

Supporting countries in local production and introduction of vector control commodities in Africa

RBM Vector Control Working Group

3 March 2022





ALMA: An alliance of 55 Heads of State and Government in Africa

ALMA was launched as a collective, coordinated response to complement efforts to rid Africa of malaria

- Provides a forum for Heads of State to review progress and address challenges in meeting the malaria targets
- Implements a continental monitoring and accountability system through the ALMA Scorecard for Accountability and Action to track results, identify bottlenecks, and facilitate action
- Supports countries with rollout and strengthening of national scorecard management tools for malaria, RMNCAH, and NTDs, as well as for nutrition and community
- Identifies and shares lessons learned for effective implementation of national and regional programmes
- Maintains focus and collective attention on malaria within the AU, international community, UN and regional organizations



His Excellency Uhuru Kenyatta, President of the Republic of Kenya and current ALMA Chair

ALMA Scorecard for Accountability and Action

ALMA Chair Legacy Agenda



1

DIGITALIZATION AND REAL TIME DATA

Improve access to malaria data through a digital platform and by using country malaria scorecards so that all citizens are aware and empowered to act.

2

ENGAGEMENT WITH REGIONAL ECONOMIC BLOCS

Work with Africa's Regional Economic Communities and Heads of State and Government to drive progress at the regional level.

3

CREATE MORE END MALARIA COUNCILS AND FUNDS

Establish 15 End Malaria Councils and Funds to mobilize additional domestic public and private resources and engage local country leaders.

4

YOUTH ADVISORY GROUP

Create an army of malaria advocates to champion political and resource commitments.

The AU has identified local manufacturing of pharmaceuticals as an important investment area in the continent. As part of our mandate to strengthen engagement with RECs, the current ALMA Chair, His Excellency President Uhuru Kenyatta of the Republic of Kenya, has prioritised activities that boost the local manufacture and regulation of health products. The focus of our work in this area is to advocate for expanded capacity in the manufacturing sector hence these activities include but are not limited to malaria (e.g. drugs, nets and insecticides) and covid-19 commodities.

Local Manufacture

- From our work in this area, a number of bottlenecks have been identified, these include:
 - High labor costs, scarcity of available expertise
 - Taxes on imported raw materials (imported finished products are exempted from taxes)
 - Unfavorable foreign currency policies
 - Lack of assurance of regional and international markets
- ALMA partners with AUDA/NEPAD, MMV and others to support local manufacture and implementation of the Pharmaceutical Manufacturing Plan for Africa, specifically to
 - Support local production of APIs in Africa (essential medicines)
 - Technology transfer
 - Support manufacturers with prequalification certification
 - Advocating for removal of duties/taxes and increased sector investment

Regulatory frameworks

- ALMA partners with Innovation to Impact (I2I) and others to support creating an enabling environment for registration of new tools for vector control.
 - ALMA supported mapping registration landscape of vector control products in Africa. Findings reveal that the registration process in Africa is very complex. Challenges include
 - Different ministries have responsibility for vector control registration
 - Some countries requiring additional assessments before registration
 - Countries using different testing protocols for registration

i2i project objectives

Key to the rapid uptake of new health products – including vector control products, is their registration at country level.

An assessment of the registration landscape of vector control products in Africa has deepened our understanding of the existing challenges of registration of vector control products and seek opportunities to optimize access to VC with stakeholders.

Involved stakeholders

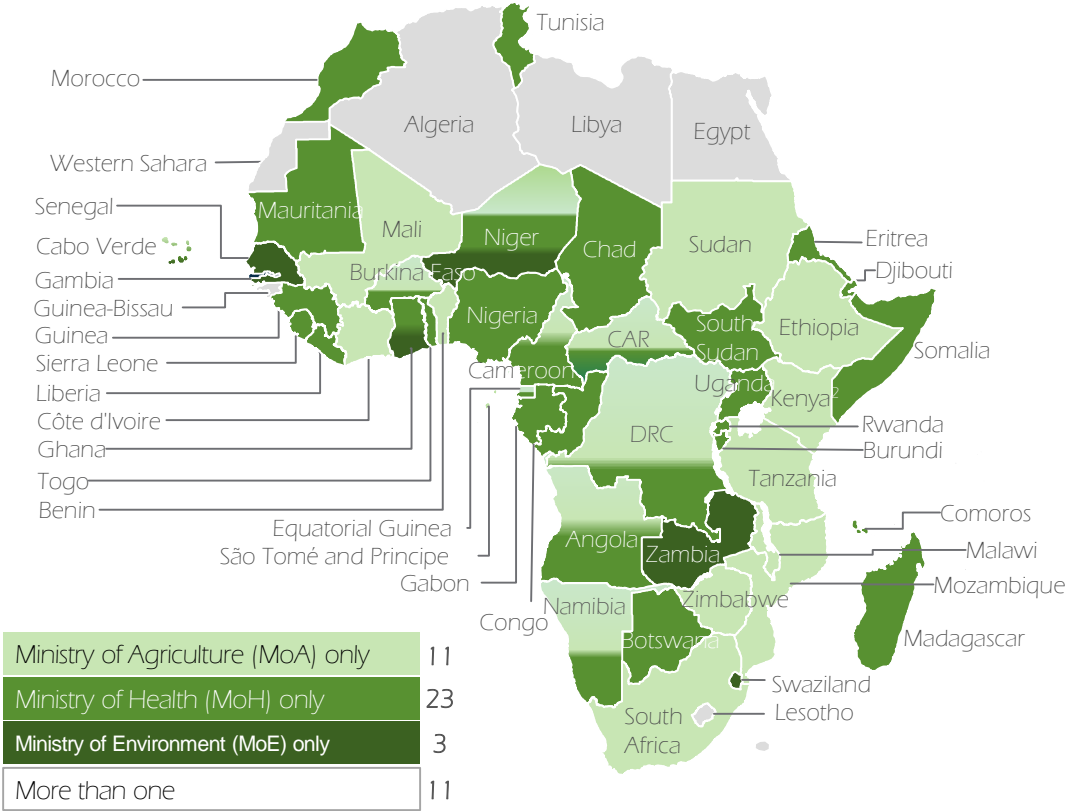


Overall, African VC registration is a complex landscape

As of August 2019

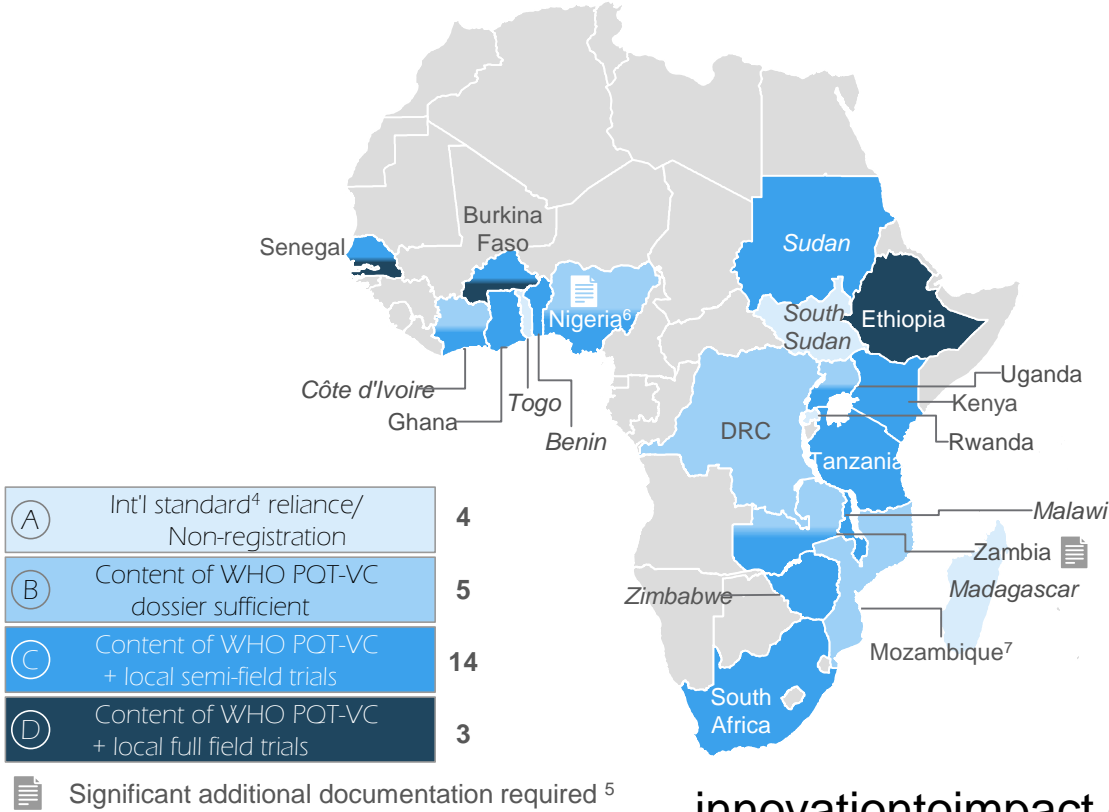


Overseeing ministry¹



Registration requirements

Italics indicate non-focus countries³



innovationtoimpact.org

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

Regulatory Frameworks and RECs

- AUC vector control registration working group is developing a vector control roadmap
- Follow up with relevant vector control regulatory groups - discussion about issues affecting access to new tools.
- Learn from the success of regional regulatory initiatives and opportunities to leveraging these models (CILSS/ECOWAS)
- Understand key regional vector control regulatory priorities
- Update on the PQ process and discuss ways to facilitate engagement
- Dissemination of information to countries – ensure informed regulatory decisions on new vector control products and to understand where our support may be helpful to achieve that



Examples of how ALMA facilitates support

- Highlight challenges/bottlenecks in local manufacturing and registration through our interactions with the ALMA Chair and African Heads of State and Government.
- Assessment of select national manufacturer capabilities (deep dives) – focused support to generic manufacturers to achieve WHO PQ (e.g. MMV technical assistance to countries).
- Leverage our advocacy strengths to support the implementation of Pharmaceutical Manufacturing Plan for Africa by NEPAD.
- Work with partners to identify opportunities to address gaps and increase investments in local manufacture and facilitate technology transfer.
- Promote harmonization of registration of vector control products through Regional Economic Communities (RECs).
- Continue to support the regulation of pharmaceuticals and the dissemination of the outcomes emerging from the assessment of regulatory frameworks.

Examples of how ALMA facilitates support

End Malaria Councils & Funds - country-led and country-owned mechanisms to mobilise multisectoral support

Continue to provide technical assistance to countries establishing EMCs and incorporating these activities as part of the mandate of council members.

e.g.

- The landscape for Kenya End Malaria Council
- Tanzanian manufacturer tech transfer

AFRICAN LEADERS
MALARIA ALLIANCE



Thank you

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