Regulation of Vector Control Products: What's New?

2 December 2019
Project objectives

Build a comprehensive fact base around VC product registration in Africa

Deepen the understanding of existing challenges

Co-create opportunities to optimize access to VC tools

Progress thus far

Created an extensive database of VC registration processes for select African countries

Built relationships with African regulators and key stakeholders

Developed case studies of collaborative models from other products
We have created an extensive fact-base using stakeholder interviews and in-depth country research.

Over 130 stakeholders interviewed ...

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

...13 countries selected for in-depth research

Selection criteria include:

- 2017 malaria burden
- Regional distribution (East, West, Central, Southern)
- Potential regional influence
Assessment was conducted along three key dimensions

Streamlined registration of VC tools

**Regulatory authorities**
- National regulatory system and authorities
- Collaborative effort with relevant entities

**Registration process**
- Submission
- Assessment and inspection
- Registration
- Post-registration

**Enabling environment**
- Human resources and technical capability
- Financial resources
- Governance and accountability
For each focus country, the fact-base includes:

- Summary of vector control tool registration
- Key authorities and legislation
- Overview of registration process
- Descriptions of process variations and exceptions
- Dossier overview
- Detail on enabling environment

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

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

innovation2impact.org
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.
Overall, African VC registration is a complex landscape.
Country examples: Vector control registration challenges

- **Ethiopia**
  - Full local field efficacy trials required, fully funded by applicant
  - Shifting responsibilities between Ministries of Agriculture and Health

- **Tanzania**
  - Efficacy trials completed at GLP sites in Tanzania are not recognized for country registration (but required for PQ)

- **Ghana**
  - Two regulatory authorities with overlapping registration mandates
Country examples: Vector control registration best practices

Zambia

- Effective collaboration and clear role definition between Ministries of Environment and Health
- Flexible about in-country trials based on product

Kenya

- Regulator is semi-autonomous due to funding structure: application fee + tariff on all imports
- Effective collaboration and clear role definition between Ministries of Agriculture and Health
Additional challenges national regulators and industry are facing across Africa

1. Lack of resources to ensure adequate evaluation or quality control

2. Requirements aren't tailored for Vector Control products

3. Delayed communication between authorities

4. Insufficient transparency on registration process/requirements
Entry of novel products will exacerbate current situation

Key stakeholders for VC do not have **regular, in-person interaction**

Regulators are **not currently prepared** for novel product pipeline

Novel products will likely **exacerbate existing challenges** with mandate and communication

Clear imperative for increased information sharing, collaboration, and the creation of a VC specific forum or conference
We researched four on-going collaborative efforts for pesticide or medicines registration

<table>
<thead>
<tr>
<th>WHO Collaborative Registration Procedure</th>
<th>EAC Medicines Regulation Harmonisation</th>
<th>CILSS/CSP &amp; resulting ECOWAS efforts</th>
<th>SEARCH &amp; resulting EAC &amp; SADC efforts</th>
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</thead>
<tbody>
<tr>
<td><strong>Member states</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Product focus</strong></td>
<td>Finished pharmaceutical products</td>
<td>Medicines</td>
<td>Pesticides, including vector control products</td>
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<tr>
<td><strong>Scope of harmonization</strong></td>
<td>Process, PQ assessment and recommendation</td>
<td>Guidelines, process, assessment and recommendation</td>
<td>Guidelines, process, assessment and registration decision</td>
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<tr>
<td><strong>Years active</strong></td>
<td>2012-Present</td>
<td>2012-Present</td>
<td>1992-Present</td>
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There are several key takeaways for the impact of collaborative efforts in regulation:

- Bring a diverse set of stakeholders together
- Respect country sovereignty and minimize the legislative changes
- Leverage existing expertise and capabilities and provide effective capacity building support
- Leverage existing forums with political pull
- Iteratively incorporate learnings
- Plan for financial sustainability
Next steps to continue momentum

- **WHO CRP** for vector control
- Increased readiness of country regulators for innovative VC products
- Clear path forward to **maximize alignment potential** within sub-regions
Thank you