Streamlining samples management to strengthen health outcomes in Africa

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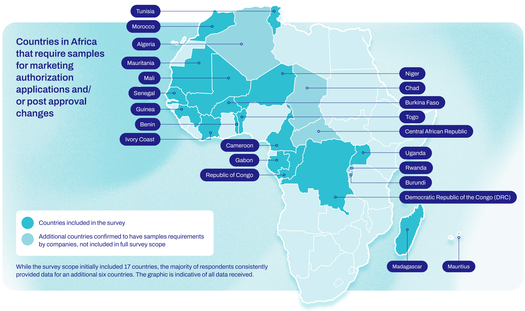
Background

Ensuring the quality, safety, and efficacy of pharmaceutical products is a cornerstone of public health. To meet these high standards, innovative multinational pharmaceutical companies perform rigorous batch release testing for every product, following internationally recognized protocols and approved specifications.

In parallel, many African countries require additional in-country testing by their National Regulatory Authorities (NRAs) or National Control Laboratories (NCLs), even for medicines that have already passed stringent international quality checks. While this practice reflects a commitment to local oversight, it also introduces important questions around efficiency, duplication, and access.

In collaboration with LEEM and LIPA, IFPMA conducted a survey of eight multinational pharmaceutical companies between November 2024 and January 2025 to understand the samples requirements across 17 Africa countries. This infographic explores the current landscape of sample requests and in-country testing requirements, helping to inform more efficient regulatory pathways and support timely access to quality medicines across the region.



While the survey scope initially included 17 countries, the majority of respondents consistently provided data for an additional six countries. The graphic is indicative of all data received.

Why this matters?

The current approach to sample requirements poses real and pressing challenges—not only for manufacturers, but more importantly, for patients and health systems across Africa.

Delayed patient access to new medicines

Securing appropriate samples—particularly French packs—can be difficult, especially for new products not yet commercially available. Producing these samples often involves logistical hurdles, limited stock, and complex storage and importation procedures; all of which can delay product registration and patient access.

Risk of supply interruptions

In some countries, implemented samples of the post-approval change is required. This poses a challenge to manufacturers as usually production of medicines with a change implemented occurs only after regulatory approval is granted.

Misuse of resources and safety risks

Sometimes large volumes of samples are required for visual inspections only and, with innovative and complex products, it is important to maximize supply availability for use in patients. Additionally, improper handling—such as incorrect storage or sample diversion—can pose significant risks to public health.

Repetitive laboratory testing across Africa

Laboratory testing of the same samples by individual NRAs leads to wastage of valuable resources such as laboratory capacity, critical reagents, reference standards, antibodies, and other finite testing materials.

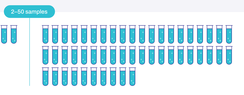
Survey findings

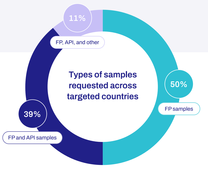
Abbreviations:

FP	Finished Product	**SLC**	Safety Label Changes
API	Active Pharmaceutical Ingredient	**HPLC**	High-Performance Liquid Chromatography

New marketing authorizations

In all surveyed countries, between 2–50 finished physical product samples are required for new marketing authorization for small molecules, vaccines, and biologics/biosimilars. In several countries, not only Finished Product (FP) samples are needed but also Active Pharmaceutical Ingredient (API) samples and other materials, such as reference standards, HPLC columns, etc. Obtaining these various sample types for new marketing authorizations can cause potential delays in the submission process.

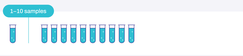


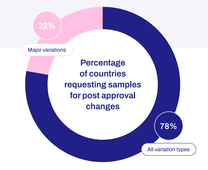


FP samples	Uganda, Benin, DRC, Congo, Gabon, Guinea, Niger, Togo, and Tunisia
FP and API samples	Madagascar, Ivory Coast, Senegal, Cameroon, Burkina Faso, Mali, and Mauritania
FP, API, and other (e.g. Reference standards or HPLC) samples	Morocco and Algeria

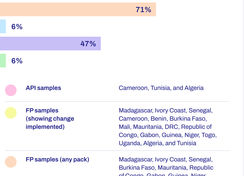
Post approval changes

In addition to physical samples required for new market authorizations, samples are also requested for post approval changes in all surveyed countries. Often, mock-ups are not accepted in place of physical samples, and a number of different types of samples are requested. These samples were typically required for either Quality Control (QC) testing or visual inspections. The average number of samples submitted for Chemistry, Manufacturing, and Controls (CMC) and Safety Label Change (SLC) ranged from 1–10.





All variation types	Burundi, Madagascar, Côte d'Ivoire, Senegal, Cameroon, Benin, Burkina Faso, Mali, Mauritania, DRC, Republic of Congo, Niger, Togo, and Gabon
Major variations e.g. additional drug product (DP) manufacturer/ packer, testing site	Tunisia, Algeria, Madagascar, and Uganda



API samples	Cameroon, Tunisia, and Algeria
FP samples (showing change implemented)	Madagascar, Ivory Coast, Senegal, Cameroon, Benin, Burkina Faso, Mali, Mauritania, DRC, Republic of Congo, Gabon, Guinea, Niger, Togo, Uganda, Algeria, and Tunisia
FP samples (any pack)	Madagascar, Ivory Coast, Senegal, Burkina Faso, Mauritania, Republic of Congo, Gabon, Guinea, Niger, Benin, Mali, and DRC
Other (FP any pack + implemented artwork)	Ivory Coast
Other (FP any pack + commitment to submit FP showing change implemented)	Ivory Coast, Senegal, Cameroon, Benin, Burkina Faso, Mali, Gabon, and Togo
Other (equipment and reagents)	Algeria

Recommendations

Reliance on testing and/or approval decisions conducted by other regulatory authorities avoids duplication of regulatory efforts, reduces lag time in patients' access to medicinal products, and prevents shortages to ensure supply continuity.

Therefore, IFPMA:

- Urges countries to reduce repetitive product sample testing for new application and post approval changes to enable greater reliance. The use of physical product samples for quality control testing should be minimized as much as possible, specifically for highly innovative and complex products, to ensure those products are available sooner for use in patients. In cases where samples requirements are embedded in legislation, NRAs are at liberty to grant waivers for these requirements based on the presence of compelling supporting data provided with the application.
- Encourages utilization of the Network of African Reliance Laboratories (NARL) in registration testing where necessary.
- Encourages the use of mock-ups of artwork, pictures of the product, and/or certificates of analysis in place of physical samples.
- Recommends prioritizing rigorous market surveillance testing based on scientific knowledge and risk analysis for more accurate supervision of the supply chain, allowing the timely detection and interception of suspicious pharmaceutical products and facilitating targeted samples requests.
- For import testing requirements, we would also recommend considering waivers.

Conclusion

For pharmaceutical companies that aim to widen patient access to medicines across the African continent, the cumulative sample requirements across the various countries may deter manufacturers from registering their products. By streamlining samples requirements in Africa, we have the opportunity to establish more harmonized, science-based regulatory practices that ultimately benefit patients, streamline processes, and strengthen health outcomes across the region.