



# Pan-African Registration Landscape for Vector Control Tools

Fact-base – July 2019

# Executive summary | Contents of this document

## Context of this document

- **Innovation to Impact (i2i)** – in partnership with AU, AUDA-NEPAD, WHO, BMGF, IVCC, ALMA, industry, RECS,<sup>1</sup> and country regulators – **has conducted an extensive study of Vector Control (VC) registration across Africa** to establish a comprehensive fact-base
- This document provides an overview of the pan-African landscape for VC tools
- For detailed materials on country-level processes, please see "Selected African Country Registration Processes for Vector Control Tools" fact-base

## Section title



### Project context



### Pan-African registration landscape for VC tools



### Summary table of selected country processes

## Summary

- Project context and objectives
- Country selection and criteria
- Interviews conducted
- Country assessment framework
- Categorization of registration processes of various African countries
- Key challenges and themes that emerged from the research
- Summary of detailed information on country-level processes

1. African Union; African Union Development Agency – New Partnership for African Development; World Health Organization; Bill and Melinda Gates Foundation; Innovative Vector Control Consortium; African Leaders Malaria Alliance, Regional Economic Communities



## Disclaimer on methods of information gathering

- Information was gathered in the following ways:
  - Interviews (over the phone and in-person) with various stakeholders<sup>1</sup>
  - Desktop research leveraging reports and officially published documentation
- Research was conducted from December 2018–August 2019, and all information presented represents the state of registration process at the time of data collection—changes may have occurred since
- Given the recent implementation of WHO PQT-VC, there is a possibility that country regulators did not have WHO PQT-VC in mind when making comments or comparisons to the WHO process
  - We expect some country regulators may have been referring to WHOPES requirements – we attempted to standardize by comparing the list of dossier requirements given to us with PQT-VC requirements
  - We interpreted imprecise comments such as "WHO approval is needed," as a requirement for a WHO PQT-VC listing
- We have collected factual information to the best of our ability. However, we acknowledge that the registration processes described are complex, that stakeholders sometimes have varied information, and that we can not always capture all of the details or nuance

1. List of stakeholder types and number of interviews can be viewed in the Project Context section

# Table of Contents

Project context	5
Pan-African registration landscape for VC tools	11
Summary table of selected country processes	19

# Table of Contents

➤ Project context	5
Pan-African registration landscape for VC tools	11
Summary table of selected country processes	19

# Project context



Malaria continues to be a significant burden, and vector control (VC) is instrumental to reducing it



A more robust WHO evaluation system (PQT-VC) for VC products is now largely in place



Crucial need to begin optimizing registration practices in endemic Sub-Saharan Africa (SSA), where processes and requirements vary significantly



i2i is collaborating with key stakeholders incl. AU, AUDA-NEPAD, WHO, BMGF, IVCC, ALMA, and industry as well as RECs<sup>1</sup> and SSA countries to address this issue

1. African Union; African Union Development Agency – New Partnership for African Development; World Health Organization; Bill and Melinda Gates Foundation; Innovative Vector Control Consortium; African Leaders Malaria Alliance, Regional Economic Communities

# Project objectives

Focus of these materials



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

# Understanding of landscape is based on interviews with over 130 stakeholders

To shape high level view of African process landscape, interviewed ...



To build country-specific knowledge, interviewed ...






# 13 countries selected for in-depth analysis based on malaria burden, and regional balance/influence

## Sub-region


## Selected countries

( ) : Ranking in malaria burden in 2017





### Southern Africa

-  Mozambique (3)
-  South Africa (38)
-  Zambia (17)

### Central Africa

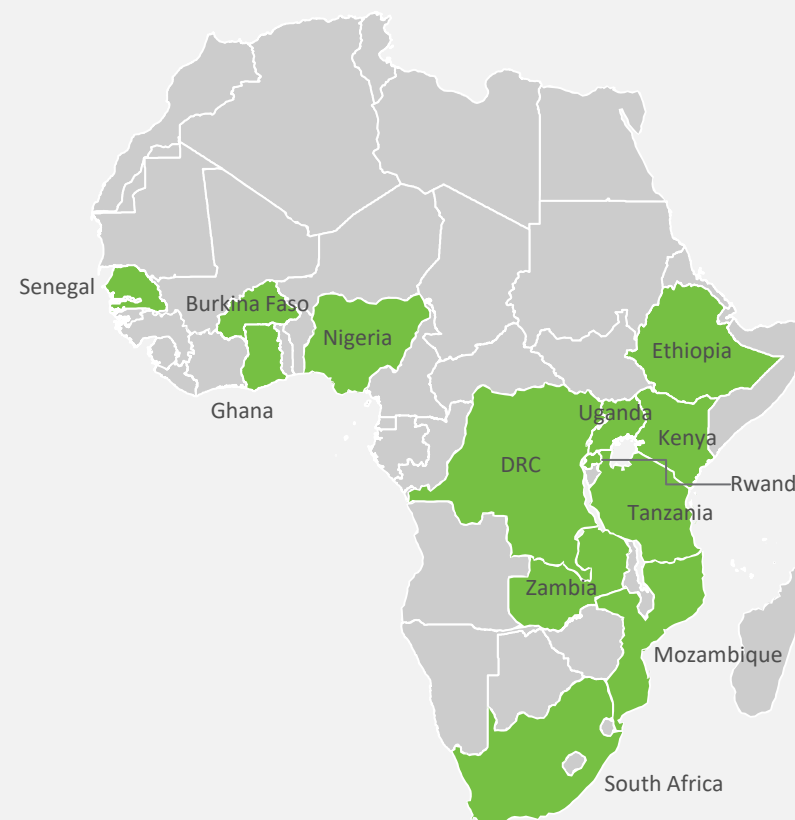
-  DRC (2)

### West Africa

-  Burkina Faso (5)
-  Ghana (6)
-  Nigeria (1)
-  Senegal (29)

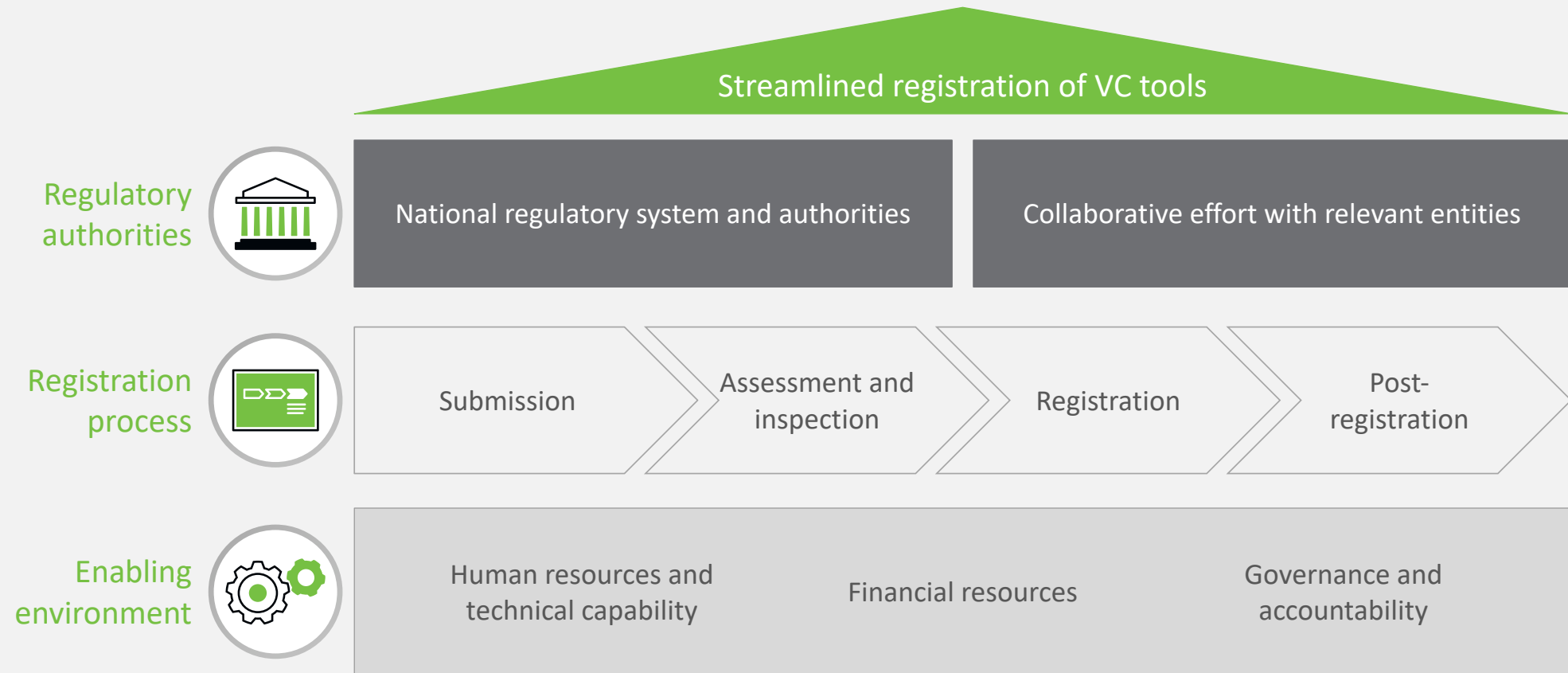
### East Africa

-  Ethiopia (22)
-  Kenya (16)
-  Rwanda (11)
-  Tanzania (10)
-  Uganda (4)





# Assessment was conducted along three key dimensions ...



# ... generating robust fact-base for each country

➤ Please see "Selected African Country Registration Processes for Vector Control Tools" database for full set of materials

### Mozambique | Summary of regulatory authorities, process steps and enablers

#### Regulatory authorities

- Ministry of Agriculture (MASA): Evaluates & registers all products, grants import permits
- Ministry of Health (MISAU) and Department of Environmental Health (MDESAU): Evaluate products, approval necessary for registration, need PNCM
- Ministry of Environment (MITADER): Evaluate products, approval necessary for registration
- Technical Assessment Committee for Pesticide Registration (MISAU, MDE, MORA, MANDRE to include in final registration, but no comments in practice)
- MISAU National Malaria Control Program (PNCM): Imports VC products, performs field trials if required

#### Registration process

**Registration fee:**

- Registration: \$50-\$50, -3 months, valid for 5 yrs (\$147 for maintenance fee)
- Renewal: \$5-\$5, <1 month

**Registration process:**

- International certificates completed (WHO PQ, FDA, EU) unlikely to be registered without certification
- Local agent's authorization to MASA

#### Enabling environment

**Human resources & technical capability:**

- 6-7 people to develop review all pesticide dossiers
- No expertise for electronic submission or data to test product composition
- 4-5 individuals to review all medicines dossiers and VC applications
- Technical capabilities focused on medicines, primarily biologists on the team
- 4 individuals to review dossiers
- Backgrounds in environmental management, chemistry and toxicology
- 2 individuals to review and approve comments
- 2 individuals to review and approve comments
- No additional testing or inspection occurs
- According to the regulatory committee structure covered to review and decide on registration, but does not occur in practice
- MASA ensures that decision and issues registration
- Agent pays annual maintenance fee

**Additional requirements to WHO PQ:**

- Criteria of WHO PQ
- Local semi-field trials if the product has a new AI and no registration in a SADC country
- Additional documents including copies of any other registrations and an environmental data sheet

**Governance & accountability:**

- VC products are not differentiated from other products
- MASA use pesticide guidelines and MISAU uses medicines guidelines for evaluation
- Joint committee has not been convened, and MASA is currently registering with only written comments
- MASA/MISAU have indicated that VC may be better registered as health products

Summary of vector control tool registration

### Mozambique | Key contacts in regulatory authorities

Authority	Authority role
Ministry of Agriculture (MASA)	Evaluates and registers all products, gives final approval. Authorizes importation of product.
Ministry of Health (MISAU) / Department of Environmental Health (MDESAU)	Reviews and comments on dossier contents, with focus on human health. Feedback necessary for registration.
Ministry of Environment (MITADER) / Department of Environmental Health (MDESAU)	Reviews dossier from MASA and coordinates with MISAU PD.
Ministry of Land, Environment and Rural Development (MATER)	Reviews and comments on dossier contents, with focus on environmental regulation and impact. Feedback necessary for registration.
National Malaria Control Program (PNCM)	Can request specific products to be registered. Conducts efficacy trials post-registration during product use.

**Relevant legislation and requirements for changing registration processes**

Legislation/Title	Year	Notes
Pesticides Management Regulation	2009	Reportedly, in (4-2018) MISAU passed a legal document that now requires international certification (e.g. WHO PQ, FDA, EU) for registered products. Any changes must be ratified by the 'Council of Ministers'

Key authorities and legislation

### Mozambique | Overview of VC registration process

Overview of registration process

### Mozambique | Process variations and exceptions

Circumstance under which variation occurs	Differences in process/requirements
Re-registration/renewal	Administrative process (e.g. letters of renewal) through MASA, with provision of some technical documents but no additional trials or samples needed. <ul style="list-style-type: none"> <li>Updates product composition or packaging has changed, &lt;2 weeks to renew</li> <li>For small changes, documentation needs to be provided, but usually &lt;1 month to process</li> <li>For large changes, the product must undergo the regular registration process</li> </ul>
Product has new AI and no registration within SADC region	If a product has a brand new AI and no registration in a SADC country, MASA requires semi-field efficacy trials in-country (3 months to 1 year in length). <ul style="list-style-type: none"> <li>Costs ~\$60K-\$100K, depending on the types of trials and who is organizing</li> </ul> <p>Applicant can work with the MISAU PNCM to organize trials through the national research institute OR can hire biologists privately and carry out the field trials themselves (e.g. agent, and two hired biologists organize huts, spraying, testing, etc.)</p>
PNCM puts product onto upcoming rotation scheme	PNCM may elect to put a product on their rotation scheme that is currently not registered in these cases they will: <ol style="list-style-type: none"> <li>1) order the product for delivery in 6-9 months and 2) require that the manufacturer register the product in that time frame, providing a letter of request from the PNCM <ul style="list-style-type: none"> <li>The product must be registered before the product is allowed to leave the port of entry</li> <li>While no clear difference in the registration process, highly unlikely the product will be rejected if the international accreditation</li> </ul> </li> </ol>

Descriptions of process variations and exceptions

### Mozambique | Dossier overview (I/III)

Dossier section	Description	Reason for additional requirement
Form RFP = Application for Registration of a Pesticide for Home Use	<p><b>Notes:</b> Indicates requirements additional to WHO PQ guidelines</p> <p><b>General information:</b></p> <ul style="list-style-type: none"> <li>Product brand name</li> <li>Applicant, formulator and manufacturer (names), address(es), contacts</li> <li>AI and concentrations</li> <li>Formulation</li> <li>Use category</li> <li>Proposed label</li> </ul> <p><b>Product:</b></p> <ul style="list-style-type: none"> <li>Active Ingredient <ul style="list-style-type: none"> <li>Common name (ISO), chemical name (IUPAC), chemical group</li> <li>Manufacturer code</li> </ul> </li> <li>Physical/chemical characteristics (e.g. state, color, odor, density, etc.)</li> <li>Technical product <ul style="list-style-type: none"> <li>Minimum content of active substance and impurities</li> <li>Physical/chemical characteristics (physical state, color, odor, heat stability, light and humidity)</li> </ul> </li> <li>Formulated product <ul style="list-style-type: none"> <li>Physical and chemical characteristics</li> <li>Concave characteristics</li> </ul> </li> </ul>	


Dossier overview

### Mozambique | Detail on enabling environment

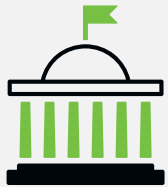
<b>Human resources and technical capability</b>	<p><b>MASA:</b></p> <ul style="list-style-type: none"> <li>6-7 people performing desktop review of dossiers (all pesticides), no website for electronic submission</li> <li>No lab to test product composition or to conduct efficacy trials for VC products</li> </ul> <p><b>MISAU/PD:</b></p> <ul style="list-style-type: none"> <li>4 people for medicines &amp; VC applications, primarily biologists</li> <li>Technical capabilities focused on medicines</li> <li>No labs to test product composition or efficacy trials for VC products</li> <li>MISAU/Department Of Environmental Health is also involved in coordinating the dossier review</li> </ul> <p><b>MITADER:</b></p> <ul style="list-style-type: none"> <li>4 individuals performing dossier review, with backgrounds in environmental management, chemistry and agronomy</li> <li>No labs to perform composition or efficacy tests for VC products</li> <li>5 entomologists and 11 insecticide labs</li> <li>Used for post-registration efficacy testing for VC products</li> </ul>
<b>Financial resources and sustainability</b>	<ul style="list-style-type: none"> <li>Estimated ~\$7 products annually (registration + renewals)</li> <li>All ministries are completely funded by government budget; registration fees paid to MASA are transferred directly to Ministry of Finance</li> <li>Most products are procured through the PNCM, financed by the World Bank, Global Fund, PMI</li> <li>Products procured by the donors have a special label on them "not for sale" designating them solely for distribution by the program</li> </ul>
<b>Governance and accountability</b>	<ul style="list-style-type: none"> <li>Joint committee has not yet been convened, and MASA is currently registering with only written comments</li> <li>Communication occurs via official letters in hard copy that are delivered by a courier</li> <li>MISAU or MITADER were seriously concerned by a product, MASA would convene the committee</li> <li>MASA does not publish what products are registered in the country</li> <li>Although MASA and MISAU have indicated that VC products may be better registered by MISAU (as their ultimate use is human health even though they contain pesticides), VC products are currently registered as pesticide products</li> </ul>

Detail on enabling environment

# Table of Contents

Project context	5
 Pan-African registration landscape for VC tools	11
Summary table of selected country processes	19

# Registration landscape differs by country, but we can broadly classify countries based on two dimensions



## Overseeing ministry

- Frame of reference for VC (e.g. as agricultural, environmental or public health products)
- May imply different processes / requirements and ease of communication with similar ministries across countries

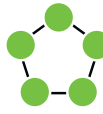


## Registration requirements

- Illustrates use of globally recognized norms (e.g. use of WHO PQT-VC guidelines)
- Illustrates complexity of the registration process for manufacturers (e.g. local trial requirements)
- May imply ease of collaborating with other similar models

Please see the next slide for an illustration of the WHO PQT-VC process and guidelines used as a comparison during our research

**Note |** Throughout this document, country application requirements are compared to those of the WHO PQT-VC process

 WHO prequalification team (PQT-VC) is set up to aid in regulating VC products

- PQT-VC replaces WHOPEs<sup>1</sup> as the WHO review source for VC products
- PQT-VC's vision is to enable access to effective, safe and good-quality vector control products to prevent the transmission of vector-borne diseases
- PQT-VC fulfils this vision by assessing vector control products and their manufacturing sites against uniform standards of efficacy, safety and quality

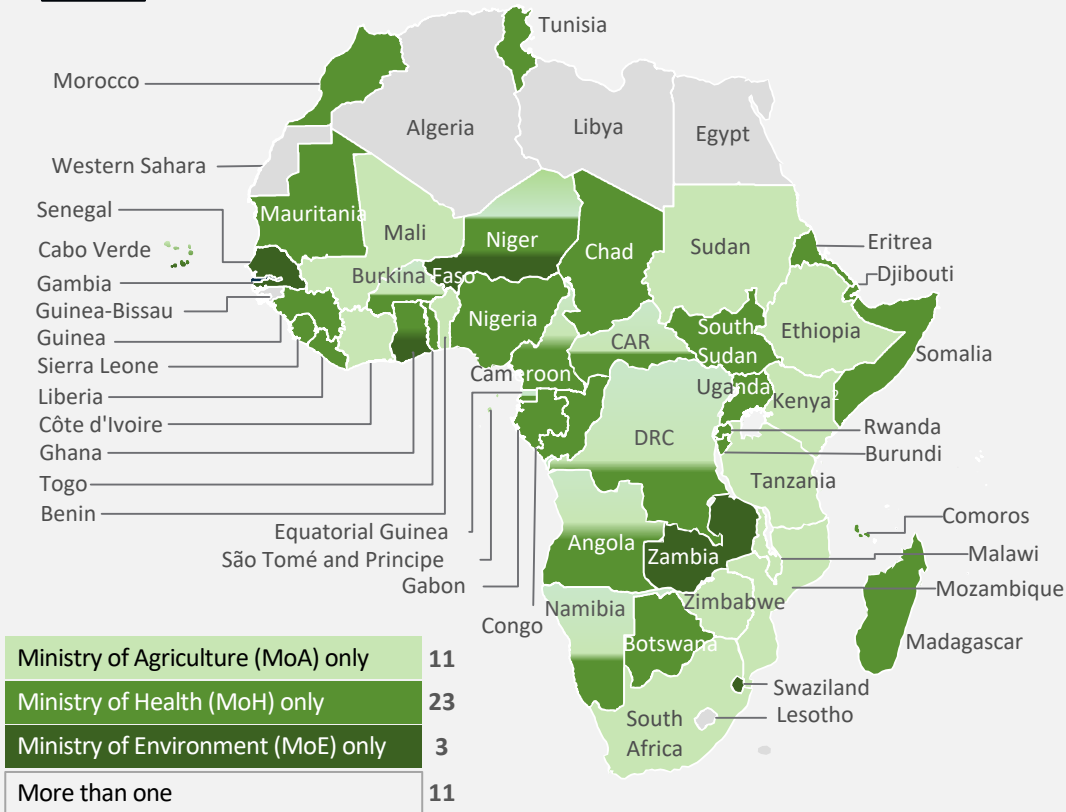
 WHO PQT-VC dossier includes the following modules

- |          |  |  |   |
|----------|--|--|---|
| <b>1</b> | Administrative information & labelling | <ul style="list-style-type: none"> <li>• Cover letter</li> <li>• Application form</li> <li>• Table of Contents</li> <li>• Letter(s) of authorization</li> <li>• Letter(s) of access</li> </ul>                   | <ul style="list-style-type: none"> <li>• Declaration of Labelling (includes the affixed label, leaflets, and product marketing materials)</li> </ul>                            |
| <b>2</b> | Discipline summaries                   | <ul style="list-style-type: none"> <li>• Summarized data and manufacturer conclusions (separately for quality, safety and efficacy dossier)</li> </ul>   |   |
| <b>3</b> | Quality dossier                        | <ul style="list-style-type: none"> <li>• Physical/Chemical Data</li> <li>• Declaration of Product Formulation</li> <li>• Description of Manufacturing</li> </ul>   | <ul style="list-style-type: none"> <li>• Process</li> <li>• Declaration of Manufacturing Sites</li> <li>• Confidential Appendices</li> </ul>                                    |
| <b>4</b> | Safety dossier                         | <ul style="list-style-type: none"> <li>• Toxicology: Acute inhalation, oral, dermal; Primary eye irritation, skin irritation, dermal sensitization</li> <li>• Product risk assessment</li> </ul>                 | <ul style="list-style-type: none"> <li>• (hazard, exposure and risk characterization)</li> <li>• AI-specific hazard assessment (or publically available information)</li> </ul> |
| <b>5</b> | Efficacy dossier                       | <ul style="list-style-type: none"> <li>• Data generated from Phase I (lab studies), Phase II (semi-field conditions) and Phase III (large scale field trials (3 years)),<sup>2</sup> where applicable</li> </ul> |   |
| <b>6</b> | Inspection dossier                     | <ul style="list-style-type: none"> <li>• Site master file(s) with all relevant data and reports</li> </ul>   |   |

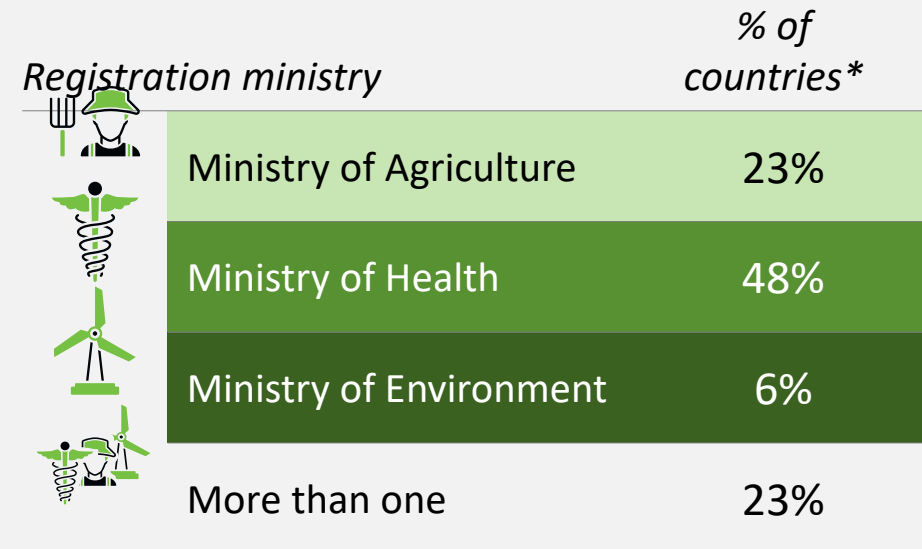
# Overseeing ministry varies significantly across the continent



## Overseeing ministry<sup>1</sup>



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



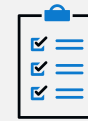
\* of the 48 African countries for which data on the registering authority was available

1. Most commonly, split authorities register different products (e.g. IRS under MoA/MoE and nets under MoH) but not always; 2. Kenya's authority (PCPB) is a semi-autonomous agency  
 Note: From this point, Ministry of Agriculture will be abbreviated as MoA, Ministry of Health as MoH, Ministry of Environment as MoE.  
 Source: 2017 ALMA; BCG analysis

# Significant variation in registration requirements as well

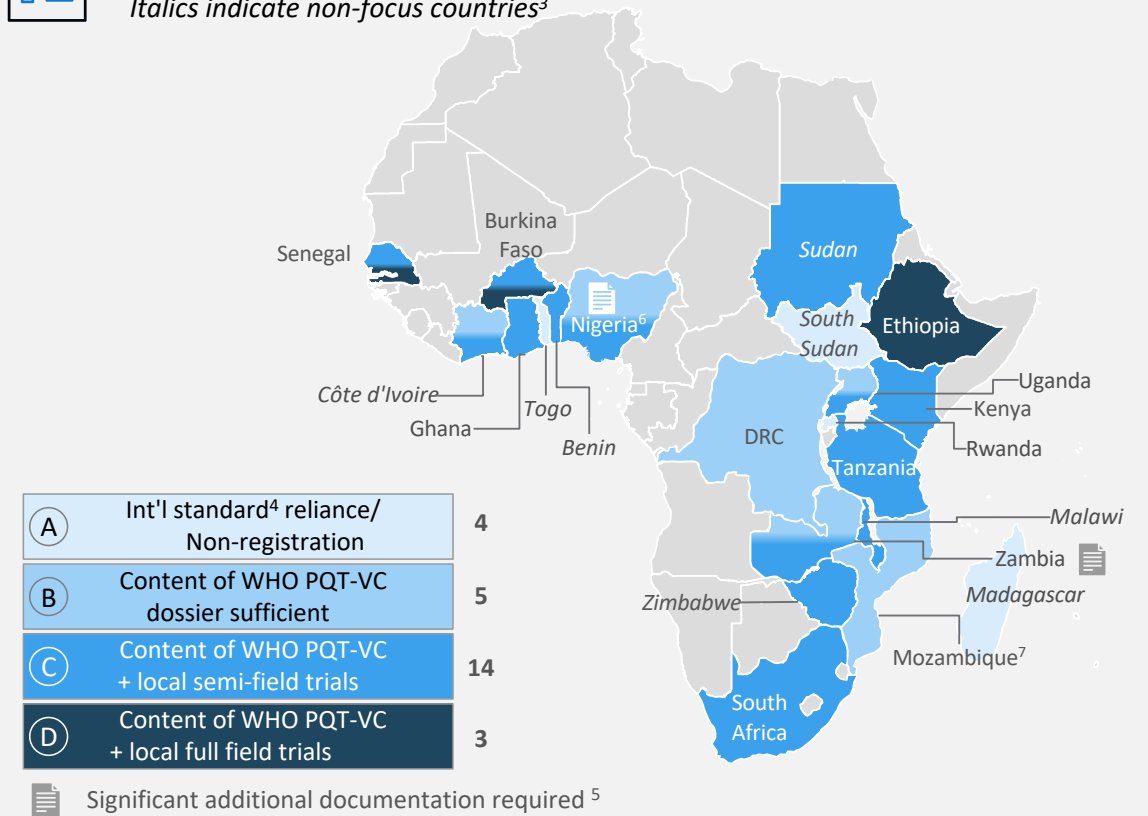
There is **no universal set of dossier requirements** specifically for vector control

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<sup>3</sup>*

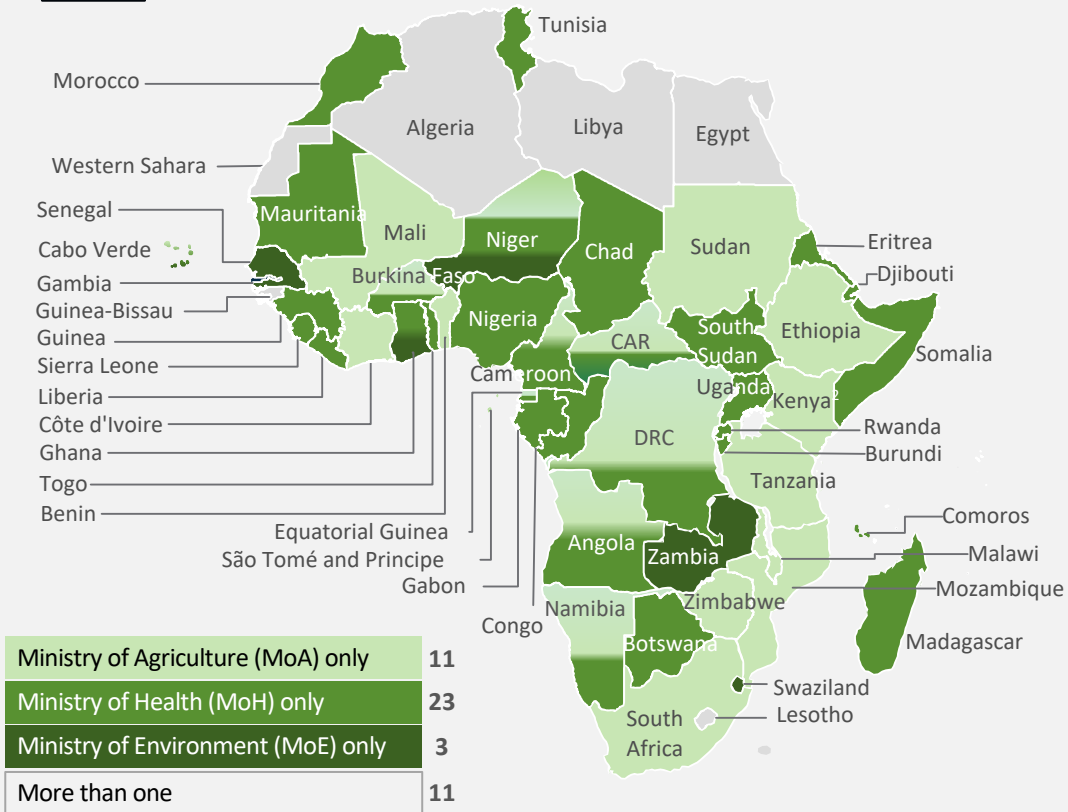


3. Country regulators were not interviewed; understanding based on interviews with int'l orgs, manufacturers, etc.; 4. e.g. WHO, US FDA, etc.; 5. Documentation varies, but can include additional safety certificates, environmental dossiers, labels and others requiring a significant investment from the applicant. 6. Trials are required only for new AI; 7. Trials are technically required for new AI, but no Source: 2017 ALMA; BCG analysis

# In summary, African VC registration is a complex landscape



## Overseeing ministry<sup>1</sup>

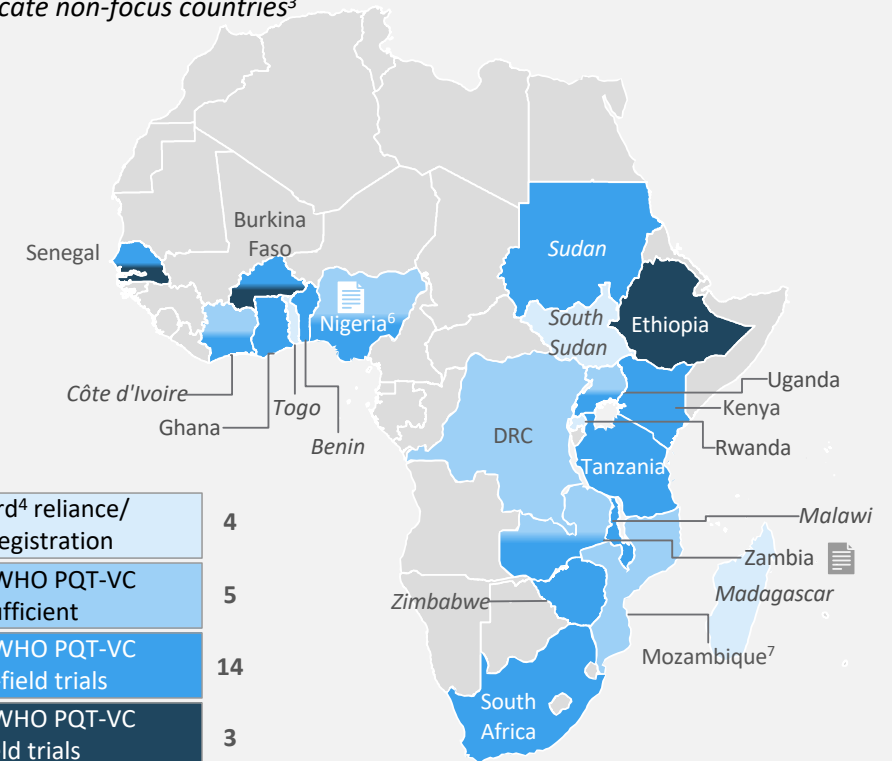


## Registration requirements

*Italics indicate non-focus countries<sup>3</sup>*

<b>(A)</b>	Int'l standard <sup>4</sup> reliance/ Non-registration	4
<b>(B)</b>	Content of WHO PQT-VC dossier sufficient	5
<b>(C)</b>	Content of WHO PQT-VC + local semi-field trials	14
<b>(D)</b>	Content of WHO PQT-VC + local full field trials	3

Significant additional documentation required <sup>5</sup>



1. Most commonly, split authorities register different products (e.g. IRS under MoA/MoE and nets under MoH) but not always; 2. Kenya's authority (PCPB) is a semi-autonomous agency; 3. Country regulators were not interviewed; understanding based on interviews with int'l orgs, manufacturers, etc.; 4. e.g. WHO, US FDA, etc.; 5. Documentation varies, but can include additional safety certificates, environmental dossiers, labels and others requiring a significant investment from the applicant. 6. Trials are required only for new AI; 7. Trials are technically required for new AI, but no historical instance of this occurring for VC products; unclear if enforced. Note: FDA is classified as MoH. Source: 2017 ALMA; BCG analysis



# Emerging challenges for VC product registration in most African countries

- 1 Unclear/overlapping mandates between national authorities**

Multiple national authorities with a mandate to register VC products, or lack of clarity on which authority is best positioned to register (largely due to the dual nature of VC as both a pesticide and human health product), which can lead to variation in standards and manufacturer confusion about where/how to register
- 2 Lack of resources to ensure adequate evaluation or quality control**

Funds not available 1) for the required expertise/technical capacity to evaluate products, 2) to convene the registration body, or 3) to adequately monitor quality or safety post-registration, causing variation in product review and/or reliance on external support
- 3 Requirements aren't tailored for Vector Control products**

E.g. pesticide-focused processes from MoE / MoA can result in superfluous requirements (e.g. residue studies), while some relevant dossier sections (e.g. efficacy studies, toxicology studies) observed as missing in some MoH dossier requirements
- 4 Delayed communication between authorities**


Back and forth efforts, slow processes in appointing committees or lack of good forums can lead to delays and less familiarity between registering/evaluating bodies
- 5 Insufficient transparency on registration process/requirements**

Unclear or insufficient communication of requirements and process steps can increase roadblocks and delays for applicants

## Double click | Selected quotes from stakeholder interviews

- 1 Unclear/overlapping mandates between national authorities**
  - **MoA regulator:** *"VC products are either chemical products managed by the MoA, or as medical products managed by the MoH. However, we know the Ministry of Health has granted Marketing Authorizations for LLINs and even IRS, which are our jurisdiction."*
- 2 Lack of resources to ensure adequate evaluation or quality control**
  - **Research institute affiliated with the MoH:** *"There are often delays when the applicant cannot pay for trials upfront, and we cannot always make up the full teams. We rely on partners like PMI, etc. and interns to support the trials."*
  - **MoH regulator:** *"We only conduct a review and a chemical composition test, and don't have the appropriate capabilities to conduct efficacy trials and other laboratory tests."*
- 3 Requirements aren't tailored for Vector Control products**
  - **Global manufacturer:** *"There's always a long back and forth with [country] because they require residue studies, which are simply irrelevant for a bed net."*
- 4 Delayed communication between authorities**
  - **MoH regulator:** *"Sometimes the Ministry of Agriculture will take several months to answer our questions regarding the dossier, if they answer them at all."*
- 5 Insufficient transparency on registration process/requirements**
  - **Global manufacturer:** *"If we knew exactly what to submit, we would have no problem doing so. But registration for VC is often a lengthy process with back-and-forth discussions for months about the necessary documentation and requirements."*

# Table of Contents

Project context	5
Pan-African registration landscape for VC tools	11
 Summary table of selected country processes	19

## Summary table | Vector Control product registration processes (I/II)

	Overseeing ministry	Ministries providing input	Registration Fees	Registration Process (in months, excl. trials)	Duration of registration (years)	Renewal Process (months)	Renewal Fees	In-country trials required?	Details on local efficacy trial requirements <sup>5</sup>
 Burkina Faso	MoA <sup>1</sup> (CILSS <sup>2</sup> pathway)	MoH, <sup>3</sup> MoE <sup>4</sup>	\$2,040	2 – 3	3 (provisional); 5 (full)	TBD	\$2,040	Always	Semi-field trials completed in a CILSS country for provisional registration, full field trials required for subsequent registration
	MoH (National pathway)	n/a	\$90	5 – 7	5	TBD	\$45	No	Contents of WHO PQT-VC sufficient
 Democratic Republic of Congo	MoH (overlapping mandate)	n/a	\$685 – \$3,000 <sup>6</sup>	0.5 – 4	5	0.5 – 4	\$685 – \$3,000 <sup>6</sup>	TBD	Efficacy trials not listed under dossier requirements
	MoA (overlapping mandate)	n/a	\$250 – \$400	3 – 4	2	3 – 4	\$250 – \$400	TBD	Efficacy trials not listed under dossier requirements
 Ethiopia	MoA	n/a	\$50	7	5	0.5	\$20	Always	Local full field trials required
 Ghana	MoE (Chemical formulation – all products)	MoH	~\$2,400	3 – 12	3	1 – 12	~\$800	Always	Local semi-field trials required
	MoH (Nets and personal use products)	n/a	Varies by product	3 – 6	3	2	Varies by product	Sometimes	Semi-field trials can be completed in a country with similar mosquito strains
 Kenya	MoA	MoH	~\$400	4 – 12 <sup>7</sup>	3	< 1 <sup>8</sup>	~\$200	Always	Local semi-field trials and/or lab tests required

1. MoA= Ministry of Agriculture; 2. CILSS= Comité Inter-Etats pour la Lutte contre la Sécheresse au Sahel; 3. MoH= Ministry of Health; 4. MoE= Ministry of Environment 5. One average, Semi-field trials range from 1-2 years; Full field trials are usually 3 years or longer; 6. Excludes the cost of site visits, which do not always occur but can cost up to \$10K; 7. Depends on manufacturer's response and length of application backlog which is 6 months as of August 2019; 8. Depends on completion and correctness of renewal application.

Note: Where two registration timelines are listed, applicants have the option of using either pathway; Source: Industry and regulator interviews; Regulator websites and documentation; BCG Analysis

## Summary table | Vector Control product registration processes (II/II)

	Overseeing ministry	Ministries providing input	Registration Fees	Registration Process (in months, excl. trials)	Duration of registration (years)	Renewal Process (months)	Renewal Fees	In-country trials required?	Details on local efficacy trial requirements <sup>5</sup>
 Mozambique	MoA <sup>1</sup>	MoH, <sup>2</sup> MoE <sup>3</sup>	\$50 – 150 +\$16/yr maintenance	3	5	<1	\$80 – \$95	Sometimes	Required for new AIs <sup>5</sup> that have not been registered in another SADC country
 Nigeria	MoH	n/a	\$760	4 – 10	5	4 – 10	\$760	Sometimes	Local semi-field trials are required if a new AI <sup>5</sup> is being registered
 Rwanda	MoH	n/a	n/a	4 – 8	Indefinite	n/a	n/a	No	Contents of WHO PQT-VC sufficient; local lab may conduct composition tests
 Senegal	MoE (CILSS <sup>6</sup> pathway)	MoH, MoA	\$2,040	2 – 3	3 (provisional); 5 (full)	TBD	\$2,040	Always	Semi-field trials completed in a CILSS country for provisional registration, full field trials required for subsequent registration
 South Africa	MoA	MoH, MoE	\$690	15 – 30 <sup>7</sup>	3	3 – 9 <sup>7</sup>	\$360	Always	WHO PQT-VC required plus local semi-field trials and stability tests
 Tanzania	MoA	MoH, MoE	\$1,150	7 – 13	5	1	\$300	Always	Semi-field trials required
 Uganda	MoH	MoE	n/a	3 – 12	TBD	n/a	n/a	Sometimes	Local lab or semi-field trials may be required on request
 Zambia	MoE	MoH	\$305	5 – 15	3	2 – 12	\$305	Sometimes	Semi-field required, but data from similar ecologies may be accepted

1. MoA= Ministry of Agriculture 2. MoH= Ministry of Health 3. MoE= Ministry of Environment; 4. One average, Semi-field trials range from 1-2 years; Full field trials are usually 3 years or longer; 5. Active Ingredient; 6. CILSS=Comité Inter-Etate pour la Lutte contre la Sécheresse au Sahel; 7. Lower bound is official timeline; upper bound is wait time given application backlog as of Feb 2019  
Source: Industry and regulator interviews; Regulator websites and documentation; BCG Analysis



Thank you