

Increasing the Availability of Quality NTD Medicines in Africa: An Integrated Data Approach

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Background

Neglected tropical diseases (NTDs) are a diverse group of diseases and conditions that cause considerable morbidity and mortality. They are endemic in 49 African countries and affect more than 600 million individuals there, representing 42% of the global burden of NTDs.¹

Lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, and three soil-transmitted helminths account for much of the NTD burden in Africa; with administration of effective preventive chemotherapy (PCT), these can be prevented and treated. USAID funded the PQM+ program to develop the NTD Medicines Information Dashboard² to share data on registration and sources of quality-assured NTD preventive chemotherapies to increase availability of these important products.

Purpose and Content of the Dashboard

The NTD dashboard promotes collaboration and transparency to help reshape availability of quality PCT NTD medicines, accelerate mitigation of NTDs, and advance public health. Efforts to increase access to NTD medicines requires up-to-date data on NTD product registrations and sources. The dashboard consolidates data on:

- Registrations of quality-assured NTD medicines, including, at present,
 - WHO-prequalified NTD medicines
 - Registrations posted online by stringent regulatory authorities and WHO maturity level 3 regulators, including in Africa (Ghana, Nigeria, and United Republic of Tanzania)
- Dosage forms/strengths
- Manufacturing sources
- Other information from regulators and global resources (e.g., WHO invitations for expressions of interest, UNICEF pricing).

Uses of the Dashboard

The following users will find helpful information in the dashboard:

	National medicines regulatory authorities (MRAs) can identify sources of quality-assured NTD medicines and can leverage reliance relationships to facilitate registration
	Procurement agents can identify potential suppliers
	Manufacturers can identify market gaps, competitors, and sources of quality active pharmaceutical ingredients (APIs)

Data in the Dashboard

Users can search the dashboard for data on finished pharmaceutical products (FPPs) and the APIs that are used to make FPPs. Data are available on seven NTD preventive chemotherapy products. Shown below are global results for PCT NTD FPPs in the dashboard:

PCT NTD Medicine	# of WHO PQs or ERP approvals	# of approvals (ML3, ML4, SRA, WHO PQ)	# of manufacturers identified
Albendazole	3	117	19
Azithromycin	0	351	37
Diethylcarbamazine	2	2	2
Ivermectin	2	42	4
Mebendazole	1	56	13
Praziquantel	2	50	8
Tetracycline eye ointment	0	2	0

Data in the online database are updated as they become available.

This shows, for example, that the dashboard contains data on:

- 3 WHO-prequalified (PQ) or Expert Review Panel (ERP) approved sources of albendazole
- 117 approvals of quality-assured albendazole by WHO PQ, WHO ML 3 MRAs, or stringent regulatory authorities
- 19 manufacturers of approved albendazole

Future Upgrades to Dashboard Content

In the future, PQM+ will add to the dashboard

- Data on manufacturer capacity
- Data on products approved in high-burden countries by MRAs that are not yet ML3 or 4

¹ Draft Continental Framework on the Control and Elimination of Neglected Tropical Diseases in Africa by the Year 2030

² <https://www.ntd.pqmplustools.com/>

To facilitate reliance and to support development of markets for continental sources of medicines, the number of registrations by advanced African MRAs and of products manufactured by African manufacturers are shown in the following table.

PCT NTD medicine	# of registrations by African ML3 MRAs	# of African manufacturers identified
Albendazole	98	12
Azithromycin (various dosage forms)	145	3
Diethylcarbamazine	0	0
Ivermectin	2	1
Mebendazole	35	6
Praziquantel	13	3
Tetracycline eye ointment	0	0

The table shows that:

- African ML3 MRAs have registered no or very few quality-assured sources of four of the seven NTD PCTs (diethylcarbamazine, ivermectin, praziquantel, and tetracycline eye ointment).
- Few African manufacturers are identified in the database for the targeted NTD medicines; only one (albendazole) has more than 10 African sources.

Notably, none of the quality-assured NTD APIs are manufactured in Africa.

Conclusions

- MRAs will be able to use the database to identify quality-assured sources of PCT NTD medicines and medicine registrations by mature regulators on which they can rely to increase medicine availability.
- Procurement agents will be able to identify quality-assured sources – including African sources – of most of these medicines.
- Manufacturers will be able to identify market opportunities.

This presentation highlights the dearth of African manufacturers and registrations of PCT NTD medicines despite the continent's disease burden; emphasizes the need to expand African manufacturers and registrations of these medicines; and solicits additional data to enhance the database's utility.