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ORIGINAL RESEARCH ARTICLE

Evaluation of Risk-Based Approaches to the Registration of Medicines: Current Status Among African Regulatory Authorities

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Abstract

Background Despite the worldwide need for increased access to safe and effective medicines, there is a lack of innovative medicines in many low- to middle-income countries. On the African continent, this is partly due to capacity limitations of National Regulatory Authorities (NRAs). One important approach to address this issue is work sharing and regulatory reliance. Therefore, the aim of this study of regulatory authorities on the African continent was to identify which risk-based approaches are being used as well as their foreseen role in the future.

Methods The study employed a questionnaire to identify which risk-based models are used for the regulatory approval of medicines and to determine which frameworks are in place to enable a risk-based approach, as well as to provide insight into the future direction for risk-based models. The questionnaire was sent electronically to 26 NRAs in the African Continent.

Results Twenty-one authorities (80%) completed the questionnaire. Work sharing was the most commonly used model, followed closely by unilaterial reliance, information sharing, and collaborative review. These methods were perceived to be an effective and efficient use of resources, enabling faster medicine availability for patients. The unilateral reliance approach by the authorities included abridged (85%), verification (70%) and recognition (50%) models for a range of products. However, challenges included a lack of guidelines to undertake a reliance review together with resource constraints, while access to assessment reports was the most common barrier to using a unilateral reliance model.

Conclusions Many authorities in Africa have adopted a risk-based approach to medicines registration and created work sharing, unilateral reliance pathways and regionalisation models to facilitate the availability of medicines. The authorities believe that in future, assessment routes should move from stand-alone reviews to risk-based models. However, this study indicated that there would be challenges to implement this approach in practice, which would include improving resource capacity and the number of expert reviewers as well as implementing electronic tracking systems.

Key Points

Limitations in regulatory capacity and experience stand as a barrier to the expedient availability of innovative medicines to the people of the African continent.

To surmount this barrier, many African countries have developed risk-based methods for regulatory review to ensure they are effectively using available resources and expertise within the authority that avoid duplication and focus regulatory efforts and resources where they are most needed. This includes work sharing, unilateral reliance, information sharing and collaborative review as part of their regulatory toolkit.

Results of this questionnaire-based study of 21 African regulatory authorities show that use of these methods has resulted in increased efficiency and experience in the regulatory review and that despite challenges in implementation, future regulatory decisions should consider these models of review.

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1 Background

Despite the growing worldwide need for increased access to safe and high-quality health technologies and medicines, there is a lack of innovative medicines in many low- to middle-income countries. On the African continent, this lack is partly due to to the capacity limitations of national regulatory authorities (NRAs) [1].

To address the challenges of a globalised market while navigating through complex supply chains, NRAs are focusing on making the best use of the available human and financial resources; however, major disparities in the regulatory capacity of NRAs exist between low- and high-income countries [2, 3]. According to the World Health Organization (WHO), almost 30% of NRAs do not have the adequate expertise, quality management systems, or necessary resources to undertake core regulatory functions [4]. In such a regulatory landscape, and especially in resource-limited settings, there is increased awareness of the need for regulators to work together to maximise their use of resources and avoid duplication of work.

One important approach to national and international collaboration and work sharing is regulatory reliance, a mechanism to strategically elevate regulatory capacity, increase the availability of medicines, and optimise the use of resources. According to the WHO, regulatory reliance is defined as "the act whereby an NRA in one jurisdiction may take into account and give significant weight to assessments performed by another authority or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others" [5].

In other words, regulatory reliance leverages the output of other regulators whenever possible while placing a greater focus at the national level on value-added regulatory activities.

1.1 African Region Initiatives

Multiple initiatives are ongoing to work toward the timely registration of safe and efficacious new medicines in African markets and the reliable availability of these medicines to help deal with the disease burden on the continent. WHO Prequalification (WHO PQ) *Guidelines for submission of documentation for a multisource (generic) finished product and preparation of product dossiers in common technical document format* [6] have been adapted or adopted for use by many low- and middle-income countries in the last decade. The Common Technical Document (CTD) format has facilitated the harmonisation of medicines registration requirements, work sharing and joint reviews on the African continent [7, 8]. Collaborative regional legislative and authority efforts continue to drive regulatory harmonisation throughout Africa to increase the safety and speed of clinical trials [7, 8].

Established in 2009, the African Medicines Regulatory Harmonisation (AMRH) initiative is the driving force behind the harmonisation of medicines regulation in Africa [7–9]. The AMRH works through regional economic blocks recognised by the African Union, such as the Southern African Development Community (SADC), East African Community (EAC), and the Economic Community of West African States (ECOWAS) [1, 8]. The SADC collaborative medicines registration initiative ZaZiBoNa, formally endorsed by the SADC Health Ministers in 2014 [10, 11], is a successful regional work-sharing initiative on the African continent—its harmonisation programme was launched in June 2015. The appellation ZaZiBoNa is derived from the first four countries involved in this initiative, namely Zambia, Zimbabwe, Botswana and Namibia. The initiative is progressing well, with 342 applications received to date, 283 reviews completed, and 153 of these recommended for registration at the national level. It takes about 10 months to receive a recommendation under ZaZiBoNa and, on average, 100 days from regional recommendation to national registration [11]. The median time to recommendation achieved by ZaZiBoNa is much shorter than the timelines reported by some of the participating countries for their national procedures [12, 13].

Working with the African Union Commission, the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD) and other partners, Rwanda became the first country to ratify the treaty for the establishment of the African Medicines Agency (AMA).

Under the EAC joint assessment procedure, 84 applications for the registration of medicines have been received, 77 evaluated, and 33 recommended for registration [13]. Currently, it takes about 9 months to receive a recommendation under the EAC procedure. The AUDA-NEPAD is working with the EAC to generate timely and reliable post-recommendation timelines for this procedure at the national level.

In addition, the Steering Committee for ECOWAS regional regulatory harmonisation initiative finalised its regional joint assessment procedure in 2019. The process gives a single filing offering access to the 350 million population of ECOWAS [14, 15].

1.2 Risk-Based Models in the African Region

Healthcare regulators are increasingly adopting risk-based approaches to define the reliance model for registration of medicines and achieve the best regulatory outcomes. In developing risk-based regulatory models, they are effectively using their available resources and expertise, which avoids

duplication and focuses regulatory efforts and resources where they are most needed. In addition to the already established reliance pathways such as ECOWAS-Medicines Regulatory Harmonisation (MRH), EAC, and ZaZiBoNa in Africa, many regulatory authorities have adopted risk-based approaches of reliance models since the onset of the coronavirus disease 2019 (COVID-19) pandemic. Commonly used risk-based reliance models followed in different countries include parallel collaborative, work share, joint assessment, centralised evaluation for a group of countries or region, and unilateral reliance approaches [16, 17].

Growing interest in fulfilling unmet needs in the regulatory landscape have resulted in an increasing interest in the assessment of various risk-based reliance models and methods to increase their effectiveness and efficiency. Accordingly, a study of regulatory authorities in the African continent has been carried out to examine the utility of risk-based programmes implemented in Africa with a view to improving their effectiveness moving forward.

1.3 Study Objectives

The aims of this study were to:

- identify which risk-based models authorities have been using for the regulatory approval of medicines;
- determine which frameworks regulatory authorities have in place to undertake or enable a risk-based approach;
- provide insight into the future direction for risk-based models.

2 Methods

2.1 Risk-Based Approaches to Medicines Registration Regulatory Authority Study

A questionnaire was designed to assess risk-based approaches to medicines registration in authorities in Africa. A pilot study was carried out with authorities from three African regions (SADC, EAC, ECOWAS) to ensure the content validy of the questionnaire. This included the following questions: Did you find the questions, clear and straightforward? Did you find the questions relevant to the aims and objectives of the study? Did you find any relevant questions missing? Did you find any questions that should be excluded? Did you find the questionnaire useful to reflect your experience of this important topic. The validated questionnaire was distributed in May 2022 to the regulatory authorities of the participating countries in Africa. The questionnaire was designed to examine experiences with risk-based approaches to medicines registration (collaboration, information sharing, work sharing, and unilateral reliance models mechanisms) as encountered by the regulatory authorities in the African continent. The questionnaire consisted of four parts: Part A: Background (Models used); Part B: Unilateral reliance; Part C: Work share; and Part D: Future direction (see electronic supplementary material).

2.2 Part A: Background

The background section of the questionnaire determines which risk-based/reliance approaches are employed by authorities in Africa: unilateral reliance; work sharing; information sharing with other regulatory authorities to cooperate on regulatory issues; collaborative review; or stand-alone evaluation that includes sharing expertise and information with other authorities reviewing the same medicine.

2.3 Part B: Unilateral Reliance

The unilateral reliance section of the questionnaire determines whether the authority leverages the assessments of another authority through use of abridged, verification or recognition reviews. The type of unilateral reliance model is also determined, such as an abridged review focusing on local benefit-risk assessment, a verification review in which the authority only verifies that the medicine is the same as that approved by a reference authority, or a recognition review, in which the authority recognises a medicine approved by a reference authority. Further information is also obtained as to what activities/systems/frameworks the authority has in place for each review type, such as legal framework, strategy, transparent internal or published criteria and guidelines, standard operating procedures, or assessment templates specific to the review and for which products a unilateral reliance model could be utilised (generics, chemical entities, biological/biotechnology, biosimilars, as well as priority/essential medicines or COVID-19 treatments).

In addition, authorities were requested to specify which reference authorities are used, or if they have a memorandum of understanding (MOU) in place, as well as what challenges they face in accessing the unredacted assessment reports of recognised reference authorities such as WHO PQ; the Pan American Health Organization (PAHO); United States Food and Drug Administration (US FDA); European Medicines Agency (EMA); Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Medicines and Healthcare Products Regulatory Agency (MHRA), UK; Health Canada; Therapeutic Goods Administration (TGA), Australia: Swiss Agency for Therapeutic Products; or Health Sciences Authority (HSA), Singapore.

Additional questions in this section related to the perceived top three key incentives/benefits to the authorities for employing a unilateral reliance model, such as the faster availability of medicines for patients, effective/efficient use

of resources, quality of decision-making practices, building regulatory capacity through improved authority knowledge and experience, or increased alignment of technical guidelines and registration processes. Authorities were also asked to indicate which challenges were faced in utilising a reliance model, such as buy-in from management, resource constraints, lack of experience, access to assessment reports, lack of guidelines to undertake a reliance review, or lack of a legal framework.

2.4 Part C: Work-Share Model

This section of the questionnaire examines whether an authority is part of a centralised/regional model (Rapporteur/ Co-Rapporteur) or responsible for reviewing part of a dossier within a work-share model. The responders were requested to provide the names of the work-share model(s) in which each authority participated; for example, Zazibona, EAC or ECOWAS and what types of work-share review it uses, i.e. full review of the whole dossier as one of the assessment authorities (either as a first assessment or second assessment), or full assessment of one part of the dossier, for example safety, quality or efficacy.

Authorities were also asked which work-share activities/ systems/frameworks they have in place; for example, legal framework, strategy, transparent published or internal criteria and guidelines, standard operating procedures, or an assessment template specific to work sharing.

They also indicated which products were the subject for a work-share model (generics, chemical entities, biological/ biotechnology, biosimilars, priority/essential medicines, COVID-19 treatments), as well as the top three incentives for the authority participating in a work-share model, such as faster availability of medicines for patients, effective/ efficient use of resources, improvement in the quality of decision making, building regulatory capacity, or increased alignment of technical guidelines and registration processes. Finally, details of challenges authorities faced in utilising a work-share model such as buy-in from management, resource constraints, lack of experience, or access to assessment reports were documented.

2.5 Part D: Future Direction

This section of the questionnaire reviews what the authorities believe would be the role of different assessment models for medicines within their jurisdiction in 5 years' time. The suggested types of review models include global collaboration on reviews by sharing expertise but undertaking an independent review, work share either regional (within the same region) or pan-regional (across different countries in different regions), unilateral reliance, information sharing only or stand-alone review.

3 Results

3.1 Study Participants

Among the 26 African countries selected from the three regions to take part in the study, 21 countries (80%) responded, i.e. Botswana, Burkina Faso, Burundi, Congo, Ethiopia, Ghana, Ivory Coast, Liberia, Mozambique, Namibia, Nigeria, Senegal, Sierra Leone, South Africa, South Sudan, Tanzania, Uganda, Togo, Zambia, Zanzibar and Zimbabwe.

The responding authorities were requested to share their experiences on the specific risk-based/reliance approaches the authorities had in place at the time of the survey and the type of information-sharing activity in which they had participated, and whether they had been a part of a parallel or collaborative evaluation process. For clarity, the outcomes of this study are provided in four parts: background, unilateral reliance, work-sharing model and future direction.

3.2 Part A: Background

3.2.1 Type of Risk-Based Approaches

All participating NRAs (21) mentioned that they had been part of a centralised/regional model (Rapporteur/Co-Rapporteur) or been responsible for reviewing a section of a dossier within a work-share initiative, closely followed by 20 of 21 (95%) authorities highlighting unilateral reliance as one of the most used models. Seventeen of 21 participating NRAs (81%) indicated that they had participated in an information-sharing activity with other regulatory authorities to cooperate on regulatory issues; for example, via bilateral or multilateral arrangements with other countries or as part of a network, such as International Coalition of Medicines Regulatory Authorities. Thirteen authorities (62%) reported that they have conducted or been part of a collaborative review process in which the authority undertook a stand-alone evaluation but shared expertise and information with other authorities reviewing the same medicine at the same time.

3.3 Part B: Unilateral Reliance

3.3.1 Abridged Review as the Preferred Type of Unilateral Reliance Model

In response to the question as to the type of unilateral reliance model employed, 17 of 20 authorities answering this question (85%) indicated abridged reviews, while 14 (70%) and 10 authorities (50%) revealed that they employed verification and recognition review processes, respectively. Seven

authorities reported employing all three types of review processes.

Responses to whether the authorities had a legal framework in place, a strategy for undertaking different types of reliance mechanisms, transparent internal and external guidelines, standard operating procedures, or an assessment template specific to the type of review are shown in Table 1. Eleven of 17 NRAs (64%) that followed an abridged review process reported having an appropriate legal framework, while 7 of 14 NRAs (50%) who followed the verification review and 5 of 10 NRAs (50%) who followed recognition review had adequate legal frameworks in place. Four NRAs had all the required activities/framework in place to implement an abridged review (Ghana, South Africa, Zimbabwe, Ethiopia) and and five NRAs had all the required activites/framework for implementing a verification review (Ghana, South Africa, Ethiopia, Nigeria, Zimbabwe). Two countries (Ghana, Ethiopia) had all the required activities/framework for implementing a recognition review (Table 1).

For those authorities employing abridged, verification and recognition review-based reliance models, 88, 86, and 70% of authorities, respectively, reported that unilateral models were being utilised for generic products (Table 2). Chemical entities and priority/essential medicines were considered for unilateral reliance by 94% of NRAs adopting abridged reviews (Table 2).

3.3.2 External Reference Authorities Utilised by Regulatory Authorities

This study identified the reference authorities considered by the regulatory authorities in the African jurisdictions and the availability of an MOU with these reference authorities. Although a number of reference authorities can be utilised, for this cohort of countries, 95% of the participating NRAs selected WHO PQ as a reference authority on which reliance would be placed, while 70% of NRAs reported that reliance was based on EMA and US FDA approvals. MOUs do not appear to be consistently used: 47% of those authorities selecting WHO PQ indicated that they have MOUs in place, but only 7% use MOUs for the EMA and US FDA. The authorities indicated the challenges they faced in accessing unredacted assessment reports from the respective recognised reference authorities, with fewer challenges being reported in obtaining assessment reports for WHO PQ products (11%, 10%), but with more reported for the EMA (43%) and US FDA (50%).

Table 2 Products for which a unilateral model is utilised

Type of product	Review type		
	Abridged [$n = 17$]	Verification [$n = 14$]	Recognition [$n = 10$]
Generics	15 (88)	12 (86)	7 (70)
Chemical entities	16 (94)	10 (71)	7 (70)
Biological/biotechnology	15 (88)	12 (86)	7 (70)
Biosimilars	14 (82)	12 (86)	8 (80)
Priority/essential medicines	16 (94)	11 (78)	7 (70)
COVID-19 treatments	14 (82)	12 (86)	8 (80)
All	13 (76)	10 (71)	7 (70)

Data are expressed as *n* (%)

COVID-19 coronavirus disease 2019

Table 1 Existing activities/systems/frameworks for each review type

Activity	Review type		
	Abridged [$n = 17$]	Verification [$n = 14$]	Recognition [$n = 10$]
Legal framework	11 (64)	7 (50)	5 (50)
Strategy	8 (47)	8 (57)	5 (50)
Transparent internal criteria and guidelines	12 (71)	11 (79)	5 (50)
Transparent published criteria and guidelines	8 (47)	5 (36)	5 (50)
Standard operating procedures	13 (76)	10 (71)	6 (60)
Assessment template—specific to the review	13 (76)	10 (71)	6 (60)
All of the above	4 (24) Ghana, South Africa, Zimbabwe, Ethiopia	4 (28) Ghana, South Africa,[a] Zimbabwe, Ethiopia, Nigeria	2 (20) Ghana, Ethiopia

Data are expressed as *n* (%)

SAHPRA South African Health Products Regulatory Authority

[a]Only one authority (SAHPRA) acknowledges 'verified review' as a possible review approach, but only applies it in terms of internal verification, i.e. verification against prior work done by SAHPRA. 'True verification review', i.e. in relation to prior work done by other reference authorities, has not yet been implemented as such and SAPHRA data have not been included in the above table

3.3.3 Incentives/Benefits to Undertake Unilateral Reliance

The perceived top three incentives/benefits for the regulatory authorities to undertake a unilateral reliance were effective and efficient use of resources, faster availability of medicines for patients and regulatory capacity building through improved authority knowledge and expertise, although these were not always measured (Fig. 1).

3.3.4 Challenges Faced by Regulatory Authorities in Utilising a Reliance Model

For the majority of authorities, access to assessment reports was a key challenge. Other challenges were lack of a legal framework, constrained resources, lack of guidance to undertake a reliance review, and a lack of experience. In addition, a lack of awareness on the part of applicants/sponsor in utilising the unilateral reliance pathway, lack of MOUs, and resistance from experts responsible for dossier review were also mentioned.

3.4 Part C: Work-Share Model

Seventeen of 19 authorities (89%) who responded to a question about the work-share model indicated that they carry out a full review of the whole dossier, either as a first or second assessment, while 11 authorities (58%) indicated that they conduct a full assessment of a part of the dossier; for example, safety, quality or efficacy; 9 authorities (47%) reported that they conduct both types of review. The authorities indicated that they have a work-share model in place and the responses mirrored the insights generated from the unilateral reliance model, where 11 (58%) have a legal framework, 9 (47%) a strategy, transparent internal [12 (63%)] and external guidelines [10 (52%)], and 13 (68%) have standard operating procedures, whereas 15 (78%) had an assessment template specific for the type of review. Four authorities (Tanzania, Ghana, South Africa and Ethiopia) reported that they have all of these activities/frameworks in place.

A number of the 19 authorities stated that the work-share model can be utilised for generic products (74%), chemical entities (84%), biological/biotechnological products (79%), biosimilars (74%), essential and priority medicines (89%), and COVID-19 treatment products (68%).

The perceived key incentives/benefits for the regulatory authorities to participate in a work-share model included regulatory capacity building through improved authority knowledge and experience, effective and efficient use of resources, faster availability of medicines for patients, and improved quality of decision making (Fig. 2). According to the responses from 19 authorities, the major challenges faced with the work-share model were resource constraints, difficulties in accessing assessment reports, a lack of experience, and buy-in from management, while other challenges mentioned were competing for resources with national work, a lack of expertise in certain areas, e.g assessment of clinical trial data, short timelines for making available the assessment reports, and a lack of guidelines to undertake work-share review.

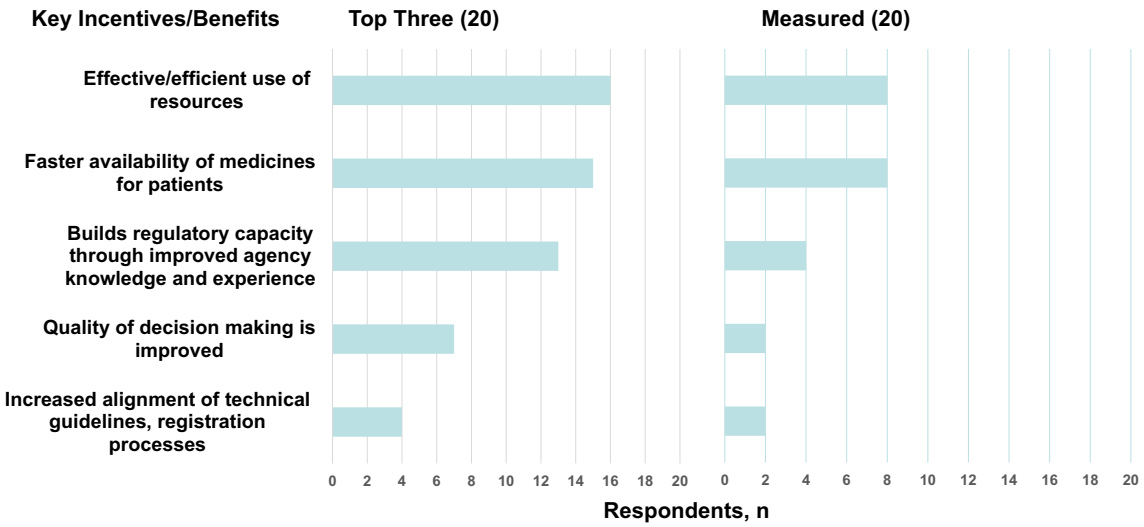

Fig. 1 Top three key incentives/benefits to undertaking a unilateral reliance strategy

3.5 Part D: Future Directions

3.5.1 Role of Different Types of Assessment Models for Medicines within the African Jurisdiction in 5 Years' Time

The responding authorities' insights into the future direction for risk-based models in the jurisdictions of Africa is shown in Fig. 3. The activities were categorised into stand-alone review; no other activity apart from information sharing; unilateral alliance; work share, either within regional or pan-regional; and global collaboration on reviews by sharing expertise but undertaking an independent review. The authorities would like to see fewer stand-alone reviews along with global collaboration as the ideal approach, but this may be challenging to implement in practice.

4 Discussion

Authorities in this study have adopted a number of risk-based approaches to medicines registrations to facilitate vaccine and treatment rollout. Many pathways had been established pre-pandemic in Africa with ECOWAS-MRH, EAC-MRH, and ZaZiBoNa, and all the authorities that responded to the questionnaire were part of one of these work-sharing initiatives as well utilising unilateral reliance reviews. However, there is an increasing interest in making these routes more effective and efficient in the future as well as understanding what other risk-based routes authorities have as part of their regulatory toolkit.

This study reports the outcomes obtained for the types of risk-based approaches authorities have in place for

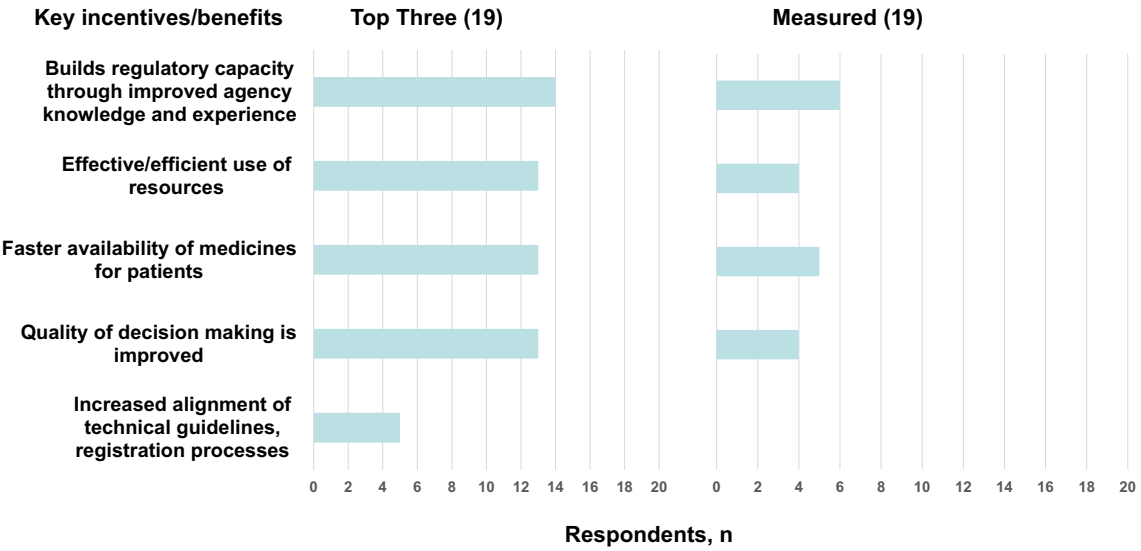

Fig. 2 Top three incentives/benefits in a work-share model

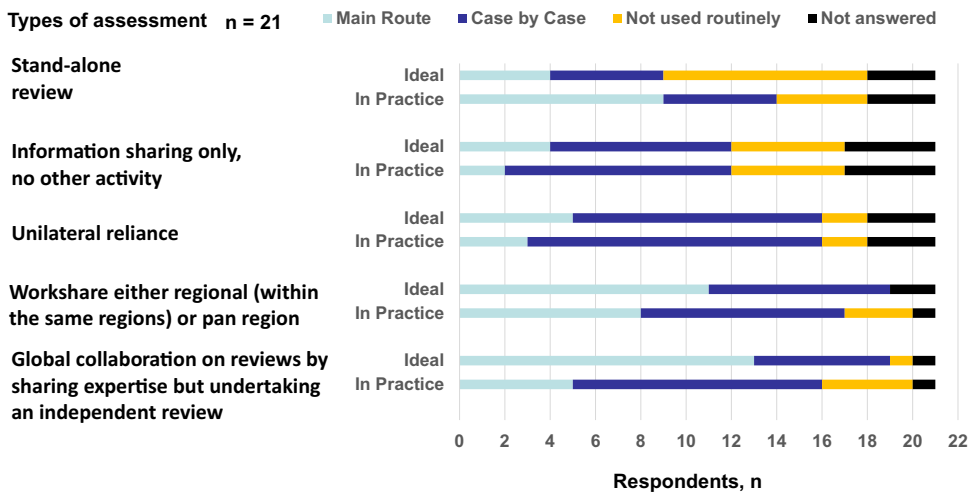

Fig. 3 Role of different types of assessment model in 5 years' time. Note: Authorities were asked what they thought would happen in practice versus what they would like to see happen in an ideal world

registration of medicines in Africa. Twenty-six authorities were given the opportunity to address these issues and 21 authorities (80%) responded. The results emphasised that all authorities were part of a work-share model with 20/21 authorities also having implemented a unilateral reliance model, and the majority engaging in information sharing and collaborative review. In terms of unilateral reliance models, authorities have, in the main, implemented an abridged model, with a number of authorities also undertaking more than one approach by also having verification and recognition review models. Seven authorities were found to have all three models as part of their regulatory toolkit. These models were used for product types including generics, chemical entities, biologicals, biosimilars and essential medicines as well as COVID-19 treatments. Effective/efficient use of resources and faster medicines availability for patients as well as the opportunity to build regulatory capacity were regarded as the key benefits of undertaking unilateral reliance or a work-sharing model. Access to unredacted assessment reports was the most common barrier to using a unilateral reliance model, while the lack of a legal framework and resource constraints were also major challenges. As authorities develop their reliance models, it is important that they consider the WHO Good Reliance Practices (GRelP) guidelines or principles [4]. This guideline promotes a more efficient approach to regulations, thereby improving and expediting access to quality-assured, effective and safe medical products, and underlines key regulatory principles such as sovereignty of decision making, transparency of process, respect of national and regional legal bases, as well as consistency and competence. This study suggests more work is needed in a number of these areas by authorities, utilising both unilateral reliance and work-share models; for example, in regard to having transparency of internal and external guidelines.

One of the areas highlighted as a challenge for unilateral reliance models is the ability to access the assessment reports of reference authorities, although a number of authorities do provide public assessment reports and the benefits that regulatory authorities derive from these would include building regulatory capacity, as reported by Papathanasiou and colleagues [18]. However, for some authorities, public assessment reports are perceived not to have all the information pertinent to leveraging the reference authority decision and therefore may seek unredacted assessment reports [4]. The importance of having online access to public assessment reports during the COVID-19 pandemic needs to be emphasised at this time. Authorities in Africa relied on the *Status of COVID-19 vaccines within the WHO EUL/PQ evaluation process* database for critically needed information to make timely regulatory decisions during the peak of the pandemic [19].

The authorities had the opportunity to comment on the different types of assessment models that they would like to see in place in 5 years' time. In general, the authorities suggested that there should be fewer stand-alone reviews, while global collaboration on reviews by sharing expertise but undertaking an independent review was considered to be the ideal.

Overall, results of this study support previous recommendations made by Keyter and associates [20], including the need to continue placing reliance on trusted reference authorities that have met the requirements of standardised regulatory benchmarking tools, with verification that applications submitted to national or regional authorities are materially the same as those submitted by a reference authority. In addition, a survey among 17 NRA members of the International Pharmaceutical Regulators Programme (IPRP) showed that reliance is increasingly being used for medical product oversight, in areas such as marketing authorisations and good manufacturing practices [21], with the view that such activities enable better resource use within authorities and should facilitate earlier access to safe, effective medicines that are quality assured. Indeed, reliance in regulatory practice should encourage comprehensive exchange of information among the regulatory authorities.

The key to moving forward is fostering a common understanding of the application of reliance and mutual recognition procedures among NRAs, which would contribute to transparency around regulatory decision making [22]. The authorities in this study recommended that there should be a follow-up evaluation of how the difficulties of obtaining unredacted assessment reports might be addressed in the future, and an exploration of what is being done in practice, particularly in countries with strong regulations, and how best to encourage inter-authority exchange of information.

5 Conclusions

Many authorities in Africa have adopted a risk-based approach to medicines registration and created work sharing, unilateral reliance pathways and regionalisation models to facilitate the availability of medicines. The authorities responding to this study believe that in future, assessment routes should move from stand-alone reviews to risk-based models; however, challenges to implement this approach in practice are anticipated.

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Author contributions NMcA designed the study, collected and analysed the data, and reviewed the draft of the manuscript. MB designed the study and reviewed subsequent drafts of the manuscript. TS, NN and MOA reviewed the draft manuscript. SW designed the study, interpreted the results, and reviewed subsequent drafts of the manuscript. All authors contributed to the article and approved the submitted version.

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