
- Patients' timely access to much-needed quality-assured medicines is compromised

FRPs, as a solution for NRAs and public health

FRP are a type of regulatory pathways available to NRAs, which are meant to facilitate and accelerate the regulatory decisions and the introduction of quality-assured products in countries, through the use of the concepts of reliance and collaboration. When well implemented:

What are Facilitated Regulatory Pathways (FRPs)?

- NRAs leverage on the work performed by others, improving efficiency of the regulatory systems by avoiding duplication of regulatory efforts and work
- NRAs optimize the use of human and financial resources and increase expertise and build capacities
- NRAs reduce the time nedeed to process a product application and reduce workload and backlog at NRAs
- NRAs perform science-based and transparent regulatory decision-making, while maintaining national independence on their decisions
- NRAs ensure timely access to priority quality-assured products in countries.

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What are the FRPs available?

What is their relation with CRP?

Level of effort, work, resources, expertise, time and duplication

Facilitated Regulatory Pathways

New Assessment

Full/Accelerated assessment

Assessment of full product dossier conducted by the NRA

New Assessment

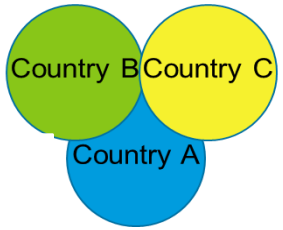
Joint Assessment

E.g. Assessment conducted jointly by 2 or more NRAs (full review or with reliance) - EU centralised procedure, **ASEAN** JA or EAC JA

New Assessment

Work-sharing

E.g. when it is agreed between 2 or more NRAs that only 1 NRA assesses (full review or with reliance) and the remaining ones grant MA based on that assessment. - EU decentralized procedure, ZAZIBONA

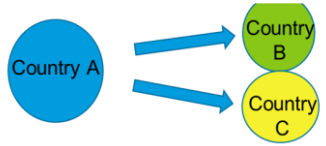


Selection of FRP for a product based on the risk-based approach of each NRA

Existing Assessment

Reliance

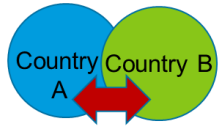
E.g. Secondary and abridged reviews of existing primary reports generated from "SRA" or WHO PQ – CRP and EU mutual recognition



Existing Assessment

Recognition

E.g. Product approval based on "SRA" or WHO PQ. Verification of the sameness without further review or assessment of product information. - CRP



Mutual recognition

Unilateral

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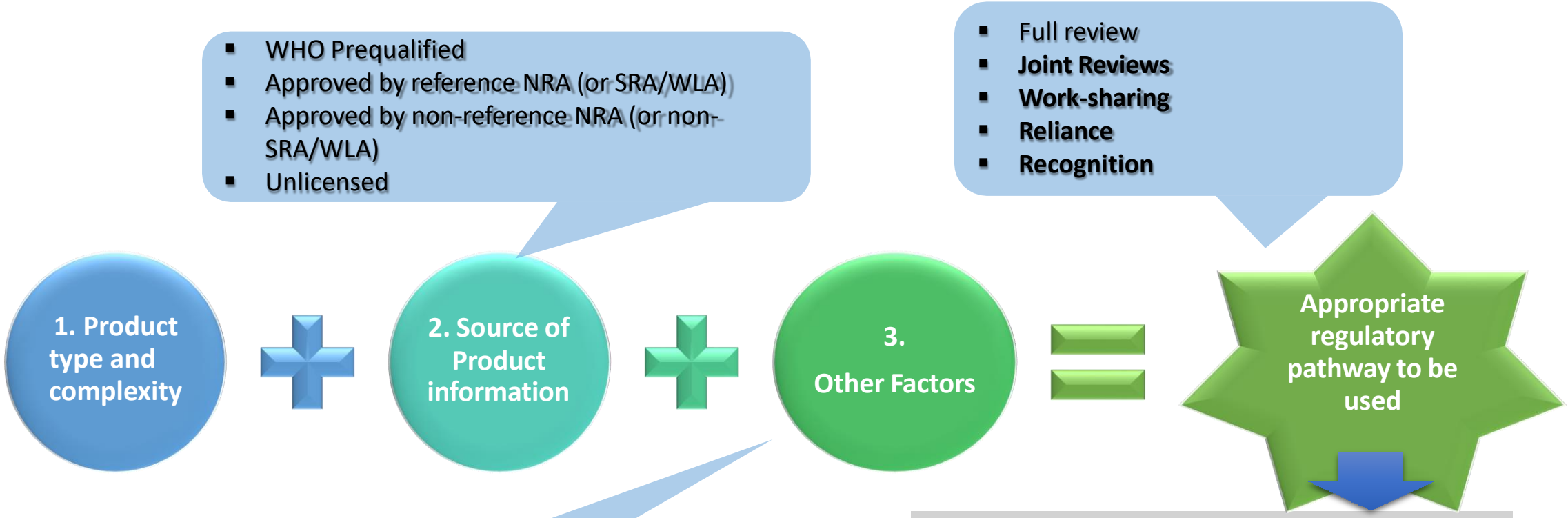
Level of collaboration, reliance and efficiency

Regulatory Risk-based approach to implement pathways:

Key considerations for Good Regulatory decision-making processes for quality-assured products



Each NRA should define its **own strategy for an appropriate risk-based approach for MA**

define/select facilitated pathways available at the NRA based on its context

The availability of FRPs, their appropriate use (i.e. adequate selection and implementation)
Good Regulatory Decision Making at NRA

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But how can NRAs apply FRPs in a confident manner?

WHO supports countries and coordinates mechanisms that facilitate regulatory decisions and products introduction by countries

WHO FPI Webpage: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction

Aligned with WHO GRP and WHO GRelP

1. Support to countries for the implementation of FRPs, as part of implementation of CRP and other Reliance approaches

- Individual countries, through CRP and RJA
- Regional systems, through CRP and RJA

2. WHO Mechanisms for collaboration/reliance between countries:

- Collaborative Registration Procedure (CRP)
  1. WHO Prequalified products
  2. SRA assessed and/or approved products
  3. Pilot on CRP-lite with FDA on HIV products
- Programmes aimed to facilitate and accelerate product registration and introduction in countries for specific public health needs and emergencies, e.g. COVAX (COVID-19 vaccines)

3. WHO supported activities for collaboration and Work-

- Technical support to Regional Joint Assessments and work- sharing arrangements among cooperating countries (ASEAN JA, African Regional JAs, CRS)
- EU-M4All Procedure & Swissmedic MAGHP program, which aim to facilitate product introduction in countries based on reliance, following EMA opinion or Swissmedic approval
- Reliance projects or programmes, such as Reliance for Post-Approval changes

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Example of FRP- Collaborative Registration Procedure (CRP)

WHAT it is and HOW does it work?

CRP facilitates exchange of information to accelerate national registrations in countries through the provision to NRAs of detailed assessment and inspection reports generated by reference NRAs/PQ

Applicant

Single product dossier

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Prod. Assessment Reports from SRA/PQ

To multiple CRP participating country(s)

Accelerated assessment and registration of quality-assured products in countries

Faster access to priority quality-assured products by the population

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Implementation of FRP in countries

5 fundamental questions NRAs need to answer to properly implement FRPs, incl. CRP:

1. Do the **national regulations of your country allow your NRA to apply reliance approaches towards MA activities**? On the contrary, do they impede the use of reliance in your NRA for MA? If yes, is there an opportunity for your NRA to incorporate reliance provisions as part of upcoming revisions of the NRA legal framework?

2. Are there **guidelines, policies or regulations at the NRA that define the reference authorities or institutions** in which your NRA can rely upon?

3. Are there **Guidelines to guide stakeholders on the existing facilitated pathways at the NRA,** respective Admin and technical requirements (for initial appoval and PAC)?

4. Are there **internal procedures/SOPs to guide the NRA staff on the process of facilitated pathways applications**, respective procedures to be followed and requirements to be met (for initial appoval and PAC)?

5. Did the **relevant NRA staff received adequate training on the procedures above to process FRPs**, including technical trainings?

WHO support

1. WHO individual meetings/trainings: Applicants-WHO

2. WHO Advocacy meetings/Workshops on CRP to applicants

3. Annual Meeting on CRP – open sessions to applicants

4. Regular interactions with applicants through different channels to support the applications

5. The first 1-3 products/submissions, WHO to follow-up closer with applicants and NRAs to provide support.

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- It is overwhelming for NRAs at all maturity levels to fulfil all regulatory work alone and independently from other regulators;
- **There are several tools nowadays available to NRAs and Industry to facilitate the regulatory decisions**, ensuring timely access to quality-assured products in countries and good regulatory-decision making. FRPs and mechanisms such as CRP and Joint assessments, are some of those tools available, using the concept of collaboration, reliance and work-sharing between NRAs, which is the future of medical products regulation.
- Applying those concepts, **NRAs and industry are able to make the best with their available resources and time**, reducing duplication of efforts and workload.

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Questions and Answers

Agnes S. Kijo
Email: kijoa@who.int

Stakeholders Workshop on Pilot of the Collaborative Registration Procedure (CRP) of Vector Control Products

Cotonou, Benin
28 -29 Septembre 2023

Overview of Collaborative Registration Procedure

Sunday Kisoma,
Consultant, Facilitated Product Introduction,
WHO – MHP/RPQ/REG/FPI

CRP mechanisms and product scope

PQ CRP - products prequalified by WHO via full assessment:

- Medicines
- Vaccines
- Biotherapeutics
- IVDs
- Applies to therapeutic areas in the scope of PQ

SRA CRP - any product assessed or approved by an SRA:

- Innovative and generic products (chemicals or biologicals): Medicines/Pharmaceuticals, multisource/generics, vaccines, biosimilars, biotherapeutics, etc.
- Products Prequalified by WHO via Abridged review (SRA approved)
- Products approved by special routes or provided with positive scientific opinion: US FDA tentative approval, EU M4-all (Article 58), Swissmedic Marketing Application for Global Health Products.
- Applies to any therapeutic area

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CRP Process (PQ CRP or SRA CRP)

1. Source of Information to rely upon:

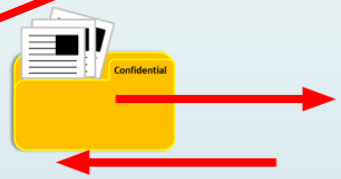
2. Documentation to be shared:

3. Actions for different stakeholders

WHO PQ

Reference Authorities (SRAs)

Applicant and WHO



a) Full Product Dossier (ICH CTD format)
b) Detailed Assessment reports (scientific evaluations, Inspections/audit reports, performance evaluation)
c) QIS validated by SRA or WHO

Applicant

Submission

NRA

NRA Review: Recognition or Reliance - 90 working days (regulatory time)

Approval / Rejection

Lifecycle management

Variations
NRA Review: Recognition or Reliance - 30 working days (regulatory time)

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Fundamental requirement : Sameness of product

1. **Same product dossier**;
2. Same **qualitative** and **quantitative** formulation,
3. Same **manufacturing site(s)** for drug substance and drug product,
4. **Same manufacturing chain, processes, control of materials and finished product**, and in the case of vaccines also by the same batch release scheme;
5. **Same excipients, active ingredient and finished product specifications**;
6. the **same essential elements of product information for pharmaceutical products**, in the case of vaccines by the same product information, packaging presentation and labelling.
7. Same provisions as for SRA CRP medicines, vaccines, and therapeutics
8. Add: Specific national requirements
   - application fees
   - product samples ..sometimes API samples
   - quality information summaries
   - site inspections

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CRP win-win outcomes for all concerned stakeholders

NRAs

- Providing a **convenient tool and procedure for NRAs wishing to apply reliance,** allowing them to **leverage the work performed by other** authorities, and **making their registration system more efficient and responsive** to the country population needs
- Having access to **data well organized in line with international and stringent requirements** - Availability of detailed SRA/WHO assessment and inspection outcomes
- **Opportunity for well-informed and quality decision-making** at NRAs, **saving efforts, resources** (human and financial) and **time**, maintaining their national independency
- **Capacity Building component** – NRAs can learn from SRA/WHO assessment reports
- **Introduction of quality-assured products** in the country in a **faster** manner.

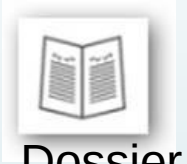
CRP win-win outcomes for all concerned stakeholders

- Providing a procedure to facilitate and accelerate national registration processes, with appealing registration timelines;
- Only one single dossier for multiple countries - harmonized data for national applications and registrations;
- Reduced burden of duplicated national GMP inspection to manufacturers and laboratory testing prior to registration;
- Enhanced and facilitated collaboration, interactions and information exchange with the NRAs, WHO and SRAs;
- Savings on time and resources;
- Allows more efficient post-registration maintenance.

WHO PQ Process

INPUTS

Expression of Interest



Dossier

WHO Guidelines

Assessors / Inspectors

Testing

PROCESS

Assessment of Dossier

+

Inspections (API, FPP, CRO)

Assessment/ Inspection/Lab Reports

OUTPUTS

List of Prequalified products

WHO Public Reports

- About Medicines Prequalification
- What We Do
- Documents A-Z
- Prequalification Pipeline
- **Prequalified Lists**
  - Finished pharmaceutical products
  - Active pharmaceutical ingredients
  - Medicines quality control laboratories
- FPPs and APIs Eligible for Prequalification ("EOIs")
- Prequalification Procedures & Fees: FPPs, APIs & QCLs
- Post-prequalification Procedures & Fees: APIs, FPPs, QCLs
- Prequalification Reports
- Collaborative Procedures for Accelerated Registration
- Guidance Documents
- Pilot Prequalification of Biotherapeutic Products

Medicines/finished pharmaceutical products

This list contains finished pharmaceutical products used to treat HIV/AIDS, tuberculosis, malaria and other diseases, and for reproductive health, that have been assessed by WHO and found to be acceptable, in principle, for procurement by UN agencies.

view medicine list >

Active pharmaceutical ingredients

This list contains sources of active pharmaceutical ingredients (APIs) that have been assessed by WHO and found to be acceptable, in principle, for use in finished pharmaceutical products procured by United Nations agencies.

Most of the APIs listed are those for which — at the time of assessment — submitted data and information submitted were evaluated and found by PQTm to meet WHO norms and standards and for which — at the time of inspection — the manufacturing site(s) were found to comply with WHO Good Manufacturing Practices. A small number of APIs have been listed on the basis of assessment and inspection carried out by stringent regulatory authorities who are willing to share information with WHO.

Disclaimer: Inclusion in the list of prequalified APIs does not constitute a WHO endorsement or warranty of fitness of purpose of the API for use in a particular finished pharmaceutical product (FPP), or of the safety or efficacy of the resultant FPP for treatment or health care. It remains the ultimate responsibility of the FPP manufacturer to ensure that the API, as accepted in principle, is suitable for the manufacture of the specific FPP.

see more >

Medicines quality control laboratories

https://extranet.who.int/pqweb/medicines

PQ CRP for medicines, vaccines & IVD.: 59 Participating NRAs, plus 1 Regional Economic Community

As of Aug 2023

Angola
Armenia
Azerbaijan
Bangladesh
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
Cape Verde
*Caribbean Community (CARICOM)
Chad
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea

Ethiopia
Gabon
Georgia
Ghana
Guinea (Republic of)
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Liberia
Madagascar
Malaysia
Malawi
Maldives
Mali
Mauritania
Moldova
Mozambique
Namibia
Nepal
Nigeria

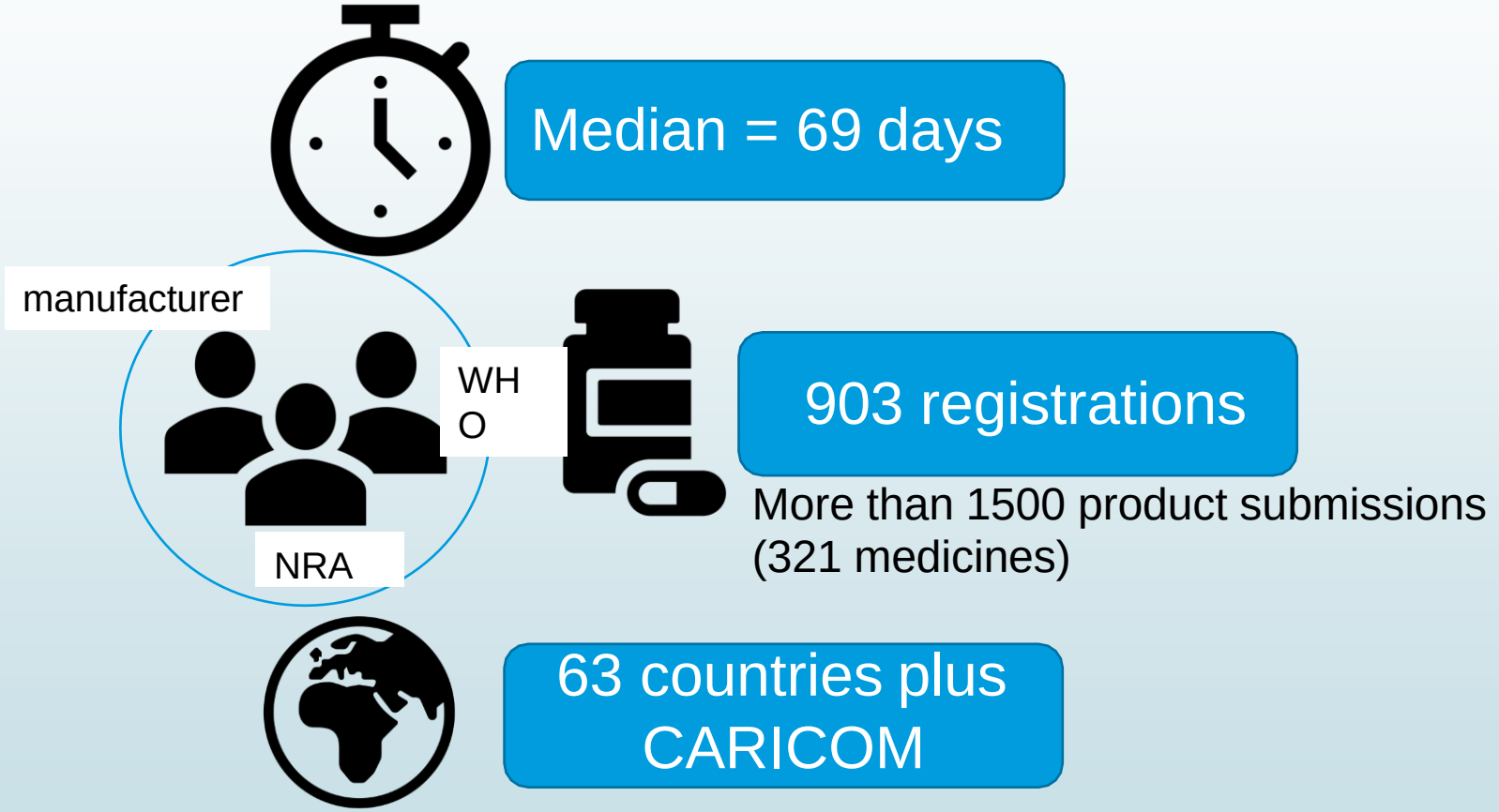
Pakistan
Philippines
Papua New Guinea
Republic of Congo
Rwanda
Sao Tome and Principe
Senegal
Sierra Leone
South Africa
Sri Lanka
Sudan
Tanzania - Mainland
Thailand
The Gambia
Timor-Leste
Türkiye
Togo
Uganda
Ukraine
Uzbekistan
Yemen
Zambia
Tanzania - Zanzibar
Zimbabwe

* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

World Health Organization

https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

PQ CRP: Country submissions and registrations of medicines



World Health Organization

IVD **In Vitro Diagnostics**

- About In Vitro Diagnostic & Male Circumcision Device Prequalification
- What We Do
- Documents A-Z
- **Prequalified In Vitro Diagnostics**
- Prequalified Male Circumcision Devices
- In Vitro Diagnostics Under Assessment
- IVDs Eligible for WHO Prequalification
- MCDs Eligible for Prequalification
- MCDs Under Assessment
- Prequalification Procedures & Fees: IVDs

Prequalified In Vitro Diagnostics

The List of WHO-prequaified In Vitro Diagnostic products contains diagnostics used to diagnose a number of conditions and diseases, and that have been assessed by WHO and found to be acceptable, in principle, for procurement by UN agencies.

- List of prequalified in vitro diagnostic products (pdf version)
- List of prequalified in vitro diagnostic products (xls version)

General information – WHO List of Prequalified In Vitro Diagnostic Products

The WHO List of Prequalified In Vitro Diagnostic Products is updated regularly, generally with the inclusion of newly-prequalified products.

Diagnostic products are added to the list (following the voluntary participation of relevant applicants) as and when the data on such products has been assessed and evaluated, and relevant sites inspected by WHO, and considered (the time of the assessment, evaluation and inspection) to meet WHO prequalification requirements, as described elsewhere on this web site. WHO cannot represent that the listed products and manufacturing sites will continue to meet the aforesaid standards. WHO may suspend or remove products from the list based on information that may subsequently become available to it.

https://extranet.who.int/pqweb/vitro-diagnostics/vitro-diagnostics-lists

Particularities of the CRP for IVDs

- **Type of reports shared with NRAs**
  - ✓ Three reports: Dossier assessment report, Site audit assessment report and performance evaluation report
- **Verification of sameness of the WHO-prequalified product vs submitted dossier**
  - ✓ the same product name
  - ✓ the same regulatory version
  - ✓ the same product code(s)
  - ✓ the same site of manufacture and quality management system;
  - ✓ the same data on quality, safety and performance;
  - ✓ the same design, with the same components from the same suppliers;
  - ✓ the same information, labelling and packaging, including instructions for use and
  - ✓ intended use.

List of SRAs as per current WHO Guidelines

TRS 1003 - 51st report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations

WHO Technical Report Series 1003

14 June 2017 | Technical document

Overview

The WHO Technical Report Series makes available the findings of various international groups of experts that provide WHO with the latest scientific and technical advice on a broad range of medical and public health subjects. Members of such expert groups serve without remuneration in their personal capacities rather than as representatives of governments or other bodies; their views do not necessarily reflect the decisions or the stated policy of WHO.

https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs

Based on the above interim definition, the following is the list of the countries whose NRAs are designated as SRAs.

Australia	Germany	Netherlands
Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Iceland	Romania
Canada	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Japan	Spain
Czech Republic	Latvia	Sweden
Denmark	Liechtenstein	Switzerland
Estonia	Lithuania	United Kingdom
Finland	Luxembourg	United States of America
France	Malta	Norway

World Health Organization

+ EMA

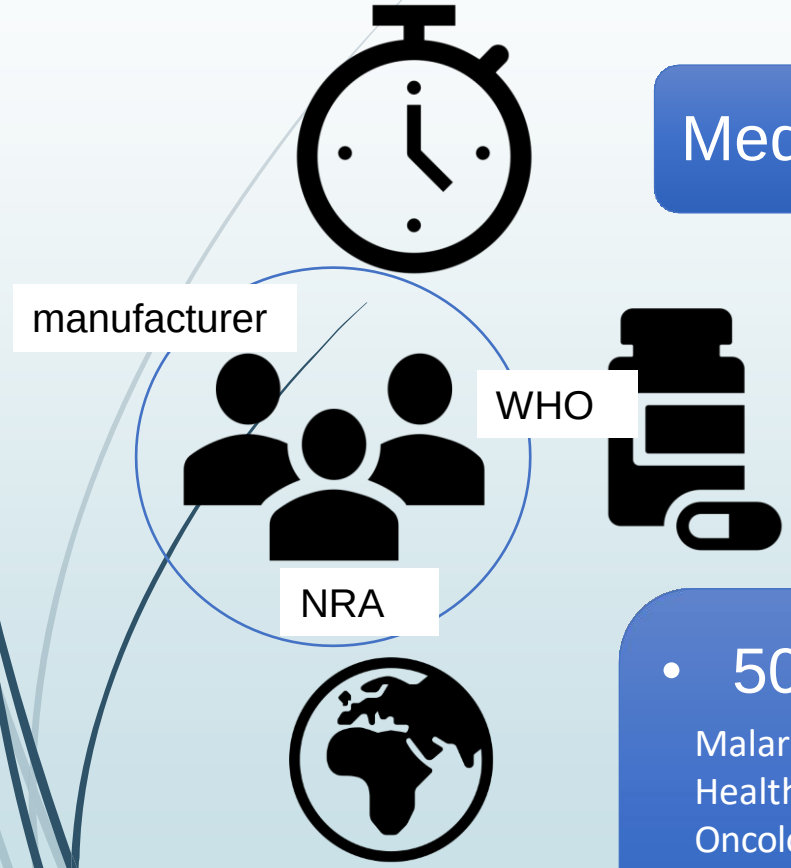
SRA CRP : 7 participating SRAs

As of 1 December 2022:

1. **European Medicines Agency (EMA)**
2. **UK Medicines and Healthcare products Regulatory Agency (MHRA)**
3. **Dutch MEB**
4. **Swiss Agency for Therapeutic Products, (Swissmedic)**
5. **Therapeutic Goods Administration Australia (TGA)**
6. **Finish Medicines Agency (FIMEA)**
7. **Medical Products Agency of Sweden (MPA)** (upcoming submissions)

World Health Organization

SRA CRP : Submissions and Countries Registrations



Median = 120 days (regulatory time + applicant time)

- 230 product submissions (approximately 80 from 2018 to July 2021)
- 115 registrations (approximately 50 from 2018 to July 2021)

- 50 medical products (16 products from 2018 to July 2021)

  Malaria, HIV/AIDS, Tuberculosis, Rep. and maternal Health, Haemophilia, Pneumococcal vaccines, Oncology, Immunostimulants, Analgesics and Anaesthetics, COVID-19 therapeutics, Psycholeptics.
- 47 countries + CARICOM (24 from 2018 to July 2021)

World Health Organization

Relevant Tools and Resources

WHO Good Reliance Practices

WHO Good Regulatory Practices

55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

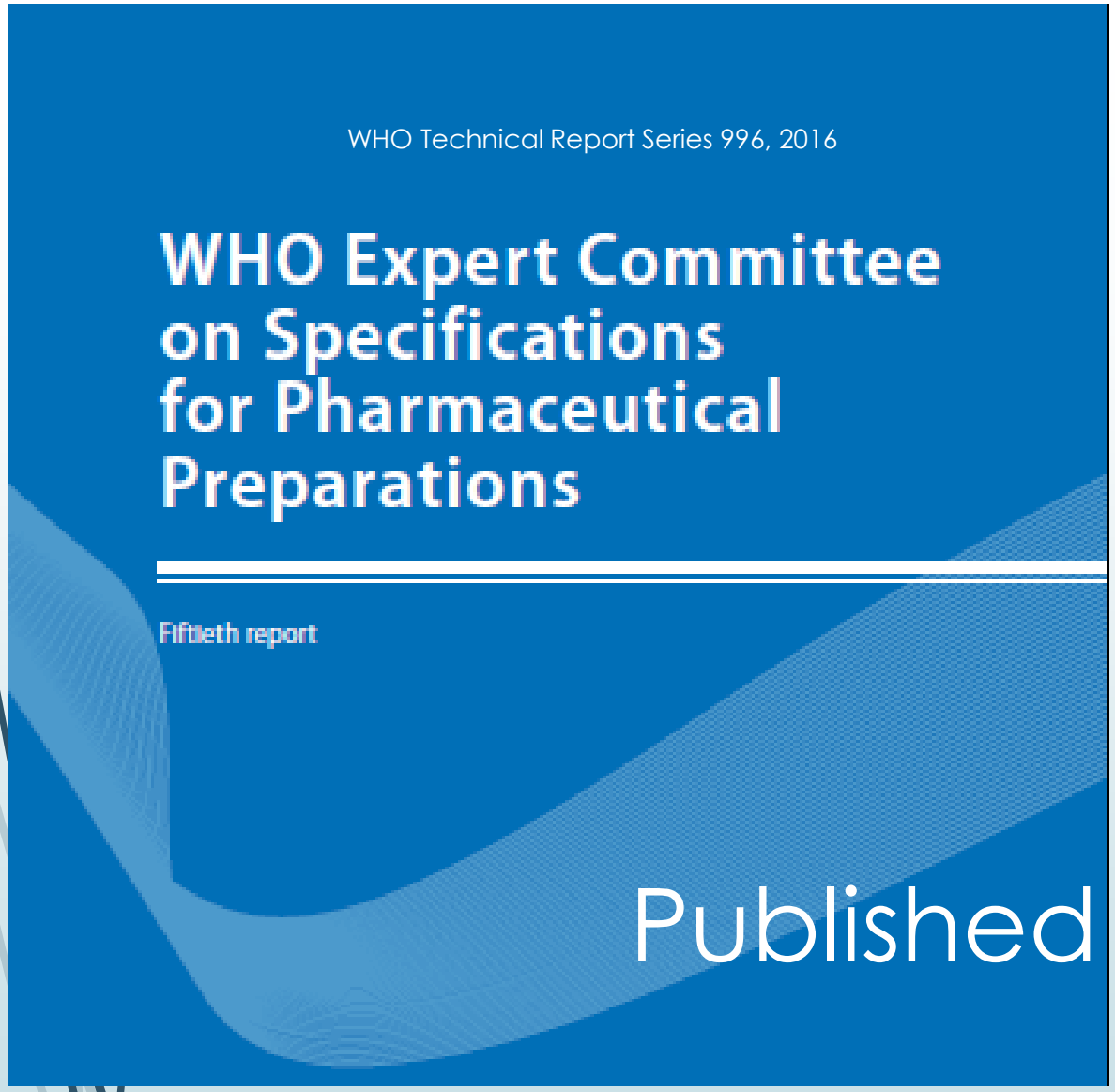
Annex 11

Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products

https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf



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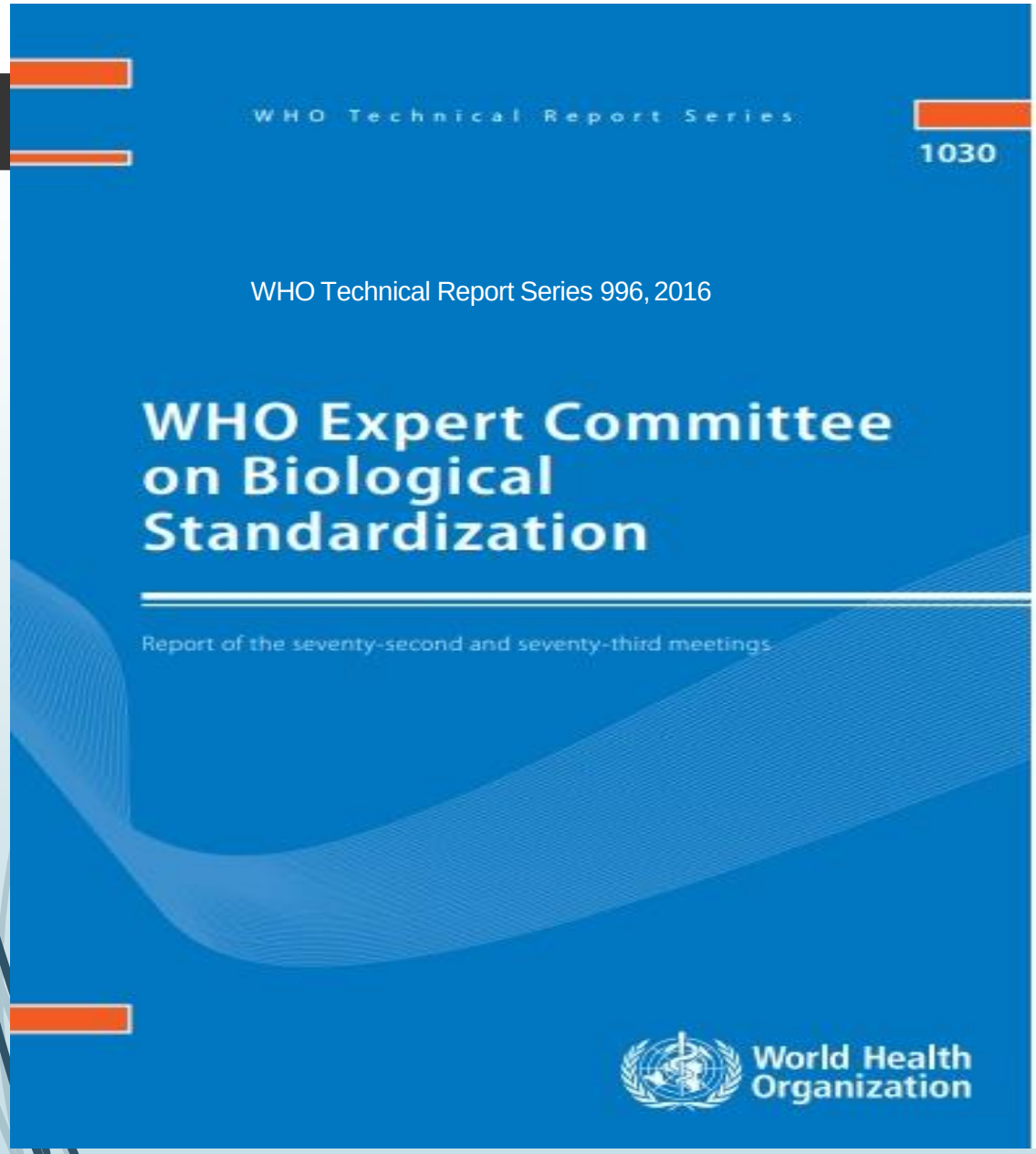
Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

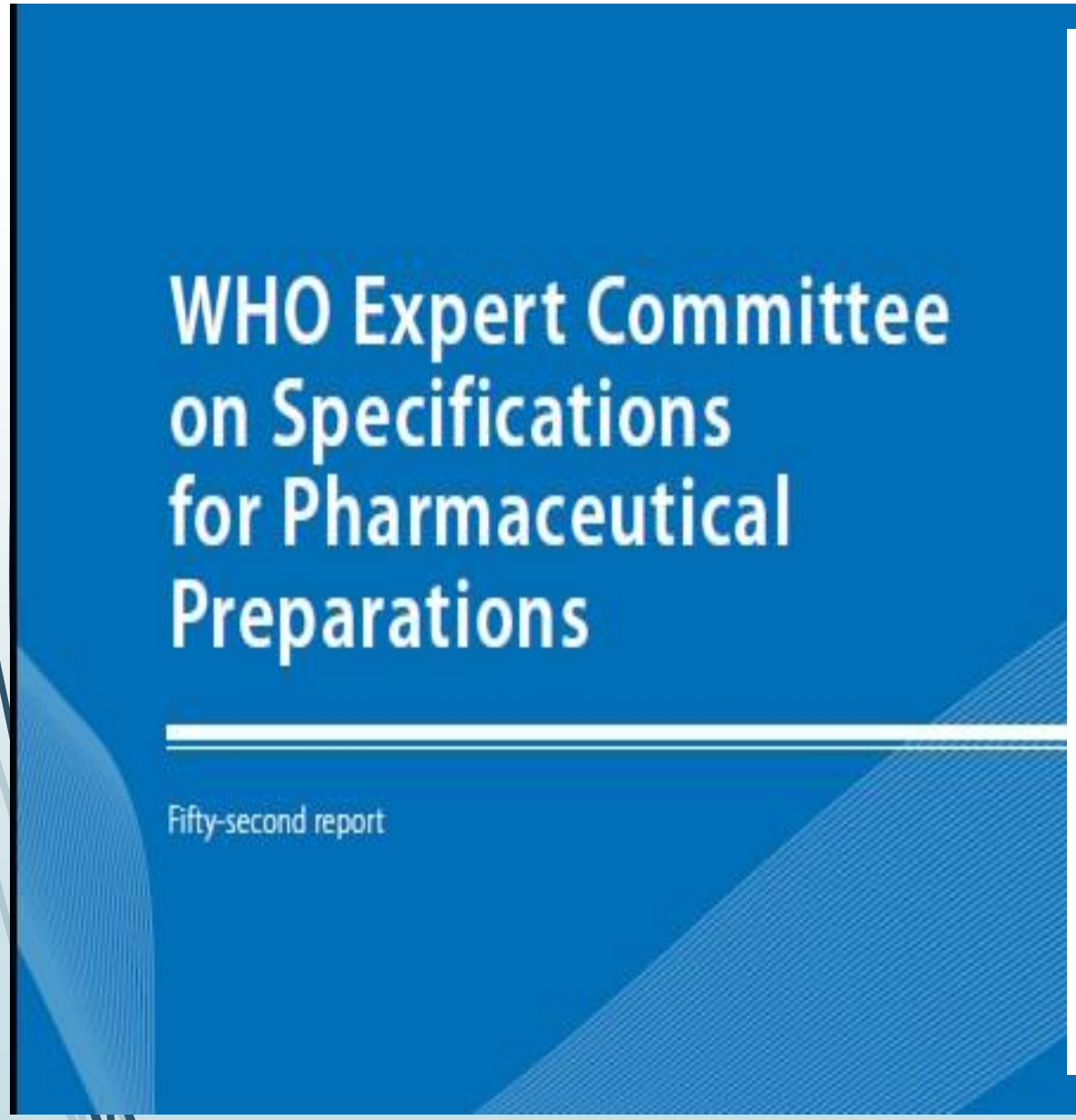


WHO Technical Report Series 996, 2016

Annex 4

Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics

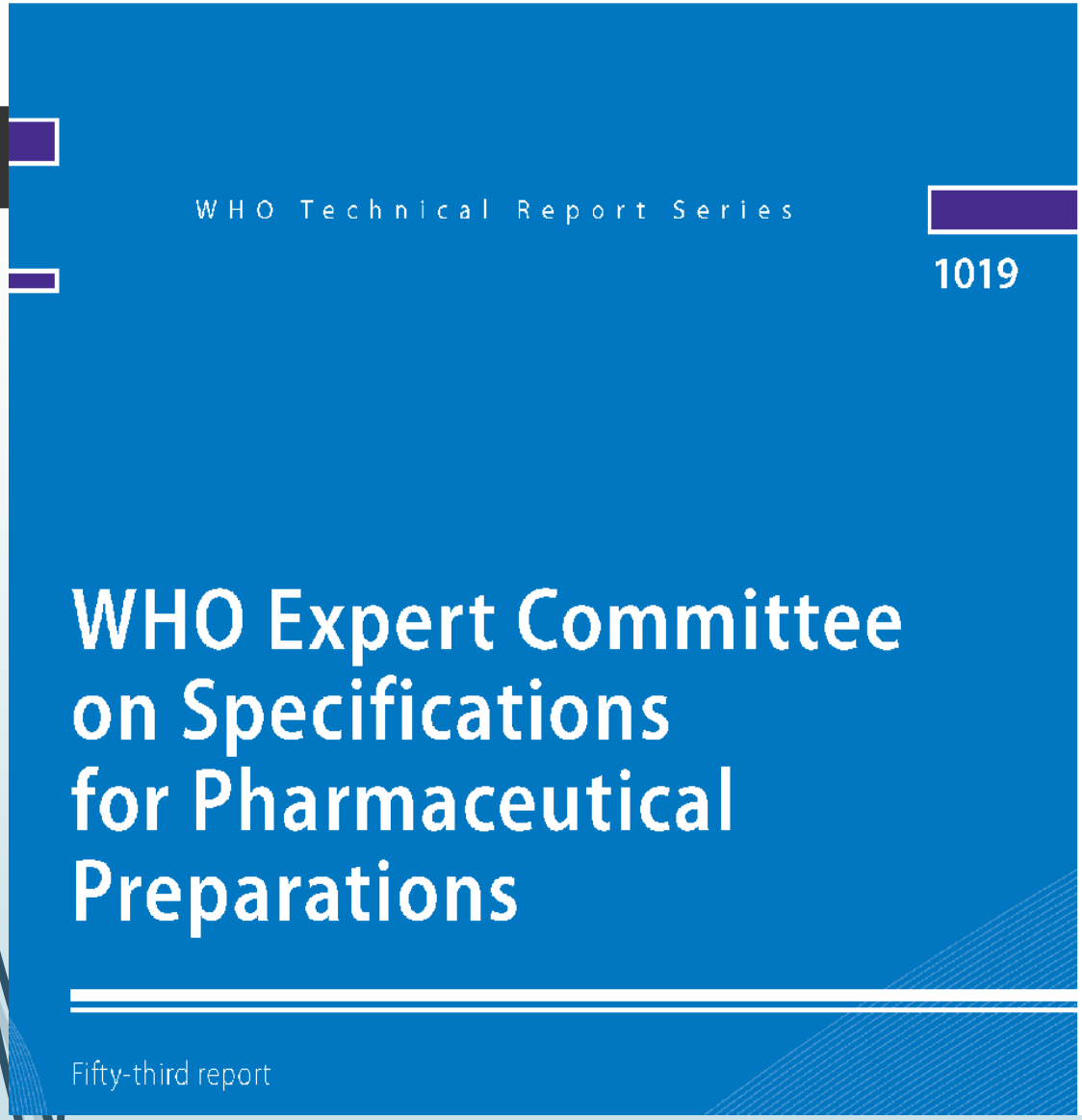
https://www.who.int/publications/i/item/9789240024373



Annex 11

Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities

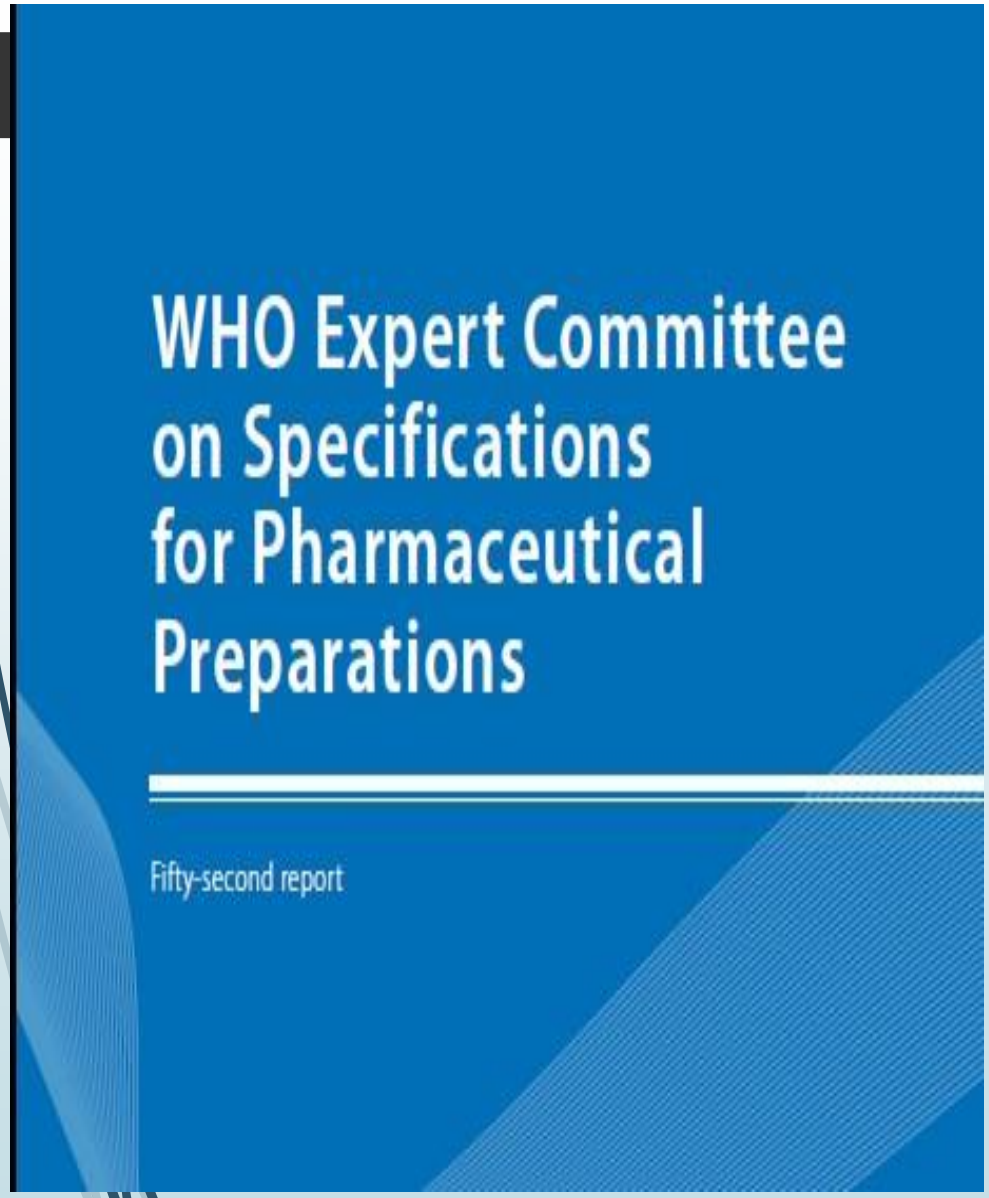
https://extranet.who.int/pqweb/medicines/faster-registration-fpps-approved- sras



Annex 6

Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products

http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210195-eng.pdf?ua=1



Annex 9

Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions

http://apps.who.int/iris/bitstream/handle/10665/272452/9789241210 195-eng.pdf?ua=1

World Health Organization

Questions and Answers

Sunday Kisoma

Thank you

Sunday Kisoma,
Consultant, Facilitated Product Introduction,
WHO – MHP/RPQ/REG/FPI

World Health Organization

Regulatory Landscape for Vector Control Products

Project objectives

Build a comprehensive fact base around registering VC products in sub-Saharan Africa

Deepen the understanding of existing challenges through selected country reach out

Co-create opportunities to optimize access to VC tools through engagement with broader African stakeholders

Involved stakeholders

African Union

NEPAD TRANSFORMING AFRICA

ALMA

Bill & Melinda Gates foundation

CropLife INTERNATIONAL

IVCC

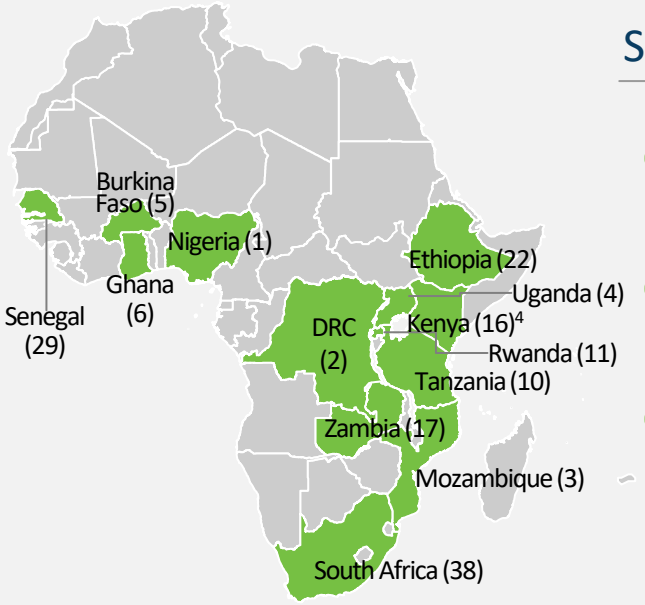
World Health Organization

We have created an extensive fact-base using stakeholder interviews and in-depth country research

Over 130 stakeholders interviewed regarding registration across the continent…

- 24 African & global partners[1]
- 9 RECs & pan-African leadership
- 37 Industry players & country reps
- 26 Regulatory authorities[2]
- 36 National Malaria Control Programs, other relevant Ministries & research institutes

…and 13 countries selected for in-depth research, including field visits for 10



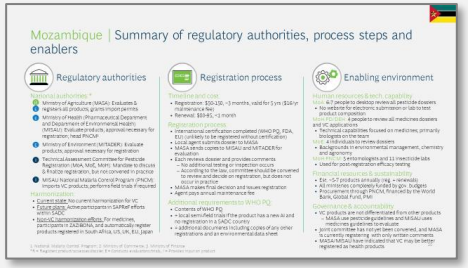
( ) : Ranking in malaria burden in 2017

Selection criteria include:

- 2017 malaria burden[3]
- Regional distribution (East, West, Central, Southern)
- Potential regional influence

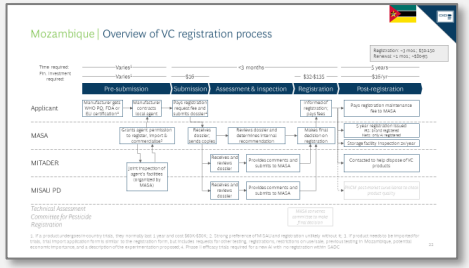
1. Includes Global Fund, PMI, Unicef; 2. Includes CILSS; 3. WHO World Malaria Report 2018; 4. In progress; data still being collected
Note: Interviews conducted between Dec 2018-July 2019

For each focus country, the fact-base includes:

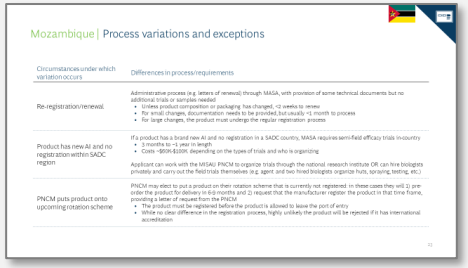


Summary of vector control tool registration

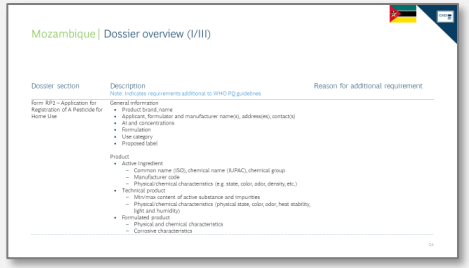
Key authorities and legislation



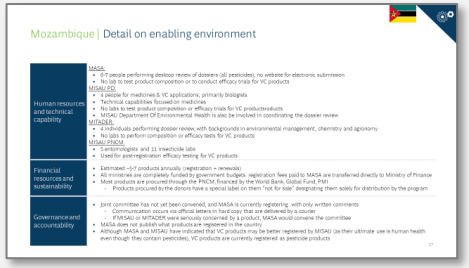
Overview of registration process



Descriptions of process variations and exceptions



Dossier overview



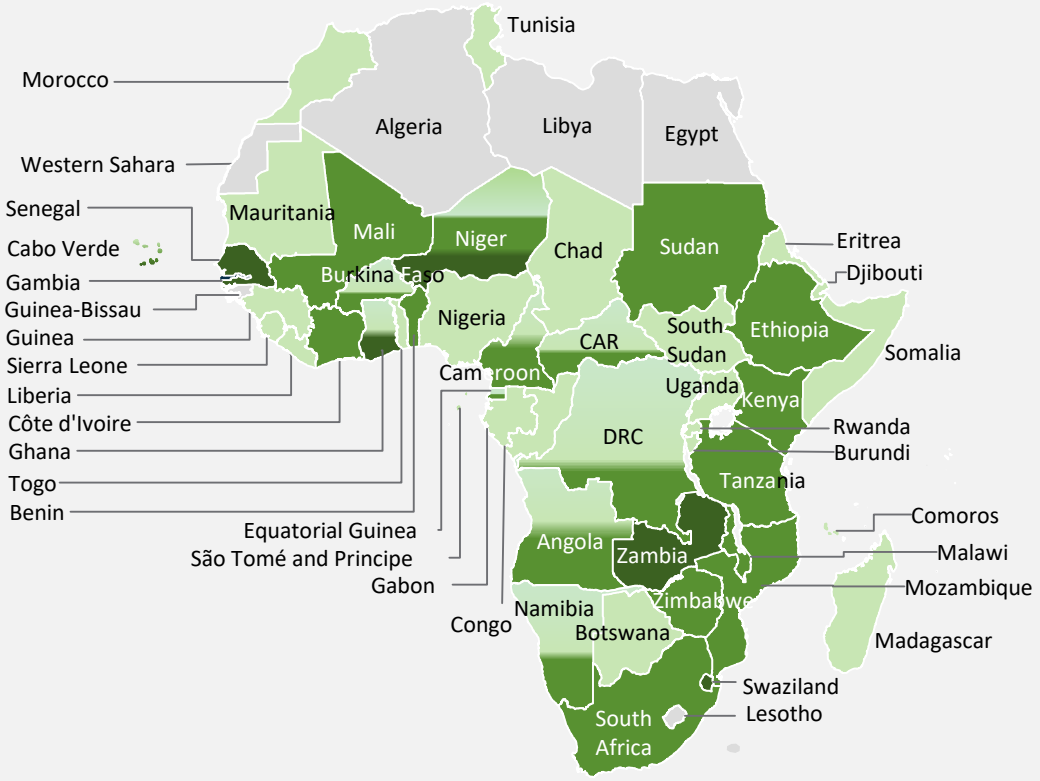
Detail on enabling environment

Today, we're only sharing our general findings across the continent…

…but please visit our website to find the full materials!

Across the continent, significant variation in registration authority

Registration authority[1]



Registration authority most commonly the Ministry of Health, but high degree of fragmentation across the continent

Registration ministry	*% of countries**
Ministry of Health	48%
Ministry of Agriculture	23%
Ministry of Environment	6%
More than one	23%

** of the 48 African countries for which data on the registering authority was available*

1. Most commonly, but not always, split authorities register different products (e.g. IRS under MoA/MoE and nets under MoH);
Note: FDA is classified as MoH. Source: 2017 ALMA; Interviews Dec 2018-July 2019; BCG analysis

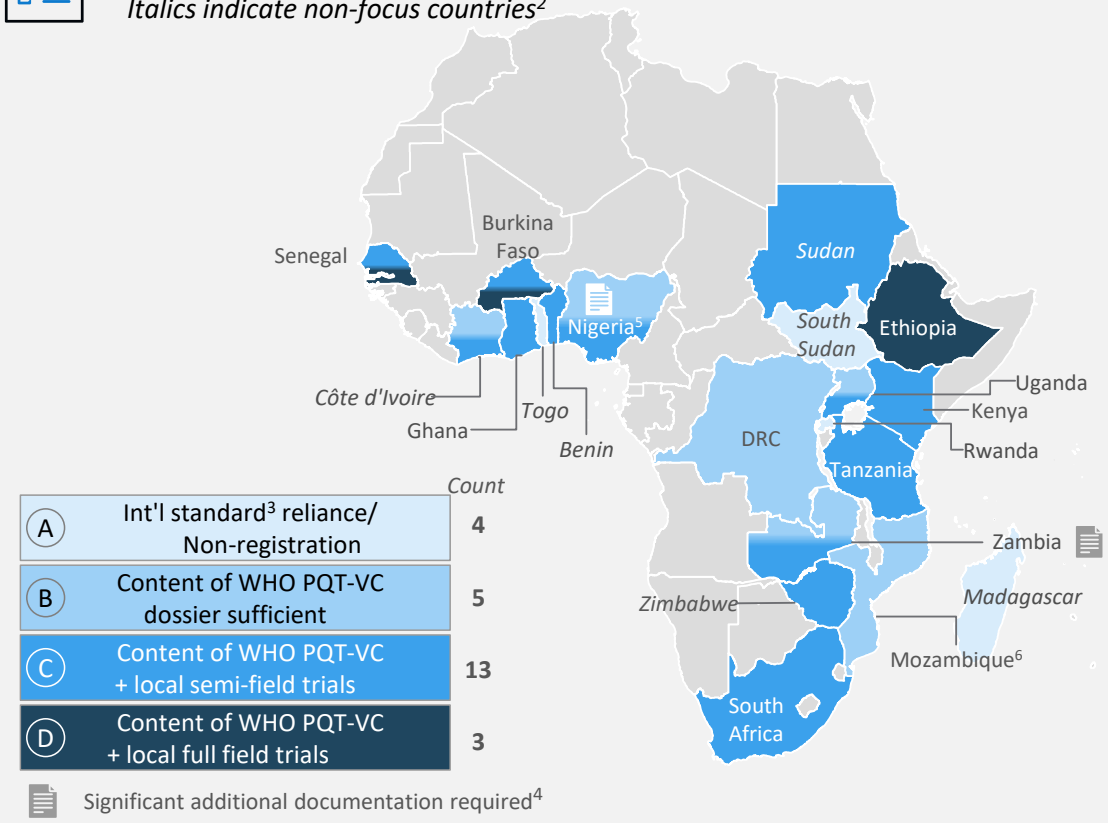
Registration requirements also differ considerably

There is no universal set of dossier requirements specifically for vector control

The largest requirement that varies is the length of in-country field trials, which can have major ramifications for registration speed

Registration requirements

Italics indicate non-focus countries[2]



		Count
A	Int'l standard[3] reliance/ Non-registration	4
B	Content of WHO PQT-VC dossier sufficient	5
C	Content of WHO PQT-VC + local semi-field trials	13
D	Content of WHO PQT-VC + local full field trials	3

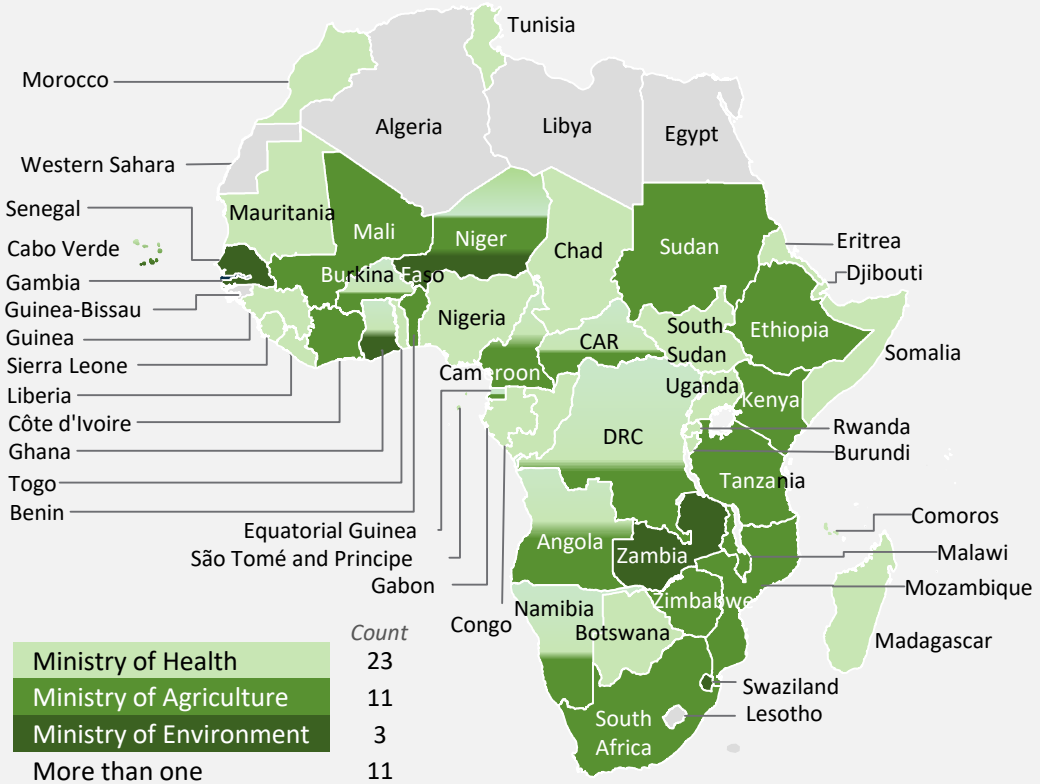
Significant additional documentation required[4]

2. Country regulators were not interviewed; understanding based on interviews with int'l orgs, manufacturers, etc. 3. e.g. WHO, US FDA, etc. 4. Documentation varies, but can include additional safety certificates, environmental dossiers, labels and others requiring a significant investment from the applicant. 5. Trials are required only for new AI 6. Trials are technically required for new AI, but no historical instance of this occurring for VC products: unclear if enforced.

Source: 2017 ALMA; Interviews Dec 2018-July 2019; BCG analysis

In summary, African VC registration is a complex landscape

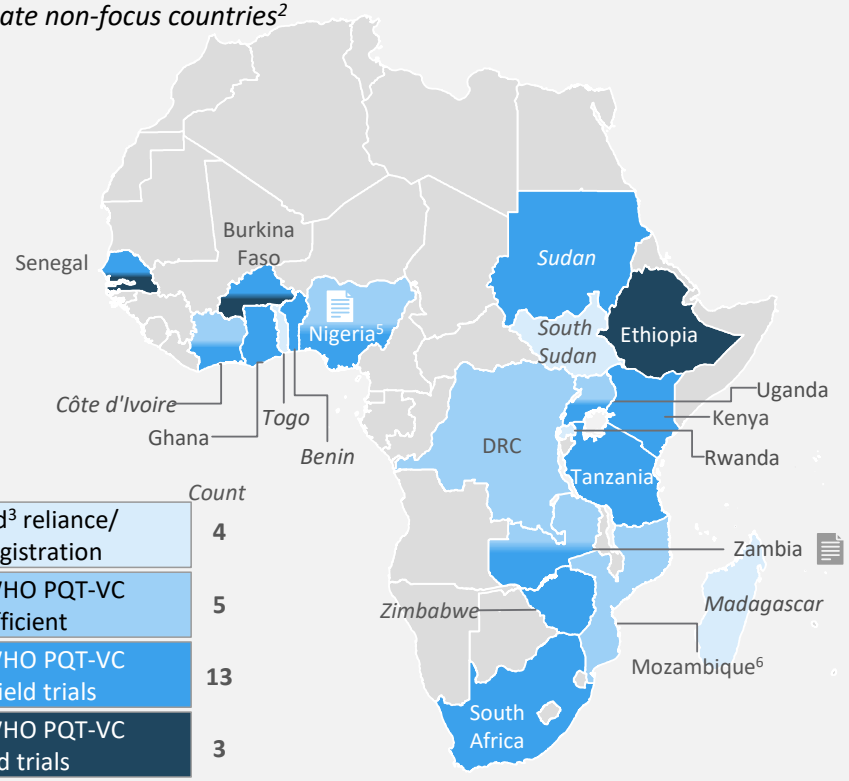
Registration authority[1]



	Count
Ministry of Health	23
Ministry of Agriculture	11
Ministry of Environment	3
More than one	11

Registration requirements

Italics indicate non-focus countries[2]



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Due to the complex nature of VC, national regulators and industry are facing multiple challenges

1 Unclear/overlapping **mandates** between national authorities

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2 Lack of funds to ensure adequate **evaluation or quality control**

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3 **Requirements** aren't tailored for Vector Control products

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3. **Requirements** aren't tailored for Vector Control products
4. Delayed **communication** between authorities

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1. Unclear/overlapping **mandates** between national authorities
2. Lack of funds to ensure adequate **evaluation or quality control**
3. **Requirements** aren't tailored for Vector Control products
4. Delayed **communication** between authorities
5. Insufficient **transparency** on registration process/requirements

Selected quotes from stakeholder interviews

1 Unclear/overlapping mandates

VC products are either chemicals managed by us or as medical products managed by the Ministry of Health, but we know the MoH has granted authorization for IRS, which are our jurisdiction

~ Ministry of Agriculture regulator

2 Lack of funds for adequate evaluation

We do a review and a chemical composition test, but don't have the appropriate capabilities to conduct efficacy trials or other lab tests

~ Ministry of Health regulator

3 Requirements aren't tailored

There is always a long back and forth with [country] because they require residue studies, which are simply irrelevant for a bed net

~ Global manufacturer

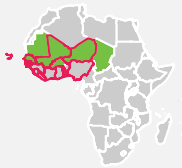
4 Insufficient transparency

If we knew exactly what to submit it wouldn't be a problem – but registration for VC often involves lengthy discussions about which documents are required

~ Global manufacturer

Source: Interviews Dec 2018-July 2019

We researched four on-going collaborative efforts for pesticide or medicines registration

	WHO Collaborative Registration Procedure	EAC Medicines Regulatory Harmonization	CILSS/CSP[1] & resulting ECOWAS efforts	SEARCH[2] & resulting EAC & SADC efforts
Member states				
Product focus	WHO Prequalified finished pharmaceutical products	Non-WHO Prequalified medicines	Pesticides, including VC products (regardless of WHO Prequalification)	Agricultural pesticides (regardless of WHO Prequalification)
Scope of harmonization	Guidelines, process and assessment	Guidelines, process, assessment and recommendation	Guidelines, process, assessment and recommendation	Guidelines
Years active	2012-Present	2012-Present	1992-Present	1996-Present

1. CILSS = Comité permanent inter-État de lutte contre la sécheresse au Sahel, CSP = Comité Sahélien des Pesticides 2. SEARCH = South East African Regulatory Committee on Harmonization; Source: WHO; AUDA-NEPAD; interviews; BCG Analysis

There are two common impacts across the efforts studied

Helps regulators make quality registration decisions

WHO CRP 5 of 6 NMRAs reported to the WHO that dossier quality was higher for PQ products, making it easier for them to assess

> *"We rely on WHO assessments, which allows us to focus our time on dossier sections we find most relevant for a particular application"*

EAC MRH Drug companies reported that queries received from joint procedure were more stringent than for national registration

Increases speed of country registration

WHO CRP Median registration for products in scope reduced from >1 year to <3 months

EAC MRH Application to decision lead time reduced from 2-4 years to ~225 days

CILSS/CSP Products registered in 9 member states with only one set of required efficacy trials and a single 1-2 month assessment

Source: Interviews Dec 2018-July 2019; 2019 Impact assessment of WHO Prequalification and Systems Supporting Activities; 2017 WHO/PQT Guidance Document, Annex: KPIs; World Bank Funding Report on the EAC MRH, 2018; Norwegian Institute of Public Health, 2018; AUDA-NEPAD; BCG analysis

There are several key takeaways for the impact of collaborative efforts in regulation

Bring a diverse set of stakeholders together when developing potential models

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Iteratively incorporate learnings throughout implementation

Plan for financial sustainability from the start

Thank you