WORKSHOP SYNOPSIS

Regulatory agency collaboration and system strengthening – How is this enabling national, regional and continental models and improving medicines availability for patients?

26-27th February 2025
Marriot Melrose Arch,
Johannesburg, South Africa

CIRS Centre for Innovation in Regulatory Science

GRAPHIC SUMMARY

CIRS brought together regulators, pharmaceutical companies, academics and non-profit organisations to discuss **success factors** for **strengthening regulatory systems** to support the implementation of **collaborative models**.

Background

The increasing complexity of new products creates regulatory challenges for national regulatory authorities (NRAs) with limited resources. NRAs must therefore strengthen their regulatory systems, alongside ensuring the best use of resources and expertise.

Most countries are implementing risk-based approaches to medicines regulation, using various models including unilateral reliance through abridged review, work sharing and collaborative procedures. These exist at the national level and increasingly within regions, such as Asia (ASEAN), Eurasia (EAEU), Middle East (GHC), and Africa (EAC, WAHO, SADC, IGAD), as well as across regions (e.g. Access Consortium and Project Orbis).

Regional models, such as those in Africa, provide learning and information exchange platforms and enable further collaboration at a continental level; however, apart from Europe, continental models are few in number. As Africa looks to build a continental system through the establishment of the African Medicines Agency (AMA), there needs to be support from strong NRAs within different regions and collaborative regional models that can provide early availability to good quality medicines.

CIRS has been promoting regulatory system strengthening in Africa at the jurisdictional level and conducting studies assessing the effectiveness and efficiency of the regional work-sharing initiatives, ultimately supporting the foundations for a continental model. CIRS has also supported jurisdictional and regional work in Asia and Latin America.

This multi-stakeholder workshop built on this work to discuss how jurisdictional system strengthening and regional regulatory collaboration can underpin the development of efficient and effective regulatory systems, which in turn builds competency and capacity, ensuring the availability of high-quality medicines to patients globally.

Workshop objectives

- Identify the critical success factors and activities that agencies need to put in place to strengthen their regulatory systems for the registration of medicines and how this is being carried out at a jurisdictional (national) level and through regional work-sharing initiatives.

- Discuss the opportunities, challenges and lessons learned from current initiatives and practices that enable jurisdictions and regional work-sharing initiatives to move from concept to practical implementation.

- Make recommendations on how jurisdictional system strengthening and regulatory collaboration can drive continental models across agencies and improve medicines availability for patients globally.

Key points from presentations and open-floor discussions

Jurisidictional regulatory strengthening: A foundation for regional and continental collaboration

NRAs must have autonomy, strong regulatory frameworks supported by legal instruments and commitment from leadership to ensure effective collaboration at regional and continental levels. Comprehensive benchmarking, such as through the WHO Global Benchmarking Tool (GBT), is important for NRAs to assess the strength of their regulatory systems and identify where improvements can be made. This has been demonstrated by the achievements of Singapore (attained Maturity Level 4 (ML4) in 2022, then WHO-Listed Authority (WLA) in 2023), South Africa (attained ML3 for vaccines in 2022) and Ghana (attained ML3 for medicines and vaccines in 2020, working to achieve ML4 by the end of 2025).

Building trust and enhancing transparency helps to enable collaboration between NRAs. However, there can be a challenge with resource allocation between national duties and supporting other NRAs, such as through regional centres of excellence.

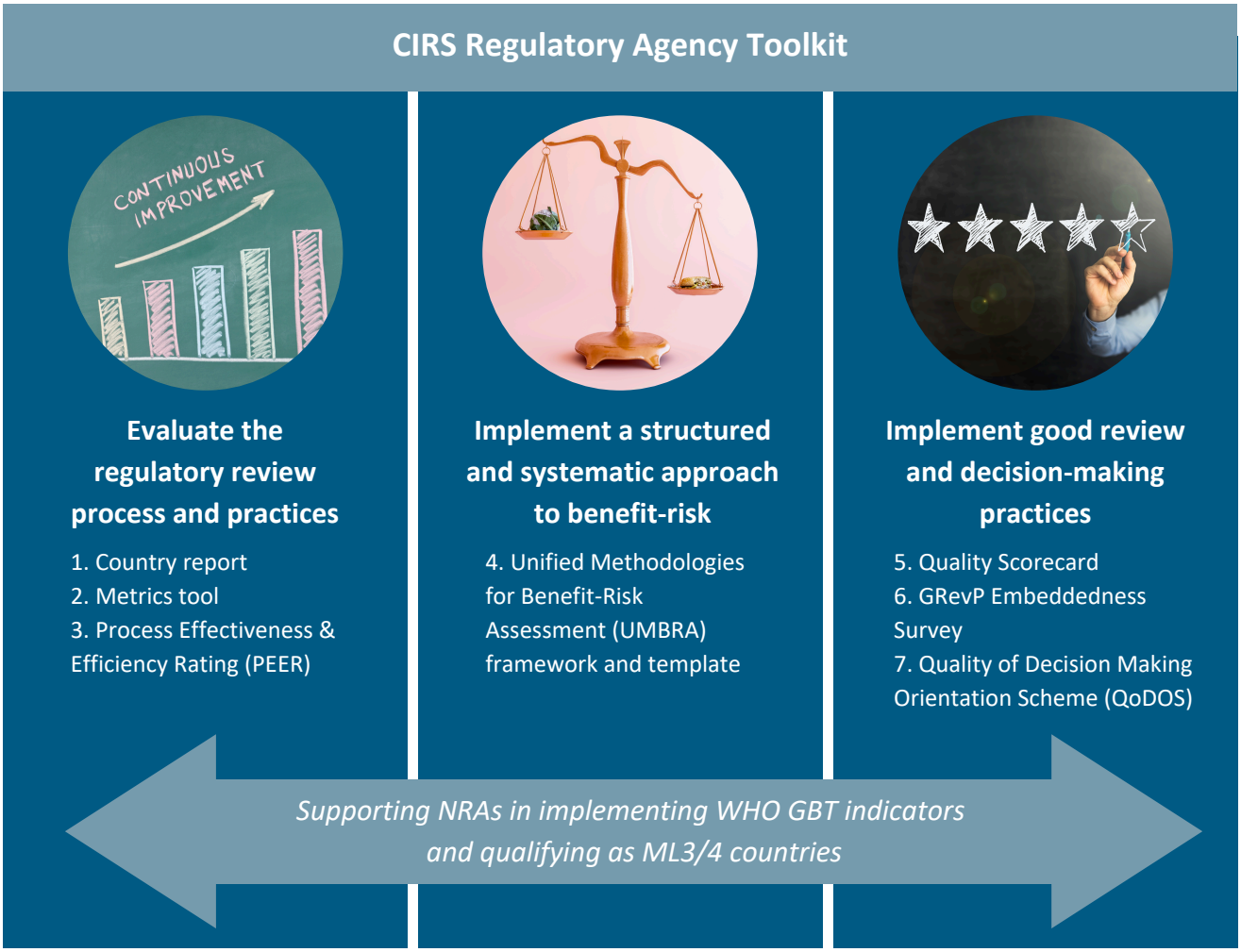
Key components of regulatory strengthening

Tools

Regulatory science tools are key to strengthening regulatory systems and to improve efficiency and effectiveness of NRAs, irrespective of maturity. These include tools to evaluate regulatory capacity e.g. WHO GBT, as well as tools to evaluate review timelines or ensure a structured approach to decision making e.g. CIRS toolkit (pictured).

The WHO GBT assessment process includes nine regulatory functions and evaluates elements like legal provisions, organisation, quality management and regulatory processes. As of February 2025, 50% of benchmarked WHO Member States are at maturity level 1, 19% at level 2, and 31% at levels 3-4. The institutional development plan in the GBT methodology provides context-specific actionable steps countries can take to advance their system's functionality and maturity.

The CIRS Optimising Efficiencies in Regulatory Agencies (OpERA) Programme provides tools that help NRAs integrate a practice of tracking and measuring performance. There are tools for process mapping and metrics, assessing embeddedness of good review practices, benefit-risk assessment and supporting quality decision making. These tools are directly linked to WHO GBT indicators and can help agencies achieve and maintain ML3 or ML4 status by providing frameworks for measuring timelines, documenting procedures and ensuring quality decision making.



Metrics

Case studies from Zambia and Brazil highlighted the importance of using metrics to measure agency performance. To support its progression to ML3 status, the Zambia Medicines Regulatory Authority (ZAMRA) conducted a study using CIRS OpERA tools to assess its review process. Recommendations from the study included establishing clear timelines for both regulatory authority reviews and industry time, publishing public assessment reports and providing more internal training on structured benefit-risk assessment methodologies.

The Brazilian Health Regulatory Agency (ANVISA) has also used CIRS OpERA tools to establish a baseline for measuring performance. More recently, as it works towards WLA status, ANVISA has been enhancing transparency of its metrics. While this brings challenges, such as higher stakeholder expectations and dependency on analytical tools, there are many benefits, including fewer information requests, better public image and clear justification of decision making.

From an industry perspective, agencies should report overall approval timelines, review milestones, company response timelines, common types of queries raised by the agency and agency adoption of harmonisation. An agency assessment of company compliance with regulations, transparency and post-market surveillance (e.g. a trust index) allows for transparent discussion between companies and agencies and provides background on agency decisions taken.

Quality decision making

Case studies from Canada and South Africa demonstrated the value of decision-making tools and resources in supporting regulatory decisions. Health Canada developed a Regulatory Decision Guide to improve internal documentation of decision-making processes, reduce litigation risk and strengthen/maintain the integrity of its decisions. The guide includes sections on roles and responsibilities, types of decisions, decision-making excellence and handling diversity of views, with practical case studies in administrative law.

The South African Health Products Regulatory Authority (SAHPRA) conducted a series of studies to investigate the value of a structured benefit-risk assessment of new chemical entities using the Universal Methodology for Benefit-Risk Assessment (UMBRA) framework. Use of the UMBRA template alongside the SAHPRA template enhanced the quality of the benefit-risk assessment and justification for the review outcomes. Completion of the UMBRA template based on public assessment reports led to shorter review timelines, suggesting that UMBRA could be a useful tool for reliance.

Reliance

Case studies from Australia and South Africa focused on the practical implementation of reliance and its economic impact, respectively. The Therapeutic Goods Administration (TGA) has relied on information from comparable regulators for decades, building confidence that has been key to recent implementation of work sharing through the Access Consortium. There needs to be early and strong buy-in from those directly impacted by and involved in reliance, with clear communication of the rationale and potential benefits. Governance arrangements supporting reliance must be continually reviewed and feedback from those working within the system listened to.

Research from SAHPRA's Backlog Clearance Project showed significant cost savings (77-81% reduction in assessor costs) through implementing reliance. This demonstrates that reliance is a tool to safeguard NRA resources and could help to offset the financial efforts required to attain higher WHO GBT maturity levels. Furthermore, an industry survey indicated support for potentially higher fees for reliance reviews, provided NRAs adhere to published timelines.

Navigating complexities of regional and transregional collaboration

Learnings from the Access Consortium and ASEAN Joint Assessment were shared. Trust and transparency among participating agencies are essential for successful collaboration. Within agencies, strong leadership and fostering a culture of learning can help to prevent potential inefficiencies in a work-sharing arrangement, for example, where reviewers may conduct a peer review of their own work before sharing it externally with partnering agencies for their peer review. Regulators should consider stronger advocacy work to promote awareness and adoption of collaborative models among industry.

From an industry perspective, there are several barriers to effective regional/transregional collaboration including limited benefit vs other procedures, lack of transparency and inefficient use of reliance. The vision should be for a single harmonised global dossier, with scientifically justified requirements and predictable timelines across countries. Measuring impact with standardised Key Performance Indicators (KPIs) is also key to refining models.

Moving from regional to continental collaboration in Africa

Africa is moving from regional to continental collaboration through the African Medicines Agency (AMA), under the leadership of the African Medicines Regulatory Harmonisation (AMRH) initiative. AMA will complement, not replace, aspects of the work of regional economic communities (RECs) and NRAs, improving efficiency and effectiveness through work sharing and reliance, and increasing capacity to assess complex medical products.

The RECs are important coordination structures that have helped to harmonise standards across African NRAs. Key challenges include varying decision-making timelines by NRAs following recommendations and the availability of competent experts to support technical work. There are plans to pilot continental technical standards, benchmarking against international ones, as well as continuing capacity development and strengthening more African NRAs towards ML3.

Vaccine manufacturing projects in Africa are progressing but face commercial, technical and regulatory challenges. Regional initiatives are key to supporting capacity for vaccine regulation in Africa. Greater focus on collaboration is needed, utilising facilitated regulatory pathways, reliance, work sharing and information sharing among vaccine regulators.

Leveraging digital solutions to support collaboration

Case studies from regulatory and industry experts were shared on the challenges and opportunities for implementing digital solutions, such as information management systems, cloud-based submission/review platforms and artificial intelligence (AI) tools, within jurisdictional and collaborative regulatory models. Cloud-based platforms enable multiple NRAs to have access to the same dossier, giving assurance of sameness and facilitating reliance and work sharing. However, individual country queues may prevent timely handling of applications. AI can automate tasks such as technical screening and report generation and potentially enhance regulatory decision making by providing actionable insights aligned with best practices.

There are several challenges for implementing digital regulatory solutions including cost, technical competencies, data security, data governance and for AI in particular, ethical issues. Nevertheless, these may be outweighed by the opportunities to improve regulatory efficiency and transparency, and in turn, enhance trust and collaboration.

Recommendations from breakout discussions

Key components of regulatory strengthening

Recommendations for further work and research to support regulatory strengthening:

- Investigate reference agencies' practices in providing unredacted assessment reports:
  - What are current practices?
  - What role do companies play?
  - What are the limitations in each agency's jurisdiction?
- Characterise different countries' regulatory frameworks that support national implementation of regional/collaborative procedures:
  - What does the end-to-end process look like?
  - What are best practices?
- Explore whether the UMBRA benefit-risk framework can facilitate reliance implementation.
- Study non-scientific country-specific requirements:
  - How divergent are they across countries?
  - What is their purpose?
  - Can they be harmonised/streamlined?

Qualitative and quantitative metrics underpinning regulatory strengthening

Recommendations for further work and research on agency metrics:

- Share case studies to support change management in agencies.
- Support the development of KPI systems and tools including:
  - Investing in capacity building / training.
  - Develop an IT solution (once metrics are known), embedding KPIs into the system operations.
  - Design decision dashboards and iterate with feedback loops.
- Publish KPIs from ML3+ countries, showcasing best practices - these can be used as a case for change by other NRAs.
- Support KPI and metrics capacity by:
  - Investigating who is using which metrics and why.
  - Establishing common terminology for KPIs and metrics.
  - Conducting pilots and publishing results from NRAs.
  - Allowing KPIs to be flexible and evolve with time.

Reliance/workshare review model for generics

Recommendations for further work and research on reliance/work-sharing models for generics:

- Identify lessons learned from agencies and industry who have experienced reliance in practice.
- Evaluate risk-based models implemented in different countries; this could be covered as part of WHO GBT assessments.
- Enable regulatory systems to allow transparency and information sharing.
- Implement unique manufacturing facility identifiers.
- Explore how AI can enable better reliance practices by different agencies.
- Agencies should develop, implement and publish criteria for prioritising applications based on public health needs, medicine shortages and multiplicity.

Workshop Programme

Session 1: Jurisdictional regulatory strengthening underpinning regional and continental collaboration	Session 2: Key components of regulatory strengthening - How can agencies improve?
Chair: Dr Steffen Thirstrup, Chief Medical Officer, EMA	**Chair: Dr Steffen Thirstrup**, Chief Medical Officer, EMA
Dr Boitumelo Semete, CEO, South African Health Products Regulatory Authority (SAHPRA) **Joseph Ofosu Siaw**, Acting Director, Business Development and International Partnerships, Food and Drug Administration, Ghana **Agnes Chan**, Director, Therapeutic Products Branch, Health Sciences Authority, Singapore **Richard Rukwata**, Director-General, Medicines Control Authority, Zimbabwe **Ginny Beakes-Read**, VP and Head, Global Regulatory Policy, Johnson and Johnson, USA	**Dr Tariro Sithole**, Technical Officer – Health Products Regulation, World Health Organisation (WHO), Ethiopia **Prof Stuart Walker**, Senior Advisor and Founder, CIRS **Constance Chisha**, Senior Registration Office Human Medicines, Medicines Regulatory Authority, Zambia **Raphael Sanches Pereira**, Deputy General Manager, Drugs Office, ANVISA, Brazil **Puvi Naidoo**, Regulatory Lead, SSA Cluster, Pfizer, South Africa
Session 3: Case studies relating to regulatory strengthening activities to improve process or meet GBT standards	**Session 4: What frameworks do agencies need to practically use regional/transregional models?**
Chair: David Mukanga, Deputy Director Africa Regulatory System, Gates Foundation, Kenya	**Chair: David Mukanga,** Deputy Director Africa Regulatory System, Gates Foundation, Kenya
Dr Supriya Sharma, Chief Medical Adviser, Health Canada **Dr Star Khoza**, Clinical Evaluator, SAHPRA **Mr Michael Wiseman**, Assistant Secretary, International Regulatory Branch, Therapeutic Goods Administration, Australia **Lorraine Danks**, Senior Program Officer, Gates Foundation, South Africa	**Chimwemwe Chamdimba**, Head of the African Medicines Regulatory Harmonisation, African Union Development Agency (AUDA-NEPAD) **Prof John Skerritt**, Enterprise Professor for Health Research Impact, University of Melbourne, Australia **Dr Eveline Trachsel**, Head of Medicinal Products Approval and Vigilance, Swissmedic **Dr Azuana Ramli**, Director, National Pharmaceutical Regulatory Agency, Malaysia **Nevena Miletic**, Regulatory Policy and Science Chapter Leader, F. Hoffmann-La Roche
Session 5: Breakout discussions	**Session 6: New ways of working - Key to success in a resource constrained environment**
Breakout A: Key components of regulatory strengthening **Chair: Dr Steffen Thirstrup**, Chief Medical Officer, EMA **Rapporteur: Nevena Miletic**, Regulatory Policy and Science Chapter Leader, F. Hoffmann-La Roche **Breakout B: Qualitative and Quantitative metrics underpinning regulatory strengthening** **Chair: Dr Murray Lumpkin,** Lead for Global Regulatory Systems Initiatives, Gates Foundation, USA **Rapporteur: John Mwangi,** Regulatory Policy Science Lead, Bayer, Kenya **Breakout C: Reliance/workshare review model for generics** **Chair: Dr Tariro Sithole**, Technical Officer – Health Products Regulation, WHO, Ethiopia **Rapporteur: Amira Younes**, Director, Global Regulatory Policy, Europe, Middle East and Africa, MSD, United Arab Emirates	**Chair: Dr Boitumelo Semete,** CEO, SAHPRA **Dr Nancy Ngum**, Programme Officer - Public Health, AUDA-NEPAD **Dominique Lagrave**, Senior Vice President, Innovation, Accumulus Synergy, USA **Mike Abernathy**, Executive Director, Global Regulatory Affairs/Digital Regulatory Innovation Lead, Amgen, USA **Suraiya Suliman**, Manager: PEM Post-registration, SAHPRA **Christelna Reyneck**, Chief Operations Officer, SAHPRA

About CIRS

The Centre for Innovation in Regulatory Science is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, and grants.

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