

THE ECONOMIC IMPACT OF RELIANCE ON A NATIONAL REGULATORY AUTHORITY: A SAHPRA CASE STUDY

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BACKGROUND

- In 2022, the South African Health Products Regulatory Authority (SAHPRA) cleared its **inherited backlog of 16,000 applications**.
- The **implementation of reliance** was a major lever in clearing the backlog.
- Many National Regulatory Authorities (NRAs) are becoming **autonomous entities** more independent from their Ministries of Health and with this comes **financial sustainability** concerns.
- The **WHO Global Benchmarking Tool** (GBT) is a sound framework to support NRAs to increase their maturity but may compound the resource constraints within LIMC medicines regulators.
- **The WHO supports reliance practices** as these have demonstrated to **alleviate pressure on NRAs** in terms of human endeavour through less duplication of efforts.

AIM

To establish the economic impact on an African NRA of investing in reliance practices, as well as to listen to the pharmaceutical industry's voice regarding the possible benefits this could have for Pharma and their patients.

METHODS

RESEARCH AREA	RESEARCH QUESTIONS
SAHPRA's OPEX & CAPEX	What does it cost to keep SAHPRA up-and-running on a daily basis?
SAHPRA's WHO GBT ML3 activities	What are the additional costs associated with ML3 efforts?
SAHPRA Backlog Clearance Project: Assessment Costs	What were the assessment duration & costs for abridged vs full review?
Review of NRA Fee Structures	Do African NRAs have differentiated fee structures for reliance and full reviews?
Pharmaceutical Industry	What is the private sector's opinion of reliance implementation and the potential cost-savings this may have to benefit African NRAs in enhancing their maturity?

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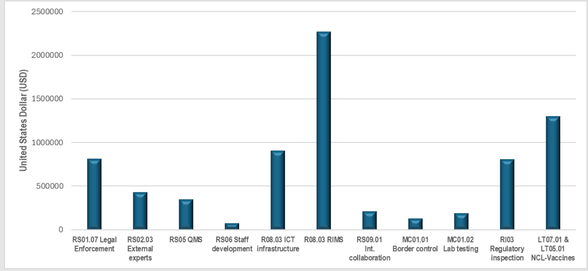
RESULTS

SAHPRA OPEX & CAPEX

- For the 2022/2023 financial year (FY), SAHPRA's annual report statistics reflected **57% revenue from application fees and 43% from a National Treasury grant**.
- However, with government austerity measures currently in place, it is anticipated that **the fiscal contribution will be reduced to 39% by 2027**, and this funding deficit will have to be off set through **greater reliance on Industry fees**.
- To remain financially self-sustaining, SAHPRA aims to recover 100% of all its direct evaluation costs, and pools product retention fees with the government grant to support indirect activities.
- For its 2023/2024 FY, **SAHPRA's main expenditure was staff remuneration** (68% of its ~$21,340,304 budget), followed by its operating costs at 20%, and the contracted laboratory costs, office rental and capital expenditure at 6%, 5% and ~1%, respectively.

COST OF WHO GBT ML3 ACTIVITIES



SAHPRA BCP ASSESSMENT TIME-AND-COST METRICS

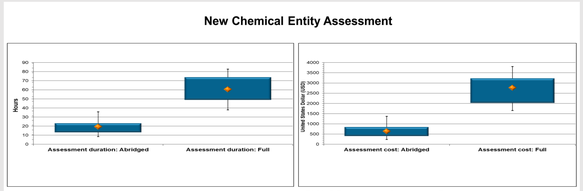


FIGURE 1: New Chemical Entity product comparison: Duration of abridged (n=33; median=19.4hrs) versus full review (n=18; median=60.5hrs) of CMC aspects (p<0.0001)

FIGURE 2: New Chemical Entity product comparison: Assessment cost of abridged (n=33; median=$636) versus full review (n=18; median=$2773) of CMC aspects (p<0.0001)

SAHPRA BCP ASSESSMENT TIME-AND-COST METRICS (CONT.)

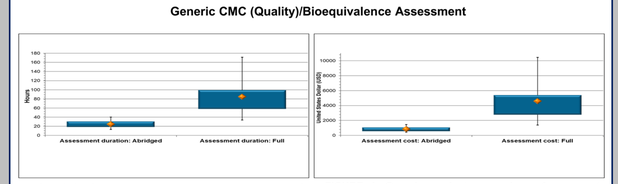


FIGURE 3: Generic product comparison: Duration of abridged (n=70; median=24.6hrs) versus full review (n=67; median=84.7hrs) of CMC/BE aspects (p<0.0001)

FIGURE 4: Generic product comparison: Assessment cost of abridged (n=70; median=$855) versus full review (n=67; median=$4,602) of CMC/BE aspects (p<0.0001)

PHARMACEUTICAL INDUSTRY OPINION

Survey by the Academy of Global Medicines Development Professionals (GMDP Academy) at King's College; 29 respondents comprising of Medical Affairs representatives of pharmaceutical companies

SURVEY QUESTIONS	YES	NO	NO RESPONSE
In instances where reliance review pathways work effectively, would your organization consider paying higher application fees to ensure quicker market access for your products?	25 (86%)	4 14%	0
Should an NRA not adhere to its service charter timelines for reliance pathways, would your organization recommend a credit on future applications?	20 (69%)	5 (17%)	4
Would your organization consider paying an annual developmental fee to enable NRAs to attain ML3/4, given the benefits of a mature NRA within the country/region both for patients and the pharmaceutical industry?	19 (66%)	8 (28%)	2
Would your organization be supportive of a cost-based fee model implemented within NRAs?	24 (83%)	3 (10%)	2

KEY MESSAGES

- Many NRAs in developing countries are dependent on government grants to operate, but austerity measures have **reduced fiscal contributions** and NRAs are increasingly relying on Industry fees and funders.
- Numerous activities falling within SAHPRA's mandate **do not generate fees** – regulation of certain products, vigilance, border controls, post-marketing surveillance and laboratory testing.
- Reliance is not just a time-saver, but also **reduces assessment cost**.
- For the 188 applications assessed in this study, the costs decreased by 77% and 81% for NCE and generic product review, respectively, with **SAHPRA conserving $277,413-35** overall.
- The majority of African **NRAs do not have a differentiated fee structure for reliance & full review**.
- The Industry respondents were **open to paying more for the assessment of reliance applications** and supportive of **the implementation of a NRA cost-based fee model**.
- More than 50% of Industry was in favour of **a credit system on future applications**, should an NRA not adhere to its published approval timeframes and would consider **an annual development fee** to enable NRAs to strengthen their regulatory systems.

CONCLUSIONS

- **ML3 NRAs** bring great benefit to a country & region in terms of **safe, efficacious and medicines of good quality**, but the financial and resource requisites for **reaching and sustaining this status are significant**.
- However, the study outcomes have shown **reliance to conserve the financial resources of an NRA**. It illustrated the ROI of an NRA investing in reliance practices.
- **Surplus funds** and reinvesting these into the NRA would be able to **advance the country-specific activities** required by the WHO and **improve the maturity** of the authority, as well as to aid improved service delivery.
- Both **EFPIA & IFPMA recommend a cost-based fee model** that takes into account the primary costs associated with the services an NRA provides, fully cognisant of the SWOT analysis of an agency, and with a future-forward perspective.
- The United States Prescription Drug User Fee Act (**PDUFA**) also **takes cognisance of the inherent costs associated with a regulator** and its fee models are examples of a holistic approach to safeguarding agency sustainability and development.
- Some RRAs have implemented **reliance pathways for which they charge higher fees** (Singapore HSA). This aligns with the general principle of fast-track services, for which one pays for faster service.

RECOMMENDATIONS

TO ENSURE FINANCIAL SUSTAINABILITY, NRAs SHOULD:

1. Put in place **a differentiated fee structure** for full and reliance review pathways for applications.
2. Encourage **governments to perform a cost analysis of the NRA needs**, thereby ensuring a mature and self-sustaining agency.
3. Develop and present **a strategic plan to governments** to ensure surplus funds are retained.
4. Institute **a development fund for additional income**, thereby improving sustainability independent of outside funders' contributions.
5. Introduce **an annual fee for pharmaceutical companies** to cover the wide range of activities not explicitly funded through application fees, with many of these required for maintaining ML3 status.

COLLABORATORS

Disclosure: None of the authors of this presentation has any disclosures to make concerning possible financial or personal relationships with commercial entities that may have a direct/indirect interest in the subject matter of this presentation.