Selected African Country Registration Processes 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,[1] 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 country-level processes for 12 focus countries
- For pan-African registration landscape, please see "Pan-African Registration Landscape for Vector Control Tools" fact-base

Section title	Summary
Project context	• The project context and objectives
Overview of in-depth analysis for selected countries	• Country selection and criteria • Interviews conducted • Country assessment framework
Country-specific fact-base	• Detailed information on the regulatory authorities, registration processes and enabling environment for selected countries

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[1]
  - 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

Source: BCG Analysis

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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[1] 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

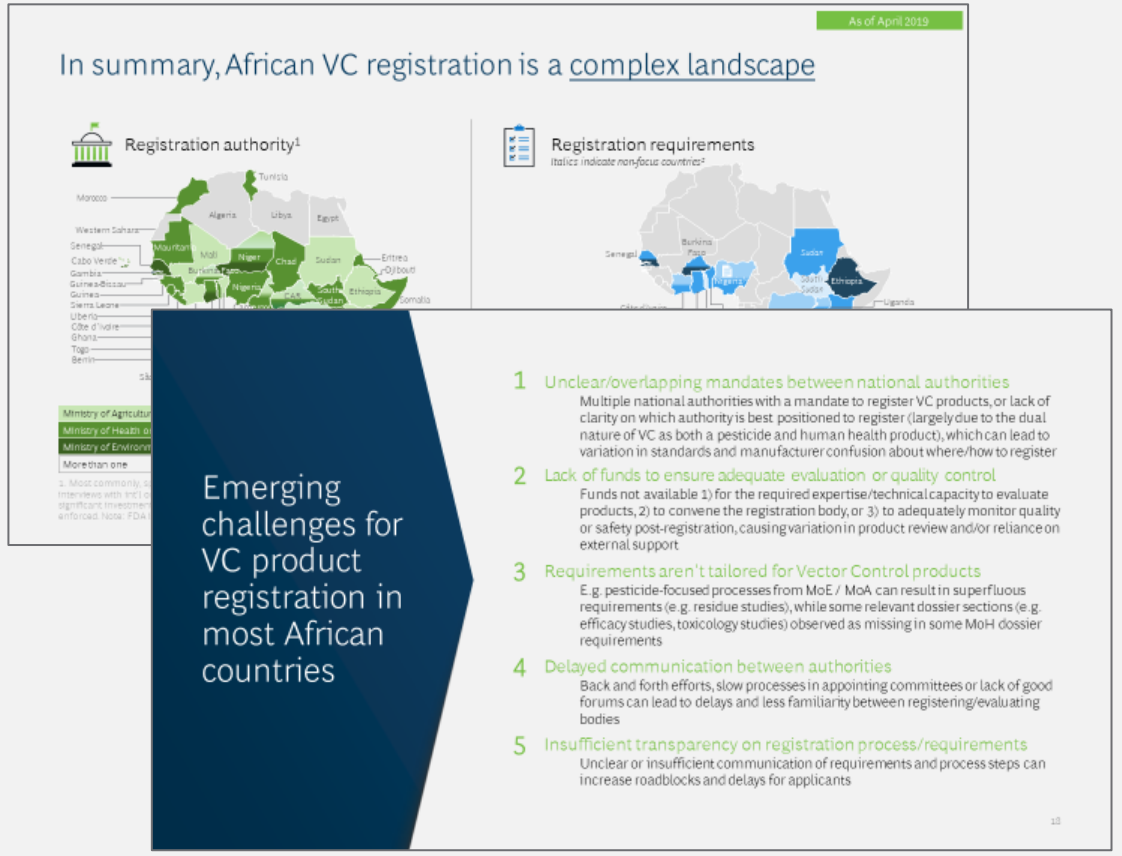
Build a comprehensive fact base around registering VC products in sub-Saharan Africa

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

For an overview of continent-wide project findings, please see:

"Pan-African Registration Landscape for Vector Control Tools"



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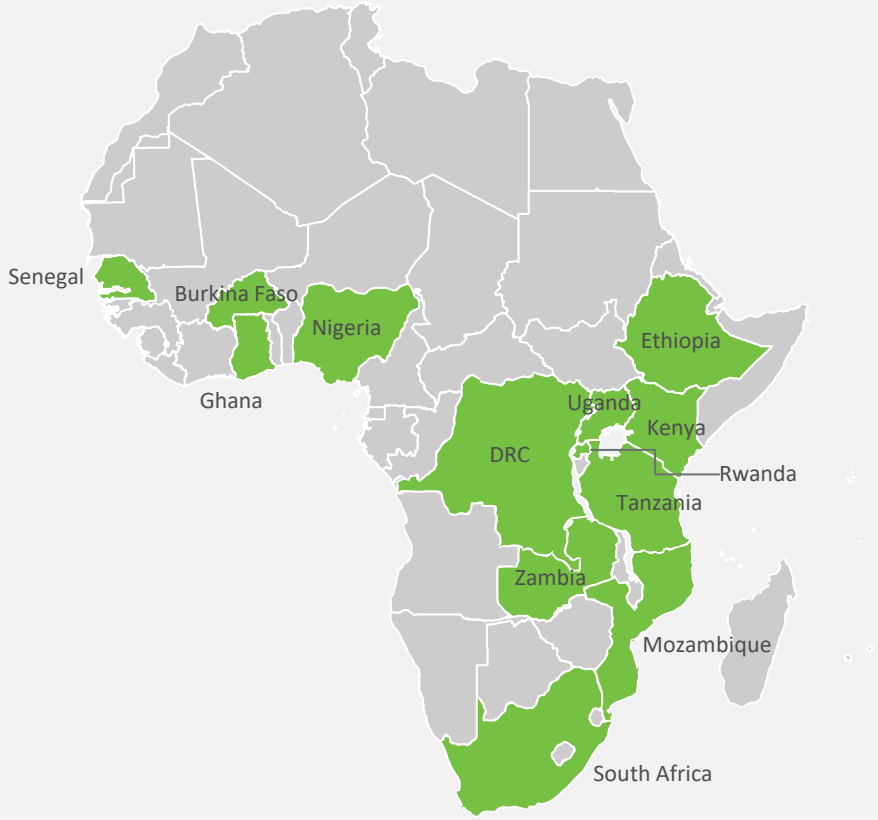
13 countries selected for in-depth analysis based on malaria burden, and regional balance/influence

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)



Source: WHO World Malaria Report 2018, number of malaria cases 2017 (point); BCG Analysis

Understanding of country processes is based on interviews with over 130 stakeholders

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

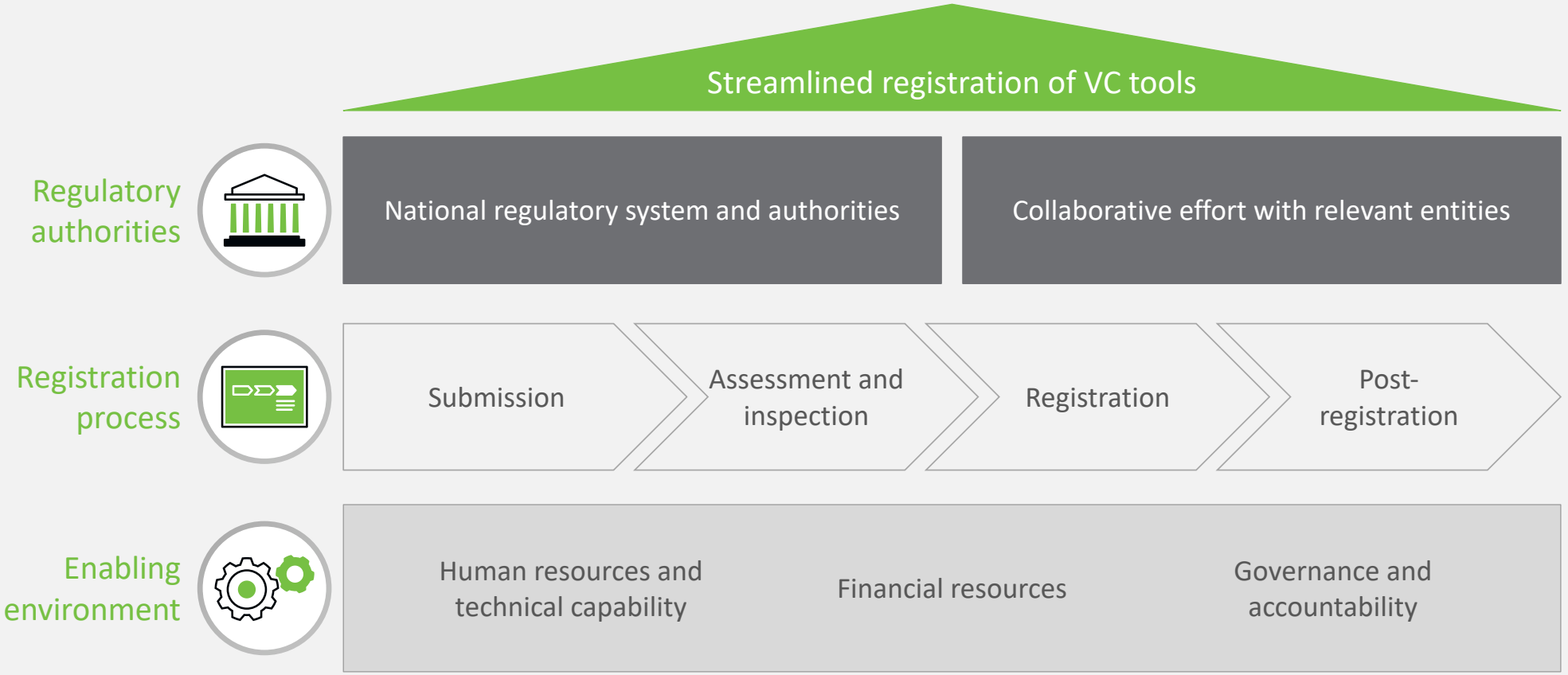
- **18** African and global partners[1]
- **9** RECs[2] and pan-African leadership
- **20** Industry players

To build country-specific knowledge, interviewed …

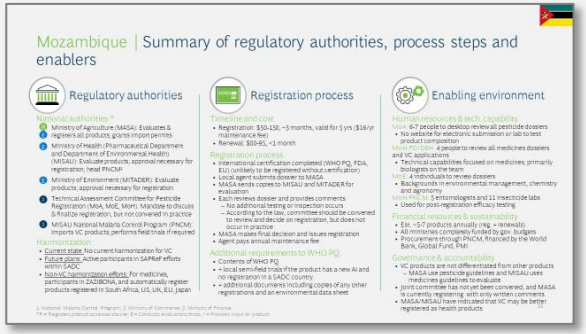
- **26** Regulatory authorities[3]
- **29** National Malaria Control Programs and relevant Ministries
- **7** National research institutes
- **6** Country-level representatives from global partners
- **17** Country-level representatives from industry players

1. Includes Global Fund, PMI, Unicef; 2. Regional Economic Communities; 3. Includes CILSS

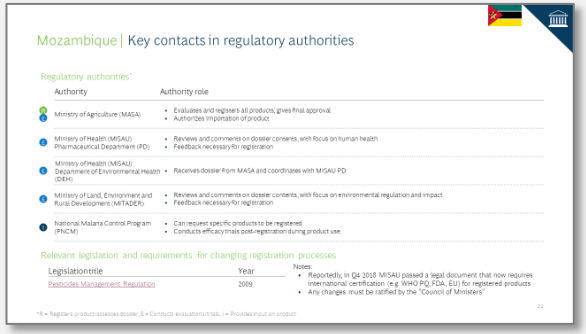
Assessment was conducted along three key dimensions …



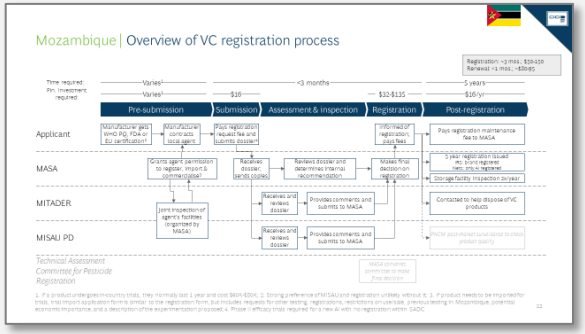
… generating robust fact-base for each country



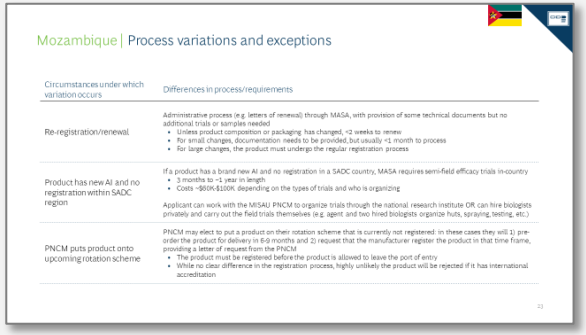
Summary of vector control tool registration



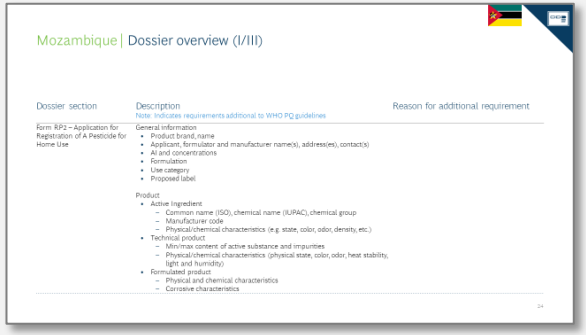
Key authorities and legislation



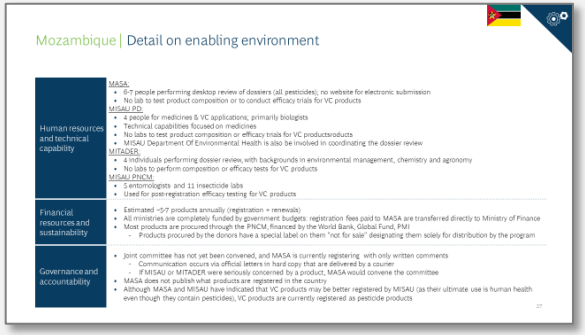
Overview of registration process



Descriptions of process variations and exceptions



Dossier overview



Detail on enabling environment

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[1] 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

1	Administrative information & labelling	• Cover letter • Application form • Table of Contents • Letter(s) of authorization • Letter(s) of access • Declaration of Labelling (includes the affixed label, leaflets, and product marketing materials)
2	Discipline summaries	• Summarized data and manufacturer conclusions (separately for quality, safety and efficacy dossier)
3	Quality dossier	• Physical/Chemical Data • Declaration of Product Formulation • Description of Manufacturing Process • Declaration of Manufacturing Sites • Confidential Appendices
4	Safety dossier	• Toxicology: Acute inhalation, oral, dermal; Primary eye irritation, skin irritation, dermal sensitization (hazard, exposure and risk characterization) • Product risk assessment • AI-specific hazard assessment (or publically available information)
5	Efficacy dossier	• Data generated from Phase I (lab studies), Phase II (semi-field conditions) and Phase III (large scale field trials (3 years)),[2] where applicable
6	Inspection dossier	• Site master file(s) with all relevant data and reports

1. WHO Pesticide Evaluation Scheme; 2. New PQT requirements for LLIN: https://www.who.int/pq-vector-control/resources/170626pqvc_020_info_note_llin_longevity.pdf?ua=1
Source: https://www.who.int/pq-vector-control/resources/dossier_req/en/

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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[5]
Burkina Faso	MoA[1] (CILSS[2] pathway)	MoH,[3] MoE[4]	$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[6]	0.5 – 4	5	0.5 – 4	$685 – $3,000[6]	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[7]	3	< 1[8]	~$200	Always	Local semi-field trials and/or lab tests required

1. MoA= Ministry of Agriculture; 2. CILSS= Comité Inter-Etate 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[5]
Mozambique	MoA[1]	MoH,[2] MoE[3]	$50 – 150 +$16/yr maintenance	3	5	<1	$80 – $95	Sometimes	Required for new AIs[5] 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[5] 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[6] 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[7]	3	3 – 9[7]	$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
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

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Ministry of Agriculture

B Content of WHO PQT-VC sufficient

C Content of WHO PQT-VC + local semi-field trials

Mozambique | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R E Ministry of Agriculture (MASA): Evaluates & registers all products except for mosquito nets (no current in-country registration required); grants import permits

E Ministry of Health (MISAU) : Evaluate products; approval necessary for registration

E Ministry of Environment (MITADER): Evaluate products; approval necessary for registration

I Technical Assessment Committee for Pesticide Registration (MoA, MoE, MoH): Mandate to discuss & finalize registration, but not convened in practice

I MISAU National Malaria Control Program (PNCM): Imports VC products; performs field trials if required

Harmonization:

- Current state: Active participants in SAPReF[1] efforts within SADC, which includes VC for Mozambique
- Future plans: Continue SADC efforts
- Non-VC harmonization efforts: For medicines, participants in ZAZIBONA[2] and automatically register products registered in South Africa, US, UK, EU, Japan

Registration process

Timeline and cost (excluding field trials):

- Registration: ~3 months, $50-150 (+$16/yr maintenance fee), valid for 5 yrs
- Renewal: <1 month, $80-95

Registration process:

- International certification completed (WHO PQT-VC, FDA, EU) (unlikely to be registered without certification)
- Local agent submits dossier to MASA
- MASA sends copies to MISAU and MITADER for evaluation
- Each reviews dossier and provides comments
  - No additional testing or inspection occurs
  - According to the law, committee should be convened to review and decide on registration, but does not occur in practice
- MASA makes final decision and issues registration
- Agent pays annual maintenance fee

Additional requirements to WHO PQT-VC:

- Local semi-field trials if the product has a new AI and no registration in a SADC country
- MISAU highly unlikely to give approval for a product with no WHO, EU or FDA approval
- Additional admin documents required, including copies of other registrations and an environmental data sheet

Enabling environment

Human resources & tech. capability

MoA: 6-7 people to desktop review all pesticide dossiers
- No website for electronic submission or lab to test product composition

MoH: 4 people to review all medicines dossiers and VC applications
- Technical capabilities focused on medicines; primarily biologists on the team

MoE: 4 individuals to review dossiers
- Backgrounds in environmental management, chemistry and agronomy

MoH PNCM: 5 entomologists and 11 insecticide labs
- Used for post-registration monitoring

Financial resources & sustainability

- Est. ~5-7 products annually (reg. + renewals)
- All ministries completely funded by gov. budgets
- Procurement through PNCM, financed by the World Bank, Global Fund, PMI, etc.

Governance & accountability

- MASA registers all product with written comments from MISAU and MITADER
- PNCM is not involved directly in registration, but can import mosquito nets without involving MASA, and can request for the registration of certain products

1. Southern African Pesticides Regulators Forum; 2. SADC Collaborative Medicines Registration Initiative

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Mozambique | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	Ministry of Agriculture (MASA) National Directorate of Agriculture and Forestry (DINAS)	• Evaluates and registers all products; gives final approval • Authorizes importation of product
E	Ministry of Health (MISAU) National Directorate of Public Health (DNSP)	• Reviews and comments on dossier contents, with focus on human health • Feedback necessary for registration
E	Ministry of Land, Environment and Rural Development (MITADER) National Directorate of Environment (DINAB)	• Reviews and comments on dossier contents, with focus on environmental regulation and impact • Feedback necessary for registration
I	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
Pesticides Management Regulation	2009

Notes:

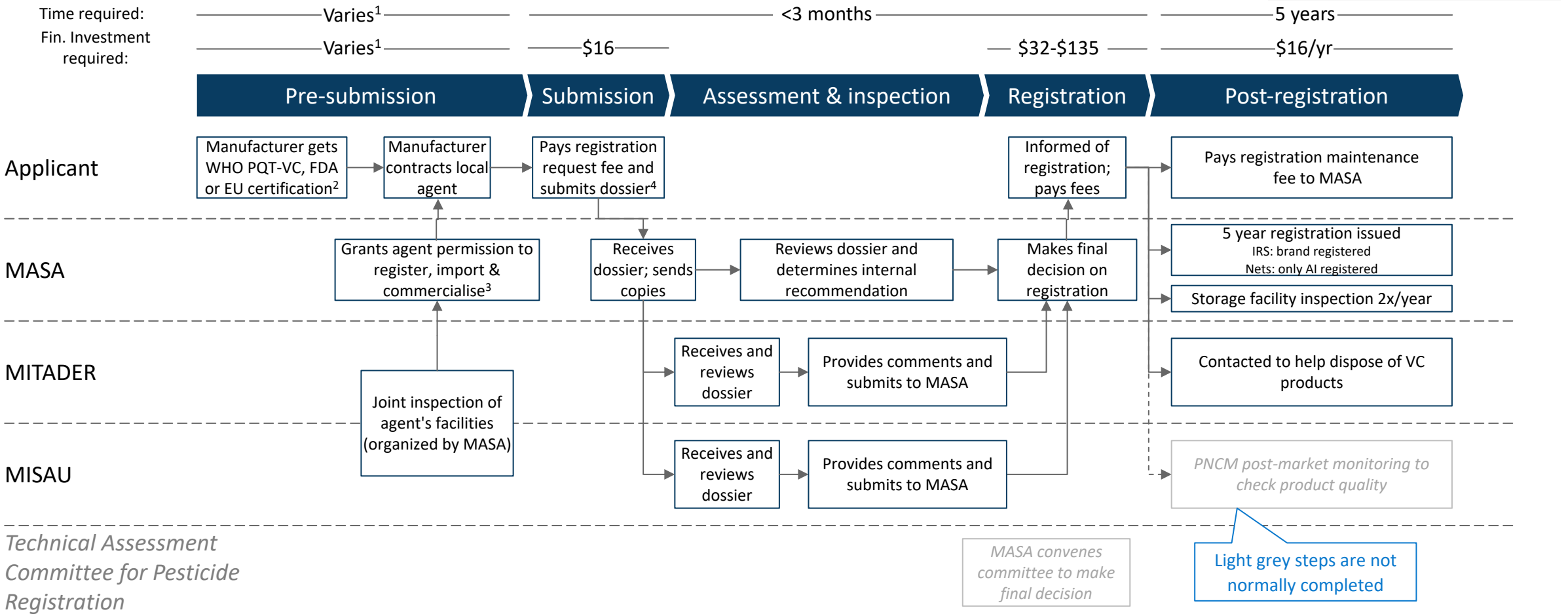
- No legal framework/requirement for registering mosquito nets in Mozambique, even if treated with a pesticide
- Any legal changes must be ratified by the "Council of Ministers"

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Mozambique | Registration process map

Timeline/cost (excluding field trials):

Registration: ~3 mos.; $50-150
Renewal: <1 mos.; ~$80-95



1. If a product undergoes in-country trials, they normally last 1 year and cost ~$60K-$100K; 2. Strong preference of MISAU and registration unlikely without it; 3. If product needs to be imported for trials, trial import application form is similar to the registration form, but includes requests for other testing, registrations, restrictions on use/sale, previous testing in Mozambique, potential economic importance, and a description of the experimentation proposed; 4. Semi-field efficacy trials required for a new AI with no registration within SADC

Mozambique | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Renewal	Administrative process (e.g. letters of renewal) through MASA, with provision of technical documents for any changes made, but no additional trials or samples needed • Unless product composition or packaging has changed, <2 weeks to renew • For small changes, documentation needs to be provided, but usually <1 month to process • For large changes, the product must undergo the regular registration process
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 would require semi-field efficacy trials in-country – has not occurred in past 10 years, if not longer • 3 months to ~1 year in length • Costs ~$60K-$100K depending on the types of trials and who is organizing 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.)
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 1) pre-order the product for delivery in 6-9 months and 2) request that the manufacturer register the product in that time frame, providing a letter of request from the PNCM • The product must be registered before the product is allowed to leave the port of entry • While no clear difference in the registration process, highly unlikely the product will be rejected if it has been requested by the PNCM and has international accreditation
Product is mosquito net	Nets do not currently legally require registration in Mozambique, even if impregnated with pesticides, and can be imported into the country with no direct oversight from MASA, MISAU or MITADER

Mozambique | Dossier overview (I/III)

Dossier section	Description
Form RP2 – Application for Registration of A Pesticide for Home Use	General information • Product brand, name • Applicant, formulator and manufacturer name(s), address(es), contact(s) • AI and concentrations • Formulation • Use category • Proposed label Product • Active Ingredient – Common name (ISO), chemical name (IUPAC), chemical group – Manufacturer code – Physical/chemical characteristics (e.g. state, color, odor, density, etc.) • Technical product – Min/max content of active substance and impurities – Physical/chemical characteristics (physical state, color, odor, heat stability, light and humidity) • Formulated product – Physical and chemical characteristics – Corrosive characteristics

Mozambique | Dossier overview (II/III)

Dossier section	Description
Form RP2 – Application for Registration of A Pesticide for Home Use (cont.)	Analytical methods (MS Data Sheet, technical specifications) • For AI, technical and formulated product Toxicology (1/2) • Acute oral, dermal, inhalation for technical and formulated product on animal test • Irritation to skin, eyes, mucous membranes of technical and formulated product • Chronic toxicity, sub-chronic and other effects in mammals • Toxicity class assigned Toxicology (2/2) • Product mode of action • Compatibility with other products Product use • Use, pests controlled • Dose and time of application • Method of application including applicator type • Results of product efficacy testing in SEARCH countries • Registration of product in SEARCH countries • Registration in country of manufacture or formulation, justification if not

Mozambique | Dossier overview (III/III)

Dossier section	Description
Form RP2 – Application for Registration of A Pesticide for Home Use (cont.)	Pesticide behavior in environment • Degradability • Bioaccumulation • Toxicity to other organisms Proposed packaging (types and sizes) Elimination of pesticides and empty containers Recommendation for safety equipment in case of fire
Safety Data Sheet	From WHO
Agent authorization letter	Authorizes agent on behalf of the manufacturer
Manufacturer authorization letter	Letter from the producer of the active substance
Certificate of authenticity	From the country of origin of the product
Proposed labels	In accordance with local guidelines
Appendices	All original data and reports corresponding to sections in RP2, including copies of the certificates of registration from other countries

Mozambique | Detail on enabling environment

Human resources and technical capability	MASA: • 6-7 people performing desktop review of dossiers (all pesticides); no website for electronic submission • No lab to test product composition or to conduct efficacy trials for VC products MISAU: • 4 people for medicines & VC applications; primarily biologists • Technical capabilities focused on medicines • No labs to test product composition or efficacy trials for VC products MITADER: • 4 individuals performing dossier review, with backgrounds in environmental management, chemistry and agronomy • No labs to perform composition or efficacy tests for VC products MISAU PNCM: • 5 entomologists and 11 insecticide labs • Used for post-registration monitoring for VC products
Financial resources and sustainability	• Estimated ~5-7 products annually (registration + renewals) • All ministries are completely funded by government budgets: registration fees paid to MASA are transferred directly to Ministry of Finance • Most products are procured through the PNCM, financed by the World Bank, Global Fund, PMI
Governance and accountability	• MASA registers all products, but must have comments from MISAU and MITADER (from the joint committee, but currently MASA registers using written comments) – If MISAU or MITADER were seriously concerned by a product, MASA would convene the committee – MASA does not publish what products receive registration • PNCM is not involved directly in registration, but can import mosquito nets without involving MASA, and can request for the registration of certain products

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Ministry of Agriculture

C Content of WHO PQT-VC + local semi-field trials

South Africa | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

- R Direct. Agricultural Inputs Control (DAIC), under Dep. of Agriculture, Forestry and Fisheries (DAFF): Screens applications and has authority to register
- E I Joint committee led by Dep. of Health (DoH, DAFF, experts, Provincial Malaria Managers): Recommends registration decision
- E I Research authorities (MRC[1] or NICD[2]): Conduct scientific evaluation/trials
- I Department of Environmental Affairs (DEA): Supports sample import permit for field trials

Harmonization:

- Current state: Registration requires SEARCH[3] form
- Future plans: No future plans
- Non-VC harmonization efforts: SAPReF[4] and SADC efforts for pesticides harmonization

Registration process

Timeline and cost (excluding field trials):

- Registration: ~15-30 months,[5] $690 registration cost, 3 yr validity
- Renewal: ~3-9 months,[5] $360

Registration process:

- WHO PQT-VC required; local small-scale semi-field trials conducted in SA if not completed already
  - DAFF supported by DEA grants import permit
- DAIC runs an administrative screening (to verify completeness)
- Joint DoH/DAFF committee runs scientific screening (to verify all scientific documents)
  - Applicant has 30 days to fulfill requests
- Committee requests additional trials, if needed, to be completed by research authorities
- Technical advisor from joint committee submits evaluation report and recommendation to registrar, who reviews and issues registration

Additional requirements to WHO PQT-VC:

- WHO PQT-VC required
- Plus local semi-field trials and stability tests
- Plus additional administrative documentation (e.g., SEARCH form)

Enabling environment

Human resources & tech. capability

- DAFF had 2 coordinators and 5 technical advisors members in 2016
- Joint committee is 10-15 members
  - Backgrounds include public health, chemistry, biology, entomology
- Trials and lab evaluations outsourced to MRC[1]/NICD[2]
- As of February 2019, 16-24 month backlog on registration applications

Financial resources & sustainability

- # registrations per year unknown
- Applicant fees fund entire process, including for additional trials or requested evaluations;
- Other funding sources unknown

Governance & accountability

- Although DAFF registers, recommendation determined by joint committee, led by DOH and informed by relevant experts, local evaluation trials and Provincial Malaria Managers (end users)

1. Medical Research Council; 2.National Institute for Communicable Diseases; 3. South East Africa Regulatory Committee on Harmonization for Regulation of Pesticides; 4. Southern African Pesticide Regulators Forum; 5. Lower bound is officially stated timeline, upper bound is current wait time given application backlog as of February 2019

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

South Africa | Overview of relevant authorities for VC tools registration

Relevant authorities*

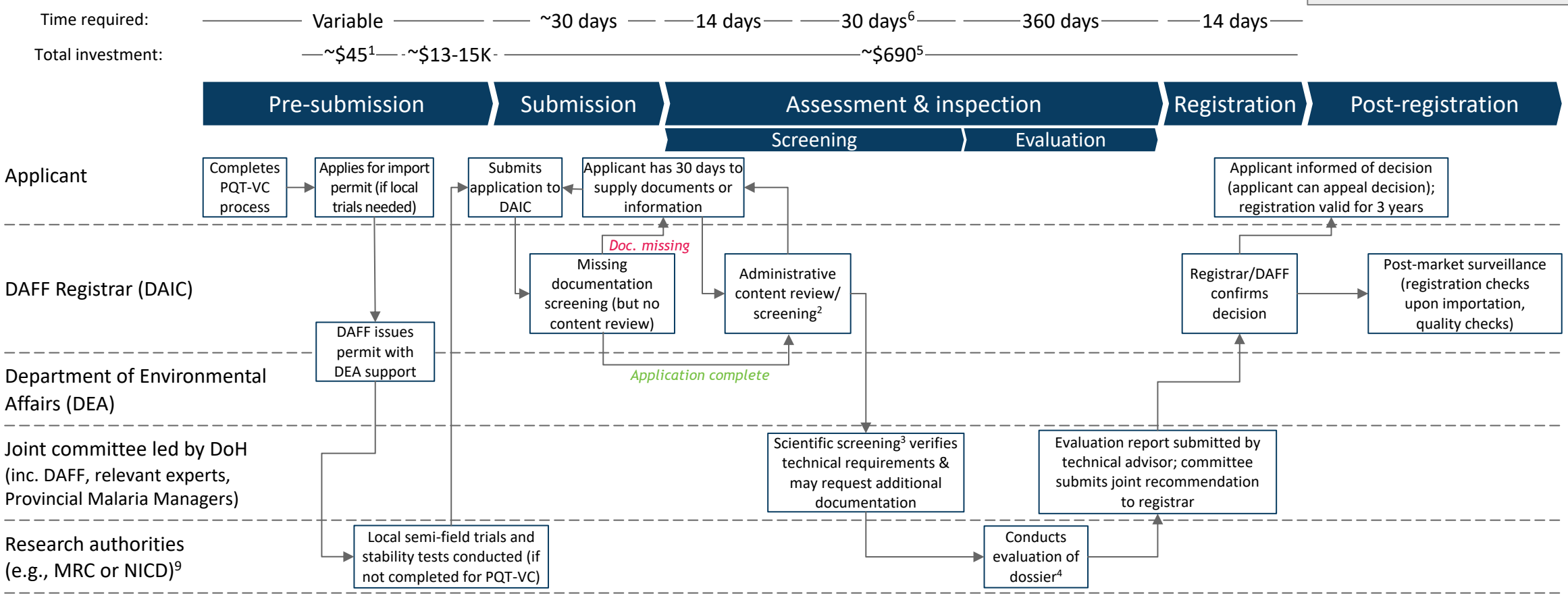
	Authority	Authority role
R	Department of Agriculture, Forestry and Fisheries (DAFF)	• Conducts all administrative responsibilities including registration of product • Reviews scientific dossier requirements • Issues short term import permits
E I	Department of Health (National Malaria Control Program)	• Heads the joint committee which reviews all scientific and technical requirements in the dossier • Submits a joint recommendation, in collaboration with research authorities on registration
E I	Research authorities	• Conducts any additional evaluations or trials • Participates in joint committee
I	Department of Environmental Affairs	• Helps issue import licenses for short term trial evaluations

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

South Africa | Registration process map (for new active ingredient)

Timeline/cost (excluding field trials):

Registration: ~15-30 mos.;[7] ~$690
Renewal: ~3-9 mos.; ~$360[8]



1. R606; 2. The following items are evaluated: cover letters, service request form, applicant details, approved person details, product registration number, forms fully filled and signed, legibility of information and initialization of any corrections, fees paid, three copies of labels, other data specified; 3. Requirements detailed in Dossier overview; 4. For all VC products, trial requirements, protocols and evaluation must follow WHO; trials must be conducted in South Africa; 5. R9728; 6. Dossier backlog as of February 2019 is 16-24 months long (before dossier reviewed); 7. Lower bound is officially stated timeline, upper bound is current wait time given application backlog; 8. R4876; 9. Medical Research Council; National Institute for Communicable Diseases

South Africa | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Renewal	• Mainly administrative, lasting ~3-9 months (depends on application backlog), administered through DAFF • Requirements: – Proof of payment of the prescribed application fee, renewal application forms, signed declaration that accompanies the renewal application; in the case of a Daughter registration being renewed, a newly signed legal agreement – Renewal will be cancelled if applicant is no longer purchasing AI from the same source they registered the product with; may need to apply for a new registration • Cost: ZAR5,145/application/product if additional/new AI, change of AI specification, change of manufacturer, amendment of shelf life
Emergency registration	• If there is an outbreak or emergency, a product can be “fast-tracked” and may not follow all administrative processes (e.g. "skips the queue but still needs evaluation) – Examples include immediate action to protect from a disaster, resistance developed to current product, need to import product that is missing that isn’t registered – E.g., At the time of an emergency, there was no registration holder for DDT so the gov’t became an intermediary registration holder in order to get the product registered • ~1-3 months, but timeline depends on how quickly the applicant gets the required documentation • Cost: ZAR1,581 per application/product
New product or new packaging with already registered active ingredient	• Product must verified with DAFF, but full process with joint committee does not take place • DAFF may require some documentation, but application is for a “new registration holder” not a new “registration” • Cost: ZAR5,145/application/product (ZAR1,055 if only minor change in formulation or change in name, address, etc.)

South Africa | Dossier overview (I/III)

Dossier section	Description
Service Request Form	Completed by the applicant/registration holder and submitted application form(s)/supporting documentation
Cover Letter	Addressed to the Registrar for the attention of the Head of the Registration Administration Office, and includes: • Name of product • Registration number if product is already registered • Reason for submission • Reference standard • Identification of the sets of documents enclosed • Letters of consent if permission from the registration holder is required

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

South Africa | Dossier overview (II/III)

Dossier section	Description
SEARCH Form	Applicant • All manufacturing sites, stock depots/warehouses and distribution agents directly controlled by the applicant Product • The relevant latest Croplife International/FAO Code • Custom Tariff Code Active Ingredient(s) • Common name • Manufacturer's name and address • Specified minimum active level or purity range Formulation • Full names and addresses of all manufacturing sites • Confirmation letter on manufacturer letterhead confirming adherence to registration and formulation details Toxicology • Toxicity data generated using OECD guidelines at an OECD GLP accredited laboratory submitted for hazard classification Packaging • Container material • Pack size

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

South Africa | Dossier overview (III/III)

Dossier section	Description
Active Ingredient: Dossier Index List I	• Designation – Common name, manufacturer code, chemical name (IUPAC), chemical group, structural and empirical formula, patent status • Physical and chemical properties • Toxicology • Ecotoxicology • Behaviour environment • Mode of action • Plant residues • Additional ad hoc requirements
Formulated Product: Dossier Index List II	• Physical and chemical properties • Toxicology • Emergency procedures • Use • Minimum label requirements • Efficacy reports – Trial requirements, protocols and evaluation for efficacy reports must follow the published WHO methods – All efficacy data must be generated from trials conducted in South Africa

Source: 2018 DAFF Guidelines On The Data And Documents Required For The Registration Of Agricultural Remedies Used In Non Crop Situations In South Africa

South Africa | Detail on enabling environment

Human resources and technical capability	DAIC had 2 coordinators and 5 technical advisors members in 2016 Joint committee is 10-15 members: • Backgrounds include public health, chemistry, biology, entomology Trials & evaluations outsourced to MRC[1] and NICD[2] As of February 2019, 16-24 month backlog on registration applications
Financial resources and sustainability	Number of registrations per year unknown Applicant fees fund entire process, including for additional trials or requested evaluations • Other funding sources unknown
Governance and accountability	Joint committee led by Department of Health (including DAFF, relevant experts, Provincial Malaria Managers (end users)) gives a recommendation to DAFF • Committee will sometime sometimes give conditional recommendations (e.g. registration subject to these conditions) National Malaria Program not explicitly on committee, but represented through DoH and Malaria Managers

1. Medical Research Council; 2.National Institute for Communicable Diseases;

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Ministry of Environment

B Content of WHO PQT-VC sufficient

C Content of WHO PQT-VC + local semi-field trials

Zambia | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R Zambian Environmental Management Agency (ZEMA): Issues import permits for all VC products, serving as de facto registration; evaluates dossier with NMEC recommendation

E Ministry of Health (MoH): National Malaria Elimination Centre (NMEC) coordinates efficacy lab/field trials and provides a recommendation to ZEMA

I Other research institutions: Can execute lab/field trials or composition tests

Harmonization:

- Current state: No harmonized approach, but trials in line with PQT-VC and forms with SEARCH[1]
- Future plans: Active participant of SAPReF[2]
- Non-VC harmonization efforts:
  - E8: Uniform VC success indicators implemented; plan for pooled procurement
  - GHS[3] adopted for labels

Registration process

Timeline and cost (excluding field trials):

- Registration: 5-15 months, ~$305, lasts for 3 yrs
- Renewal: 2-12 months, ~$305

Registration process:

- Applicant receives information on requirements and submits dossier to ZEMA
- If local trials completed at accredited institution:
  - ZEMA reviews dossier contents, requests MoH approval letter (if not already submitted) and communicates decision
- If no local trials completed at submission:
  - Applicant reaches out to NMEC, which assesses and organizes trials (if necessary), supplies results and letter of approval
  - ZEMA conducts dossier review and communicates decision to applicant
- Products with and without PQT-VC can be registered

Comparison with WHO PQT-VC:

- Additional admin doc. required (e.g. label)
- In principal, local full field trials required for new formulation and semi-field for all others; in reality, some products receive NMEC approval & registration with no local trials

Enabling environment

Human resources & tech. capability

- 6 people on ZEMA registration team
- Neither ZEMA nor NMEC has a lab to test product composition/quality
- Research teams are often filled by scientists from PATH/PMI/others and NMEC interns

Financial resources & sustainability

- 1-3 new applications/yr; 10-15 re-registrations
- Trials are funded entirely by applicant; potential delays if they do not pay up front
- Registration fees submitted to Zambia central government and then redistributed through yearly budgets to ZEMA

Governance & accountability

- ZEMA is accountable for all registrations, and registers products at the request of the manufacturer, not necessarily in line with the NMEC plan
- NMEC provides efficacy evaluation for ZEMA
- Decision about product use (regardless of registration) is made at a committee involving NMEC and researchers

1. South East Africa Regulatory Committee on Harmonization for Regulation of Pesticides 2. Southern African Pesticide Regulators Forum 3. Globally Harmonized System of Classification & Labelling of Chemicals

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Zambia | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R	The Zambian Environmental Management Agency (ZEMA)	• Oversee process and authorized to issue import permits • Verify dossier requirements and assesses environmental impact materials
E	National Malaria Elimination Centre (NMEC) under Ministry of Health (MoH)	• Provides recommendation to ZEMA based on efficacy data; will conduct efficacy trials (lab based, semi-field and full field depending on the data submitted and assessed need for additional data generation)
I	Labs and other research authorities	• Can execute efficacy trials separately or coordinated by NMEC: – Tropical Disease Research Centre, MACHA Malaria Research Institute, MACHA Research Trust • Conduct composition tests at ZEMA's request: – Food and Drug Laboratory, Zambia Bureau of Standards, National Institute of Scientific Research, University of Zambia

Relevant legislation and requirements for changing registration processes

Legislation title	Year
The Environmental Management Act No. 12	2011
Statutory Instrument 112	2013

Notes:

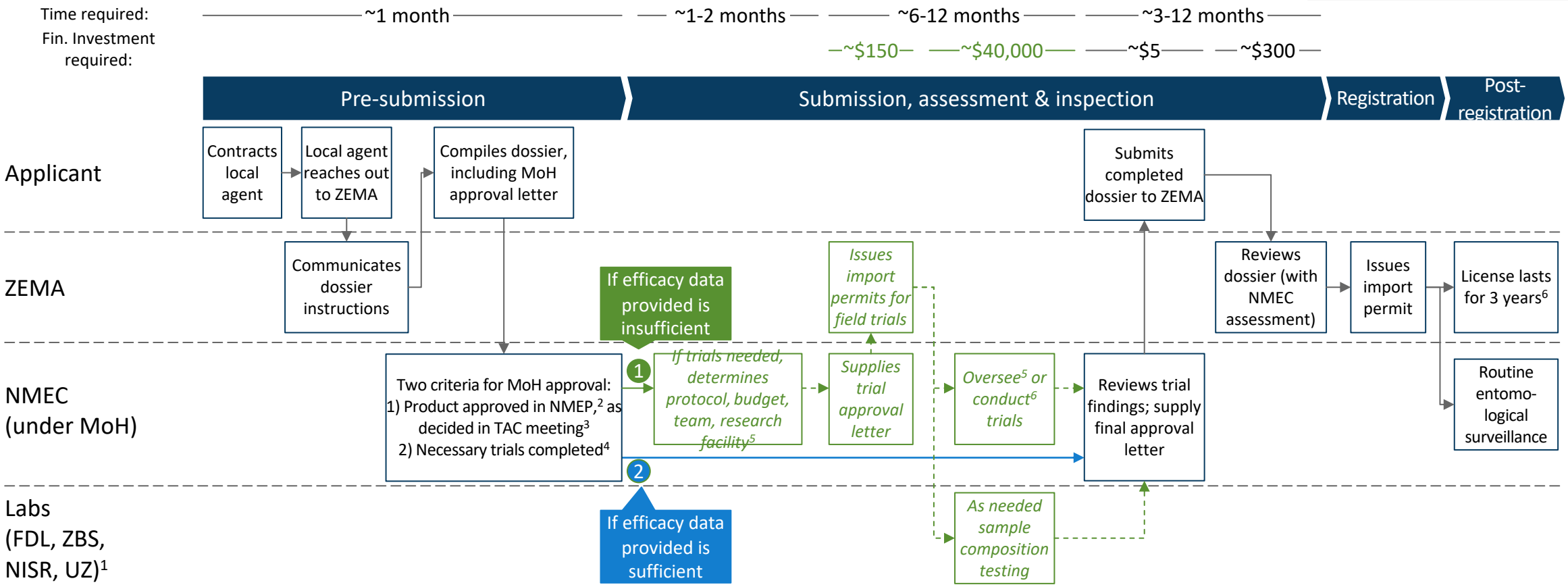
- While no mandate to register exists in Zambia under the Environmental Management Act No. 12, ZEMA is authorized to issue import permits for all VC products, serving as de facto registration; this has minimal, if any, tangible impact on the process
- Changes to the registration process would have to be added as a statutory instrument with approval from the Prime Minister, but would not go through Parliament

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Zambia | Registration process map

Timeline/cost (excluding field trials):

Registration: 5-15 mos, ~$305
Renewal: ~2-12 mos.; ~$305



1. Food and Drug Laboratory, Zambia Bureau of Standards, National Institute of Scientific Research, University of Zambia; 2. National Malaria Elimination Plan; 3. Technical Advisory Committee, comprises of MoH, ZEMA, NMEC and researchers, WHO, procurement, supporting NGOs, etc.; 4. NMEC must approve that the product has sufficient efficacy data for registration. Field trials from other similar ecologies may be sufficient. If efficacy data is missing or insufficient, NMEC will work with the applicant to determine the protocols and setup for field trial completion in Zambia;
5. NMEC may outsource trials to another lab; 6. For new AI/new formulation, trials consist of mortality, stability, decay rate in a lab, semi-field and full field setting. For no new formulation or AI, trials consist of a lab susceptibility test on lab and wild mosquitos, as well as a small-scale field trial; 6. To renew must apply 6 months before expiry

Zambia | Process variations and exceptions (I)

Circumstances under which variation occurs	Differences in process/requirements
In-country efficacy trials completed prior to dossier submission	If trials are completed at a accredited research institution (NMEC, TDRC, MMRI, MRT),[1] then ZEMA will review dossier and request a simple approval letter from NMEC given the results and make a decision (no further trials)
Registration granted with no in-country efficacy trials	If NMEC deems product can be recommended based solely on a literature review, then they will provide an approval letter with no in-country efficacy lab or field trials • Requires that the product has undergone efficacy trials in some country (usually an ecologically similar one) and usually applies only to PQT-VC listed products • Will not occur if product has any major safety/efficacy concerns
Provisional registration	In some special cases, NMEC may give recommendation before the full efficacy tests are completed using a preliminary report (outlined and agreed to by ZEMA, NMEC and applicant in protocols): ZEMA will issue provisional 1 year registration • This can occur after only 6 months of field trial for products with 1 year efficacy or 12 months of field trial for products claiming 2-3 year efficacy in order to get products to market faster • Full results must be submitted once completed, and registration will then be confirmed or withdrawn • Example: One product received registration after 12 month trials (despite 24 month trials in place) because it became WHO PQT-VC listed and preliminary results were agreed upon to be satisfactory
Emergency registration	A provisional permit might be given to a product before the MoH evaluation reports are done in order to fast-track deployment, usually in cases of emergency • Post-deployment, the product will receive a full permit when evaluations are completed • Example: One product was registered in Zambia prior to getting PQT-VC approval and full MoH evaluation, because Zambia needed to rotate products and didn't have an alternative at the time

1. National Malaria Elimination Center, Tropical Disease Research Centre, MACHA Malaria Research Institute, MACHA Research Trust

Zambia | Process variations and exceptions (II)

Circumstances under which variation occurs	Differences in process/requirements
Re-registration/renewal	Administrative (e.g. letters of renewal) through ZEMA, with no additional trials or samples required • Must apply 6 months before registration ceases • Process is supposed to last ~2 months, but can last up to 12 months from submission due to processing delays
Product is genetically modified	If the product submitted is genetically modified, product would be sent by ZEMA to the National Biosafety Authority

Zambia | Dossier overview (I/V)

Dossier section	Description
Application for a Pesticide and Toxic Substance Licence (Form VIII)	Cover sheet • Name of Applicant • Type of facility • Certificate of incorporation no. • Notification address and numbers • Authorized contact person • Local agent if different from registration holder • Product to be manufactured, blended, formulated, re-formulated, processed, reprocessed or changed • Facilities to be licensed (if any) • Reasons for import/export Appendices to include • 1: Decision Letter • 2: Returns • 3: Efficacy report • 4: Name and qualifications of person responsible for pesticide/toxic substance management, compliance with the Act and the conditions of the license • 5: Chemical dossier • 6: Details of field trials (where applicable)

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

Zambia | Dossier overview (II/V)

Dossier section	Description
Application for a Pesticide and Toxic Substance Licence (Form VIII)	Product identification • Product Registration Number (if applicable) • Product status (trial/non-trial) • Type of pesticide or toxic substance • Trade name, trade mark, trade mark holder • Specify if product is registered in country of origin, manufacture, and formulation • Registration in SADC and other countries • Full chemical names, common names, • Empirical and structural formal for each AI • Concentration of AI • Percentage of purity • Physical and chemical properties of each ingredient (e.g. appearance, density, flammability, wettability, suspendability, emulsion stability, corrosiveness, known incompatibilities) • Containers size and nature • Stability of formulation

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

Zambia | Dossier overview (III/V)

Dossier section	Description
Application for a Pesticide and Toxic Substance Licence (Form VIII)	Toxicology • Toxicology (AI, formulated product) • WHO classification, GHS classification • Summary of other mammalian toxicological studies Ecotoxicology • Toxicity to a variety of animals • Persistence • Other available toxicological data for non AI Packaging • Type, size, method of disposal Other requirements • Directions for safe disposal • Measures to minimize operator exposure • Sanitary measures • Clearance by phytosanitary authorities (country of origin, recipient country) • Phytotoxicity • Safety precautions • Hazard to environment, residue data • Proposed use, directions of use • Biological effectiveness and benefit in use

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

Zambia | Dossier overview (IV/V)

Dossier section	Description
Label approval (Form X)	Details of label for: • Trade Name • Active Ingredients • Chemical name • Intended use • Directions for use • Details of the manufacturer, supplier and local distributor • The withholding period • Warnings, in pictograms, on the safe use • Hazard warnings of the contents • Warning against the re-use of containers • Instructions for safe disposal of a surplus or expired pesticide/ toxic substance or de-contamination of empty containers • First aid instructions and medical advice on treatment • Date of manufacture and expiry • Net contents • Colour code • Toxicity, Hazard class(es) • Appendix: Proposed label • Appendix: Consent Letter from the Supplier/Manufacturer

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

Zambia | Dossier overview (V/V)

Dossier section	Description
Appendices/attachments	• Safety Data Sheet (SDS) • Full efficacy reports from trials • Certificate of Analysis (COA) • Certificate of registration if any (from country of origin, SADC region) • Letter of consent from the supplier/manufacturer • Summary of Technical and Formulation of product report

Source: The Environmental Management Act, 2011 (Act No. 12 of 2011); The Environmental Management (Licensing) Regulations, Statutory Instrument No.112 of 2013

Zambia | Detail on enabling environment

Human resources and technical capability	ZEMA: • 6 people employed handling 300-500 applications every year for pesticides and toxic substances • Employees are often inspectors as well as registration officers with field responsibilities NMEC: • Research teams often filled by scientists from partners and NMEC interns • No entomologist currently employed by Zambian government - rely on implementing partners (e.g. PATH/MACEPA,[1] PMI[2]) Neither ZEMA nor NMEC has a lab to test product composition/quality
Financial resources and sustainability	~15 applications ever year, ~1-3 of which might be new products • Trials are funded entirely by applicant; delays if they do not pay up front Application fees are sent to the Zambia Revenue Authority, which redistributes during annual budgeting to ZEMA
Governance and accountability	Products registered by ZEMA at the request of the manufacturer, not necessarily in line with the NMEP[3] rotation. However, registration requires an approval letter from the Ministry of Health, who is unlikely to recommend if the product is not in line with the NMEP plan. Decision about whether product should be used or not made at the Insecticde Resistance Management Technical Advisory Committee (IRMTAC), which involves NMEC and other research partners, MoH, ZEMA, NMEC and researchers, WHO, procurement, supporting NGOs, etc. ZEMA is authorized to issue import permits for all VC products, serving as de facto registration under Environmental Management Act No. 12

1. Program for Appropriate Technology in Health: Malaria Control and Elimination Partnership in Africa; 2. President's Malaria Initiative 3. National Malaria Elimination Program

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DRC | Summary of regulatory authorities, process and enablers

Regulatory authorities[1]

National authorities:*

- R E Directorate of Pharmacy and Medicine (DPM) under Ministry of Health: Grants Marketing Authorization (IIM) for human health products (of which MoH includes VC products), which allows manufacturers to import and sell in DRC and functions as registration. Almost all VC products are registered through MoH
- R E Directorate of Plant Protection (DPP) under Ministry of Agriculture: Mandate to register all pesticides (of which the MoA includes VC products); can only issue temporary registration because permanent authorization rests with non-operational Committee. Only 2 VC products in last 5 years registered through MoA.
- R E National Control Committee (MoH, MoA, MoE): Non-operational, but mandate to conduct technical review & issue permanent registration of phytosanitary products, which contains VC

Harmonization:

- Current state: No harmonization for VC products
- Future plans: No known plans
- Non-VC harmonization efforts: Part of ZAZIBONA[2] project for medicines registration

Registration process

Timeline and cost (excluding field trials):

- MoH: Registration and renewal: 0.5-4 mos.; $685-3,000 for registration, ~$10K for site visits; 5 yr validity
- MoA: Registration: 3-4 mos,; $250-$400; 2 year validity

Registration process:

MoH DPM

- Manufacturer contracts local agent, who in turn contracts a pharmacist (usually MoH but not always)
- Agent gives pharmacist the dossier and 50 samples; pharmacist liaises with the DPM
- DPM Certification Committee reviews the application
  - Pharmacist coordinates any additional requests
- DPM submits recommend. for Minister of Health's signature
- DPM performs manufacturing site visit, and issues IIM

MoA DPP

- Local agent submits dossier and samples
- DPP reviews dossier, performs a chemical risk evaluation, and sends samples to a lab to verify AI
- DPP submits recommendation to Secretariat General who issues temporary registration

Additional requirements to WHO PQT-VC:

- Efficacy trials not listed under dossier requirements
- MoA requests an environmental dossier and label
- MoH requests pharmacology and teratogenic tests

Enabling environment

Human resources & tech. capability

MoH: ~10 people on review committee

- Focused on medicines
- Do not currently have lab capabilities

MoA: ~15 people involved in process

- Focused on agricultural pesticides
- Do not currently have lab capabilities

Financial resources & sustainability

- Number of registrations per year unknown
- Process funded through fees and government finances

Governance & accountability

- MoH: DPM's Certification Committee meets quarterly for the granting of Marketing Authorization; connection to malaria program (PNLP) regarding registration is unclear
- MoA: Main actor in temporary registration decision; no official forum or connection to the malaria program (PNLP) or other ministries
- National Control Committee was instituted in 2006 by inter-ministerial decree, but has not yet been convened due to a lack of resources

1. Overlapping mandate of MoA/MoH due to no specific legal definition of VC products. Both ministries aware of the other's registrations, and consider them unlawful. 2. SADC Collaborative Medicines Registration Initiative; Note: *R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

DRC| Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	MoH: Directorate of Pharmacy and Medicine (DPM)	• Grants Marketing Authorization (IIM) for human health products (of which MoH includes VC products)
R E	MoA: Directorate of Plant Protection (DPP)	• Mandate to register all pesticides (of which the MoA includes VC products)
I	Programme National de Lutte contre le Paludisme (PNLP)	• Provides input to the MoH; does not provide input to MoA registrations

Relevant legislation and requirements for changing registration processes

Legislation title	Year	Comments
Memo: Circular Note No. 014/SG/AGRIPEL/2018 FROM ….. /12/2018 Concerning the approval/ registration procedures and pesticide/plan protection product distribution in the DRC	2016	MoA: Renews/outlines mandate and procedures for pesticides registration • "Establishments selling pesticides fall under the exclusive jurisdiction of the central government and are managed by the Directorate of Plant Protection. The Secretary General of Agriculture alone is in a position to issue the authorization of the opening of an establishment selling pesticides or any other phytosanitary products"
Decree No. 005/162	2006	MoA: • Indicate that the activities pertaining to phytosanitary products, including marketing, are subject both to prior authorization of the opening of the establishment selling the products, and to the approval and registration of phytosanitary products duly issued by the Department of Agriculture • Establishes the National Control Committee
Law No. 11/022	2011	
Law giving mandate to MoH TBD		

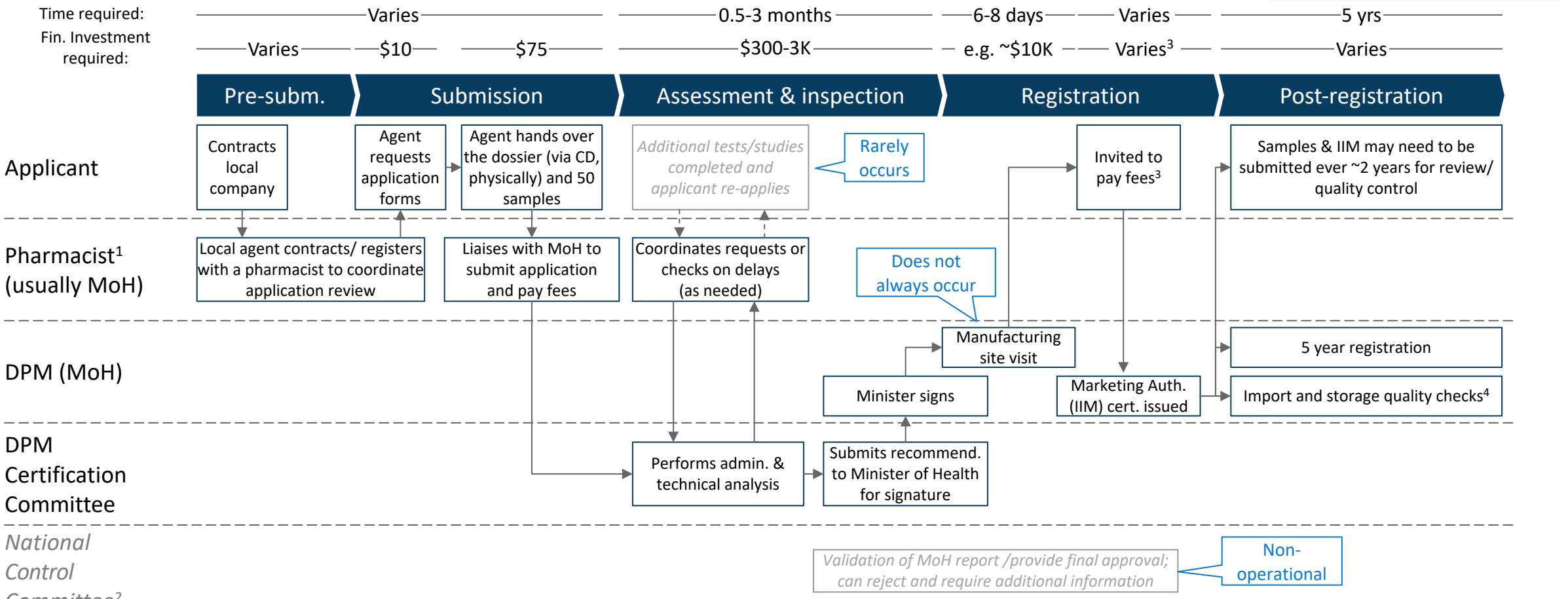
*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

DRC | Registration process map (Ministry of Health)

MoH has mandate to register human health products (under which it includes VC products) but aware of MoA granting registration

Timeline/cost (excluding field trials):

Registration and renewal:
0.5-4 months; > $10.7K-13K



1. Pharmacist is the strategic link with MoH, who coordinates the full process, and is tasked to maintain regular contact with the Ministry (either to follow up on dossier, or just to stay informed on any changes that may occur which can impact the process—new policies, requirements etc.) 2. Commission Nationale d'Homologation—non-operational; 3. Administrative tax and expert fees, assessed by a DPM accountant at the time of invitation; 4. Post-market activities rarely occur due to lack of funding

DRC | Registration process map (Ministry of Agriculture)

MoA has mandate to register pesticides (under which it includes VC products) but aware of MoH granting Marketing Authorization for LLIN, IRS

Timeline/cost (excluding field trials):

Registration: 3-4 mos.; ~$250-400
Renewal: 3-4 mos.; ~$250-400

Time required: 3-4 mos. | 2-3 mos. | Varies

Fin. Investment required: $20 | $80 | $150-300 | $400 | Varies | $0

Assessment	Submission & inspection	Registration	Post-registration

Applicant

- Applicant requests forms from MoA
- Applicant files the dossier (physically) and submits samples[1]

Greyed out testing is part of official process, but not completed for VC products because no VC-specific capabilities at the moment

Directorate of Plant Protection (MoA)

- Admin. check for completion
- Chemical risk evaluation
- *Biological efficacy tests (semi-field, 2-3 months)*
- Submit report/ recommendation to Secretariat General
- Registration certificate issued
- 2 year temporary registration permit granted (only Commission can grant full permit)
- Checking certificates, storage inspection

University laboratories

- Laboratory physico-chemical analysis to verify AI, concentration

Chemical laboratory in Kenya

- *Laboratory chemical residue analysis*

National Control Committee[2]

- *Validation of MoA findings; can reject and require additional information*
- Non-operational
- *Provide final approval and grant full registration permit*

1. No specific import permits are required, and importation is handled by the MoA 2. Commission Nationale d'Homologation—non-operational

DRC | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Emergency exemption	MoH: Exceptional exemption can be granted in emergency cases only • e.g. Malaria crisis requiring specific products • Product can be registered in 1-2 days
Accelerated registration	MoH: Potential to convene a special meeting of the DPM Certification Committee if the product is WHO PQT-VC listed and the Committee agrees to meet (and has the funding to do so) • Circumstances under which committee agrees to meet unknown • Products can be registered in ~15 days
Re-registration/renewal	For both MoA and MoH: Same process as registration

DRC| Dossier overview (Ministry of Agriculture) (I/III)

Dossier section	Description
Overview/Cover	• Pesticide that contains an AI and/or formulation not identical to an authorized product • Transfer of registration • Modification to existing registration • Marketing under own label or not • Proposed date of commercialization
1. Applicant	• Type of applicant (importer, formulator, distributor) • Address, telephone, email, fax
2. Product	• Brand name, trade mark holder, description • Function of product • Intended user • Target pest and host • Method, rate of dosage, and frequency and timing of application • Type of formulation, formulation code • Existing registration number • International customs tariff code • Registration in other SADC countries, any other countries • Registration in country of fabrication, formulation and justification

1. Department of Agriculture Pesticide Registration Request Form

DRC| Dossier overview (Ministry of Agriculture) (II/III)

Dossier section	Description
3. Active substance	• Active substance (technical grade according to FAO specifications, if applicable (can be attached in sealed envelope) • Common name(s) • Original letter of supply from the manufacturer, the name and address • Minimum % of purity in active substance • Scale
4. Formulation	• Formulation (can be attached in a sealed envelope) • Formulator (Name) • Address
5. Composition	• Composition (can be attached in a sealed envelope) • Ingredients and function – g/l, g/kg, scale
6. Toxicology (of formulated product)	• Experimental and calculated toxicities – Acute oral toxicity (LD50 mg/ kg) – Acute dermal toxicity (LD50 mg/kg) – Inhalation LC50 (mg/hour) • Rabbit skin and eye irritation • Guinea pig sensitivity • WHO classification (Ia, Ib, II, III, U) • Summary of toxicological studies on other animals

1. Common Technical Document—Set of specification for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States

DRC| Dossier overview (Ministry of Agriculture) (III/III)

Dossier section	Description
6. Summary of the environmental effects	• Toxicity for bees, fish and aquatic life, birds, earthworms and soil microorganisms, other non-target organisms • Persistence in environment • Other effects
7. Packaging	• Packaging materials/container (e.g. plastic pot, glass bottle, etc.) • Size of packaging • Disposal of empty containters
8. Declaration by the applicant or by the duly appointed representative	• Name, date, title, signature

DRC| Dossier overview (Ministry of Health)

Dossier section	Description
For a product containing conventional chemicals	• Technical file of the drug – Manufacturing ode/reference of laboratory, site, description of the active ingredients and excipients, method of manufacture, chemical and biological analysis • Pharmacological effects of the drug • Toxicological effects of the drug • Chemical effects of the drug • Certificate of good manufacturing practices of the manufacturer laboratory issued by the national drug regulatory authority of the country of laboratory residence • Marketing Authorization of the country of origin of the medicinal product concerned • Analysis bulletin certifying the quality control of the drug in a local laboratory, approved by MoH • List of countries that have already registered the product • Pharmacovigilance
For a product containing new chemical substances (innovative product)	• Chemical data (structure, physical properties, synthesis, specifications, impurities and stability) • Studies of pharmacological properties in animals • Toxicological data (short-term and long-term studies in animals including carcinogenicity studies) • Study of teratogenic effects in animals • Results of good manufacturing practices of the manufacturer laboratory • Marketing Authorization of the country of origin of the medicinal product concerned • Analysis bulletin certifying the quality control of the drug in a local laboratory, approved by MoH

1. http://dpmrdc.org/Services/Homologation-et-enregistrement-des-medicaments-et-produits-de-sante

DRC | Detail on enabling environment

Human resources and technical capability	MoH DPM[1] • ~10 persons involved in the registration process • Primarily focused on medicines and medical products MoA DPP[2] • ~15 people involved in the process • Primarily focused on agricultural pesticides
Financial resources and sustainability	• Number of registrations per year unknown • Reported insufficient financial resources to hire experts, fund labs and conduct post-market surveillance
Governance and accountability	MoH DPM • Certification Committee meets quarterly for the granting of Marketing Authorization • Connection to malaria program (PNLP) regarding registration is unclear MoA DPP • Main actor in temporary registration decision • No official forums or connection to the malaria program (PNLP) or other ministries National Control Committee • Instituted in 2006 by inter-ministerial decree, but has never been put into practice due to lack of resources • If functional, would include members from MoH, MoA, MoE, other experts and the PNLP

1. Ministry of Health Directorate of Pharmacy and Medicine; 2. Ministry of Agriculture Directorate of Plant Protection

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Ministry of Agriculture
Ministry of Health

B Content of WHO PQT-VC sufficient

C Content of WHO PQT-VC + local semi-field trials

Burkina Faso | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

CILSS[1] pathway:

R Sahelian Pesticide Committee (CSP) evaluates dossiers
E and decides on registration

I National Committee for Pesticide Management (chaired by Ministry of Agriculture) provides import authorization for in-country testing and performs post-market surveillance

E Approved national institutes conduct efficacy trials (mutual recognition across CILSS countries)

I Ministry of Commerce provides import authorization

Independent national pathway:

R Ministry of Health evaluates product dossier, decides
E on registration

Harmonization:

- Current state: Pesticide registration (including for VC) harmonized across CILSS countries[2]
- Future plans: As a member of ECOWAS, Burkina Faso is one of the countries that endorsed the creation of the West African Committee for Pesticide Registration (WACPR) in 2008, but this committee is not yet operational

Registration process

Timeline and cost (excluding field trials):

CILSS pathway:

- Registration: 2-3 months, ~$2040, 3 yr validity[3]
- Renewal: TBD months, ~$2040, 3 yr validity

Independent national pathway:

- Registration: 5-7 months, ~$90, 5 yr validity
- Renewal: TBD months, ~$45, 5 yr validity

Registration process:

CILSS pathway:

- Applicant completes local semi-field efficacy trials with research institute in a CILSS country, applicant submits dossier, CSP evaluates dossier and decides on registration

Independent national pathway:

- Applicant files dossier and imports samples, MoH evaluates dossier and conducts tests for composition and toxicology, MoH decides on registration

Comparison with WHO PQT-VC:

CILSS pathway:

- Semi-field efficacy trial to be done in CILSS country for initial registration; full field trial to be completed for subsequent registration

Independent national pathway:

- WHO PQT-VC material sufficient for registration

Enabling environment

Human resources & tech. capability

- CILSS pathway: 3 people in secretariat; rely on 26 member country experts for evaluation
- Independent national pathway: 10 people working on vector control product registration (part time)
- Limited VC experts nationally to conduct evaluation

Financial resources

CILSS pathway:

- ~10 product registrations per year
- Funding sources: registration fees, member state contributions

Independent national pathway:

- Funding sources: registration fees, gov. funding, donors

Governance & accountability

CILSS pathway:

- Equal country representation of member countries in bi-annual registration meetings; representation of private and public stakeholders in National Committee for Pesticide Management. Limited link to NMCPs.[4]

Independent national pathway:

- MoH main actor in making registration decisions. NMCP not involved in registration

1. Le Comité Permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel; 2. Togo, Benin, Guinea and Ivory Coast do not participate in the common registration process, although they are CILSS members 3. Can apply for 5 year registration after full local field trials are complete; 4. National Malaria Control Programmes.
*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Burkina Faso | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
CILSS pathway	R E Sahelian Pesticide Committee	• Evaluates VC dossiers and decides on registration
	I National Committee for Pesticide Management	• Chaired by the Ministry of Agriculture; ; Ministry of Health and Ministry of Environment invited • Provides import authorization for in-country testing and performs post-market surveillance
	E Approved national research institutes	• Conduct efficacy trials (mutual recognition across CILSS countries)
	I Ministry of Commerce	• Provides import authorization
Ind. national pathway	R E MoH	• Evaluates product dossier, decides on registration of products designed for human medical benefit, including LLINs

Relevant legislation and requirements for changing registration processes

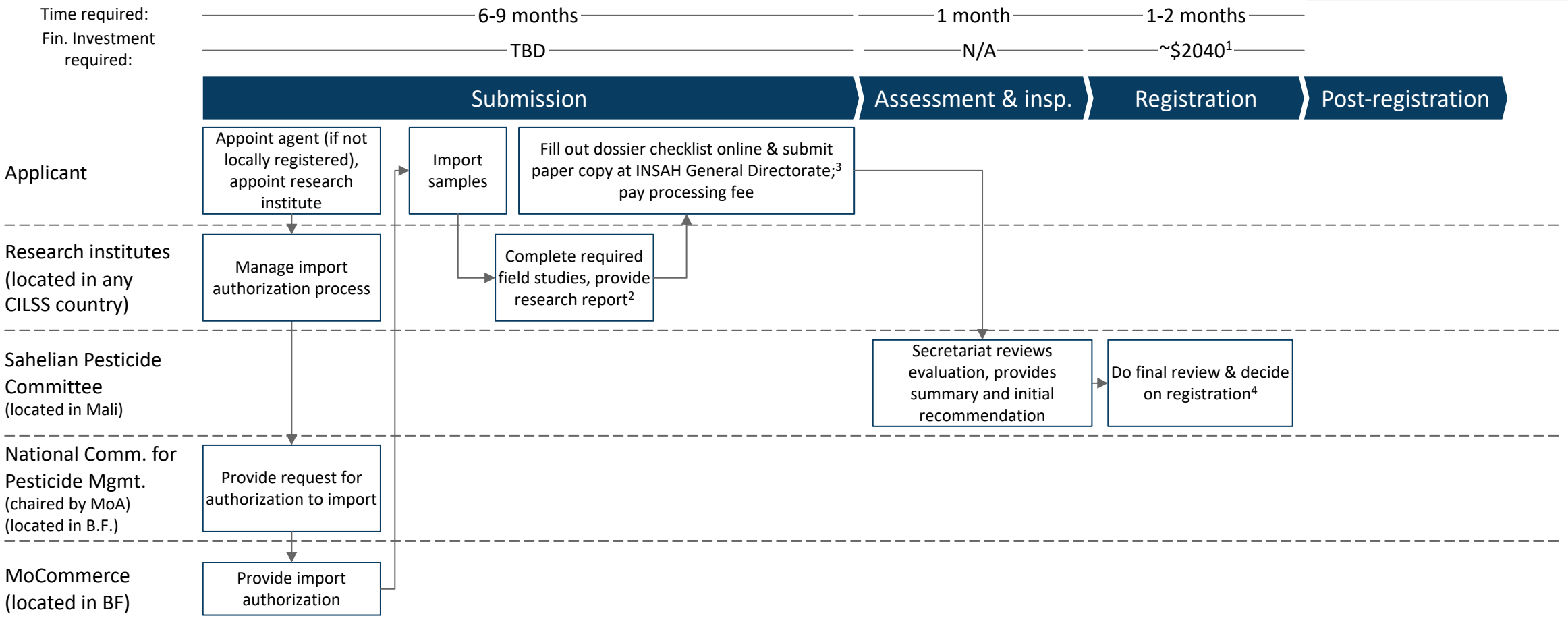
Legislation title	Year	Comments
Loi n°026-2017	2017	• Acknowledges CSP as the body for the registration of pesticides
Loi n°23/94/ADP	1994	• On the Public Health Code, gives mandate to the Ministry of Health

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Burkina Faso | Registration process map (CILSS harmonized pathway)

Timeline/cost (excluding field trials):

Registration: 2-3 mos.; ~$2040
Renewal: TBD mos.; ~$2040

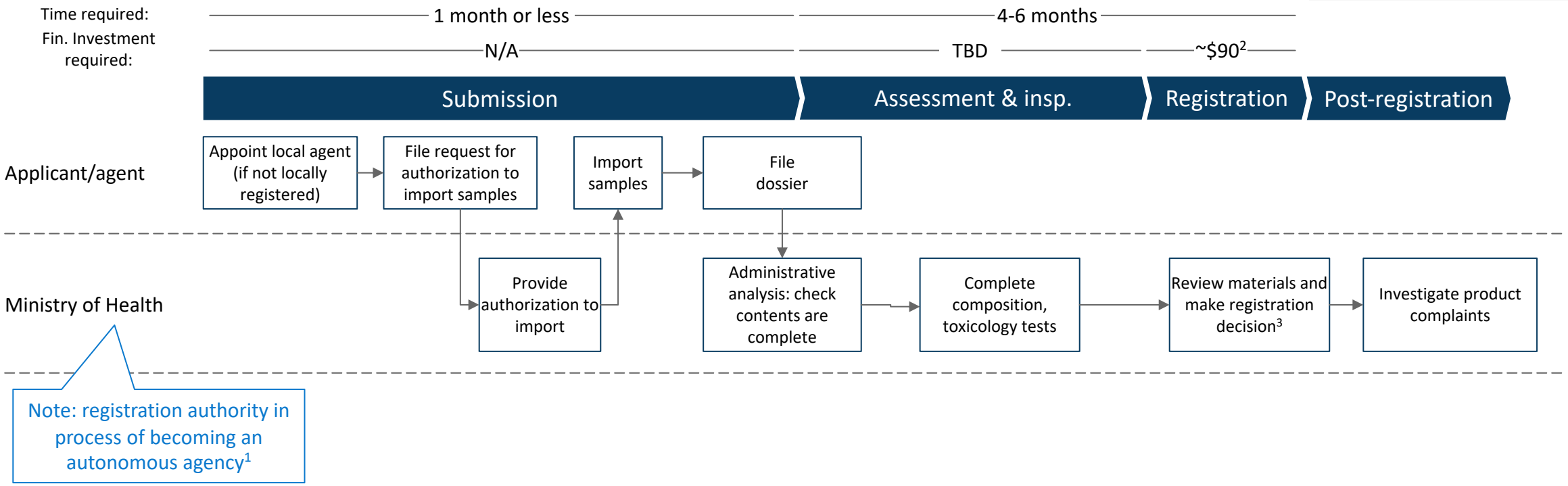


1. Plus ~$850 per active ingredient if more than 1; 2. Not required if WHO approved, as long as field studies have been done in a CILSS member country; 3. Institut du Sahel - will forward to CSP; 4. Meetings occur twice annually, in May and November. Following the review of the dossier, CSP will make one of the following decisions: refuse registration, request additional information, provide provisional authorization of 3 years (can be renewed once), provide final authorisation (homologation) valid for 5 years (after 6 years of provisional authorization and renewal of provisional authorization has passed). Individual countries may decide to ban specific pesticide products, but may not have a parallel registration process

Burkina Faso | Registration process map (independent national pathway)

Timeline/cost (excluding field trials):

Registration: 5-7 mos.; ~$90
Reregistration: TBD mos.; ~$45



1. Will have decision making authority without needing any final authorization from the minister; 2. For products not produced in ECOWAS. Fee is 12,500 FCFA for products produced in Burkina Faso, and 25,000 FCFA for products produced in ECOWAS. Registration valid for 5 years; 3. Four sessions per year;

Burkina Faso | Process variations and exceptions (CILSS harmonized pathway)

Circumstances under which variation occurs	Differences in process/requirements
WHO PQT-VC listed products	If a product is WHO PQT-VC listed with efficacy trials completed in a CILSS common evaluation member state, efficacy trials do not have to be redone
Renewal	First renewal is granted for a 3 year period – administrative requirements unknown Following renewal (valid for 5 years) require full dossier submission, including results of full field trial

Burkina Faso | Process variations and exceptions (independent national pathway)

Circumstances under which variation occurs	Differences in process/requirements
Mass donor campaigns	Process can be expedited in the case of a mass campaign
Renewal	Submit administrative dossier only – technical dossier not required (unless changes in product composition have occurred)

Burkina Faso | Dossier overview (CILSS harmonized pathway) (I/V)

Dossier for pesticides meant for public health use

Dossier section	Description
Request for registration	Administrative information • Address of the applicant • Name and address of brand owner • Name and address of the manufacturer of the formulated product and the place of manufacturing • Name and address of the manufacturer of the active(s) ingredient(s) and the place of manufacturing Identity of the formulated product • Name of the formulated product • Composition of the formulated product: names and proportions • Type of formulation • WHO toxicological classification of the formulation Identity of the active ingredients • International common name (ISO) • Purity • Identities and proportions of additives and impurities Suggested use • Type of pesticide • Suggested uses • List of countries (with similar ecologies) where the formulated product is approved and the authorizations of usage in these countries

Burkina Faso | Dossier overview (CILSS harmonized pathway) (II/V)

Dossier for pesticides meant for public health use

Dossier section	Description
Dossier summary	Summary form of: • Identification of product • Physicochemical properties • Biological effectiveness • Toxicological information • Safety measures
Physico-chemical dossier	Physico-chemical properties of: • Formulated product • Active ingredients of technical quality • Pure active ingredients
Biological effectiveness dossier	Reports of the effectiveness tests • Test requirements • Contents of the reports Summary recalling • The mechanism of action of the active(s) ingredient(s) • Methods of use • Limits of use • Incompatibilities of the product with other pesticides • Information on the appearance or the possible development of a resistance

Burkina Faso | Dossier overview (CILSS harmonized pathway) (III/V)

Dossier for pesticides meant for public health use

Dossier section	Description
Analytical dossier	Formulated product: • Methods of extraction, identification dosage of the active(s) ingredient (s) included in the commercial product Residues: • Methods of extraction and dosage of the residues and of its (their) metabolites belonging to the definition of residues • Methods of study of the residues in the treated substrate or likely to be contaminated
Toxicological dossier	Toxicity studies with the active(s) ingredients • Acute toxicity • Skin irritation • Eye irritation • Sensitization • Oral toxicity by reiterated administration • Toxicity by reiterated administration by other routes • Genotoxicity • Long-term toxicity/Carcinogenesis • Teratogenicity and embryotoxicity • Effects on the reproduction • Delayed Neurotoxicity • Studies of toxico-kinetic • Other studies

Burkina Faso | Dossier overview (CILSS harmonized pathway) (IV/V)

Dossier for pesticides meant for public health use

Dossier section	Description
Toxicological dossier	Toxicity studies with the formulated product • Acute toxicity • Skin irritation • Eye irritation • Sensitization • Data relating to exposure A synthesis on the toxicity observations with the formulated product for humans Recommendations concerning the therapy and the precautions • Diagnosis and symptoms of poisoning • Measurements of first emergency in the event of poisoning and counter-indications • Therapy and antidotes • Safety measures
Environmental dossier	Studies on the behavior and the fate of pesticide in the environment • The fate and behavior in the soil • Fate and behavior in water • Definition of the residue Studies of the effects of the pesticide on the not-targets organism • Toxicity towards the birds • Toxicity towards fish • Toxicity towards the aquatic invertebrates • Toxicity towards the aquatic algae

Burkina Faso | Dossier overview (CILSS harmonized pathway) (V/V)

Dossier for pesticides meant for public health use

Dossier section	Description
Residue dossier	Data on the residues of the formulated product and its metabolites on: • Soil • Walls • Water • Blood • Materials impregnated
Packaging and labelling dossier	Packaging Model of the label Labels for small packaging
Registration certificate in country of origin	
Product samples	Sample of pure active ingredient Sample of active ingredient of technical quality Standards for the analysis of the characteristic metabolites Samples of the substances of reference for the impurities contained in the formulated product Sample of the formulated product
Letter of agreement between manufacturer and manufacturer of active ingredient (if different entities)	

Burkina Faso | Dossier overview (independent national pathway)

Dossier section	Description
Administrative module	Letter to the MoH requesting registration
	Certificate of origin of the product
	Certificate of good production practices
	Any other document or certificate proving conformity to international standards of quality, e.g. WHO PQT-VC
	Confirmation of wholesale price before tax
	Information on identity of both local representatives (distributors) and producer(s)
Quality module	Production dossier describing raw materials used
	Proof of tests performed on finished products, including related results
	Stability studies
Samples	10 samples of each products, including notice manual (in French and English)

Burkina Faso | Detail on enabling environment (CILSS harmonized pathway)

Human resources and technical capability	• 3 permanent staff (permanent secretary, scientific secretary, admin assistant) who coordinate meetings and do initial evaluation of dossier (capacity permitting) • 26 members of national committees of pesticides management (relevant technical experts), who decide on recommendation in biannual sessions
Financial resources and sustainability	• ~10 VC product registrations per year • Funding sources: registration fees, member state contributions
Governance and accountability	• Equal country representation of member countries in biannual registration meetings • Representation of private (e.g. pesticide industry association) and public (e.g. minisries of agriculture, health) stakeholders in National Committee for Pesticide Management • Limited link to National Malaria Control Programmes

Burkina Faso | Detail on enabling environment (independent national pathway)

Human resources and technical capability	~10 people working in medicines product registration in MoH, including VC products. • Complete mostly administrative review of the dossier; their backgrounds are mostly in pharmacy Technical experts committee made up of 13 different experts in e.g. medicine, pharmacy, veterinary studies • Evaluates the technical components of dossiers and provides a recommendation for registration National commission of medical products registration includes representatives from MoH, Minister of Animal Resources, customs office, research institutes
Financial resources and sustainability	Funding sources: registration fees, government funding, donors
Governance and accountability	National commission of medical products registration (registration decision body) composed of various stakeholder groups (see above) • Meets quarterly NMCP not involved in registration

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Ministry of Agriculture
Ministry of Health
C Content of WHO PQT-VC + local semi-field trials

Ghana | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:

Note: Vague definition of "pesticides" and "household chemicals" in existing legislation can result in necessity to register product with both FDA and EPA

R E Environmental Protection Agency (EPA)—evaluates and gives registration recommendation for IRS and the formulation of the active ingredient used on all products, including nets – National Pesticide Committee ratifies EPA recommendation

R E Food and Drug Authority (FDA)—registers nets (even if they have a pesticide component) and indoor products for use by individuals (e.g. personal sprays, coils, etc.)

Harmonization:

- Current state: Not harmonized for VC
- Future plans: Ghana is engaging with ECOWAS on establishing West African Committee for Pesticide Registration (expansion of CILSS model), but no defined operating model as of July, 2019. Additional efforts include Pan-African Harmonization Working Party for medical devices, and proposed adoption of GHS[1]

Registration process

Timeline and cost (excluding field trials):

EPA:
- Registration: 3-12 months, ~$2,400, 3yr validity
- Renewal: 1-12 months,[2] ~$800, 3yr validity

FDA:
- Registration: ~3-6 months, cost varies,[3] 3yr validity
- Renewal: ~2 months, cost as for registration, 3yr validity

Registration process:

- EPA: Applicant completes semi-field trial; applicant completes all dossier requirements; EPA evaluates contents and recommends registration; National Pesticide Committee decides on registration
- FDA: Applicant completes semi-field trial; applicant completes all dossier requirements; FDA evaluates contents; FDA decides on registration.

Comparison with WHO PQT-VC:

- EPA: Semi-field efficacy trials completed in Ghana
  FDA: Semi-field efficacy trials completed in country with similar ecology/mosquito strains

Enabling environment

Human resources & tech. capability

- EPA: ~10 people employed in registration of all pesticides
- FDA: ~30 people employed in registration of all medical devices, cosmetics & household chemicals
- In-country capabilities reported to exist for all required assessments other than manufacturing site inspections

Financial resources

- EPA: <20 registrations/re-registrations p.a.
- FDA: 20-25 registrations/re-registrations p.a. (but includes other products, e.g., coils)
- EPA is self-funding, e.g., through registration fees, import duties
- FDA partly self-funding (through reg. fees, import duties, donor funding) but salaries paid by gov.

Governance & accountability

- Malaria Vector Control Oversight Committee meets quarterly and includes MoH (under which FDA), EPA and National Malaria Control Programme
- In practice, seemingly minimal regular interaction about VC between FDA and NMCP or EPA
- EPA vs. FDA mandates can result in manufacturers needing to register a product with both authorities

1. Globally Harmonized System of Classification and Labelling of Chemicals; 2. Less than 3 months for renewal, 3 – 6 months for registration when National Committee has been established, but may take longer if Committee must be reconstituted after an election year; 2. $900 for LLIN (class 1 medical device); ~$228 (GHC 1200) for malaria indoor sprays and chemicals; $1500 for multipurpose indoor sprays
*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Ghana | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	Environmental Protection Agency (EPA) (under Ministry of Env.)	• Evaluate any new pesticides or chemical formulations (including IRS and the formulation applied/imbedded in nets) • Provide registration recommendation to National Committee for Pesticide Registration (on which EPA is also represented), which makes the final registration decision • National Committee for Pesticide Registration composed of representatives from: - EPA, MOH, Ghana Standards Authority, Ghana Revenue Authority/Customs Division, Ministry of Trade, Association for Ghana Industry, National Farmers Association, Cocoa Board etc.
R E	Food and Drug Authority (FDA) (under Ministry of Health)	• Evaluate and decide on registration for any "medical devices" or "household chemicals", of which it includes vector control products for indoor use by individuals (e.g. nets, treated nets, personal sprays, coils, etc.)

Relevant legislation and requirements for changing registration processes

Legislation title	Year	Comments
Environmental Protection Agency Act	1994	• Describes EPA mandate
Public Health Act	2012	• Describes FDA mandate

Notes:

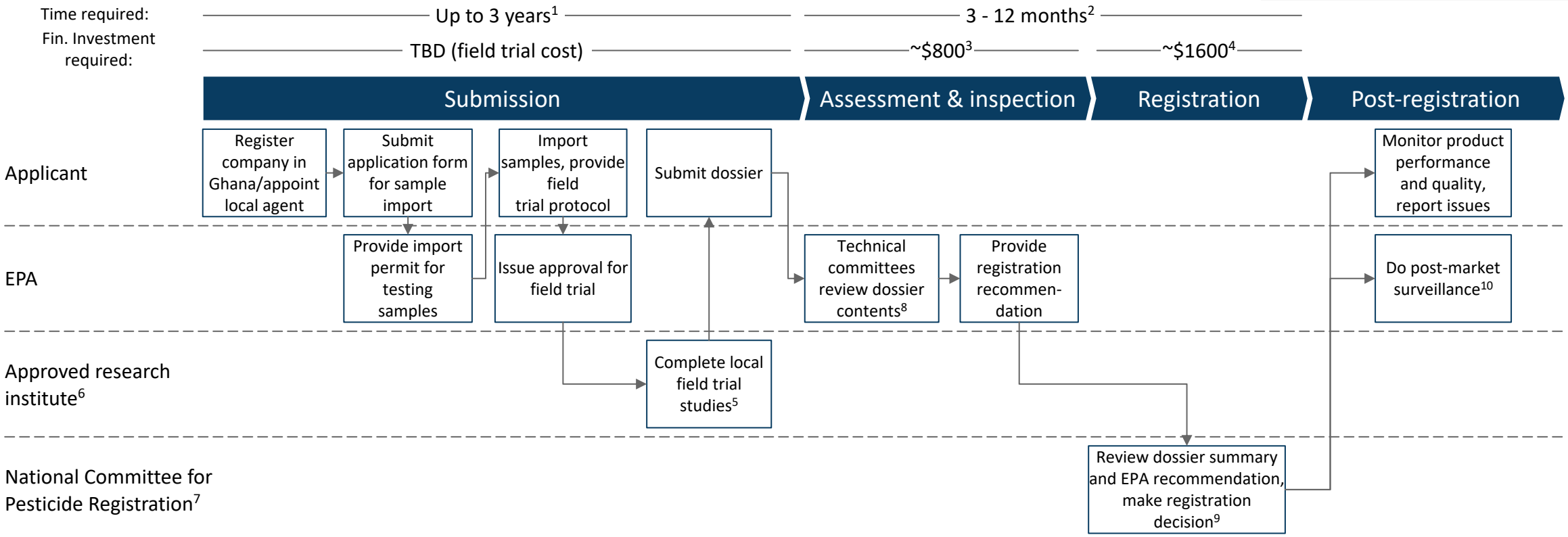
- EPA, FDA have legally defined mandates, so change in registration authority would have to be ratified by parliament
- However, registration processes and standards followed by EPA, FDA are set by authorities themselves, so amendments to processes and standards do not require parliamentary ratification

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Ghana | Registration process map (EPA)

Timeline/cost (excluding field trials):

Registration: 3-12 mos.; ~$2400
Renewal: 1 – 12 mos.; ~$800



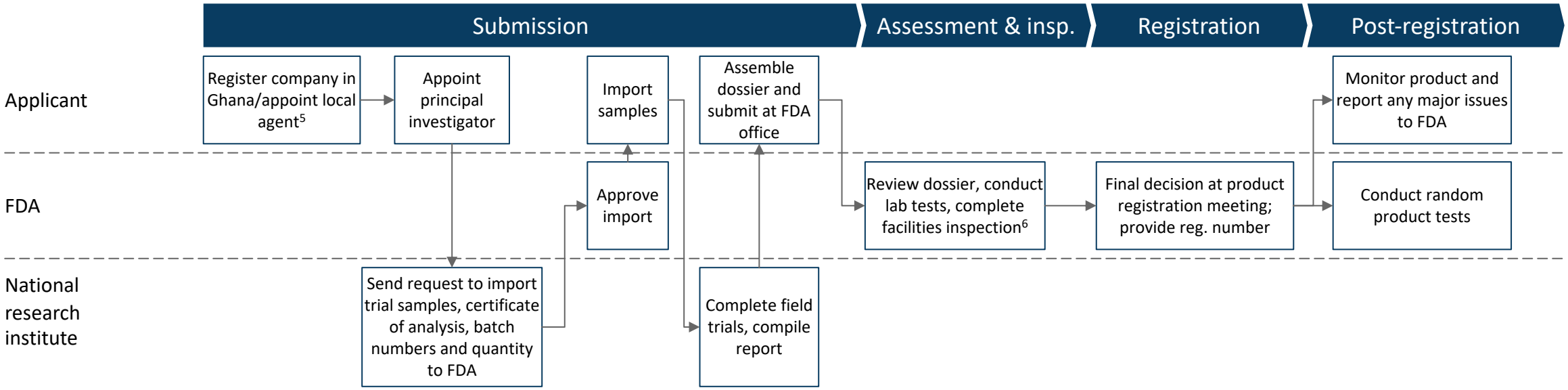
1. No specific guidance given by EPA – research institution determines what would be adequate and justifies in final report; 2. Less than 3 months for renewal, 3–6 months for registration when National Committee has been established, but may take longer after an election year when Committee has to be reconstituted; 3. For processing; additional fees apply for new active ingredients and if there is a mixture of more than 1 active ingredient 4. For full registration; 5. Semi-field/phase II trials; 6. E.g. Noguchi, CSIR; 7. Full list of participants on "Overview of relevant authorities" page. 8. EPA staff supplemented by outside technical experts as required; 9. Meetings occur on quarterly basis; 10. Selecting products on market and testing chemical composition in line with what was registered

Note: All fees can be found on the fee schedule: https://www.epa.gov/pria-fees/fy-2019-fee-schedule-registration-applications#registration

Ghana | Registration process map (FDA)

Timeline/cost (excluding field trials):
Registration: ~3 - 6 mos.; cost product dependent[4]
Renewal: ~2 mos.; cost as for registration

Time required: ~2 years[1] — 3 - 6 months[2]
Fin. Investment required: TBD (field trial cost) — N/A[3] — Product dependent[4]



1. No specific guidance given by FDA—research institution determines what would be adequate and justifies in final report 2. Assuming all required documentation is submitted 3. May be some cost if facilities inspection required ($10k for W. Africa, $15k for rest of Africa, $20k for rest of world), but facilities inspection rare. 4. $900 for LLIN (class 1 medical device); ~$228 (GHC 1200) for malaria-specific indoor sprays and chemicals; $1500 for multipurpose indoor insecticide sprays 5. Locally registered company corporate body registered in Ghana, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters relating to the registration of a medical device(s) in Ghana 6. Facilities inspection rare - will likely not occur if product has PQT-VC

Ghana | Process variations and exceptions

Circumstances under which variation occurs		Differences in process/requirements
EPA	Renewal	Unless product has undergone any evolution (e.g. in terms of ingredients), would follow same process but with decreased requirements: • Renewal form • Renewal fee
	Provisional clearance	Process and requirements same as for full registration, but renewal required at earlier date (after 1 year) • Typically granted when registration authority has not found any issues with registration documentation, but does not have full trust in manufacturer's consistency in applying quality standards.
FDA	Renewal	Unless product has undergone any evolution (e.g. in terms of ingredients), would follow same process but with decreased requirements: • Renewal letter (prescribed format) • Product samples and certificate of analysis • Renewal fee Lasts about 2 months
	PQT-VC approved	Same process will be followed but steps will typically be shorter, e.g. because: • Site visit results will be accepted as is • Efficacy study results will be examined, but not e.g. study protocols
FDA, EPA	National emergency	May grant waiver in case of national emergency, but no example of this occurring in recent history

Ghana | Dossier overview (FDA)

Dossier requirements for class 1 medical devices (incl. bed nets)

Note: Efficacy studies not an official requirement as per dossier description, but will be requested.

Dossier section	Description
Cover letter (including signed declaration)	• Contact details of applicant, manufacturer, and local agent • Description of product • Summary of manufacturing procedure • History of past registrations globally • Declaration of accurate information
Application (2 copies)	
Certificate of analysis of finished product	
Manufacturing license	
Free sale certificate	
Product samples[1]	
Product labelling[2]	
Real/accelerated stability data	
Contract agreement (where applicable)	
Additional documents (where applicable)	E.g. certificates of registration from other countries

1. In final proposed packaging for Ghana (compliant with all specifications) 2. Must be in line with Ghanaian specifications

Ghana | Dossier overview (FDA)

Dossier requirements for household chemicals

Note: Efficacy studies not an official requirement as per dossier description, but will be requested.

Dossier section	Description
Cover letter (including signed declaration)	
Application (2 copies)	
Certificate of analysis of finished product	
Manufacturing license	
Free sale certificate	
Product samples[1]	
Product labelling[2]	
Material safety data sheet	

1. In final proposed packaging for Ghana (compliant with all specifications) 2. Must be in line with Ghanaian specifications

Ghana | Dossier overview (EPA) (I)

Dossier requirements for pesticides, including all VC products

Dossier section	Description
Form A (application form)	Summary of application, including information on: • Applicant identification • Product information (incl. designation, composition, origin, uses, previous registrations) • Product formulation features (incl. physical and chemical properties, toxicology, emergency measures in case of accident and fire, labelling, packaging • Efficacy trial information (incl. site, object, layout, treatments, observation and results, assessment) • Active ingredient features (incl. designation, physical and chemical properties, purity, toxicology, residues in plants, ecotoxicology, behaviour in the environment)

1. In final proposed packaging for Ghana (compliant with all specifications) 2. Must be in line with Ghanaian specifications

Ghana | Dossier overview (EPA) (II)

Dossier requirements for pesticides, including all VC products

Dossier section	Description
Annexures	Stipulated in dossier description document: • Analysis report • Complete composition in sealed envelope • Certificate of origin • Technical leaflet • Registration certificates • Safety data sheet • Label pattern • Packaging specifications • Experimental protocol • Efficacy trial report • Summary of toxicological dossier • Summary of residue dossier • Summary of ecotoxicological dossier • Summary of studies on behavior in the environment • Summary of other relevant studies (if applicable) Additional documents requested by registration authority (verbally communicated): • Marketing plan and overview of materials

1. In final proposed packaging for Ghana (compliant with all specifications) 2. Must be in line with Ghanaian specifications

Ghana | Detail on enabling environment (EPA)

Human resources and technical capability	• 10 people employed in pesticide registration secretariat
	  – Backgrounds in chemistry, agriculture, entomology
	  – Supplemented by in-country experts for registration technical committees
	• In-country capabilities said to exist for all required assessments, although limited capacity for manufacturing site visits

Financial resources and sustainability	• Receive <20 new pesticide registrations/re-registrations, <10 public health related registrations per year • EPA required to be fully self-funding, through registration fees, import duties
Governance and accountability	• FDA and EPA have unclear mandates for pesticide registration, which can cause manufacturers to register a product (e.g. a net with a new chemical formulation) with both EPA and FDA • MoH (under which FDA), EPA and NMCP all on Malaria Vector Control Oversight Committee—meets quarterly to decide on registration recommendations made by EPA

1. For admin., summary of technical documents and conducting of required desktop research

Ghana | Detail on enabling environment (FDA)

Human resources and technical capability	• Team of ~30[1] full time employees for registration of all household chemicals, cosmetics and medical devices products – Expertise includes e.g., chemistry, medical engineering, pharmacy, biology, botany—no entomologists • Part-time expert support from technical advisory committees requested as needed
Financial resources and sustainability	• Receive ~20-25 VC registrations/re-registrations, but this number is including e.g., coils, other household repellents • FDA partly self-funding, through reg. fees, import duties, donor funding—salaries paid by government
Governance and accountability	• FDA and EPA have unclear mandates for pesticide registration, which can cause manufacturers to register a product (e.g. a net with a new chemical formulation) with both EPA and FDA • No regular interaction with EPA regarding vector control • No regular interaction with NMCP regarding vector control • Registration decisions made FDA-internally

1. Estimated breakdown: 7 people working in registration (admin. and document evaluation) for cosmetics and household chemicals, 7 in registration for medical devices, 7 in inspection, 6 in post-market surveillance, 1 head of department.

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Ministry of Health

B Content of WHO PQT-VC sufficient

C Content of WHO PQT-VC + local semi-field trials

Nigeria | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R National Agency for Food and Drug Administration and Control (NAFDAC): Evaluate and register vector control products

I Ministry of Industry, Trade and Investment: Provide trademark registration

I Local research institutes (e.g., Nigerian Institute of Medical Research): Complete local semi-field trials if required

Harmonization:

- Current state: Registration process not currently harmonized for VC products
- Future plans: As a member of ECOWAS, Nigeria is one of the countries that endorsed the creation of the West African Committee for Pesticide Registration (WACPR) in 2008. However, neither WACPR nor the required National Pesticide Management Committee is operational yet.

Registration process

Timeline and cost (excluding field trials):

- Registration: ~4-10 months[1], ~$760, valid for 5 yrs
- Renewal: ~4-10 months[1], ~$760, valid for 5 years (same process as for registration)

Registration process:

- Applicant submits required administrative documents and NAFDAC checks for completeness
- NAFDAC issues sample import permit, applicant imports samples and submits technical dossier
- NAFDAC completes sample analysis and completes site inspection if required
- NAFDAC decides on registration of product; may need to complete local semi-field trials before registration (see below)

Comparison with WHO PQT-VC:

- Local semi-field trials required if a new active ingredient is being registered
- Extra documentation required, including e.g., a notarized declaration from the Nigerian consulate in the country of the product's origin

Enabling environment

Human resources & tech. capability

- >100 people working in the registration and Regulatory, Veterinary Medicines and Allied Nutrition[2], and Laboratories teams – but covering all other food and drug registrations as well
- Reported training need regarding field trial monitoring, laboratory assessments, assessment of VC products

Financial resources & sustainability

- ~10 applications received per annum
- Funded through internally generated revenues (e.g., registrations) and additional government support (for salaries)

Governance & accountability

- NAFDAC is the sole authority involved in the registration decision

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

1. Typical timelines excluding field trials are on shorter end of range 2. Responsible for site inspections

Nigeria | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	NAFDAC	• Evaluate and register vector control products
I	Ministry of Industry, Trade and Investment	• Provide trademark registration
I	Local research institutes	e.g., Nigerian Institute of Medical Research • Complete local semi-field trials if required

Requirements for changing registration processes

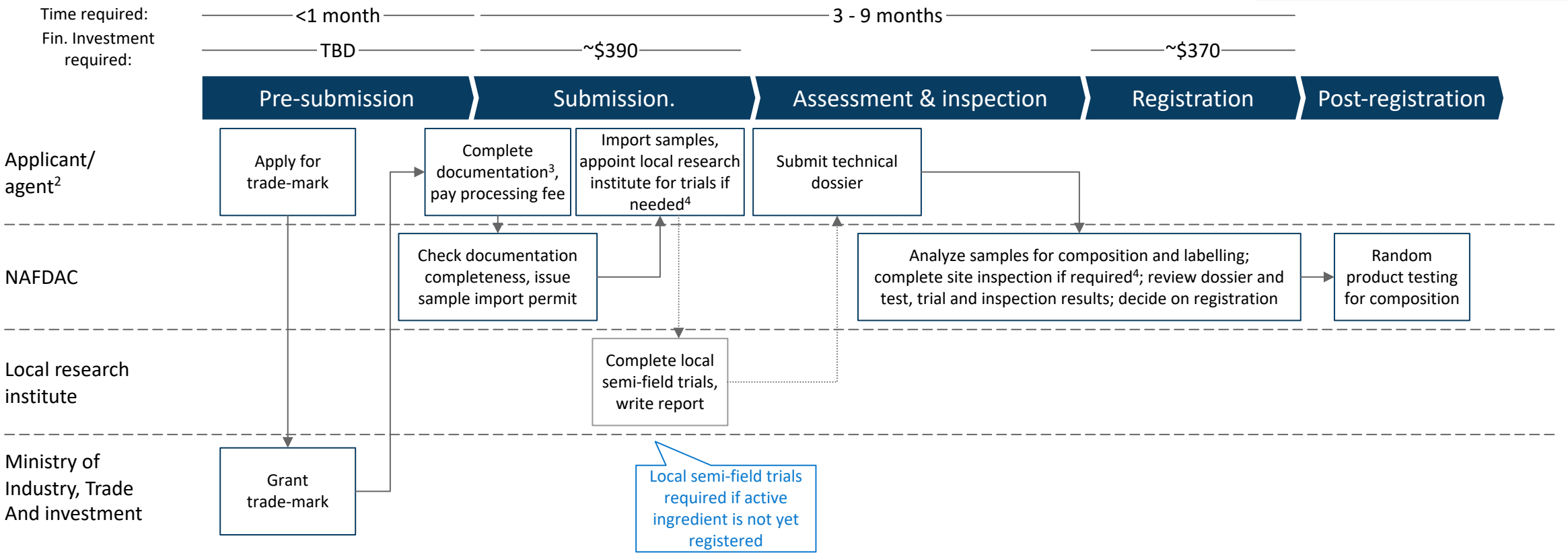
- Changes to regulatory process/requirements would require adaptation of regulation, but this can be done within NAFDAC (no external sign-off required)

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Nigeria | Registration process map

Timeline/cost (excluding field trials):

Registration and renewal:
4 - 10 mos.; ~$760[1]



1. Exactly same process and requirements for renewal as for registration, except that it is not necessary to apply for a sample import permit. Typical timelines excluding field trials are on shorter end of range; 2. If applying company is not locally registered, will have to appoint a local agent in order to register products; 3. Not including technical dossier – administrative documents; 4. E.g. if no prior inspection from a reputable international counterpart, e.g., USFDA

Nigeria | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
No new active ingredient	Local semi-field trials are not required if product being registered does not include a new active ingredient

Nigeria | Dossier overview

Dossier section	Description
Technical dossier	• Contact information of applicant • Name and classification of product • Packaging presentation • Name and quantity of product ingredients • Chemical name and structural formula of each active ingredient • Methods of manufacture • Description of product usage • Analytical method of each ingredient • Toxicity studies • Description of global registration status • Efficacy trial report • Material safety data sheet • Stability study
Additional documentation	• Notarized declaration from Nigerian consulate in country of origin confirming manufacture • Power of Attorney (for agents) or Contract Manufacturing Agreement (for company representatives) • Certificate of Manufacture and Free Sale • Certificate of Analysis • Evidence of Business Incorporation of the importing company with the Corporate Affairs Commission in Nigeria • Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment • Product label • Letter of Invitation for Good Manufacturing Practice (GMP) Inspection

Nigeria | Detail on enabling environment

Human resources and technical capability	• >100 people working in the registration and Regulatory, Veterinary Medicines and Allied Nutrition[1], and Laboratories teams—but covering all other food and drug registrations as well • Reported training need regarding e.g., field trial monitoring, laboratory assessments, assessment of vector control products
Financial resources and sustainability	• ~10 applications received per annum • Funded through internally generated revenues (e.g., registrations) and additional government support (for salaries)
Governance and accountability	• NAFDAC is the sole authority involved in the registration decision • No regular interaction between National Malaria Control Programme and NAFDAC

1. Responsible for site inspections and for monitoring field trials

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Ministry of Environment

C Content of WHO PQT-VC + local semi-field trials

Senegal | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R Sahelian Pesticide Committee (CSP under CILSS[1])
E evaluates dossiers and decides on registration

I National Commission for Chemicals Management (CNGPC) chaired by the MoE, grants permission to import samples for trials; performs post-market surveillance; delivers authorization at national level

E Approved national institutes conduct efficacy trials (mutual recognition across CILSS countries)

Harmonization:

- Current state: Pesticide registration (including for VC) harmonized across CILSS countries[2]
- Future plans: As a member of ECOWAS, Senegal is one of the countries that endorsed the creation of the West African Committee for Pesticide Registration (WACPR) in 2008, but this committee is not yet operational

Registration process

Timeline and cost (excluding field trials):

- Registration: 2-3 months, ~$2040, 3 yr validity[3]
- Renewal: TBD months, ~$2040, 3 yr validity

Registration process:

- Applicant completes local semi-field efficacy trials with research institute in a CILSS country, applicant submits dossier, CSP evaluates dossier and decides on registration

Comparison with WHO PQT-VC:

- Semi-field efficacy trial to be done in CILSS country for initial registration; full field trial to be completed for subsequent registration

Enabling environment

Human resources & tech. capability

- 3 people in secretariat; rely on 26 member country experts for evaluation
- Limited VC experts nationally to conduct evaluation

Financial resources & sustainability

- ~10 product registrations per year
- Funding sources: Registration fees, member state contributions

Governance & accountability

- Equal country representation of member countries in biannual registration meetings; representation of private and public stakeholders in National Committee for Pesticide Management
- National Malaria Control Programme not involved in registration activities; has an operation role post-registration

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

1 Le Comité Permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel; 2. Togo, Benin, Guinea and Ivory Coast do not participate in the common registration process, although they are CILSS members 3. Can apply for 5 year registration after full local field trials are complete

Senegal | Overview of relevant authorities for VC tools registration

Relevant authorities*

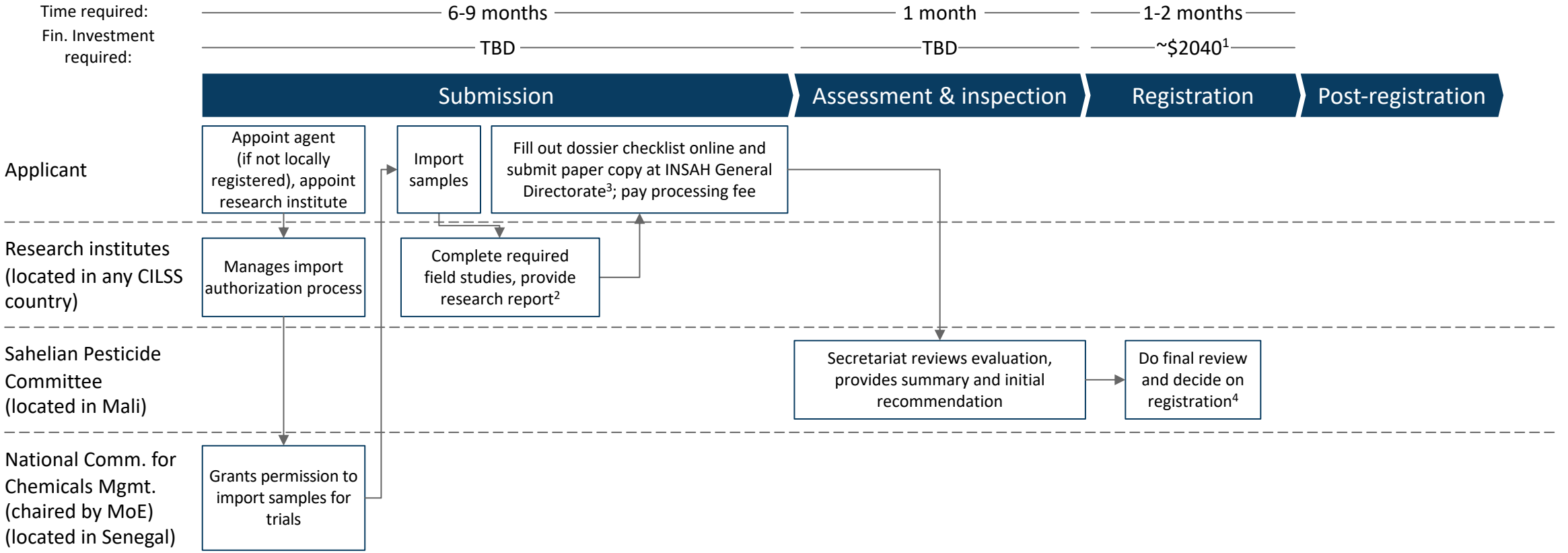
	Authority	Authority role
R E	Sahelian Pesticide Committee	• Evaluates VC dossiers and decides on registration
I	National Commission for Chemicals Management	• Chaired by the Ministry of Environment; Ministry of Health and Ministry of Agriculture invited • Reviews dossier and gives an opinion to CSP; delivers authorization at national level • Grants permission to import samples for trials; performs post-market surveillance
E	Approved national research institutes	• Conduct efficacy trials (mutual recognition across CILSS countries)

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Senegal | Registration process map (CILSS harmonized pathway)

Timeline/cost (excluding field trials):

Registration: 2-3 mos.; ~$2040
Renewal: TBD mos.; ~$2040



1. Plus ~$850 per active ingredient if more than 1 active ingredient 2. Not required if WHO approved, as long as field studies have been done in a CILSS member country; 3. Institut du Sahel - will forward to CSP; 4. Meetings occur twice annually, in May and November. Following the review of the dossier, CSP will make one of the following decisions: refuse registration, request additional information, provide provisional authorization of 3 years (can be renewed once), provide final authorisation (homologation) valid for 5 years (after 6 years of provisional authorization and renewal of provisional authorization has passed). Individual countries may decide to ban specific pesticide products (and may not have a parallel registration process)

Senegal | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Mass donor campaigns	Process can be expedited in the case of a mass campaign
Renewal of registration	Submit administrative dossier only – technical dossier not required (unless changes in product composition have occurred)

Senegal | Dossier overview (CILSS harmonized pathway) (I)

Dossier for pesticides meant for public health use

Dossier section	Description
Request for registration	Administrative information • Address of the applicant • Name and address of brand owner • Name and address of the manufacturer of the formulated product and the place of manufacturing • Name and address of the manufacturer of the active(s) ingredient(s) and the place of manufacturing Identity of the formulated product • Name of the formulated product • Composition of the formulated product: names and proportions • Type of formulation • WHO toxicological classification of the formulation Identity of the active ingredients • International common name (ISO) • Purity • Identities and proportions of additives and impurities Suggested use • Type of pesticide • Suggested uses • List of countries (with similar ecologies) where the formulated product is approved and the authorizations of usage in these countries

Senegal | Dossier overview (CILSS harmonized pathway) (II)

Dossier for pesticides meant for public health use

Dossier section	Description
Dossier summary	Summary form of: • Identification of product • Physicochemical properties • Biological effectiveness • Toxicological information • Safety measures
Physico-chemical dossier	Physico-chemical properties of: • Formulated product • Active ingredients of technical quality • Pure active ingredients
Biological effectiveness dossier	Reports of the effectiveness tests • Test requirements • Contents of the reports Summary recalling • The mechanism of action of the active(s) ingredient(s) • Methods of use • Limits of use • Incompatibilities of the product with other pesticides • Information on the appearance or the possible development of a resistance

Senegal | Dossier overview (CILSS harmonized pathway) (III)

Dossier for pesticides meant for public health use

Dossier section	Description
Analytical dossier	Formulated product: • Methods of extraction, identification dosage of the active(s) ingredient (s) included in the commercial product Residues: • Methods of extraction and dosage of the residues and of its (their) metabolites belonging to the definition of residues • Methods of study of the residues in the treated substrate or likely to be contaminated
Toxicological dossier	Toxicity studies with the active(s) ingredients • Acute toxicity • Skin irritation • Eye irritation • Sensitization • Oral toxicity by reiterated administration • Toxicity by reiterated administration by other routes • Genotoxicity • Long-term toxicity/Carcinogenesis • Teratogenicity and embryotoxicity • Effects on the reproduction • Delayed Neurotoxicity • Studies of toxico-kinetic • Other studies

Senegal | Dossier overview (CILSS harmonized pathway) (IV)

Dossier for pesticides meant for public health use

Dossier section	Description
Toxicological dossier	Toxicity studies with the formulated product • Acute toxicity • Skin irritation • Eye irritation • Sensitization • Data relating to exposure A synthesis on the toxicity observations with the formulated product for humans Recommendations concerning the therapy and the precautions • Diagnosis and symptoms of poisoning • Measurements of first emergency in the event of poisoning and counter-indications • Therapy and antidotes • Safety measures
Environmental dossier	Studies on the behavior and the fate of pesticide in the environment • The fate and behavior in the soil • Fate and behavior in water • Definition of the residue Studies of the effects of the pesticide on the not-targets organism • Toxicity towards the birds • Toxicity towards fish • Toxicity towards the aquatic invertebrates • Toxicity towards the aquatic algae

Senegal | Dossier overview (CILSS harmonized pathway) (V)

Dossier for pesticides meant for public health use

Dossier section	Description
Residue dossier	Data on the residues of the formulated product and its metabolites on: • Soil • Walls • Water • Blood • Materials impregnated
Packaging and labelling dossier	• Packaging • Model of the label • Labels for small packaging
Registration certificate in country of origin	
Product samples	• Sample of pure active ingredient • Sample of active ingredient of technical quality • Standards for the analysis of the characteristic metabolites • Samples of the substances of reference for the impurities contained in the formulated product • Sample of the formulated product
Letter of agreement between manufacturer and manufacturer of active ingredient (if different entities)	

Senegal | Detail on enabling environment

Human resources and technical capability	• 3 permanent staff (permanent secretary, scientific secretary, admin assistant) who coordinate meetings and do initial evaluation of dossier (capacity permitting) • 26 members of national committees of pesticides management (relevant technical experts), who decide on recommendation in biannual sessions
Financial resources and sustainability	• ~10 VC product registrations per year • Funding sources: registration fees, member state contributions
Governance and accountability	• Equal country representation of member countries in biannual registration meetings • Representation of private and public stakeholders in National Committee for Chemicals Management • National Malaria Control Programme not involved in registration activities; has an operation role post-registration

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Ethiopia | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R Plant Health Regulatory Directorate, Ministry of Agriculture: Has authority to register pesticides, including those for public health use

E Approved research Institutes: Responsible for conducting trials on samples and writing evaluation report

I

Harmonization:

- Current state:
  - Ethiopia implemented SEARCH[1] guidelines, although limited further harmonization within EAC and IGAD[2]
  - Worked with FAO and State of Netherlands on Pesticide Risk Reduction Program, although updates not implemented yet
- Future plans: None as of Feb 2019

Registration process

Timeline and cost (excluding field trials):

- Registration: ~7 months, $50, valid for 5 years
- Renewal: ~2 weeks, $20, valid for 5 years

Registration process:

- Applicant submits letter requesting to register a product to PHRD, including material safety data and selected research institute
- PHRD authorizes institute to conduct trials
- Research institute develops protocols for local trials, conducts trials and makes technical recommendation on application
- Applicant submits application and complete dossier to PHRD
- Complete application including trial results reviewed by PHRD working committee

Comparison with WHO PQT-VC:

- Local efficacy trials (full field trials) required

Enabling environment

Human resources & tech. capability

- Team of 12 experts with expertise in entomology, toxicology and efficacy

Financial resources & sustainability

- Registration fees are minimal -registration function almost fully funded by Ministry of Agriculture
- Applicant funds local trials in full

Governance & accountability

- Shifting responsibility between MoA and MoH
  - MoA initially responsible for registration of vector control tools, then shifted to DACA (under MoH) for a few years until 2017, before responsibility shifted back to the MoA
  - MoA requires renewals to undergo full registration process as part of shift back from DACA
- Malaria program not directly involved in registration process

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

1. South East Africa Regulatory Committee on Harmonization for Regulation of Pesticides; 2. The Intergovernmental Authority on Development

Ethiopia | Key historical developments

1

Shifting responsibility between MoA and MoH

Plant Health Regulatory Directorate (PHRD) under Ministry of Agriculture initially responsible for registration of vector control tools

Responsibility was shifted to the Drug Administration and Control Authority (DACA) that was under the MoH for a few years until 2017

Responsibility was then shifted back to the MoA in 2017

2

MoH registrations not being renewed, and products must be re-registered

Registrations that were issued by DACA were recognized by the PHRD in 2017

However, renewal of these registrations is not being allowed, and applicants have to re-register using PHRD guidelines

3

PHRD recently terminated issuance of temporary registrations

During efficacy trials, applicants were able to apply for a temporary registration, valid for 1 year, allowing manufacturers to import their products while the trials were ongoing

In 2019 the PHRD communicated to applicants that they will no longer be issuing temporary registrations

Ethiopia | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R	Plant Health Regulatory Directorate (PHRD)	• Evaluates and registers vector control products
E I	Research Institutes (EPHI)	• Conduct trials and reports results

Relevant legislation

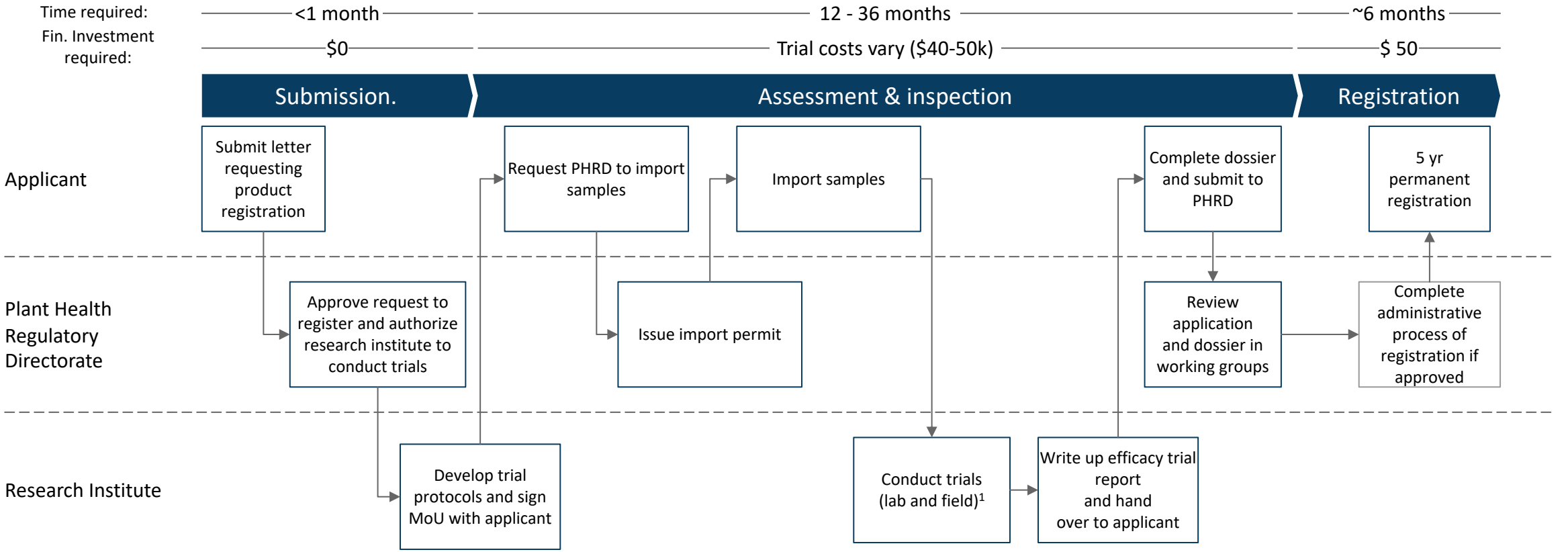
Legislation title	Year	Comments
Pesticide Registration and Control Proclamation	2010	• Establishes registering bodies and guidelines

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Ethiopia | Registration process map

Timeline/cost (excluding field trials):

Registration: ~7 mos., $50
Renewal: ~2 mos.; $20



1. Full field trials required, but specific duration decided by research institute, in line with WHO PQT protocols

Ethiopia | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Urgent product need	Ministry of Health is able to request PHRD to allow importation of an unregistered product in case of emergency such as malaria outbreak
Renewal	Simple administrative process, taking approximately 2 weeks, with most recent licenses required

Ethiopia | Dossier overview (I)

Dossier section	Description
Active ingredient dossier	• Designation • Physical and Chemical Properties • Toxicology and Ecotoxicology • Behavior in environment • Mode of action • Residues
Formulated product dossier	• Physical and Chemical Properties • Toxicology and Ecotoxicology • Emergency measures in cases of accidental exposure or poisoning • Emergency procedures in case of fire/spillage • Uses • Minimum label requirements

Ethiopia | Dossier overview (II)

Dossier section	Description
Local efficacy report	• Usually based on lab, semi-field and full field trials
Sample of the technical grade and the formulated product	
Agency agreement between the local agent and the registration holder	
Third party batch certificate of analysis from accredited laboratory	• Authenticated by chamber of commerce or any relevant government office
Manufacturing license	• Authenticated by chamber of commerce or any relevant government office and should be the original
A letter of recognition that the pesticide is registered and is permitted to be produced in the country of origin	

Ethiopia | Detail on enabling environment

Human resources and technical capability	• 12 experts work part-time on regulation of pesticides within the PHRD, with expertise in entomology, toxicology and efficacy • At least one research institute, EPHI, has capacity and capabilities to conduct Phase 1, 2 and 3 trials (laboratory, insectary, experimental huts and sentinel site)
Financial resources and sustainability	• Registration fees are nominal (<$100), registration function almost fully funded by Ministry of Agriculture • Applicant funds local trials in full
Governance and accountability	• Shifting responsibility between MoA and MoH – MoA initially responsible for registration of vector control tools, then shifted to DACA (under MoH) for a few years until 2017, before responsibility shifted back to the MoA – MoA requires renewals to undergo full registration process as part of shift back from DACA • Malaria program not directly involved in registration process

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Kenya | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:

- R E Pest Control Products Board (PCPB), affiliated with the Ministry of Agriculture (MoA): regulates all pest control products and vector control tools, including registration and post market surveillance
  - E Technical and Registration Committee (TRC): issues recommendations for product registration
  - R Board of Management (BOM): makes final decision by endorsing TRC recommendations
- E National Malaria Control Programme (NMCP), under Ministry of Health (MoH): conducts efficacy trials required for registration process and also conducts post-registration surveillance

Harmonization:

- Current state: Not harmonized for VC
- Future plans: Continue with EAC and SADC initiatives in medicines and pesticides
- Non-VC harmonization efforts: Existing work on harmonizing various other regulatory functions with EAC such as medicines and medical devices

Registration process

Timeline and cost (excluding field trials):

- Registration: 4 – 12 months[1]; ~$400, valid for 3 years
- Renewal: less than 1 month[2] ; ~$200, valid for 2 years

Registration process:

- Applicant hires local agent who completes and submits application
- PCPB Registration department receives and pre-screens the application
- If pre-screen passed, applicant pays introduction fee
- PCPB issues experimental permit
- Applicant applies for import license, of which when issued by the PCPB, enables applicant to import sample for trials
- NMCP conducts efficacy trials; submits report to PCPB
- Applicant also submits a summary form to PCPB
- Under PCPB, the TRC conducts assessment and makes recommendation to the board of management
- BOM authorizes recommendation to register product
- Initial registration is 3 years; registration must then be renewed every 2 years

Additional requirements to WHO PQT-VC:

- Local lab and semi-field trials required
  - For IRS: 6 - 9 months
  - For LLIN: 21 washings, e.g. ~3 – 6 months

Enabling environment

Human resources & tech. capability

- Both PCPB and NMCP have qualified researchers such as entomologists, toxicologists, chemists and environmentalists
- PCPB has website outlining application process, but no electronic submission of applications
- PCPB has 6 registration officers
- NMCP has technical capabilities (e.g. labs) to carry out efficacy trials and post-market resistance monitoring
- PCPB has technical capabilities for post-market surveillance

Financial resources & sustainability

- ~180 products registered for public health as of Aug 2019
- NMCP is funded by external funders such as the Global Fund and PMI (85%) and the government (15%)
- PCPB is funded through application and import permit fees – 0.4% on all imports (FOB)[3]

Governance & accountability

- PCPB is semi-autonomous
- TRC meets two times per quarter to discuss applications
- BOM meets every quarter to endorse TRC recommendations
- Minister appoints BOM every 3 years but this can sometimes take a while

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product.

1. Depends on manufacturer's response and length of application backlog which is 6 months as of August 2019; 2. Depends on completion and correctness of renewal application; 3. Freight on Board

Kenya | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
E R	Pest Control Products Board (PCPB)	• Registration department – Receives and pre-screens all applications – Authorizes both importation of product samples and inception of efficacy trials – Receives imported trial samples from manufacturer and forwards to NMCP – Conducts comprehensive dossier review and provides summary to TRC – Conducts post-market surveillance activities (e.g. lab testing of product samples) • Board of Management (BOM) - comprises of chairperson (appointed by the president) and representatives from ministries such as of trade, environment and health, and experts in pest control in crop and animal production etc. – Makes final decision by endorsing TRC recommendations • Technical and Registration Committee (TRC) - includes participants from Ministry of Health, Ministry of Agriculture, Kenya Agricultural Research Institute, Coffee Research Foundation, Kenya Bureau of Standards and universities – Issues recommendations for product registration
E	National Malaria Control Programme (NMCP)	• Designs efficacy trials with input from the applicant • Conducts efficacy lab and field trials • Conducts post-market resistance monitoring

Relevant legislation

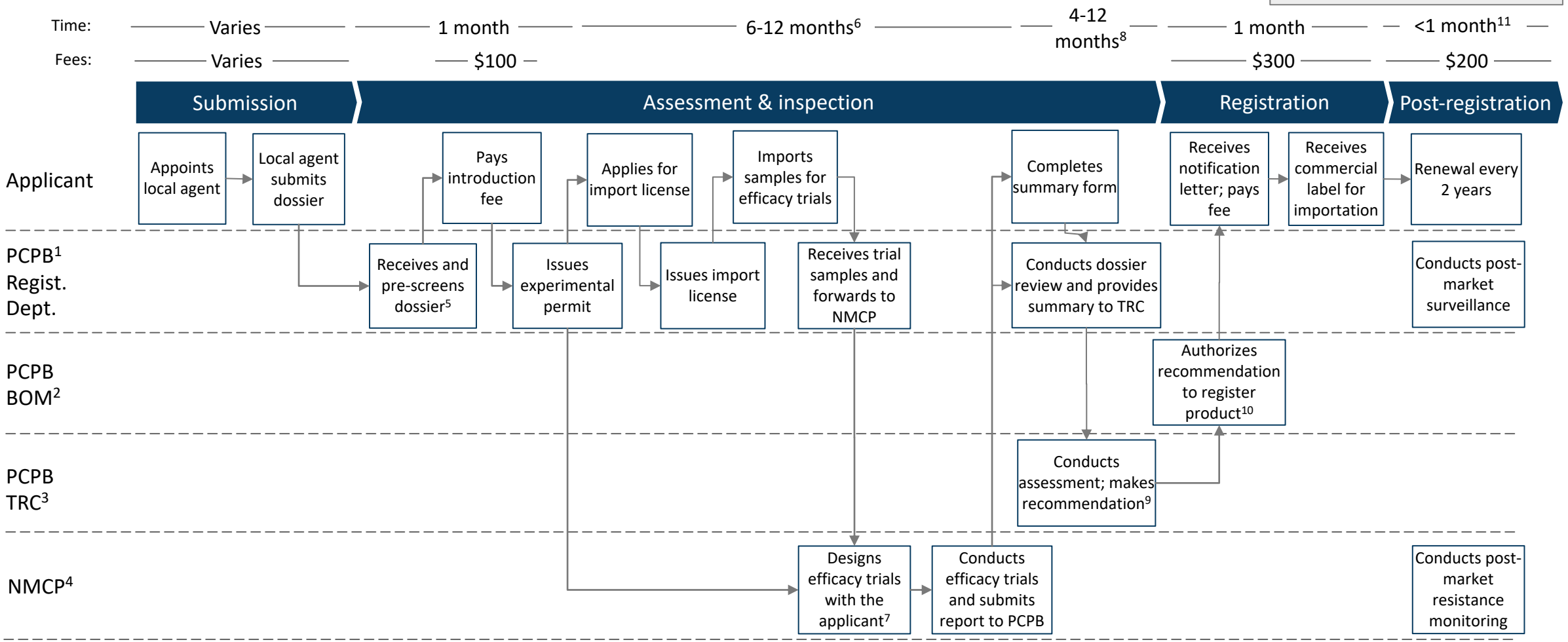
Legislation title	Year	Comments
Pest Control Products Act	1982	• Outlines regulations for importation and exportation, manufacture, distribution and use of pest control products in Kenya

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Kenya | VC registration process map

Timeline/cost (excluding field trials):

Registration: 4-12 months; ~$400
Renewal: <1 month; ~$200



1. PCPB = Pest Control Products Board. 2. BOM = Board of Management 3. TRC = Technical and Registration Committee. TRC includes participants from Ministry of Health, Kenya Agricultural Research Institute, Coffee Research Foundation and Kenya Bureau of Standards. 4. NMCP = National Malaria Control Programme; 5. Includes admin screening as well as light-touch content review (e.g. of toxicology). 6. Timeline includes up to 3 months for importation and receipt of product sample for trials plus 6 - 9 months for IRS or 3 – 6 months for LLINs. 7. NMCP informs PCPB of field trial scope and then PCPB and applicant visit field trial site if necessary. 8. Depends on manufacturer's response and length of application backlog which is 6 months as of August 2019; 9. Meets twice a quarter; 10. Meets quarterly; 11. Depends on completion and correctness of renewal application. If all documents are correct, can take 1 or 2 days

Kenya | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Renewal	Renewal process is much simpler than initial registration process • Applicant advised to renew registration at least 3 months before expiration of current license • Application for renewal is accompanied by five copies of the current label for the VC product • Renewal takes less than 1 month, and take 1 or 2 days if all aspects of application are correct and complete • Renewed registration is only valid for a 2 year period (compared to 3 years for initial registration)
Generic VC product	Pre-registration consultation between applicant and PCPB is strongly recommended Form A4 is submitted for registration • This is a form for identical products that are manufactured after the expiration of the patent of an original/proprietary registered product Additional product information is added where applicable, for example: • Patent expiration date and former holder's name if the product contains a generic active ingredient • Label information if product has new marketing details
Locally made products	Pyrethrum Board of Kenya produces pyrethrum-related VC products which go through PCPB registration • Agent not required • Import license not applicable
Genetically modified VC product	The National Biosafety Authority (NBA), under Ministry of Education, and the Kenya Plant Health Inspectorate Service (KEPHIS), under Ministry of Agriculture, provide expert opinion on and approve genetically modified pest control products PCPB then completes registration of those products

Kenya | Dossier overview (I/VII)

Dossier section	Description
Form A – Application form for the registration of a pest control product submitted before efficacy trials are completed	Applicant information • Name of applicant/ corporate name of company • Name of registration holder • Name of local agent in country (if different from registration holder) • Status of applicant (importer/formulator/distributor) • Business Reg. No., address(es) and contact details (telephone, fax and email) Product information • Description of product: trade name, trade mark and trade mark holder • Function of product (e.g. insecticide, herbicide etc.) • Intended use (e.g. veterinary, public health, industrial, agriculture, forestry, etc. • Target pest(s) and host(s) • Method, dosage rates and frequency of application • Type of formulation (e.g. EC, WP, etc.) • Information on whether product is registered in country of manufacture and formulation • Names of SEARCH countries in which product has been registered • Other countries where product is registered • Customs tariff code Composition of active ingredients information • Active ingredient(s): common name(s) • Manufacturer name and address • Minimum Active Ingredient (AI) % purity; AI range %

Kenya | Dossier overview (II/VII)

Dossier section	Description

Form A – Application form for the registration of a pest control product submitted before efficacy trials are completed (cont.)	Formulation
	• Formulator name, addresses (postal and physical)
	• Internal code
	• Composition: list of ingredients and function, concentration and range
	
	Toxicology of formulated product
	• Tests on rat: acute oral, acute dermal, inhalation
	• Tests on rabbit: irritation to skin and eyes
	• Skin sensitization tests in guinea pig
	• WHO classification
	• Summary of other mammalian toxicological studies e.g.. livestock, wildlife, poultry and pets
	• Summary of environmental effects
	  • Toxicity to bees, fish and other aquatic organisms, earthworms and soil microorganisms and other non target microorganisms
	  • Persistence in environment
	  • Other effects
	
	Packaging
	• Packaging material/container
	• Pack size(s)
	• Disposal of empty container(s)

Kenya | Dossier overview (III/VII)

Dossier section	Description

Form A – Application form for the registration of a pest control product submitted before efficacy trials are completed (cont.)	Other specific requirements
	• Operator exposure
	  • Dermal exposure
	  • Likely operator exposure under field conditions
	  • Available toxicological data relating to other ingredients in formulation (non-active additives in formulation)

Active ingredient dossier	Applicant compiles separate dossier for each active ingredient Dossier provides details of the following sections: • Designation • Physical and chemical properties • Toxicology • Eco-Toxicology • Behavior in environment • Residues • Mode of action • Other specific requirements
List I – Active ingredient dossier index	Supplied as check list to ensure that applicant has provided all relevant data

Kenya | Dossier overview (IV/VII)

Dossier section	Description
Formulated product dossier	Dossier states methods used in the following sections: • Physical and chemical properties of the manufactured product • Toxicology • Emergency measures in cases of accidental exposure or poisoning • Emergency procedures in case of fire/spillage • Efficacy data • Minimum label requirements
List II – Technical product dossier index	Supplied as check list to ensure that applicant has provided all relevant data
3 copies of draft labels	As per PCPB requirements
Product samples	The applicant may be required to submit: • Sample of the pest control product • Sample of the technical grade of its active ingredient • Sample of the laboratory standard of its active ingredient • Any other sample as may be required by the Board

Kenya | Dossier overview (V/VII)

Dossier section	Description
Summary form – submitted after efficacy trials are completed	General information • Trade name • Name and address of formulator • Common name of active ingredient (s) • Concentration of active ingredients • Source of active ingredients • Chemical name • Formulation type • Proposed uses • Packaging/containers (material size) • Registrant (name, address, status) • Agents/distributors in Kenya • Premises 9reg. No, and date of issue) Toxicology of formulated product • Physical/chemical properties of a.i • Physical/chemical properties of the technical grade material • Composition of the technical product (purity%, nature and content of impurities, isomers, by-products – other details should be provided in the dossier) • Physical/Chemical Properties of the Formulated Product • Composition of the Formulated Product (Concentration of a.i. in the formulation. other details should be provided in the dossier) • Method of analysis for determination of the a.i. in technical and formulated products

Kenya | Dossier overview (VI/VII)

Dossier section	Description
Summary form – submitted after efficacy trials are completed (cont.)	Biological (efficacy) Data • Target Pest(s), Diseases(s), Host(s) • Method, Rate, Frequency of application • Recommendations for use in Kenya • Recommendations for use by authorized bodies outside Kenya Toxicology data • Acute toxicological data of the active ingredient(s) • Acute toxicity data of the formulated product • Short term toxicity studies • Other toxicological studies • Recommendations for use by authorized bodies outside Kenya Residue data • Principal residues • Disappearance and fate of residues • Method(s) of analysis (crops, soil, water, feedstuffs etc.) Environment and wildlife hazards • Degradation and mobility studies (soil, water, air) • Toxicity to birds • Toxicity to fish • Toxicity to honeybees/beneficial insects • Toxicity to earthworms, other soil invertebrates • Changes in soil ecology

Kenya | Dossier overview (VII/VII)

Dossier section	Description
Summary form – submitted after efficacy trials are completed (cont.)	Information on approvals/registrations in other countries
	Draft of local label (as per Legal Notice No.89/1984)
	Information of individual who completed form (name, signature, official stamp and date)
	Decision of the PCPB registration Sub-Committee

Kenya | Detail on enabling environment

Human resources and technical capability	PCPB Registration Department: • 6 registration officers • Qualified inspectors and analysts such as toxicologists, chemists and environmentalists • Website and database accessible to the public for information and awareness creation, but not for electronic submission of applications • Has technical capabilities (e.g. labs) for post-market surveillance PCPB BOM: • Comprises of chairperson (appointed by the president) and representatives from ministries such as of trade, environment and health, and experts in pest control in crop and animal production etc. TRC: • Includes representatives from Ministry of Health, Ministry of Agriculture, Kenya Agricultural Research Institute, Coffee Research Foundation, Kenya Bureau of Standards, universities etc. – they are also members of the BOM NMCP: • 7 workers under national government and several more malaria coordinators employed under each of the 47 counties • Qualified researchers with various relevant bachelor's and advanced degrees, and laboratory certifications (e.g. in entomology) • Has technical capabilities (e.g. labs) for efficacy trials and post-market resistance monitoring
Financial resources and sustainability	• ~180 products registered for public health as of August 2019 • PCPB funded through application and import permit fees – 0.4% on all imports (FOB) • NMCP funded by external funders (85%) and the government (15%) -- external funders include the Global Fund, PMI and the Gates Foundation
Governance and accountability	• PCPB is semi-autonomous • TRC meets two times per quarter to discuss applications • BOM meets every quarter to endorse TRC recommendations • Minister appoints BOM every 3 years; Appointments can sometimes take months thus delaying product registration

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Rwanda | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R Rwanda Food and Drug Authority (FDA): Mandated to register and control vector control products in Rwanda

E Rwanda Biomedical Centre (RBC) Develops national
I malaria strategy, including vector control strategy – product import permit will not be granted if not included in strategy

Harmonization:

- Current state: No harmonized approach
- Future plans:
  - None as of Feb 2019
- Non VC harmonization efforts:
  - Existing work on harmonizing various other regulatory functions with EAC such as medicines and medical devices

Registration process

Timeline and cost (excluding field trials):

- Authorization: 4-8 months, free, lasts indefinitely

Registration process:

- RBC evaluates vector control interventions to be leveraged, based on criteria such as efficacy, durability and cost
- Applicants submit simple application with proof of registration with a stringent regulatory authority, such as WHO PQT-VC
- If product is in Rwanda's Malaria strategy then granted import permit, if not then product is put on hold and cannot be imported

* Currently FDA is developing a new registration process – existing process might have changed

Comparison with WHO PQT-VC:

- WHO PQT-VC dossier content is sufficient with no additional local efficacy trials required
- RBC may conduct product composition testing in a lab

Enabling environment

Human resources & tech. capability

- Currently Rwanda FDA does not have any dedicated vector control registration staff, although there is provision in the org. structure for 3 officers

Financial resources & sustainability

- Fee regulations recently instituted by Rwanda FDA, although fees not yet published

Governance & accountability

- RFDA regulates authorization and import of products, however relies heavily on the RBC for their recommendation
- RBC determines which products are in the malaria strategy, thus setting the guidelines for which products should be allowed in the country by the RFDA

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Rwanda | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R	Rwanda Food and Drug Authority (FDA)	• Mandated to register and control vector control products in Rwanda
E I	Rwanda Biomedical Center (RBC)	• Develops national malaria strategy, including vector control strategy – product import permit will not be granted if not included in strategy

Relevant legislation

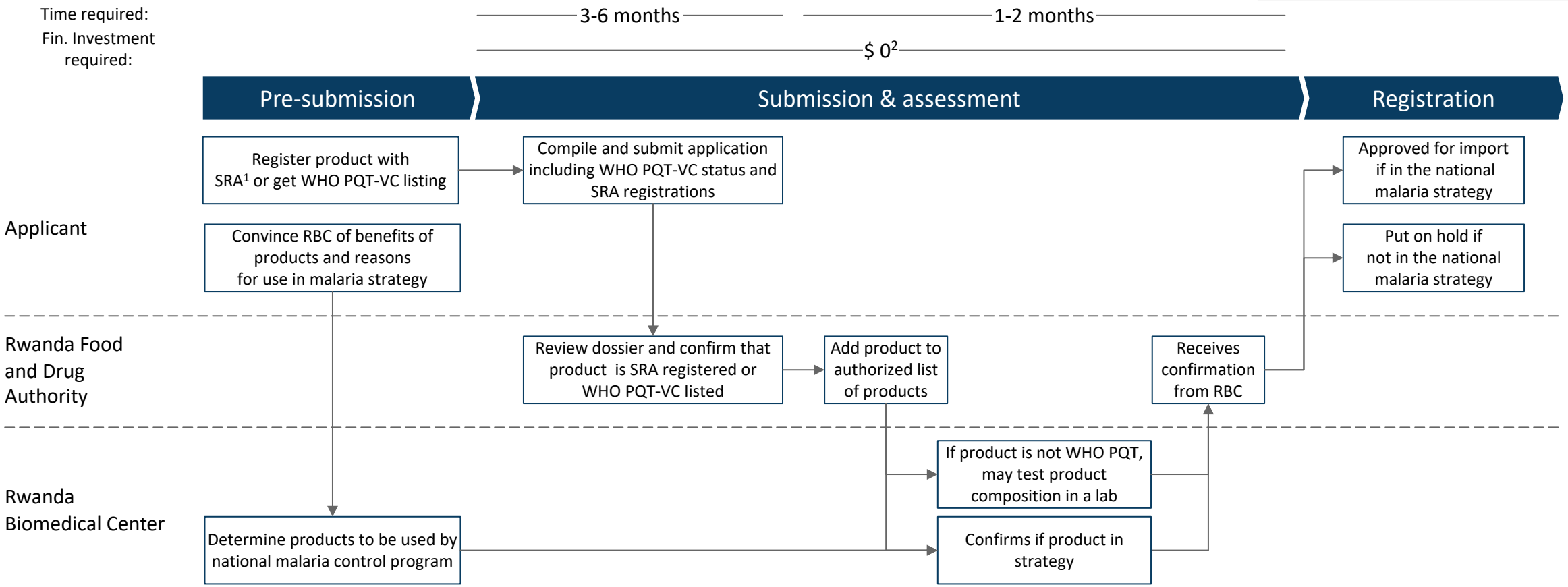
Legislation title	Year	Comments
Establishing Rwanda Food and Drugs Authority and Determining Its Mission, Organisation and Functioning	2018	• Establishment and mandate of Rwanda FDA

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Rwanda | Registration process map

Timeline/cost (excluding field trials):

Registration: 4-8 mos, $0[2]
Renewal: None



1. Stringent regulatory authority; 2. Fees will be instituted in the near future as Rwanda is in the process of formalizing its registration

Rwanda | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Urgent product need	A temporary waiver could be issued in the situation of an outbreak of a disease, confirmed by the Prime Minister or MoH • Has not been issued in the past for vector control products

Rwanda | Detail on enabling environment

Human resources and technical capability	• Rwanda FDA made up of 14 staff in Jan 2019, expected to grow to over 100 individuals in 2019 • RBC has 30 sentinel sites for monitoring insecticide resistance, but only one entomologist
Financial resources and sustainability	• Number of products unknown • Fee regulations recently instituted by Rwanda FDA, moving from free authorizations
Governance and accountability	• Although registration wholly controlled by Rwanda FDA, RBC (and the national malaria strategy it sets) specify which products can be used in Rwanda – E.g., import permits will not be granted without product being included in RBC strategy

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Ministry of Agriculture

C Content of WHO PQT-VC + local semi-field trials

Tanzania | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R Tropical Pesticide Research Institute (TPRI): Mandate to register all pesticides incl. VC tools

E Pesticides Approval and Registration Technical Sub-Committee (PARTS): Convened by TPRI to review applications

I National Plant Protection Advisory Committee (NPPAC): Convened by the Ministry of Agriculture; endorse PARTS decision

Harmonization:

- Current state: TPRI working with EAC on Harmonization of Pesticides Management and with SADC on SAPReF[1]
- Future plans: Continue with EAC and SADC initiatives
- Non-VC harmonization efforts: Existing work on harmonizing various other regulatory functions with EAC such as medicines and medical devices

Registration process

Timeline and cost (excluding field trials):

- Registration: 7-13 months, ~$1,150, valid for 5 years
- Renewal: ~1 month, $300

Registration process:

- Applicant completes and submits dossier
- Applicant aligns on trial protocols with TPRI researcher, researcher conducts trials (lab and semi-field)
- TPRI evaluates all relevant information (dossier and trial results) to make a recommendation
- TPRI convenes Pesticides Approval and Registration Technical Sub-Committee (PARTS) to discuss approval
- MoA convenes National Plant Protection Advisory Committee that endorses the recommendation from the PARTS
- TPRI completes admin process to issue registration

Comparison with WHO PQT-VC:

- Content of WHO PQT-VC plus locally relevant evidence from lab and semi-field trials

Enabling environment

Human resources & tech. capability

- Researchers who conducts trials have entomological training
- TPRI has a lab to test product composition and quality

Financial resources & sustainability

- Funded through registration, trials and import permit fees
- ~3-5 applications received annually
- 0.5% of all imports (FOB)[2] to be paid to TPRI

Governance & accountability

- TPRI responsible for convening PARTS to review products
- MoA responsible for convening NPPAC to endorse PARTS decision so that registration can be issued
- National Malaria Control Program not involved in either PARTS or NPPAC; both committees are convened ad hoc

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

1. Southern African Pesticides Regulators' Forum; 2. Free on Board

Tanzania | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	Tropical Pesticides Research Institute (TPRI)	• Pesticides Approval and Registration Technical Sub-Committee (PARTS) reviews and evaluates products • TPRI registers all pesticides
I	National Plant Protection Advisory Committee (NPPAC)	• Convened by the Ministry of Agriculture; endorse PARTS decision • By law, should involve at least one representative from the following ministries or departments: - (i) agriculture; (ii) health; (iii) environment; (iv) natural resources; (v) justice; and (vi) finance.

Relevant legislation

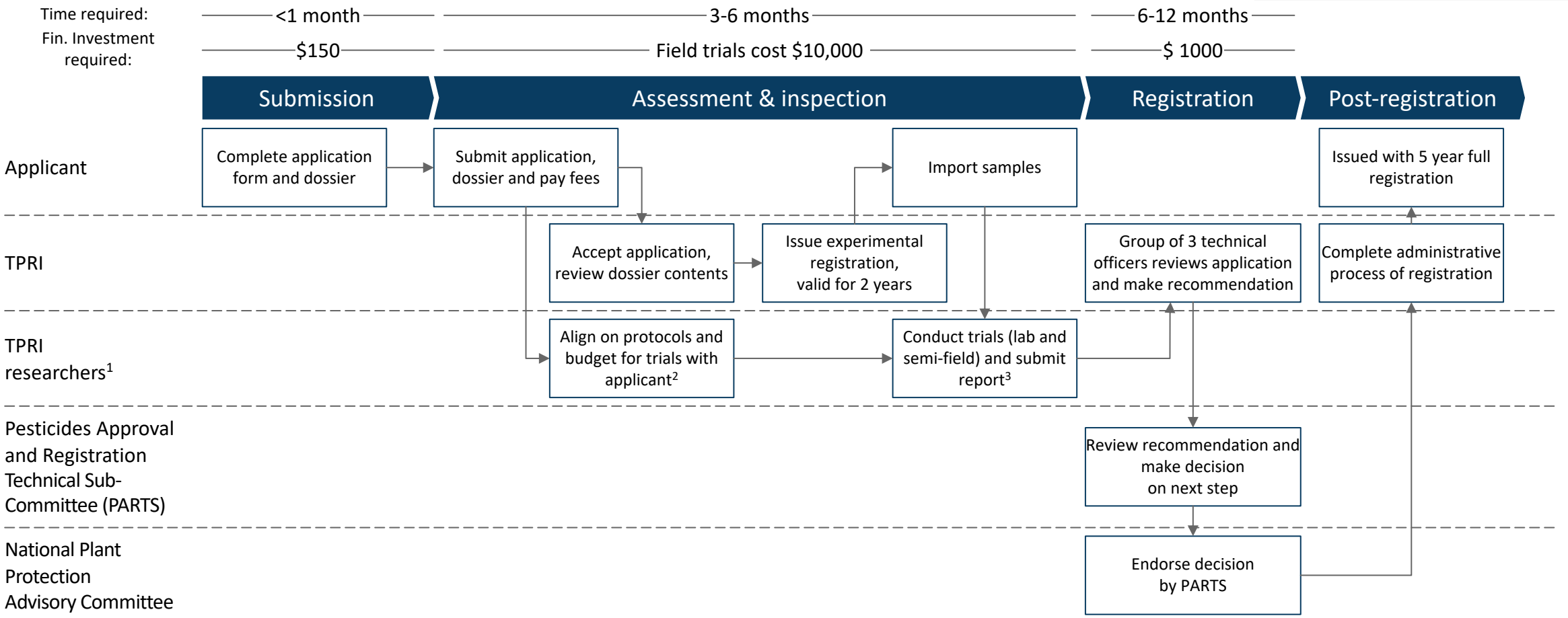
Legislation title	Year	Comments
Plant Protection Act	1997	• Outlines mandate of TPRI to regulate pesticides in Tanzania; does not specify that pesticides for public health use fall under this mandate, but TPRI is the de-facto regulator
Plant Protection Regulations	1999	• Outlines regulations for pesticides in Tanzania

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product
Note: To change the mandate, will require an amendment in legislation to the Plant Protection Act

Tanzania | Registration process map

Timeline/cost (excluding field trials):

Registration: 7-13 mos.; $1,150
Renewal: ~1 mos.; $300



1. TPRI is supposed to assign a research institute from an approved list of institutes; in practice, they will oversee trial execution themselves; 2. Protocols reportedly based on WHOPES guidelines and manufacturer claims; 3. There are no additional requirements for products with a brand new active ingredient

Tanzania | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Renewal	Simple administrative process (e.g., letters of renewal) through TPRI, with no additional trials required for renewal • Must apply 3 months before registration ceases • Process usually lasts 1 month
National emergency	May grant waiver in case of national emergency, with one waiver recently issued in 2017
Data previously generated in Tanzania exists	Data previously generated in Tanzania (lab and semi-field) will not be acceptable for registration purposes if a TPRI researcher was not part of the trial

Tanzania | Dossier overview (I)

Dossier section	Description
Certificates	• Licenses of the companies involved (ISO, registrations etc.) • Free sale certificate • Product manufacturing licence
Pesticide and Toxic Substances Regulation Form (3 copies)	• Details of the product – Common name(s) – Trade name(s) or code number – Chemical name(s) – Molecular formulae of AI(s) – Molecular weight – Structural formulae of AI – Main active ingredient(s) – Content by weight/volume – List of adjuvant name(s) – Content by weight/volume – Type of pesticide – Type of formulation • Toxicology – Classification (in accordance with the WHO guidelines) – Decimal and oral mammalian toxicity (LD) – Two weeks cumulative mammalian toxicity

Tanzania | Dossier overview (II)

Dossier section	Description
Pesticide and Toxic Substances Regulation Form (3 copies) contd.	• Physical properties – Solubility of the pesticide in aqueous and/or organic solvents – Emulsifiability/suspensibility (or emulsion stability) – Physical description – Wettability – Stability/comparability (eg hydrolysed by alkali) – Spraying/dusting properties – Moisture content – Melting point – Setting point – Boiling point – Vapour pressure – Accelerated storage – Flammability – Active ingredient by weight/volume – Acidity/Alkalinity – Tolerance limits for the characteristics in (k) above
Labels	Samples of labels under label guidelines
Trials	Lab and semi-field trial results

Tanzania | Detail on enabling environment

Human resources and technical capability	• Researchers who conducts trials have entomological training • TPRI has a lab to test product composition and quality
Financial resources and sustainability	• ~3-5 applications received annually • Funded through registration, trials and import permit fees – 0.5% of all imports (FOB) to be paid to TPRI • Financial resources required to convene PARTS and NPPAC
Governance and accountability	• TPRI responsible for convening PARTS to review products – Participants: Registrar of Pesticides, Chief Analyst, University of Dar es Salaam, Chief Chemist, Tanzania Bureau of Standards, Tanzanian Food and Drugs Authority, Ministry of Agriculture, National Environment Management Council • MoA responsible for convening NPPAC to endorse PARTS decision so that registration can be issued • National Malaria Control Program not involved in either PARTS or NPPAC; both committees are convened ad hoc

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Ministry of Health

B Content of WHO PQT-VC sufficient

C Content of WHO PQT-VC + local semi-field trials

Uganda | Summary of regulatory authorities, process and enablers

Regulatory authorities

National authorities:*

R E National Drug Authority (NDA): Evaluates application and provides import permit for vector control products (no official registration process)

E I National Environment Management Authority (NEMA): Provides environmental clearance for IRS

E I National Bureau of Standards (NBS): Provides clearance for LLINs through some testing

E I National Malaria Control Program (NMCP): Provides input to NDA whether specific interventions are in the vector control regimen after evaluating the product; product must be in strategy to be imported

Harmonization:

- Current state: No history of harmonization for vector control tools
- Future plans: None as of Feb 2019
- Non-VC harmonization efforts: EAC Harmonization of Pesticides Management as well as East Africa Medicine Registration Harmonization

Registration process

Timeline and cost (excluding field trials):

- Import permit: 3-12 months, no application fee

Registration process:

- Applicant submits documents to request an import permit, including WHO PQT-VC status, environmental clearance from NEMA (for IRS) and clearance from National Bureau of Standards (for LLINs)
- NDA reviews documentation and confirms with NMCP that product is in VC regimen
- NDA issues import permit and applicant able to import products
- NDA then conducts post-shipment lab tests once products are in-country and provides import clearance

Comparison with WHO PQT-VC:

- WHO documentation sufficient for registration
- In practice, local lab/semi-field may be requested before import permit is granted

Enabling environment

Human resources & tech. capability

- No dedicated vector control assessors
- NDA have a lab to test product composition and quality

Financial resources & sustainability

- ~3-5 applications received annually
- Subsidized by other NDA revenue streams

Governance & accountability

- NDA Regulation indirectly lies with NMCP as the only source of technical advice
- No defined timelines or metrics for registration identified

*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Uganda | Overview of relevant authorities for VC tools registration

Relevant authorities*

	Authority	Authority role
R E	National Drug Authority (NDA)	• Evaluates application and provides import permit for vector control products (no official registration process)
E I	National Environment Management Authority (NEMA)	• Provides environmental clearance for IRS
E I	National Bureau of Standards (NBS)	• Provides clearance for LLINs through various testing (e.g. bursting strength, etc.)
E I	National Malaria Control Program (NMCP)	• Policy formulation body leading the development of malaria policy and coordinate various agencies • Responsible for evaluating products for use in national malaria strategy • Product cannot be imported if not included in the strategy

Relevant legislation

Legislation title	Year	Comments
National Drug Policy and Authority Act	1999	• NDA evaluating and granting import permits for vector control products based on their authority to regulate drugs
Importation and Exportation Of Drugs Regulations	2014	

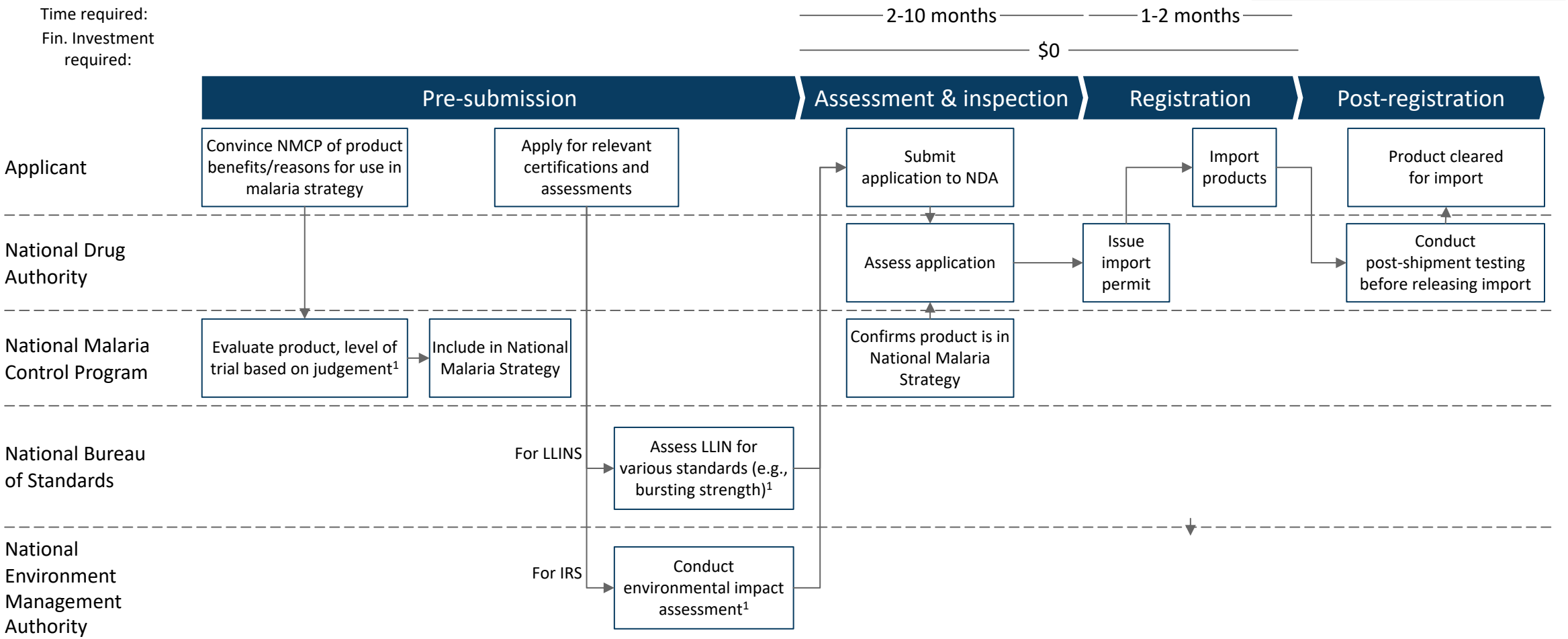
*R = Registers product/assesses dossier, E = Conducts evaluations/trials, I = Provides input on product

Note: Changes to act are underway to widen scope of NDA and include officially vector control tools, medical devices etc.; completion date unknown

Uganda | Registration process map

Timeline/cost (excluding field trials):

Registration: 3-12 mos., no application fee



1. Protocols reported to be based on WHOPES guidelines and manufacturer claims

Uganda | Process variations and exceptions

Circumstances under which variation occurs	Differences in process/requirements
Cautious introduction	Possible to introduce a product without local data and then monitor efficacy in the field, based on judgment of NMCP
National emergency	May grant waiver in case of national emergency, although not been issued in recent history

Uganda | Application requirements overview

Dossier section	Description
Manufacturing license	• Basic requirement
Certificate of conformity	• Basic requirement
WHO PQT-VC status	• WHO PQT-VC required
Additional registration statuses	

Uganda | Detail on enabling environment

Human resources and technical capability	• No dedicated resources in NDA to evaluate vector control tool applications • NDA have a lab to test product composition and quality
Financial resources and sustainability	• ~3-5 applications received annually • Subsidized by other NDA revenue streams
Governance and accountability	• NDA is the registrar, but close communication between NMCP and NDA on products to be registered • Product must be included in the national malaria strategy of the NMCP in order to be imported

Thank you