# Collaborative models for regionalisation, work and information sharing:

## How do these fit into the regulatory toolkit?

5th & 6th July 2022

# Workshop Report

CIRS Centre for Innovation in Regulatory Science

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## Report details

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**About CIRS**

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS' 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 and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science. 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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# Section 1: Executive Summary

## Background to the workshop

This workshop looked at how maturing markets are building risk-based approaches into regulatory assessment, building on recent CIRS workshops in Singapore (2019) and South Africa (2018). The workshop also explored work CIRS has been undertaking in Asia, Middle East, Africa and Latin America (LATAM), with an assessment of the changed regulatory landscape following the COVID-19 pandemic.

Over the last two years, there has been increased collaboration and information-sharing between agencies due to the ongoing pandemic. In order to facilitate vaccine and treatment roll-out, many agencies adopted a risk-based approach to medicines registration, as well as creating work-sharing, reliance pathways and regionalisation models. Although many pathways had been established pre-pandemic, there is now increasing interest in understanding how these routes can become more effective and efficient in the future. These efforts are being facilitated by promoting international information-sharing and collaboration; convergence of international standards; guidelines promoting good regulatory/review/reliance practices (WHO); and the use of flexible regulatory pathways to best utilise resources.

One way to strengthen regulatory systems is to look at the collaborative models agencies are using and discuss how these can be optimised or expanded, as well as understand the legal and infrastructure challenges in doing so. Collaborative models, including information sharing, work-sharing and regionalisation, have the opportunity to add value as agencies are challenged, not just with the learnings from the last two years, but also with the pace of change with new technologies, innovations and increasingly complex products.

This workshop reviewed how collaborative models add value to a jurisdiction's regulatory tool kit. In addition, there was a focus on understanding the challenges associated with these models and how they must evolve to ensure timely availability of medicines for unmet need.

## Workshop objectives

- To discuss how collaborative models are implemented into regulatory frameworks for the registration of medicines, as well as lessons learned from the pandemic and also the challenges and opportunities around regionalisation
- To identify the different work-sharing and regional models being utilised to enable agencies to increase efficiency and effectiveness and which frameworks have the opportunity to enable success both internally with staff and externally with stakeholders
- To make recommendations on frameworks and/or policies that will enable sustainable information sharing/work-sharing/regional regulatory processes for the review of new medicines.

## Venue/format

The workshop was held virtually over two days, 5th and 6th July 2022.

## Definitions

'Risk-based approaches' includes unilateral reliance, where one agency leverages the decision of another agency, information sharing, collaborative and workshare consortium, in addition to centralised and regional models for the registration of medicines.

## Workshop Programme

*Please note, affiliations are stated as they were at the time of the meeting, 5th and 6th July 2022.*

**5th July 2022**

| **Session 1: Collaborative and workshare regulatory reviews – What is their impact and how should they be expanded to other regions?** | |
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| *Over the last decade there has been increasing interest for agencies to establish risk-based approaches to medicines registration, where they have the ability to leverage expertise from other agencies in order to be able to utilise their resources. This has led to different risk-based approaches, which include unilateral reliance, where one agency leverages the decision of another agency, information sharing, collaborative and workshare consortium in addition to centralised and regional models for the registration of medicines. This session will discuss how such models are part of a risk-based approach and are being used by agencies as part of their regulatory toolkit.* | |
| **08:05** | **Chair's introduction to the session**<br>**Prof Hans-Georg Eichler**, Consulting Physician of the Association of Austrian Social Insurance Institutions |
| **08:15**<br>**08:35** | **Has the pandemic led to strengthen global regulatory coordination for development review and access to vaccines and therapeutics?**<br>**international Coalition of Medicines Regulatory Authorities (ICMRA) – Emer Cooke,** Executive Director, European Medicines Agency<br>**International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) viewpoint – Dr David Jefferys**, Senior Vice President, Head of Global Regulatory, Eisai Europe and **Janis Bernat**, Director, Scientific & Regulatory Affairs, IFPMA |
| **08:55** | **Risk-based approaches to the review and registration of medicines – What should a future regulatory toolkit look like?**<br>*Centralised, regional, workshares, collaborative, and unidirectional reliance - What are the key considerations as agencies look to implement risk-based mechanisms for the review of medicines? What are key learnings for such models from the pandemic? How is WHO supporting the development of risk-based approaches? Why should agencies consider having more than one risk-based approach within their toolkit?*<br>**Dr Samvel Azatyan**, Team Lead, Regulatory Convergence and Networks, WHO |
| **09:15** | **Discussion** |
| **09:25** | **Survey of agencies on practical use of risk-based approaches within their agencies for medicines registration – CIRS presentation**<br>**Dr Neil McAuslane**, Director, Centre for Innovation in Regulatory Science |
| **09:40**<br>**09:55**<br>**10:10** | **Well-resourced agencies have established different models for working together - How well do they work in practice?**<br>*What are the critical success factors for each model? What works well and what does not? Could such models be expanded within or developed amongst other agencies?*<br>**EU centralized review, the OPEN initiative and other collaborative pathways -**<br>**Martin Harvey**, Head of International Affairs, European Medicines Agency<br>**ACCESS Workshare model – Adj Prof John Skerritt,** Deputy Secretary for Health Products Regulation, Department of Health, Australia<br>**Work-sharing and collaborative models – How would companies like to see these models evolve so that they enable global registration and medicine availability? -**<br>**Priti Shah,** Executive Director, International Regulatory Strategy, AstraZeneca, UK |
| **10:25** | **Discussion** |
| **11:00** | **Break (30 min)** |

| Session 2: Optimising the availability of medicines to patients through regional collaboration | |
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| *A number of regional models have been established to aid medicines registration in the Middle East, Association of South East Asian Nations (ASEAN) and Caribbean regions. This session will review these initiatives and discuss how they are working from an agency and company perspective.* | |
| **11:30** | **Chair's introduction to the session**<br>**Professor John Lim,** Executive Director, Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School and Senior Advisor, Ministry of Health, Singapore |
| | **Three regional models - Agency and company perspectives - how are they working, how should they evolve? What are the weakness and strengths over individual agency approvals** |
| **11:40** | **ASEAN Joint Assessment for Pharmaceuticals: Moving beyond the pilot stages - how should it evolve – Malaysia**<br>**Rosliza Binti Lajis,** New Drugs Section, National Pharmaceutical Regulatory Agency (NPRA) |
| **11:55** | **Company perspective**<br>**Dr Sannie Chong,** Regulatory Policy, Asia Pacific, Roche, Singapore |
| **12:10** | **Discussion** |
| **12:20** | **GHC - Improving patient access – how is the process being optimized?**<br>**Dr Hajed M bin Hajed,** Deputy General Manager, Gulf Health Council (GHC) |
| **12:35** | **Discussion** |
| **12:45** | **CARPHA – Enabling the registration of safe, effective and quality medicine**<br>**Dr Rian Marie Extavour,** Programme Manager, Caribbean Regulatory System, Caribbean Public Health Agency, CARICOM |
| **13:00** | **Company perspective - Does this enable efficient and effective roll out to the region**<br>**Dr Max Wegner,** SVP, Head of Regulatory Affairs, Bayer, Germany |
| **13:15** | **Q&A and discussion** |
| **13:30** | **End of day one** |

**6th July 2022**

| Session 3: Focus on Africa – Optimising performance through regional models – How are these operating and are they fit for purpose? | |
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| *The regional models established within the African continent play a critical part in enabling quality medicines to be delivered to patients and will have a major role in ensuring the success of the newly established African Medicines agency. This session will focus on how these regional initiatives are evolving and what needs to be in place for these to enable both an efficient and effective process for medicines registration as well as how they function in conjunction with the priorities of individual countries.* | |
| **08:05** | **Chair's introduction to the session**<br>**Professor Stuart Walker,** Founder, CIRS |
| **08:15** | **African Medicines Agency (AMA) – How is this developing and how will the regional models already established fit into delivering a continental approach to medicines registration?**<br>**Margareth Ndomondo-Sigonda,** Co-ordinator Health Progammes, African Union Development Agency (AUDA-NEPAD) |
| | **Three Case Studies: 15 minutes each to describe the current regional initiatives, how are these developing to meet both regional and individual country needs?**<br>*What are seen as success criteria, key challenges and how should the initiatives evolve to ensure quality medicines are being delivered to patients in a timely manner?* |
| **08:35** | **Regional Initiative 1 – Zazibona - What are the success criteria? - Tariro Makamure-Sithole,** Projects and Public Relations Manager, Medicines Control Authority of Zimbabwe |
| **08:50** | **Regional Initiative 2 – East African Community (EAC) – Utilising metrics to measure and improve performance - Nancy Ngum,** Public Health Officer, AUDA-NEPAD |
| **09:05** | **Regional Initiative 3 – Economic Community of West African States (ECOWAS) -What are the key challenges? Mercy Owusu-Asante**, Head, Drug Industrial Support Dept, Food and Drugs Authority, Ghana |
| **09:20** | **Discussion** |

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| | **Panel Discussion - How does the Africa regional model fit into an agency toolkit from a country perspective? Are these fit for purpose and what advantages do Heads of Agencies see for their patients?**<br>Heads of individual agencies to briefly outline the role they see for actively participating in regional models as part of their regulatory toolkit, what they see as the opportunities/challenges and how they would like such models to evolve to enable availability of medicines for patients.<br>**Chair – Professor Stuart Walker,** Founder, CIRS |
| **09:30**<br>**09:40** | **West Africa – Prof Christianah Mojisola Adeyeye,** Head, Nigeria National Agency for Food & Drug Administration |
| **09:50** | **East Africa – Yonah Hebron,** Tanzania Medicines & Medical Devices Authority (TMDA)<br>**Company perspective – Nevena Miletic,** Regulatory Policy Lead, F.Hoffmann-La Roche, Switzerland |
| **10:00** | **Q & A and Discussion** |
| **10:30** | **Break (30 min)** |

| **Session 4: Future perspectives: How should collaborative models evolve and how should they fit into the regulatory toolkit?** | |
|---|---|
| *A number of regional models have been established to aid medicines registration in the Middle East, ASEAN and Caribbean region. This session will review these initiatives and discuss how they are working from an agency and company perspective.* | |
| **11:00** | **Chair's introduction to the session**<br>**Martin Harvey**, Head of International Affairs, European Medicines Agency |
| **11:10**<br>**11:25** | **Key stakeholders' future perspective on the benefits and weaknesses of regional models and how stakeholders would like them to evolve?**<br>**Funder's viewpoint**: **Dr David Mukanga,** Senior Program Officer Regulatory Affairs, Africa Systems, Bill and Melinda Gates Foundation<br>**Procurer's viewpoint: Robert Matiru,** Director, Programme Division, UNITAID, Switzerland |
| **11:40** | **Discussion** |
| **11:50**<br>**12:00**<br>**12:10**<br>**12:20**<br>**12:30** | **Panel Discussion: Future development of global risk-based approaches**<br>Each panellist has 10 minutes to provide their thoughts on:<br>• How to build on current initiatives? Can today's models be expanded to other agencies or provide a basis for other agencies to consider?<br>• What does the future evolution of the regulatory tool kit look like and what direction agencies should consider - collaborative, workshare, regional models or a mixture of fit for purpose routes.? What frameworks need to be in place?<br>• Recommend possible research areas for CIRS and other groups to undertake to support /inform/enable future optimisation or expansion of collaborative, workshare or regional models.<br>**WHO perspective – Marie Valentin,** Technical Officer, WHO<br>**Regulatory agency perspective – Dr Evelyn Soo,** Director, Bureau of Gastroenterology, Infection and Viral Diseases, Health Canada<br>**Regulatory agency perspective – Dr Suchart Chongprasert,** Director, Medicines Regulation Division, Thailand Food and Drug Administration<br>**Company perspective – Judith Macdonald**, Senior Director, Global Regulatory Policy Development, Pfizer, UK<br>**Academic perspective – Dr James Leong,** Assistant Professor, Head, Health Products & Regulatory Science, CoRE, Singapore |
| **12:40** | **Discussion** |
| **13:30** | **Close of workshop** |

## Key points from presentations

*Please note that the following summaries represent the views of the individual presenter and do not necessarily represent the position of the organisation they are affiliated with. Affiliations are stated as they were at the time of the meetings (5th and 6th July 2022).*

**5th July 2022**

**Session 1: Collaborative and workshop regulatory reviews – What is their impact and how should they be expanded to other regions?**

**Emer Cooke,** *Executive Director, European Medicines Agency (EMA)*, outlined how the pandemic has strengthened global regulatory collaboration for the development and review of vaccines and therapeutics, but highlighted that there are still issues with access to these products. International Coalition of Medicines Regulatory Authorities (ICMRA) had an important role in facilitating collaboration between regulators, which led to successes in clinical trials, remote inspections, regulatory agilities in manufacturing, and communication. Next steps will involve exploring platform trials for emergencies and conducting pilots on collaborative assessments of post-approval and hybrid inspections.

**Dr David Jefferys,** *Senior Vice President, Head of Global Regulatory, Eisai Europe* and **Janis Bernat**, *Director, Scientific & Regulatory Affairs,* International Federation of Pharmaceutical Manufacturers & Associations (*IFPMA),* described how collaboration, cooperation, co-creation, creativity and confidence were demonstrated by both regulators and industry during the pandemic. The IFPMA Regulatory Agilities Project reviewed trends, challenges and recommendations on the implementation of agilities under three key headings: regulatory, clinical trials and quality. Both in preparation for the next pandemic, and to strengthen normative processes, regulators should consider increasing digitalisation of working practices; adopting risk-based approaches in decision-making; increasing collaboration; and prioritising post-approval change management.

**Dr Samvel Azatyan,** *Team Lead, Regulatory Convergence and Networks, WHO,* gave an overview of WHO efforts to facilitate good decision-making, including promoting Good Regulatory Practices, strengthening health systems, regulatory workforce development, reliance and work-sharing. Reliance is implemented via facilitated registration pathways, such as the WHO collaboration registration procedure for pre-qualified products; stringent regulatory authority (SRA) collaborative registration procedures; and regional regulatory harmonisation initiatives and networks. International Conference of Drug Regulatory Authorities (ICDRA) recommendations for WHO and member states include identifying and adopting regulatory flexibilities, reliance best practices and regulatory tools that proved effective during the pandemic.

**Dr Neil McAuslane,** *Director, Centre for Innovation in Regulatory Science,* presented results from a CIRS survey of agencies in the Americas, Africa, Middle East, and Asia, to identify current use of risk-based models and future directions for these models. Unilateral reliance was the most used model. Effective and efficient use of resources and faster medicines availability were key benefits for undertaking reliance or work-sharing. The most common barrier was access to assessment reports. Participants believed that assessment routes should move from stand-alone reviews to collaborative/work-sharing risk-based models, though there were doubts this would happen in practice.

**Martin Harvey,** *Head of International Affairs, EMA*, stated that reliance and collaboration are part of a modern way of doing regulatory business, critical for efficiency and resource-saving in the 21st Century. Examples of collaborative pathways that are in place in the EU include *EU-Medicines For All,* where The EMA evaluates and gives an opinion on medicinal products for human use outside the EU, according to the same standards and processes as for EU authorisation. EMA also participates in the *WHO Collaborative Registration Procedure.* Part of EMA's response to the pandemic was the OPEN (**O**pening our **P**rocedures at **E**MA to **N**on-EU authorities) initiative. This initiative allows active international participation in EMA scientific

evaluation. OPEN facilitated assessment of the same data by multiple authorities, deepening collaboration and moving the exchange of information to active engagement. OPEN allowed regulators to accelerate and align on decisions, leading to fewer questions for industry / labelling differences, while maintaining independence in decision-making. EMA is engaging with all stakeholders to consolidate and expand OPEN in a step-wise approach.

**Adj Prof. John Skerritt,** *Deputy Secretary for Health Products Regulation, Department of Health, Australia,* gave an overview of the ACCESS Consortium, a work-sharing model where agencies review different parts of the submitted dossier, but retain independence in decision-making. Work-sharing has challenges, including difficulties aligning submission timeframes, but the benefits outweigh these challenges, such as reducing duplication of efforts. ACCESS has successfully approved 14 new active substances and has helped reduce submission gaps for participating agencies. Agencies interested in work-sharing should consider transaction costs and agilities, as well as use of regional models with small numbers of partners.

**Priti Shah,** *Executive Director, International Regulatory Strategy, AstraZeneca, UK,* provided a company perspective on work-sharing and collaborative models. Companies strive for simultaneous availability of medicines globally. The pandemic highlighted issues regarding global vs. local/regional development, and that reliance and work-sharing are not yet optimal. To build a sustainable regulatory infrastructure, further development of global and regional work-sharing and collaborative approaches are needed, with focus on building health authority capacity; increasing collaboration; harmonising requirements; and ultimately accelerating patient access.

## Session 2: Optimising the availability of medicines to patients through regional collaboration

**Rosliza Binti Lajis,** *New Drugs Section, National Pharmaceutical Regulatory Agency (NPRA),* introduced the ASEAN Joint Assessment initiative, which supports harmonisation and regional cooperation in South East Asia. ASEAN Joint Assessment has evolved since its 2017 pilot to promote more participation, expand its list of priority products and establish an information management system. Product registration approval is a national decision. Key challenges include issues with country-specific requirements, differences in format/elements included within evaluation reports and timelines issues. ASEAN Joint Assessment continues to foster mutual trust and reliance amongst member states.

**Dr Sannie Chong,** *Regulatory Policy, Asia Pacific, Roche, Singapore,* gave an overview of ASEAN Joint Assessment from the company perspective, highlighting how it enables smart regulation through reliance, reducing duplication and releasing valuable resources to tackle local issues. Launch lag is inevitable, but can be minimised if the joint assessment timeline is comparable to the reliance pathway in each member state. ASEAN Joint Assessment allows for approval from multiple member states, although gaps remain in alignment with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)/WHO. Industry will continue to work with ASEAN to operationalise the joint assessment procedure.

**Dr Hajed M bin Hajed,** *Deputy General Manager, GHC,* gave an overview of how the GHC is helping to enable early availability of medicines across the Gulf Cooperation Council (GCC). Approval times have decreased with implementation of a reliance strategy (end of 2019), and reliance processes have since been improved, based on recommendations from the Gulf Central Committee for Registration. Key changes include immediate approval of registration of any product in the six GCC countries, and bypass of manufacturing inspections if a visit has been made by a member state within 2 years. A new electronic patient leaflet is expected to be finalised in 2022, in addition to guidance on harmonised labelling.

**Dr Rian Marie Extavour,** *Programme Manager, Caribbean Regulatory System (CRS), Caribbean Public Health Agency (CARPHA), CARICOM,* introduced the CRS, a centralised unit within CARPHA that

reviews medicines using reliance and verification procedures and issues recommendations for marketing authorisations to CARICOM member states. A total of 267 products have been recommended by CRS, including 34 WHO prequalified medicines and 10 COVID-19 vaccines. Key challenges include differences in regulatory frameworks, low quality submissions and variations in uptake of recommendations by member states. CRS plans to continue building capacity in the region, develop a joint review framework, and strengthen liaisons with regional regulators.

**Dr Max Wegner,** *SVP, Head of Regulatory Affairs, Bayer, Germany,* provided an overview of CARPHA and the CRS from the company perspective. CARPHA is a prime example of regulatory collaboration and reliance, through the CRS process. While limited at present, experience of the CRS process has been generally positive, although there are some opportunities for optimisation, such as extending the process to lifecycle management. If further optimised, the CRS process could enable efficient and effective roll-out to the Caribbean.

**6th July 2022**

## Session 3: Focus on Africa – Optimising performance through regional model – How are these operating and are they fit for purpose?

**Margareth Ndomondo-Sigonda,** *Co-ordinator Health Progammes, AUDA-NEPAD,* presented how the AMA is developing, and how existing regional models will fit into a continental approach to medicine registration. The AMA Treaty has been ratified by 22/55 member states and signed by 28/55 member states. The African Medicines Regulatory Harmonisation (AMRH) initiative provides technical support to operationalise the AMA, advocates for ratification, and supports countries not yet party to the AMA Treaty. Successful operationalisation of AMA will require a strong foundation at national level, with collaboration, partnership and coordination among all key stakeholders essential for AMA.

**Tariro Makamure-Sithole,** *Projects and Public Relations Manager, Medicines Control Authority of Zimbabwe,* introduced ZaZiBoNa, a work-sharing initiative in the Southern African Development Community (SADC), that has successfully assessed over 300 applications. Based on a recent survey, key challenges for the initiative are lack of centralised submission and tracking, as well as dependence on country processes and resources. There is a need to review whether this model is still fit for purpose, as the promised benefits of shorter approval timelines and simultaneous market access are not being met. Recommendations for improvement include capacity building, increasing transparency and establishing an SADC regional medicines agency.

**Nancy Ngum,** *Public Health Officer, AUDA-NEPAD,* introduced the EAC Medicines Regulatory Harmonisation work-sharing initiative. Based on a recent study, perceived benefits of the initiative to patients were increased availability and quicker access to quality assured medicines. Key challenges were lack of ability to mandate central registration and lack of detailed information on the process for applicants. Recommendations for improvement include introducing incentives for using the joint evaluation pathway, more engagement with industry and establishing an EAC regional medicines agency.

**Mercy Owusu-Asante**, *Head, Drug Industrial Support Dept, Food and Drugs Authority, Ghana,* introduced the West African Regulatory Harmonisation project, a joint assessment procedure for registration of medicines within the ECOWAS region. According to a recent survey, key challenges for joint assessment include lack of detailed information on the process; unequal workloads among partner states; lack of a centralised submission process and tracking; and failure by manufacturers to adhere to deadlines for responses to questions. Moving forward, a regional administrative body must be established and transparency must be improved.

### Panel discussion: How does the Africa regional model fit into an agency toolkit from a country perspective? Are these fit for purpose and what advantages do Heads of Agencies see for their patients?

*Heads of individual agencies were asked to briefly outline the role they see for actively participating in regional models as part of their regulatory toolkit, what they see as the opportunities/challenges and how they would like such models to evolve to enable availability of medicines for patients.*

**Prof Christianah Mojisola Adeyeye,** *Head, Nigeria National Agency for Food & Drug Administration,* described how incorporating regional approval with national regulatory has several benefits, such as more efficient use of resources and improving regulatory collaboration and harmonisation. Critical issues need to be addressed, including inefficient communication and knowledge gaps in conducting regulatory activities within regions. Individual national regulatory agencies must be strengthened enough to be able to collaborate and effectively contribute to the regional initiative.

**Yonah Hebron,** *Tanzania Medicines & Medical Devices Authority (TMDA),* described key benefits of regional models, including pooling resources to address common problems and sharing technical knowledge. There are challenges with disparity between countries, and lack of a body to compel states to implement agreed resolutions, which leads to delays. Regional models should evolve by focusing on common and complex agendas and issues. In relation to AMA, regional initiatives act as a platform to elevate common regional issues and uplift capacity in their region.

**Nevena Miletic,** *Regulatory Policy Lead, F.Hoffmann-La Roche, Switzerland,* described how there are many opportunities for filings with development of the African regulatory ecosystem, but it can be challenging for companies to choose the optimal route. Offered pathways must have distinct advantages for companies. Key learnings from using national versus regional procedures relate to harmonization of requirements, clear guidance and adherence, resource sustainability, scope, transparency, administrative burden and digitalisation. For AMA to be successful, there must be clear distinction of scopes, roles, and responsibilities, and defined ways of working, among national, regional and continental authorities.

## Session 4: Future perspectives – How should collaborative models evolve and how should they fit into the regulatory toolkit?

**Dr David Mukanga,** *Senior Program Officer Regulatory Affairs, Africa Systems, Bill and Melinda Gates Foundation,* provided a funder's viewpoint on how collaborative models should evolve. Regional platforms in Africa have delivered progress in harmonisation of requirements, standardisation of procedures, joint assessment, post-approval changes, capacity strengthening and trust building. Challenges relate to transparency of timelines, fees, national translation of regional recommendations, and limited industry awareness of regional models. Moving forward, there are opportunities to link regional recommended products to procurement decisions, conduct inter-regional reliance, establish regional registration databases, and create incentives to enable greater access.

**Robert Matiru,** *Director, Programme Division, UNITAID, Switzerland,* provided a procurer's viewpoint on how collaborative models should evolve. UNITAID has established partnerships with global stakeholders like Global Fund to support scalability of interventions. Procurement and regulatory medications should evolve so that continental, regional, and country levels have different focuses (I.e., continental focus on complex products, while countries use reliance for established essential medicines). UNITAID's strategy focuses on a market-based approach to domestic/regional manufacturing, creating systemic conditions for sustainable, equitable access and foster inclusive and demand-driven partnerships for innovation.

### Panel discussion (Session 4): Future development of global risk-based approaches

*Panellists were asked to provide their thoughts on how to build on current initiatives; what the future evolution of the regulatory toolkit should look like; and possible areas for additional research and guidance to enable optimisation or expansion of collaborative, workshare or regional models.*

**Marie Valentin,** *Technical Officer, WHO,* highlighted the need to build on the work of the WHO Regulatory System Strengthening Programme, activities promoting convergence and harmonisation, as well as lessons learned from the COVID-19 pandemic. The future will be collaborative, with reliance in action to promote better use of global regulatory resources. The regulatory toolkit should evolve to better encompass electronic data and the patient voice. More guidance and research are needed in areas of reliance, innovation and production transparency.

**Dr Evelyn Soo,** *Director, Bureau of Gastroenterology, Infection and Viral Diseases, Health Canada,* highlighted the need to build on current initiatives in terms of approaches; resources; priorities; and communication. The regulatory toolkit should evolve to be fit-for-purpose and flexible, while balancing earlier access and cost-effectiveness of process. To support future development of global risk-based approaches, there must be further research on successes and barriers to date; the impact of collaboration on regulatory decisions and access; and infrastructure and resource needs.

**Dr Suchart Chongprasert,** *Director, Medicines Regulation Division, Thailand Food and Drug Administration,* noted that in order to effectively collaborate, regulatory agencies must build similar, strong regulatory systems and use a common language. The regulatory toolkit must evolve to include a wide range of models as there is no one-size-fits-all approach and agencies must be able to mix and match. Future research should focus on qualitative measures of regulatory process, e.g., quality of collaborative reviews, as well as practical advice for agencies interested in collaboration and reliance models.

**Judith Macdonald**, *Senior Director, Global Regulatory Policy Development, Pfizer, UK,* highlighted that multiple risk-based options are needed, and the company perspective must be considered. The future regulatory toolkit must feature next-level collaboration, fewer duplicative submissions, technology to unlock efficiencies, secure data-sharing platforms, and continuation of national-only review capabilities. There is a need to monitor which countries produce public assessment reports; survey regulators' expectations around unredacted assessment reports; and measure the impact of WHO-Listed Authority systems on regulatory assessment and procurement.

**Dr James Leong,** *Assistant Professor, Head, Health Products & Regulatory Science, CoRE, Singapore,* highlighted current gaps in understanding principles of risk-based approaches; infrastructure and capabilities to mitigate risks taken; implementation and change management; platforms for industry and regulators to explore regional collaborations. Regulator training must focus on technical competency and change management. Further research should focus on defining and obtaining consensus on the principles of risk-based approaches and validating measures of successful implementation.

# *Summary of panel discussion (Session 4): Future development of global risk-based approaches*

## We can build on:

- Lessons from COVID-19
- Transparency and communication
- Using WHO guidance documents
- Understanding and aligning infrastructure requirements
- Considering cost-effectiveness
- Practical guidance and implementation for agencies
- Sameness of product dossier
- Using existing models across the product lifecycle
- Improving IT and data-sharing platforms
- Ensuring there are multiple risk-based options available
- Considering the company perspective
- Building trust and confidence

## Future evolution of regulatory toolkit should involve:

- Ensuring a wide range of models that are flexible and fit-for-purpose
- A focus on public health priorities
- Improving technology capabilities, including data-sharing, IT, electronic records, etc
- Making best use of global regulatory resources, like WHO guidance documents
- Listening to the patient voice
- Collaborating with industry to reduce burden, i.e. fewer duplicative reviews
- Maintaining some national capabilities
- Focus training on technical competency and change management

## Guidance and research required:

- Transparency, communication and dispelling misinformation
- Alignment on how to fit new innovations within existing legislative frameworks
- Assessment of barriers and successes of current models
- Change management / mindset
- Considerations for choosing a risk-based approach
- Qualitative measures of collaborative reviews
- Expectations and interpretations unredacted assessment reports
- Understanding local infrastructure and what needs to change
- Impact of regulatory decision-making – speed vs. quality of decisions
- Validating measures of successful implementation

# Section 2: Presentations

*Please note that the following presentation summaries represent the views of the individual presenters and do not necessarily represent the position of the organisation they are affiliated with. The slide featured in each of the following summaries is attributed to the individual presenter and has been reproduced with their permission. Affiliations are stated as they were at the time of the meetings, 5th and 6th July 2022.*

## Session 1: Collaborative and workshop regulatory reviews – What is their impact and how should they be expanded to other regions?

### Has the pandemic led to strengthen global regulatory coordination for development review and access to vaccines and therapeutics?

#### The International Coalition of Medicines Regulatory Authorities (ICMRA) viewpoint

**Emer Cooke,** Executive Director, European Medicines Agency

ICMRA is a strategic coalition of 24 regulatory authorities worldwide, 15 associate members, with the World Health Organisation (WHO) as an observer (see below).

Through this forum, ICMRA was able to share the latest developments and approaches to regulatory requirements for vaccines and therapeutics during the pandemic. This was a time of intense collaboration to understand and manage emerging safety issues, with weekly updates to global regulators in an attempt to socialise the concept of risk-based and reliance approaches.


**Communications, misinformation and managing vaccine hesitancy**

ICMRA was heavily focused on managing unexpected waves of misinformation and disinformation, which impacted on vaccine confidence. The coalition was on a mission to facilitate the delivery of high quality, safe and effective products, but also to reassure the public that vaccines are safe, effective, and high quality. Working under intense press and public scrutiny, ICMRA expanded its communications efforts, in an attempt to counter misleading information.

ICMRA joined forces with WHO to publish regular statements helping healthcare professionals answer questions from patients on COVID-19 vaccines and therapeutics. It also published a joint statement in May 2020 on transparency and data integrity, and access to clinical trial data, especially for COVID-19 vaccines and therapeutics.

**Collaboration successes – and future projects that further enhance collaboration**

In many ways, the pandemic showed how things could be done differently, highlighting opportunities for collaboration. As well as running regular update meetings and topic-focused workshops, ICMRA facilitated successful international collaboration in areas such as vaccine safety, real-world evidence, manufacturing capacity and remote inspections.

*Product quality knowledge management*

ICMRA is running two global pilots related to product quality knowledge management – one related to collaborative assessment of post-approval changes, which was highly necessary during the pandemic; and the other, focused on collaborative hybrid inspection. During the pandemic, there was no way to visit all of the necessary sites as individual regulators, so joining forces and organising hybrid and remote inspections was required.

*Clinical trials and public health emergencies*

ICMRA is focused on enabling more platform-type trials that can be readily launched 'off-the-shelf'. During the pandemic, it was clear many clinical trials were too small and too slow; they did not produce well-powered actionable data and outcomes. If these trials could be combined, the evidence generated on a global scale could be more useful.

**Efforts in Europe have paid off**

Although global development and review have been very successful, there are still problems with access; but regulators were not a barrier to access during the COVID-19 pandemic.

In answer to the original question posed by CIRS, *has the pandemic led to strengthened global regulatory coordination for development review and access to vaccines and therapeutics?* the answer is a resounding yes. In Europe, efforts have paid off. Less than 2.5 years after the start of the pandemic:

- Six new vaccines have been authorised for COVID-19
- Eight therapeutics for COVID-19 have been indicated (authorised or indication extended) for COVID-19
- Potential safety signals have been rigorously followed up, with action taken when necessary
- Manufacture of over 1.2 billion vaccine doses, distributed in the EU, has been enabled; 2.2 billion doses exported to 167 countries worldwide.

**Summary**

International regulatory collaboration and reliance has been instrumental to the successful global regulatory response to the COVID-19 pandemic. Regulators have achieved unprecedented alignment, working together through forums like ICMRA on development, authorisation, approaches to clinical trials, communication, and regulatory agilities, amongst other issues.

The challenge now is to bring these learnings into the daily business of global regulatory agencies, using newly acquired knowledge and expertise to support development and regulation of products that better meet patients' needs, both locally and globally.

As regulators, we have seen the concept of reliance achieving practical results, a success that must be built upon in the future. Continued work on pharmaceutical product quality management, clinical trials in emergency settings, and development of regulatory agilities will allow for further enhanced collaboration.

## Has the pandemic led to strengthen global regulatory coordination for development review and access to vaccines and therapeutics?

### Industry viewpoint

**Dr David Jefferys,** Senior Vice President, Head of Global Regulatory, Eisai Europe

**Janis Bernat,** Director Scientific & Regulatory Affairs, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

The pandemic posed extraordinary challenges for the pharmaceutical industry, not only in responding to the pandemic, but also meeting demands for all medicines. For example, global supply chain and market disruption, stockpiling, and severe staff shortages, as well as concerns around maintaining ongoing clinical trials, monitoring product safety and enabling technology transfer. The additional burden of approving COVID-19 vaccines and treatments led to delayed approval of other products.

Unprecedented efforts to collaborate and innovate meant it was possible to find ways to collectively facilitate change that may benefit patients in the future. These learnings are relevant both during 'non-COVID' times and in preparedness for future pandemics.

**Regulatory Guiding Principles**

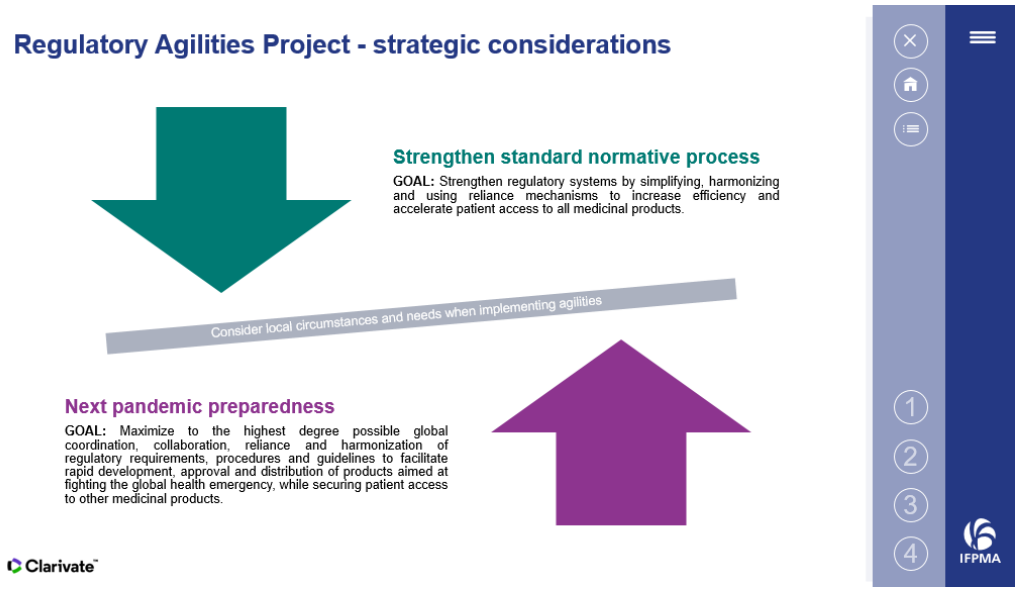
In May 2020, IFPMA published regulatory guiding principles for the biopharmaceutical industry, which set out how industry would:

- Work in partnership with national registration agencies (NRAs) to define the best science-based strategies for ensuring availability of COVID-19 medicines and vaccines
- Progress clinical research into new treatments and prevention of non-COVID-19 conditions
- Maintain supply of all medicines and vaccines globally, enabling continuity of manufacturing and availability of product supply, which are imperative for public health
- Ensure medicines and vaccines continued to meet appropriate standards for quality and safety.

**The IFPMA Regulatory Agilities Project**

Experiences gained during the pandemic provide opportunities to strengthen normative processes and prepare for potential future pandemics. The IFPMA Regulatory Agilities Project, initiated alongside Clarivate in October 2021, had these two objectives at its core (shown over the page), taking into account local circumstances and context.

The project aimed to capture lessons from primary and secondary research on the use of regulatory agilities emerging from the COVID-19 pandemic. It reviewed trends, challenges and recommendations on the implementation of agilities in three categories: regulatory, clinical trials and quality.




The project found many different agilities were implemented regionally. For example:

- In Japan, the opportunity to consult with the relevant review offices to deal with divergences from clinical trial protocols
- In the UK, expedited assessment of variations and applications, flexibilities were introduced around good manufacturing practices, good distribution practices as well as reduced retesting of imported products
- In Ghana and other African countries, products that had current marketing authorisation could be renewed without the receipt of all documents, to ensure continuous supply of non-COVID-19 related products already on the market.

Some agilities were not formalised into legislation. For example, around informal communication and opportunities for real-time discussion; and 'in parallel' rather than subsequent submission of documentation. There was also an acceptance of some projects that had existed for a long time prior to the pandemic, such as the e-Certificate of Pharmaceutical Products.

*Learnings: Strengthening standard normative processes*

There are opportunities to maximise on several reported themes to improve standard normative processes, as follows:

- Increase digitalisation of working practices, e.g., using e-signatures to support decentralised and hybrid clinical trials, and use of e-labelling
- Increase reliance, helping to improve efficiencies and avoid redundancies
- Share best practices highlighted across various fora, including by the ICMRA, in CIRS workshops, or from experienced NRAs
- Promote and improve transparency and responsible data sharing practices.

*Learnings: Next pandemic preparedness*

Several themes are important for future pandemic preparedness, including:

- A need for speed and clarity
- International convergence for evidence reviews and approval
- Accelerated and simplified processes
- Prioritisation of risk-based approaches
- Temporary suspension of non-urgent activities (restarting before creating a backlog)
- Support for public confidence in NRAs and industry; amongst others.

**Summary**

Whether to prepare for the next pandemic or to strengthen standard normative processes, NRAs should ensure the regulatory dialogue is iterative, responsive, holistic and voluntary in the future. There is a need for strong political will to facilitate changes to regulatory frameworks for the benefit of patients. Moreover, there is a need to consider regional differences and leverage local organisations for advocacy purposes, as needed.

In particular, there should be a focus on:

- Digitalisation of practices and ways of working
- Prioritisation of post-approval changes to allow faster manufacturing and supply
- Adoption of risk-based approaches to decision-making
- Increased collaboration, work-sharing and alignment between agencies.

## Risk-based approaches to the review and registration of medicines – What should a future regulatory toolkit look like?

**Dr Samvel Azatyan,** Team Lead, Regulatory Convergence and Networks, WHO

Good health is impossible without access to medicinal products, but today, an estimated 2 billion people have no access to essential medicines. There are numerous reasons for this, including insufficient or inadequate regulatory capacity and lack of collaboration and work-sharing between countries in regulation of medicinal products.

To address this situation, the WHO is putting forward a number of initiatives, focused on:

- Improving overall governance and transparency in regulation of medicinal products, by way of a set of guidelines, including the Good Regulatory Practices document
- Promoting and facilitating processes to help build strong national regulatory systems, by way of a global benchmarking process.

### The concept of 'reliance'

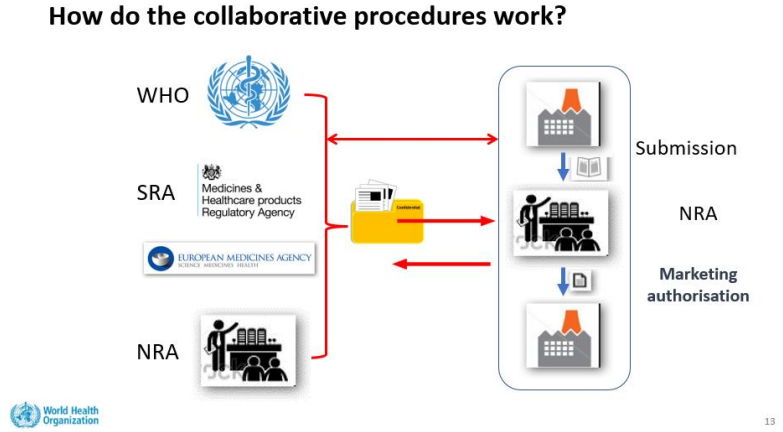
Promotion of reliance is important to global regulatory cooperation, convergence and harmonisation. Although reliance is not a new concept, a definition was proposed for the first time in the WHO Good Reliance Practices document:

*"The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision."*

Many countries now choose to use reliance to help them reach a national regulatory decision, avoiding duplication and saving precious resources. Importantly, the national regulatory authority remains independent and accountable. Properly implemented, reliance will support good quality national regulatory decision making, improving access to high-quality, effective, and safe medicines across the entire life cycle.

### Collaborative registration procedures

Collaborative procedures are very simple, essentially based on sharing information, as shown over the page. When an applicant expresses their willingness to take part in the collaborative registration procedure, WHO helps to organise the process. Once the initial report is shared with national regulatory authorities (NRAs), they agree to grant their decision within agreed timelines.




*WHO prequalification collaborative registration procedure*
Via this procedure, which has existed since 2004 (first for vaccines, then medicines), the outcomes of the WHO prequalification process are shared with participating NRAs, who agree to grant national authorisation within a defined timeframe. There are 52 participating NRAs, plus one regional

economic community. More than 700 registrations have been made, the majority in line with the 90-day target approval.

*Stringent regulatory authority collaborative registration procedure*
This procedure is based on approvals by stringent regulatory authorities (SRAs) and the European Medicines Agency. There are 40 participating NRAs, plus one regional economic community; with 179 applications submitted and 78 regulatory approvals achieved to date. Following recent changes, the concept of SRAs will be replaced with 'WHO-listed Authorities'.

*Regional regulatory harmonisation initiatives and networks*
Lastly, there are regional regulatory harmonisation initiatives that are actively using reliance to achieve faster national registration. For example, the African Medicines Regulatory Harmonisation Initiative and the Caribbean Regulatory System.

**ICDRA recommendations to shape the future regulatory landscape**

Several recommendations intended to shape the future regulatory landscape were proposed at the International Conference of Drug Regulatory Authorities (ICDRA) conference in 2021:

- Promote use of the *WHO Global Benchmarking Tool,* which can be utilised by all countries, regardless of maturity level, to enhance their regulatory capacity; better implement the Good Regulatory Practices document; and promote reliance and continuous improvement
- Ensure the *WHO-listed Authorities* designation process is risk- and evidence-based, simple to understand, transparent and independent. In addition, information on the evaluation process, evidence reviewed, and time period for designation should be included in the listing
- Member states should identify regulatory flexibilities/agilities and reliance best practices that proved effective during the pandemic and consider adopting such practices/approaches into national regulations, guidelines and regulatory processes. WHO will support NRAs to implement Good Regulatory Practices and Good Reliance Practices principles.

**Summary**

WHO efforts to facilitate good quality decisions include promoting Good Regulatory Practices, strengthening of health systems, regulatory workforce development, and promotion of reliance and work-sharing. Reliance is implemented via facilitated registration pathways, such as the WHO collaboration registration procedure for pre-qualified products, SRA collaborative registration procedures and regional regulatory harmonisation initiatives and networks. ICDRA recommendations for WHO and member states include identifying and adopting regulatory flexibilities, reliance best practices and regulatory tools that proved to be effective during the pandemic.

## Survey of agencies on practical use of risk-based approaches within their agencies for medicines registration – Centre for Innovation in Regulatory Science (CIRS) presentation

**Dr Neil McAuslane,** Director, CIRS

### Background and objectives

Due to the COVID-19 pandemic, many agencies have adopted risk-based approaches to medicines registration, with many pathways well-established pre-pandemic. CIRS conducted a survey amongst regulatory agencies (primarily in the Americas, Africa, Middle East, and Asia) to explore use of risk-based approaches, looking particularly at how to make these more effective and efficient going forward. Of 50 agencies approached, 32 responded.

The survey objectives were to:

- Identify which risk-based models agencies have been using for regulatory approval of medicines
- Determine which frameworks agencies have in place to undertake or enable a risk-based approach
- Provide insight into the future direction for risk-based models.

Types of risk-based model referred to in the survey are:

- Unilateral reliance – agency has leveraged the review of another agency through an abridged verification or recognition review
- Information sharing – agency has participated in an information sharing activity with other regulatory agencies, e.g., via bilateral or multilateral arrangements as part of a network
- Work-sharing – agency has been part of a centralised/regional model, or has been responsible for reviewing part of a dossier within a workshare
- Collaborative review – agency has conducted or been part of a collaborative evaluation in which the agency undertook a standalone evaluation, while sharing expertise and information with other agencies.

### Results

*Risk-based approaches currently in place*

The majority of agencies (n=30) have some form of unilateral reliance in place. Processes for information sharing (n=25), followed by work-sharing (n=23), were also in place in many regions. Some agencies (n=18) had been part of collaborative review processes.

The majority of agencies (n=25) use an abridged review model, where the agency undertakes an abbreviated review, focused on clinical benefit risk. Others use verification review (n=17) or recognition review (n=14). Only nine agencies indicated they use all three.

In terms of work-sharing activities, out of 20 agencies, 17 indicated they do a full review (full review of whole dossier, either as first assessment or second), 11 indicated they do a full assessment (part of the dossier, e.g., safety, efficacy), while some do both.

*Reference agencies used*

The main reference agencies are World Health Organisation (WHO) prequalification (n=25), followed by European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) (both n=23). Fewer challenges getting access to unredacted assessment reports were reported for WHO prequalification, with more reported for the FDA.

*Activities and systems / frameworks in place*

For both unilateral reliance and work-sharing, CIRS asked whether the agencies have: 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. About 50% (or more) of agencies have something in place in relation to these items.

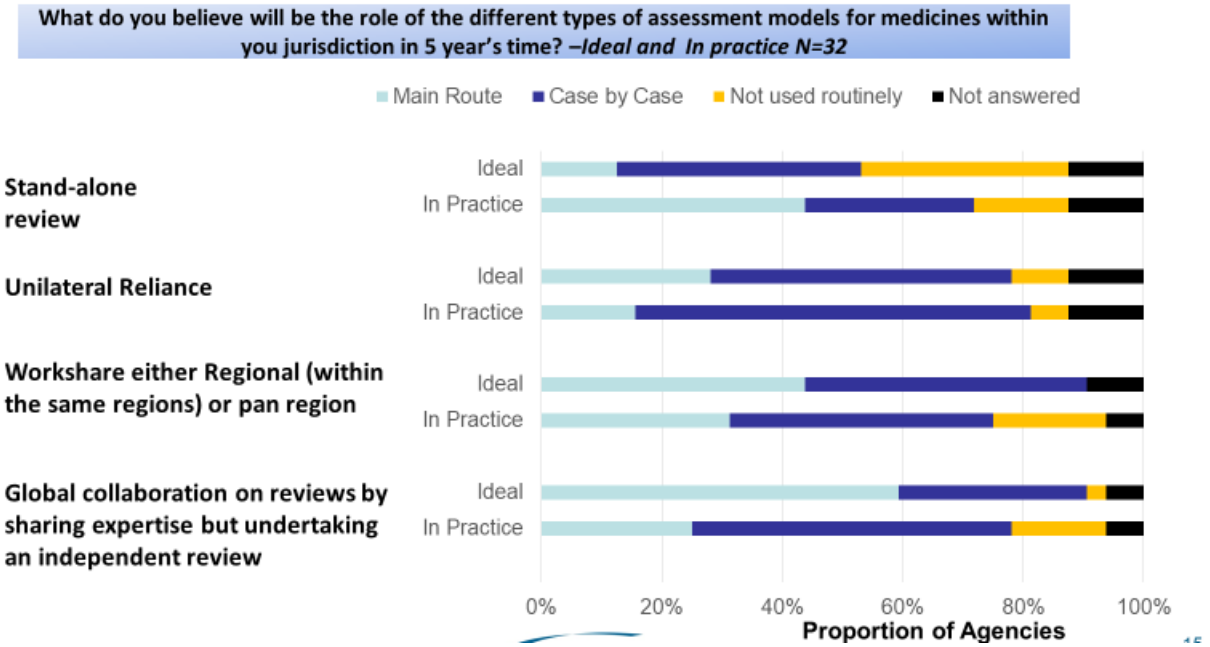
*Incentives and challenges*

For unilateral reliance, effective and efficient use of resources is critical, with faster availability of medicines for patients also being a key incentive. The same is true for work-sharing, while improved quality of decision making was also highlighted as important. For the majority of agencies, access to the assessment report was a key challenge for unilateral reliance. Other challenges mentioned by agencies included lack of awareness on the part of applicants/sponsor in utilising the unilateral reliance pathway and resistance from experts responsible for dossier review.

In terms of work-sharing, resource constraints were the number one challenge highlighted by agencies, including competing for resources with national work, but also lack of expertise or guidelines to undertake the work-sharing review.

*The future of risk-based models*

In the future, agencies would like to see fewer stand-alone reviews, with global collaboration being the ideal approach; but in practice, this may not happen




The agencies suggested topics for further discussion, which included:

- Exploring what is being done in practice, particularly in countries with strong regulations
- Encouraging interagency exchange of information
- Overcoming access challenges to unredacted assessment reports
- Fostering common understanding/application of reliance and recognition procedures among national regulatory authorities.

**Summary**

CIRS undertook a survey of regulatory agencies in the Americas, Africa, Middle East and Asia to identify which risk-based models are being used and future directions for these models.

Unilateral reliance was the most used model, followed by information sharing, work-sharing and collaborative review. Effective/efficient use of resources and faster medicine availability for patients were key benefits of undertaking unilateral reliance or work-sharing. The most common barrier to using a reliance model was access to unredacted assessment reports.

It was believed that, in the future, assessment routes should move from stand-alone reviews to risk-based models, though there were doubts that this would happen in practice.

## Well-resourced agencies have established different models for working together - How well do they work in practice?

## EU centralised review, the OPEN initiative and other collaborative pathways

**Martin Harvey,** Head of international Affairs, European Medicines Agency (EMA)

Reliance and collaboration are a modern way of doing regulatory business, critical for efficiency and resource-saving in the 21st Century. The European Medicines Network is a unique system based on full transparency and sharing information, representing reliance in action.

**Examples of collaborative pathways**

*EU-Medicines For All (EU-M4all)*

This procedure has been running for several years. The EMA evaluates and gives an opinion on medicinal products for human use outside the EU, according to the same standards and processes as for EU authorisation. The only differences are there is no marketing authorisation at the end of the process and the risk-benefit assessment is taken in terms of the countries where the product is intended for use.

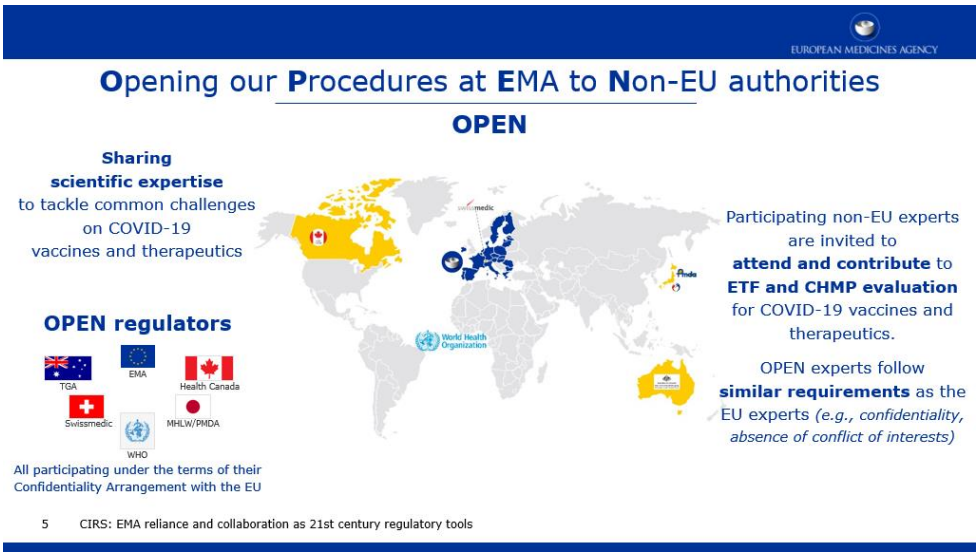
EMA involve the World Health Organisation (WHO), along with experts and regulators from where the product is intended for use, across the whole assessment life cycle; from early-stage development to scientific assessment, through post-authorisation and safety monitoring. Five medicines still hold EU-M4all scientific opinion, with approvals in 79 countries worldwide, leading to 127 marketing authorisations.

*WHO Collaborative Registration Procedure*

This procedure accelerates national approval in countries where resources may be limited, based on regulatory work already carried out by authorities, such as EMA. So far, the collaborative registration procedure has resulted in 65 marketing authorisations across the world (from nine medicines with an EU marketing authorisation).

**The OPEN procedure**

Part of EMA's response to the pandemic was to develop the OPEN (**O**pening our **P**rocedures at **E**MA to **N**on-EU authorities) procedure (shown over the page), an international collaboration framework of near-concurrent review among international regulators. The focus was on sharing scientific expertise and tackling common challenges related to COVID-19 vaccines and therapeutics.




OPEN regulators participated under the terms of their confidentiality arrangement with the EU. They were encouraged to be part of EMA's scientific assessment of COVID-19 vaccines and therapeutics - listening, participating, contributing, discussing, and sharing - while maintaining scientific and regulatory independence.

The OPEN pilot has had several successful outcomes:

- Enhanced communication channels, with global expertise from Health Canada, Swissmedic, TGA Australia, WHO, and Japanese colleagues
- Parallel assessment of similar data, reducing work duplication
- Alignment and fewer labelling differences
- Accelerated decisions on COVID-19 medicines and access to patients outside the EU, leading to a significant global public health impact
- Independence of decision making; each regulatory agency ultimately took their own decision.

*Global impact of OPEN*

For five of the six vaccines approved in the EU, the EMA was the recorded regulatory authority, which means WHO Emergency Use listing (EUL) relies on EMA scientific output. Under EUL, more than 160 low- and middle-income countries have approved COVID-19 vaccines, meaning they can then be procured and deployed in those countries.

*What happens next?*

**Consolidate**: EMA is engaging with all stakeholders to consolidate OPEN: defining more detailed terms of reference, increasing visibility with more systematic and coordinated communication by participants, and reducing the submission gap between applications to OPEN regulators.

**Expand**: Antimicrobial resistance is a global challenge, potentially even more significant than that presented by COVID-19. Increasing global cooperation for the approval of antimicrobial products will be enormously important. As a continuation of the International Coalition of Medicines Regulatory Authorities pilot, EMA are also looking to facilitate collaborative assessment of post-approval change management.

**Explore**: Other areas of interest include exploring designation of priority medicines under the PRIME scheme and use of OPEN for public health emergencies, if one should occur.

**Summary**

Reliance and collaboration are modern regulatory tools. The objective of the OPEN pilot project was to allow active international participation in EMA scientific evaluation.

OPEN facilitated assessment of the same data by multiple authorities, deepening collaboration and moving the exchange of information to active engagement. It allowed regulators to accelerate and align on decisions, leading to fewer questions and labelling differences, while maintaining independent decision-making.

EMA is engaging with all stakeholders to consolidate OPEN and expand to identified areas in a stepwise approach.

## Well-resourced agencies have established different models for working together - How well do they work in practice?

## ACCESS Work-sharing model

**Adj Prof John Skerritt,** Deputy Secretary for Health Products Regulation, Department of Health Australia

**What is ACCESS and how has it developed?**

The ACCESS Consortium is a group of five regulators from Australia, Canada, Singapore, Switzerland, and UK, working for ~160 million patients in advanced economies. Participating agencies review different parts of submitted dossiers and share and extensively discuss their reviews but retain independence in decision making related to approval of the medicine.

ACCESS work-sharing came out of a bilateral collaboration between Australia and Canada. The first step towards wider ACCESS work-sharing collaboration was sharing of information on regulatory systems, followed by a process of confidence building as a prelude to work-sharing, followed by a pilot stage. The first three work-sharing targets were all oncology drugs; however, a wide range of different therapeutic areas have been covered since.

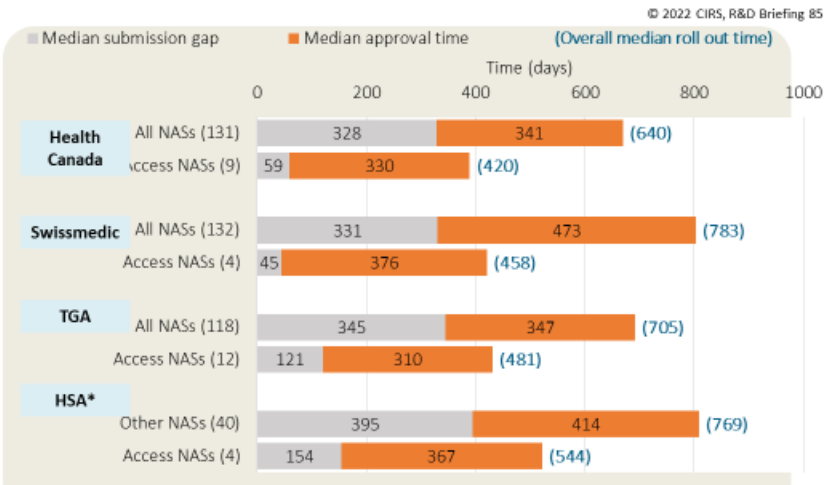
Applications are currently under evaluation across ACCESS partners, including small molecules and monoclonal antibodies, being reviewed either as new active substances (NASs), label extensions (i.e., new indications), and generic medicines. In total, 34 NASs are either approved, under review or under consideration in processes involving two to five partners. These numbers are evidence of the success of ACCESS to date.

There has been some work to encourage the right work-sharing applications, involving outlining governance processes, confidentiality agreements between organisations and information-sharing processes for supportive documents, such as expressions of interest, Q&As and guidance for industry. Importantly, ACCESS partners decide which applications are appropriate for work-sharing.

**Impact and success of ACCESS**

Beyond the numbers, there have been several other positive impacts of ACCESS. These include reduction in work / reduced duplication of effort, more consistent regulatory decisions, aligned questions for the sponsor, and a significant reduction in approval submission lag (shown below) [1].

**Reduction in submission gap for NASs approved via the Access Consortium between 2018-21**




Sponsors applying for ACCESS work-sharing are also putting drugs into the process sooner; they are not waiting many months after a US Food and Drug Administration (FDA) or an EU submission, which is important to ensure early patient access to new drugs. For regulators, ACCESS has improved efficiency and effectiveness of processes, with potential to reduce regulatory effort. It has also given

greater exposure to emerging global trends, maintained sovereign decisions, increased alignment, and facilitated better quality decisions through collaboration.

On the other hand, industry gets near simultaneous market authorisation in all participating countries, predictable timeframes, greater transparency of regulatory decisions and reduced burden with global dossiers, with just one set of questions

**Challenges associated with ACCESS**

While the benefits of work-sharing certainly outweigh the challenges, there is a need to be mindful of the potential challenges of work-sharing and to find ways to address them.

Challenges included:

- Alignment of submission timeframes to different regulators, particularly for generic medicines where patent expiration dates may differ
- The need for increased coordination of effort and communication across time zones
- The need to accommodate specific national regulatory requirements and differences between technical guidelines (such as reference standards for bioequivalence for generics)
- Shorter evaluation timeframes need to accommodate peer review (which meant that work-sharing was not feasible for a number of COVID-19 products)
- Differences in risk-benefit analysis or data interpretation between regulators
- Differences in administrative processes between regulators
- Alignment with payor and health technology appraisal processes differs between countries.

Work-sharing becomes increasingly complicated the more people, and the more countries, try to work share. The concept of working with a larger number of partners than five may seem democratic, but consideration should be given to the amount of time spent on video conferences and telephone calls, or waiting for European Medicines Agency (EMA) responses, which could delay rather than accelerate review. Information exchange is often just as valuable as work-sharing, as found with review of COVID-19 vaccines.

**Work-sharing is just one approach to market authorisation**

In Australia, work-sharing is just one approach to facilitate market authorisation of medicines, which means increased flexibility and speed, but the added price of complexity. Other approaches include Project Orbis, invited participation in EMA's OPEN initiative, two reliance pathways based on reviews by comparable international regulators, priority review and provisional approval. The Australian Therapeutic Goods Administration also provides support for WHO prequalification and regional regulatory collaboration in Asia and the Pacific.

**Summary**

The ACCESS Consortium is a work-sharing initiative where the participating agencies review different parts of the submitted dossier but retain independence in decision making related to approval of the medicine. ACCESS has been successful in approving a large number of NASs in a range of therapeutic areas and is helping to reduce submission gaps to participating agencies compared with those to US FDA or EMA. However, work-sharing has had several challenges, including difficulties aligning submission timeframes, but the benefits outweigh these, such as reducing duplication of effort. Agencies interested in work-sharing should consider transaction costs and agility as well as the use of regional models with small numbers of partners.

**References**

[1] Centre for Innovation in Regulatory Science (2022) R&D Briefing 85: New drug approvals in six major authorities 2012–2021: Focus on Facilitated Regulatory Pathways and internationalisation. Centre for Innovation in Regulatory Science (CIRS), London, UK. Accessed from: https://cirsci.org/publications/cirs-rd-briefing-85-new-drug-approvals-in-six-major-authorities-2012-2021/

## Work-sharing and collaborative models: How would companies like to see these models evolve so they enable global registration and medicine availability?

**Priti Shah,** Executive Director, International Regulatory Strategy, AstraZeneca UK

Companies strive for simultaneous access to medicines globally. However, even with a first global approval, there is still delay in registration in some emerging markets. There are several reasons for this, including reliance on the reference country, company strategy, medical practice, and affordability. To achieve universal access, countries must have sustainable regulatory practices.

**What the pandemic taught us**

*At present, reliance and work-sharing practices are not optimal* - For Vaxzeria, even with WHO approval and EMA as a stringent regulatory authority (SRA), AstraZeneca received thousands of questions under the reliance-type process when applying for national registration. These did not result in substantial changes to approvals.

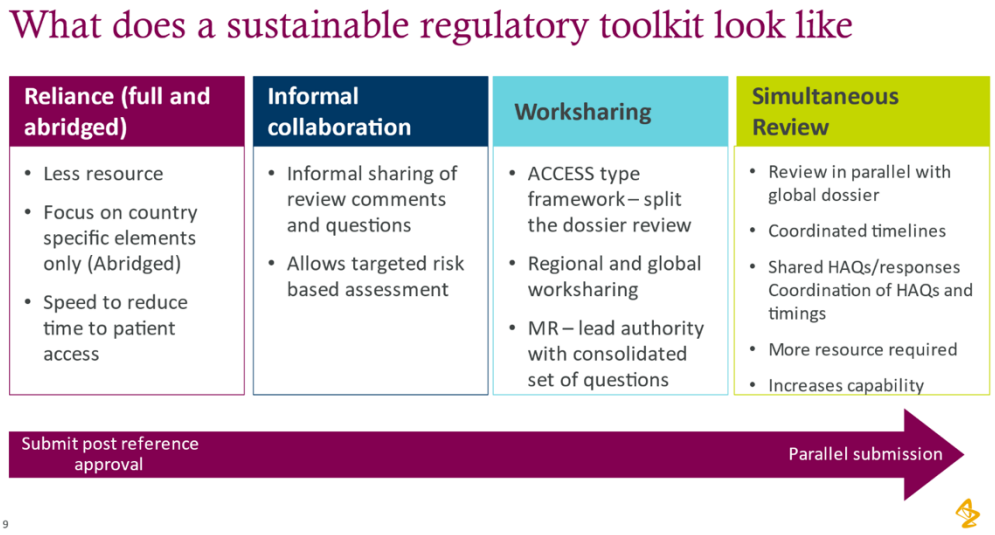
*A sustainable toolkit of regulatory pathways is needed* – Companies have an increasingly complex portfolio of products, with new technologies and innovations. Authorities must build sustainable toolkits of optimised regulatory pathways that suit the different situations industry face.

*Global medicines development versus local and regional development* - There should be increasing focus on local manufacturing and regional production, which allows countries to establish their own healthcare priorities, create a sustainable infrastructure for their country and create investment in regional supply chains.

**What does a sustainable regulatory tool kit look like?**

The following elements should be included within a sustainable regulatory toolkit (and shown below):

- *Reliance (full or abridged):* True reliance (without duplicate questions) should be part of a sustainable regulatory toolkit, focused on country-specific elements only
- *Informal collaboration:* Informal sharing of review comments and questions will allow targeted risk-based assessment for authorities
- *Work-sharing:* This includes ACCESS-type frameworks, where the dossier review is split. We need both regional and global work-sharing
- *Simultaneous review*: The same dossier should be submitted in parallel to authorities, with coordination of timelines and sharing of authority questions/responses



Industry believe reliance is not the only option to be explored. There should be a focus on collaborative review and work-sharing, since these will help build health authority capability and capacity, enabling a sustainable system for the future. These approaches can support harmonisation of regulatory requirements and promote risk-based review, as well as greater interagency collaboration, since reviews could be conducted in parallel. In essence, this would increase patient access.

**What are the key elements needed in any collaborative review and work-sharing process?**

- *One globally aligned dossier*, with harmonised requirements and reduced duplicative requirements, for example on inspections and testing
- *Optimised processes and timings* within regulatory processes, not only for new products but also life-cycle variations. There is a need for accelerated review timings and a process for managing review differences
- *Alternative reference countries*, beyond SRAs. Established criteria for who could be a reference authority are needed
- *A suitable platform for agency collaboration* that is very agile. New countries need to be added quickly so they can share real-time information, including electronic submissions.
- *Capability and capacity to build for the future*, through partnership and mentoring with other agencies. This could lead to regional or local portfolios of products.

**Summary**

While companies strive for simultaneous availability of medicines globally, the pandemic highlighted that reliance and work-sharing approaches are not yet optimal, which means this is not always easy to achieve. The international regulatory community needs to be more innovative, coordinated, and focused to help patients access medicines.

To build a sustainable regulatory infrastructure, further development of global and regional work-sharing and collaborative approaches are needed, building health authority capability and balancing capacity to increase collaboration, promote harmonisation of requirements, and accelerate patient access. Reliance is not the only process we should be exploring.

# Session 2: Optimising the availability of medicines to patients through regional collaboration

## Agency and company perspectives - how are they working, how should they evolve? What are the weakness and strengths over individual agency approvals?

## ASEAN Joint Assessment for Pharmaceuticals: Moving beyond pilot stages - how should it evolve?

### Regulatory agency perspective

**Rosliza Binti Lajis,** New Drugs Section, National Pharmaceutical Regulatory Agency (NPRA), Malaysia

**ASEAN initiatives to support harmonisation and regional cooperation**

In 1999, the Association of Southeast Asian Nations (ASEAN) Consultative Committee for Standards and Quality (ACCSQ) established a Pharmaceutical Product Working Group (PPWG), whose objective was harmonisation of pharmaceutical regulations between ASEAN member countries. The PPWG has since developed a number of harmonisation initiatives (shown below), including the ASEAN Joint Assessment Coordinating Group (JACG), which all aim to ensure regulatory work is not carried out in isolation and to eliminate duplications of efforts.


**ASEAN Joint Assessment Coordinating Group**

The JACG's aim is to ensure access to good quality, effective medicines for all ASEAN citizens, by strengthening the implementation of harmonised regulatory requirements. The key purposes of the ASEAN JACG are to:

- Strengthen NRAs' technical capacity, since this is currently lacking in some areas.
- Foster mutual trust and reliance among the ASEAN member states before proceeding with other activities in the ASEAN region
- Ensure regulatory work is conducted in a timely and efficient manner
- Facilitate review of priority medicines throughout the ASEAN region, while respecting national decision-making processes.

Under the joint assessment process, the same application is submitted to all the participating ASEAN national regulatory authorities (NRAs) at the same time, and assessment work is carried out by participating NRAs working together. A joint assessment report is then prepared at the end of the assessment.

**Pyramax: the pilot joint assessment**

The first product assessed through the JACG joint assessment procedure was Pyramax, a malaria medication. Seven countries participated, with Malaysia as the lead country, and technical support from the World Health Organisation (WHO) and European Medicines Agency. As this was a pilot, the timeline was long (July 2017 – August 2019), accounting for lack for experience. During the pilot, exposure to the concept of reliance and the opportunity to learn from one another was beneficial. In terms of challenges, there were several country-specific requirements that could not be avoided, as well as differences in the format of the evaluation report. Additionally, timeline issues arose related to capacity of evaluators. Based on this experience, the process was improved, by agreeing on common templates and a timeline for joint assessment, and a panel of experts was established. Engagement with industry is also being improved, in order to communicate the potential benefits that the joint assessment procedure could provide.

**How has the joint assessment procedure evolved?**

Previously, only one pathway was available: the full joint assessment. Now, applications can now be submitted via three routes, within which there are two options: full joint assessment or an expedited joint assessment. These are:

- responsive applications – applicants propose products included in the priority list
- proposed applications – applicants propose products not in the priority list
- invited applications – applicants are approached by ASEAN NRAs or WHO.

Previously, at least three participating NRAs would collaborate for every joint assessment, with one appointed as the lead NRA. Now, under the expedited joint assessment, a minimum of two NRAs can join the review. The joint assessment procedures are now open to products outside the priority list under the proposed and invited application processes. The list of priority products has also expanded beyond malaria, tuberculosis, and human immunodeficiency virus infection/acquired immunodeficiency syndrome (HIV/AIDS), to include biological products and several other areas of interest, such as rare disease and oncology.

An information management system has also been set up, which allows applicants to upload a dossier that can be assessed at the same time by all the participating NRAs. In addition, reference NRAs can upload assessment reports and other relevant documents. The system has helped the lead NRA to manage and coordinate the joint assessment process.

**What does the future look like?**

The next step is to consider a work-sharing initiative for ASEAN joint assessment, whereby the participating regulatory authorities would share assessment activities. This may translate to shorter assessment timelines and facilitate better use of available expertise. Improved communications are needed with industry and other stakeholders. Lastly, there is a need to optimise the expedited joint assessment procedure.

**Summary**

ASEAN joint assessment is one of many initiatives that support harmonisation and regional collaboration in the region. It is a project under the ASEAN PPWG, with a purpose to foster mutual trust and reliance among member states. Since it was established in 2017, ASEAN joint assessment has evolved in several ways to promote more participation, including expanding possible assessment pathways and opening up the list of priority medicines. Importantly, product registration approval is a national decision.

# ASEAN Joint Assessment for Pharmaceuticals: Moving beyond pilot stages - how should it evolve?

## Company perspective

**Dr Sannie Chong,** Regulatory Policy, Asia Pacific, Roche, Singapore

### ASEAN Joint Assessment (AJA): developments to date

According to industry, there have been several welcome developments to the AJA process, including expansion of the list of priority products for joint assessment to more disease areas. Moreover, involvement of Australian Therapeutic Goods Administration and World Health Organisation (WHO) in 'retrospective' review of products enabled regulators to gain first-hand experience of joint assessment. Industry recommends AJA to consider leveraging this model for approving more recent new drug applications, including those containing new molecular entities. Furthermore, industry welcomes the availability of both full and expedited pathways via the joint assessment procedure.

### How should AJA evolve?

*Procedures*

Since AJA is a reliance pathway, the prerequisite is approval from one or two reference agencies, and as a result there is significant delay in submission to begin with. It is envisaged that this gap may potentially lead to duplication of work and even longer timelines, which could jeopardise the true spirit of reliance, without enhancing the value of regulatory oversight. Moreover, compared with national reliance pathways in some ASEAN members states, AJA has much longer timelines.

Industry recommends that each ASEAN member state participating in AJA considers accepting the submission prior to approval of the reference agency, to reduce turnaround time e.g., in the product selection stage. Upon approval by the first reference agency, a decision can then be made fairly quickly, within 30 to 90 calendar days (comparable to national pathways). This would demonstrate good use of reliance by focusing on issues in the local context, rather than conducting a full review again. In addition, industry recommends AJA be implemented for all product and submission types, including post-approval variations.

*Alignment*

Alignment with the WHO and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is essential. When companies submit the same dataset to WHO/ICH and AJA, it may not be deemed adequate for AJA country-specific requirements. For example:

- In order to claim the same shelf life approved by the reference agency, stability data may be required to be 'topped up' (up to 12 months, or up to shelf life claimed, is often required by ASEAN member states)
- ASEAN member states require 'one-site-one-licence', rather than accepting multiple manufacturing sites on one licence, as practised by WHO/ICH (this duplication is more administrative than science-driven)
- A Certificate of Pharmaceutical Product (CPP) is required by ASEAN member states in addition to the reference agency's assessment report, which is not required in ICH countries.

Therefore, industry recommends alignment with WHO/ICH, potentially by reducing country-specific requirements, especially in the areas of stability data, one-site-one-license and CPP requirements.

*Access to assessment reports*

It can be challenging for agencies to gain access to the unredacted assessment report from some reference agencies, so industry suggests using other surrogate documents in its place, such as the

complete public assessment reports, approval letter, approved Prescribing Information, and/or list of questions.

Shown below is an outline of what this evolution could look like in practice.

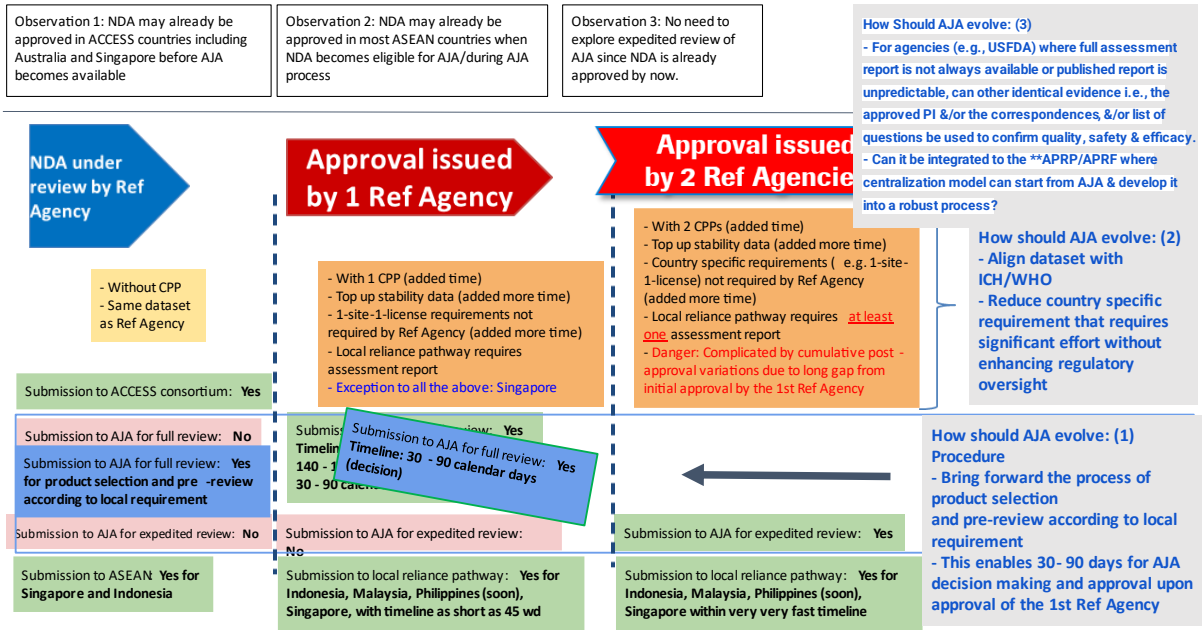



Diagram 2: How should AJA evolve in the spirit of reliance to get head start and to align with ICH/WHO

## Summary

AJA enables smart regulation through reliance, reducing duplication and allowing valuable resources to tackle local issues. While launch lag is inevitable, this can be minimised if the joint assessment timeline is comparable to the reliance pathway timelines of each member state. Although there are still gaps in aligning with WHO/ICH, specifically in the requirements for stability data, multiple sites in one licence, and CPP, AJA offers potential benefits for getting approval from multiple ASEAN countries. Industry will continue to collaborate with ASEAN to operationalise AJA with efficiency and enhanced expertise.

## Gulf Health Council – how is the process being optimised?

**Dr Hajed M bin Hajed,** Deputy General Manager, Gulf Health Council

The Gulf Health Council (GHC) represents the six countries of the Gulf Cooperation Council (United Arab Emirates, Oman, Qatar, Bahrain, Saudi Arabia, and Kuwait) as well as Yemen. The GHC is responsible for coordinating all health matters in Gulf Cooperation Council (GCC) countries and established the central registration system for pharmaceutical products in 2000.

**Improving implementation of reliance**

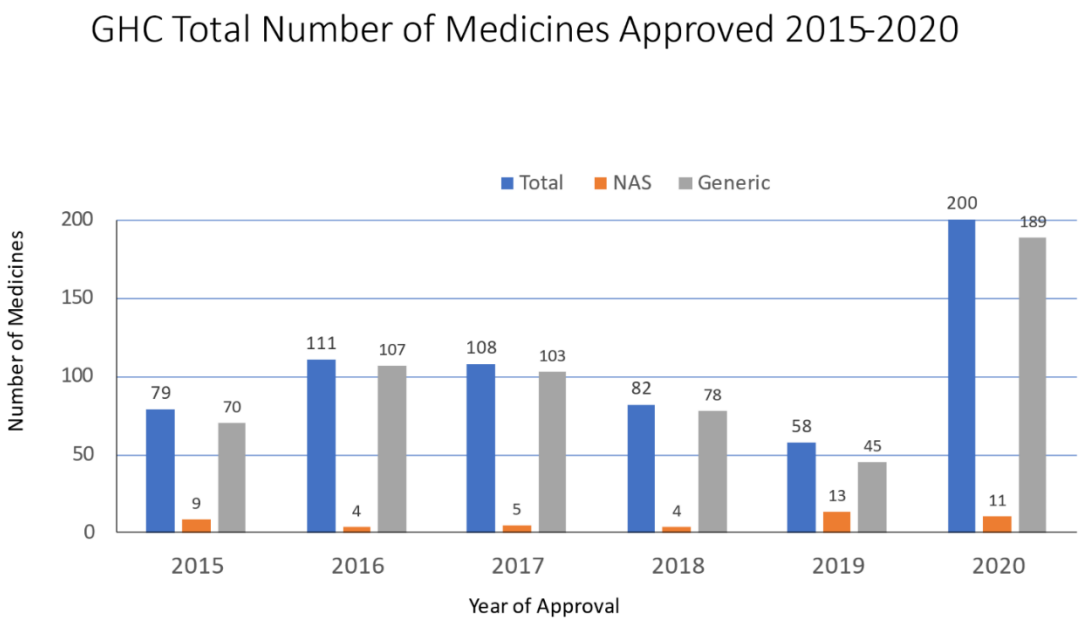
Between 2020-2021, the GHC improved implementation of reliance for pharmaceutical product registration, based on recommendations from the Gulf Central Committee for Registration. This led to optimisation of available resources and reduced review efforts in the assessment of safety and efficacy of pharmaceutical products.

Several key changes have been made:

- If a product is already approved in two or more GCC member states, it will be registered by the GHC and the registration certificate will be issued within five working days
- If the product is approved in six GCC member states, it will receive immediate approval from the GHC and the registration certificate is issued within days (for free, without any fee)
- If a visit to a manufacturing site has been made by a GCC member state in the past two years, further inspection visits will be bypassed; usually the registration committee will accept the existing inspection report (if it is dated within two years)
- For variation requests, companies must provide member states with product files according to the life cycle variation of the product (if different from what is presented centrally).

**The positive impact of reliance**

According to GHC data, implementing the concept of reliance has had a positive impact on the number of medicines being approved (see below). More than twice as many medicines were approved in 2020 compared with 2015. Moreover, in terms of median approval times, the number of days to approval has also highly reduced in 2019 and 2020. As such, using the concept of reliance has accelerated patient access to products.




**Other changes in progress**

The GHC is working on implementation of electronic Patient Information Leaflets, whereby the patient can scan a barcode to access the leaflet, which is due to be finalised in Q4 2022. This will make the leaflets easier to access and will reduce the cost of manufacturing and use of paper. The GHC also plan to produce one harmonised GCC Outer Pack, which will benefit the manufacturer, the patient as well as the Gulf regulators; guidance on this harmonised labelling is expected to be published in 2022.

**Summary**

The implementation of a reliance strategy in 2019 has helped to accelerate patient access to pharmaceutical products in the Gulf region, as demonstrated by faster GHC approval times and increasing numbers of approvals. In 2020 and 2021, the GHC improved the application of reliance based on recommendations of the Gulf Central Committee for Registration. Key changes included immediate approval of the registration of any product in the six GCC countries and the bypass of manufacturing inspections if a visit has been made by one of the member states within the past 2 years. A system for an electronic Patient Information Leaflet is expected to be finalised in 2022, in addition to guidance on more harmonised labelling.

## Caribbean Public Health Agency – Enabling the registration of safe, effective and quality medicine

**Dr Rian Marie Extavour,** Programme Manager, Caribbean Regulatory System, Caribbean Public Health Agency (CARPHA), Caribbean Community (CARICOM)

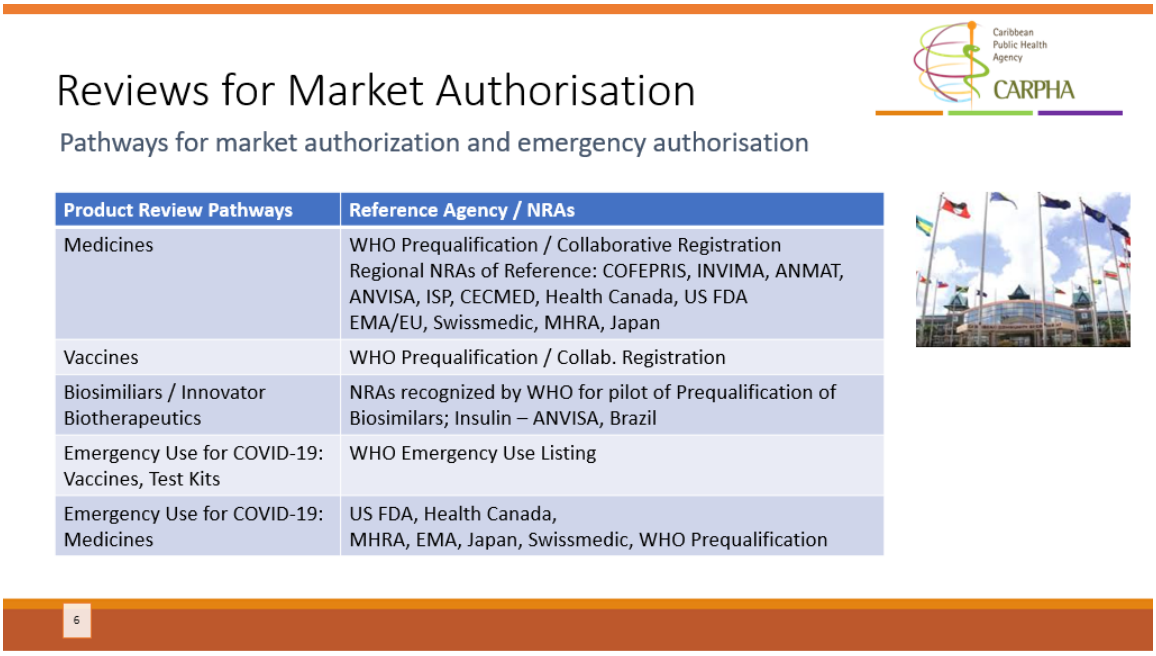
### Introduction to CARPHA

CARICOM is a Caribbean community of 15 member states, representing over 18 million people. CARPHA was launched in 2013 in response to Pan-American Health Organisation (PAHO) assessments of CARICOM's regulatory functions, which were deemed lacking in several areas, including clinical trials, information systems, manufacturing, quality testing, financing and human resources.

The Caribbean Regulatory System (CRS) was set up in 2016 as a centralised unit to provide reviews for medicines and vaccines using regulatory reliance as well as pharmacovigilance support. The CRS' process utilises a reliance mechanism of verification to make recommendations for market authorisation and/or import approval to CARICOM.

### Pathways for market authorisation

One of the first pathways applied by the CRS was the World Health Organisation (WHO) Collaborative Registration Procedure. Since then, reliance has been applied to products assessed by other national authorities in the Americas, as well as other reference authorities including in Europe, Switzerland, UK and Japan (see below).




| Product Review Pathways | Reference Agency / NRAs |
|---|---|
| Medicines | WHO Prequalification / Collaborative Registration<br>Regional NRAs of Reference: COFEPRIS, INVIMA, ANMAT, ANVISA, ISP, CECMED, Health Canada, US FDA<br>EMA/EU, Swissmedic, MHRA, Japan |
| Vaccines | WHO Prequalification / Collab. Registration |
| Biosimiliars / Innovator Biotherapeutics | NRAs recognized by WHO for pilot of Prequalification of Biosimilars; Insulin – ANVISA, Brazil |
| Emergency Use for COVID-19: Vaccines, Test Kits | WHO Emergency Use Listing |
| Emergency Use for COVID-19: Medicines | US FDA, Health Canada,<br>MHRA, EMA, Japan, Swissmedic, WHO Prequalification |



In total, over 267 products have been recommended by CRS up until June 2022, including 34 WHO-prequalified medicines and 10 COVID-19 vaccines. In addition, CRS has reviewed 370 post-approval changes / variations. Uptake of CRS recommendations varies across the region, but is growing in several countries, including in Belize, Jamaica, The Bahamas, Saint Lucia, Grenada, Barbados and Guyana. CARPHA-CRS has standardised templates and provides guidance to sponsors and applicants. Reliance-type processes are relatively new in the region, so pre-submission meetings with sponsors or applicants are useful, in particular, to explain why certain additional information is needed. Verification reviews are important to check key aspects of submissions, such as indications, formulation, product information, manufacturing, and stability or shelf life.

**Challenges and solutions**

Key challenges for CRS include differences in regulatory frameworks between countries, low quality submissions and variations in uptake by member states. Integration of the CRS' recommendations at the national level is limited by current legislative frameworks, each country's individual capacity to integrate reliance mechanisms, and differences in requirements, approvals processes and procedures.

The voluntary nature of the process means that CARPHA does not have control over country-level registration, but continues to collaborate with Member States. For example, for vaccines, webinars have been hosted outlining the verification steps and helping to develop capacity.

CARPHA is working on a joint review framework, as well as agreements with other reference authorities, in collaboration with PAHO, to facilitate sharing of confidential information. There is a need to continue educating sponsors and importers, helping them to put together improved dossiers and applications.

**Summary**

The CRS is a centralised unit within CARPHA that reviews medicines using reliance and verification procedures, and issues recommendations for marketing authorisations to CARICOM member states. As of June 2022, 267 products have been recommended by CRS, including 34 WHO-prequalified medicines and 10 COVID-19 vaccines. Key challenges for CRS include managing differences in regulatory frameworks, varying quality submissions, and variation in uptake across member states. CRS plan to continue building capacity in the region, develop a joint review process, and strengthen liaisons with regional regulators.

## Caribbean Public Health Agency – Enabling the registration of safe, effective and quality medicine

## Company perspective: Does this enable efficient and effective roll-out to the region?

**Dr Max Wegner,** Senior Vice President, Head of Regulatory Affairs, Bayer, Germany

**Regulatory collaboration and reliance frameworks: drivers and benefits**

With rapidly evolving regulatory science, and globalisation of markets and supply chains, capacity to perform all required regulatory activities can be limited at the national level. There has never been more of a need for collaborative approaches, which deliver a 'win-win' to all stakeholders.

For patients, regulatory collaboration and reliance frameworks enable timely access to high quality, safe, and innovative medicines and technologies. For regulators, collaboration establishes trust, facilitates efficient use of limited resources, allows optimisation of regulatory frameworks, and ultimately, improves efficiency and speed of market registration. Benefits to industry include streamlined management of regulatory submissions and global supply chains, predictable and timely decision making, and efficient roll-out of global submissions.

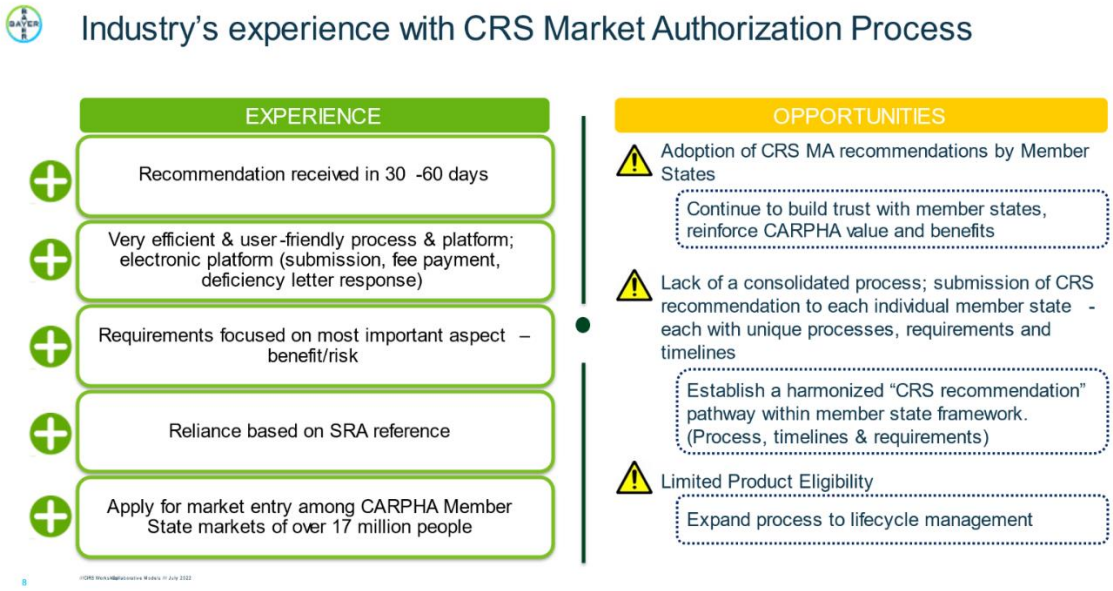
There are many forms of regulatory collaboration, all enabling greater convergence, trust and reliance, but there is no one-size-fits-all model. These mechanisms span from work-sharing programmes to regional reliance models through to mutual recognition.

**An example of regulatory collaboration: Caribbean Public Health Agency (CARPHA)**

CARPHA was established in 2011, began operating in 2013, and now services 26 member states in the Caribbean region. The Caribbean Regulatory System (CRS) is a unit of CARPHA, responsible for marketing authorisations and pharmacovigilance. The CRS marketing authorisation process utilises a reliance mechanism of verification. CRS performs a verification review, then makes recommendations to member states for market authorisation and import. To meet eligibility criteria, a product must be an essential medicine, vaccine, or biotherapeutic product listed on the World Health Organisation (WHO) Essential Medicines List or PAHO Strategic Fund; or be WHO-prequalified; or assessed by a reference authority.

**Industry's experience with the CRS market authorisation process**

While limited, Bayer's experience with the CRS process has been positive (see below). CRS recommendations are received within 30 to 60 days, due to an efficient and user-friendly platform. Utilisation of the reliance approach is based on Stringent Reference Authority reference, leading to quick receipt of a positive recommendation.




However, challenges have been encountered in terms of adoption of the CRS recommendation by member states. There is a lack of consolidation, with submission of CRS recommendations required to individual member states, each with unique processes, requirements and timelines. There is a continued need to build trust with member states, to reinforce the value and benefit of the CARPHA. Additionally, product eligibility is currently limited.

A harmonised CRS recommendation pathway for adoption within member states would significantly improve the roll-out of products offered by pharmaceutical companies in the Caribbean region. Another potential opportunity would be to extend the process to life cycle management, as the benefit of the process is currently limited by the scope of product eligibility.

**Summary**

Regulatory collaboration and reliance are the future of a robust and efficient regulatory framework, with trust as the foundation. Many forms of regulatory collaboration and reliance exist, but there is no one-size-fits-all model. CARPHA is a prime example of regulatory collaboration and reliance through the CRS process. While limited, our experience of the CRS process was generally positive, although there are some opportunities to optimise the process, including consolidation of recommendation pathways within member states and expansion of scope. If further optimised, the CRS process could enable efficient and effective roll-out to the Caribbean.

## Session 3: Focus on Africa – Optimising performance through regional model – How are these operating and are they fit for purpose?

### African Medicines Agency – how is this developing and how will the regional models already established fit into delivering a continental approach to medicines registration?

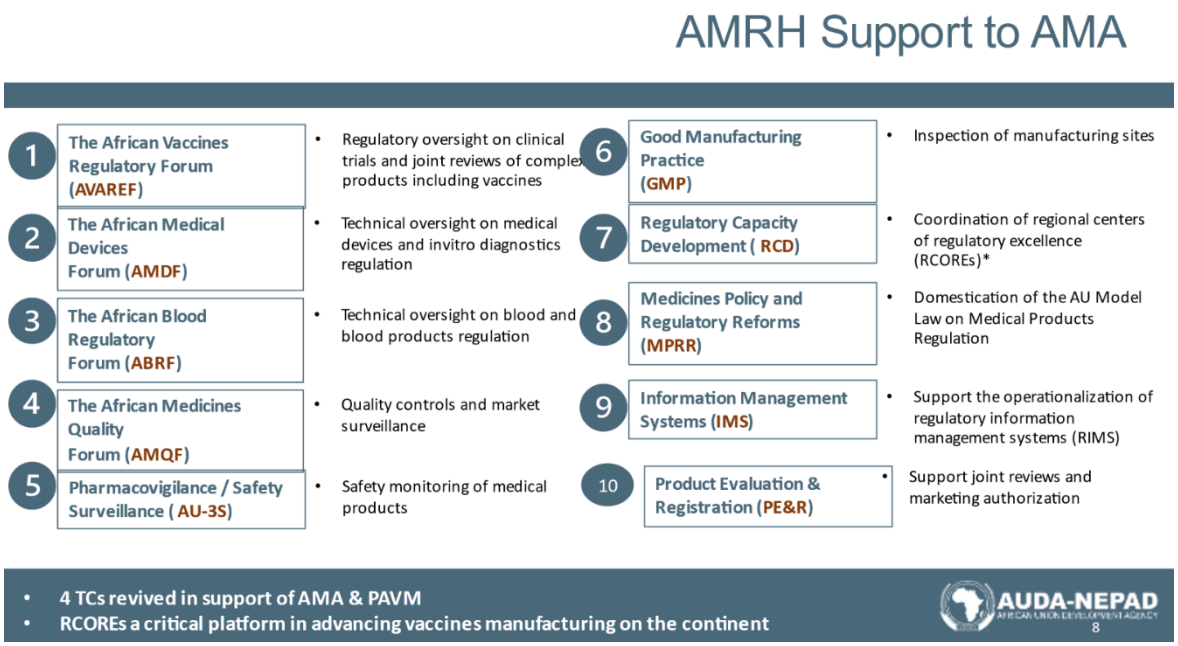
**Margareth Ndomondo-Sigonda,** Co-ordinator of Health Programmes, African Union Development Agency New Partnership for Africa's Development (AUDA-NEPAD)

#### African Medicines Agency (AMA) ratification process

To date, 22 of 55 African Union (AU) member states have ratified the AMA Treaty and deposited the instrument of ratification at the African Union Commission, while 28 member states have signed the AMA Treaty. The first conference of parties to the AMA Treaty was held in June 2022 to outline its governance framework, with Ghana elected as chair. A governing board will soon be nominated, made up of five agency heads representing various regions on the continent, and a director general will be recruited. Once these are in place, AMA will be fully operational. The intention is to ensure that all 55 AU member states eventually ratify the Treaty.

#### AMRH role in supporting AMA operations

AUDA-NEPAD has been responsible for coordination of the African Medicines Regulatory Harmonisation (AMRH) initiative for more than a decade. AMRH plays several roles in supporting operationalisation of AMA, including strengthening technical committees in specialised areas (i.e., clinical trial oversight, medical devices and *in vitro* diagnostics regulation, blood and blood product registration, amongst others; see below), supporting participation of countries not yet party to the AMA Treaty, and advocating for ratification.




Successful operationalisation of AMA requires a strong foundation at the national level. AMRH is working to ensure a link between the national, regional, and continental entities, by strengthening existing regional harmonisation initiatives. AMRH is also working on domestication of the AU Model Law on medical product regulation. This is an important tool for countries to ensure they align with

regional and continental activities. Moreover, AMRH is strengthening the research- and capacity-building efforts undertaken by regional centres of regulatory excellence.

AMRH is also encouraging adoption of technical guidance documents and approval processes. It is supporting the Partnership for African Vaccine Manufacturing, as well as other initiatives aimed at improving access to high-quality, safe and effective medicines and health technologies. Finally, AMRH is working towards strengthening existing regulatory infrastructures, in terms of IT systems, information- and knowledge-sharing among regulators and regions, and eventually, the continent.

**Role of heads of national regulatory authorities**

The African Medicines Regulators Conference (AMRC) Assembly of the AMRH was held in June 2022, bringing together 55 heads of national regulatory authorities to discuss the white paper on 'regulatory ecosystems in Africa during the AMA era'.

The following actions were agreed by the agency heads:

- Allocate and release staff to participate as experts in regional and continental activities of technical committees
- Put in place processes and systems to facilitate timely uptake of recommendations from their regional economic communities, technical committees, and from the AMA, to inform their own formal national regulatory decision-making processes
- Update national policies and laws to allow for recognition of reliance on AMA and regional economic community technical standards and products recommendations, as per the AU Model Law on medical products regulation
- Create a strengthened network of reliance through AMRC learning from EU experience, to build a strong AMA
- Have a unified continental voice and communicate information widely, such as harmonised policies and strategies to inform international stakeholders on the agenda and direction of the African continent, with regards to regulatory systems strengthening
- Identify and address in-country barriers/challenges to ratification of the AMA Treaty and intensify advocacy efforts.

**Summary**

The AMA Treaty has been ratified by 22/55 member states and signed by 28/55 member states. The AMRH initiative provides technical support to operationalise AMA, support for countries not yet party to the AMA Treaty, and advocates for ratification. Successful operationalisation of AMA will require a strong foundation at the national and regional levels. Collaboration, partnership and coordination amongst all key stakeholders is essential for supporting AMA.

## Current regional initiatives, how are these developing to meet both regional and individual country needs?

## Regional Initiative 1: ZaZiBoNa – Regulatory authorities' evaluation of the successes and challenges

**Tariro Makamure-Sithole,** Projects and Public Relations Manager, Medicines Control Authority of Zimbabwe

### Background

ZaZiBoNa is a collaborative medicines registration initiative, which falls under the Southern African Development Community (SADC) Medicines Registration Harmonisation (MRH) project. ZaZiBoNa was founded in 2013 by four countries: Zambia, Zimbabwe, Botswana, and Namibia (from which its name is derived), with the support of World Health Organisation (WHO) prequalification and the Southern African Regional Program on Access to Medicines (SARPAM). At the time, these countries faced common challenges, including poor retention of human resources and inadequate capacity to assess certain types of products or applications, resulting in registration backlogs and long timelines.

Today, ZaZiBoNa has grown to all 16 SADC countries, participating either as active members, non-active members, or observers. As of March 2022, 340 products have been assessed under the initiative with an overall median time to recommendation of 12 months, which is shorter than the timelines being achieved by the individual participating countries.

The objectives of ZaZiBoNa, which are also its success criteria, are to reduce regulatory workload and improve approval timelines; develop mutual trust and confidence in regulatory collaboration; test the mechanism of cooperation among regulatory authorities; provide a platform for training and capacity building; and facilitate harmonisation of regulatory requirements.

### Benefits and challenges of the ZaZiBoNa initiative

A recent study identified views of participating regulatory authorities on the benefits and challenges of the ZaZiBoNa initiative as well as opportunities for improvement [1]. Study participants were active member countries (namely, Botswana, Congo, Malawi, Mozambique, Namibia, South Africa, Tanzania, Zambia, and Zimbabwe). The Process Effectiveness & Efficiency Rating questionnaire was used to conduct the study.

*Strengths and benefits*

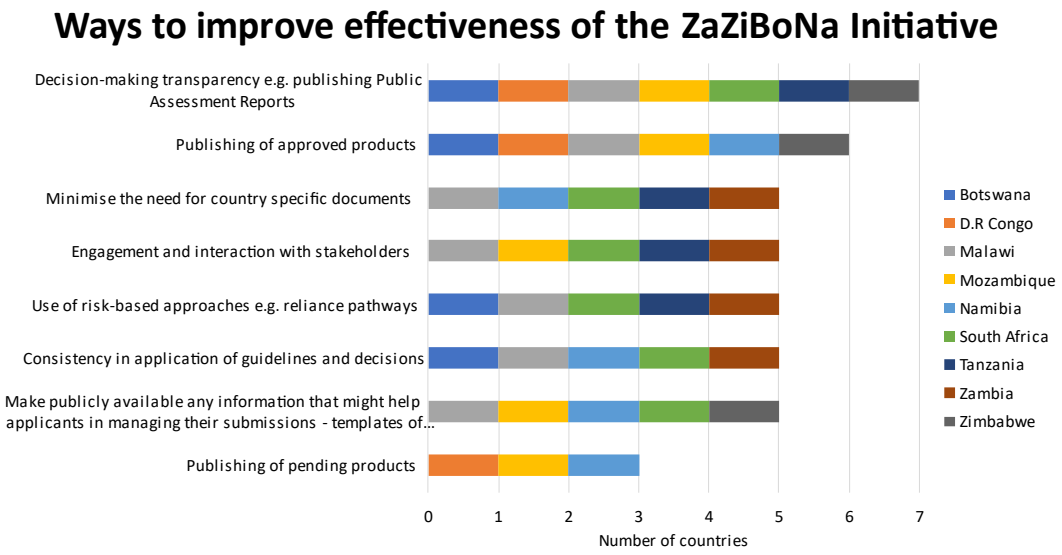
Study participants highlighted capacity building for assessments and information sharing among regulators as key benefits of the ZaZiBoNa initiative. At a country level, strengths were believed to be availability of information on the submission process and timelines on participant country websites, priority review of ZaZiBoNa products, regular committee meetings enabling timely finalisation of products after recommendation and the separate register and tracking of ZaZiBoNa products.

*Challenges*

When asked about challenges of the initiative, study participants felt that lack of centralised submission and tracking was a key issue, closely followed by dependence on each individual country's processes for communication with applicants and expert committees. At a country level, top challenges included inadequate human resources, as well as failure by manufacturers to adhere to deadlines for responses. Differing labelling requirements in participating countries was highlighted as a key challenge for applicants. A SADC labelling guideline is currently under development, which should help to address this challenge.

*Improving effectiveness and efficiency*

To improve effectiveness of the initiative, study participants felt that the highest priorities should be transparency in decision making e.g., by publishing Public Assessment Reports, and publishing approved products on the ZaZiBoNa and country websites (shown below). Top ways to improve efficiency were felt to be improved central tracking of products, as well as a centralised system for submission and communication with applicants.




### Addressing the challenges

Based on this study, the following recommendations have been made to improve the efficiency and effectiveness of the ZaZiBoNa initiative:

- Measuring, monitoring and publication of regulatory timelines should include the time taken in individual countries to finalise products after a recommendation has been made
- Training and capacity-building activities should be separated from assessment activities
- Information for applicants should be available on every participating country's website
- Transparency should be improved by making scientific summaries for approved products available on the ZaZiBoNa and country websites
- An SADC regional medicines agency should be established; in the short term, a regional administrative body to centrally coordinate applications and communication with applicants should be piloted.

### Summary

ZaZiBoNa is a work-sharing initiative in the SADC region, which has successfully assessed over 300 applications. A recent study identified strengths and weaknesses of the initiative. Although several strengths were identified, lack of centralised submission and tracking, dependence on individual country's processes and limited resources were identified as major challenges.

There is a need to review ZaZiBoNa's current operating model to ascertain if it is still fit for purpose, as the promise of shorter approval timelines and simultaneous access to various markets is not always being met. Recommendations for improvement include capacity building, increasing transparency and establishment of a SADC regional medicines agency.

### References

[1] Sithole T, Mahlangu G, Walker S and Salek S (2022) Regulatory Authority Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. Frontiers in Medicine. 9:898743. doi: 10.3389/fmed.2022.898743.

## Current regional initiatives, how are these developing to meet both regional and individual country needs?

## Regional Initiative 2: East African Community Medicines Regulatory Harmonisation initiative – Utilising metrics to measure and improve performance

**Nancy Ngum,** Public Health Officer, African Union Development Agency (AUDA-NEPAD)

**Background**

The aim of the African Medicines Regulatory Harmonisation (AMRH) is to improve access to medical products and technologies in Africa through harmonisation of medicines regulation. It is being implemented in five regions of Africa, namely, the East African Community (EAC), Southern Africa Development Community (SADC), Intergovernmental Authority on Development (IGAD) in Eastern Africa, Economic Community of Central African States (ECCAS) and Economic Community of West African States (ECOWAS). To operationalise this initiative, medicines regulatory harmonisation (MRH) projects were established in each of these regions. The EAC-MRH was the first to be launched (in 2012).

A study was conducted among the seven national medicines regulatory agencies in the EAC to determine their views on the effectiveness and efficiency of the EAC-MRH initiative [1]. One of the recommendations from this study was to conduct a similar study with applicants, the results of which are outlined below.

**Applicants' perspectives of the EAC-MRH**

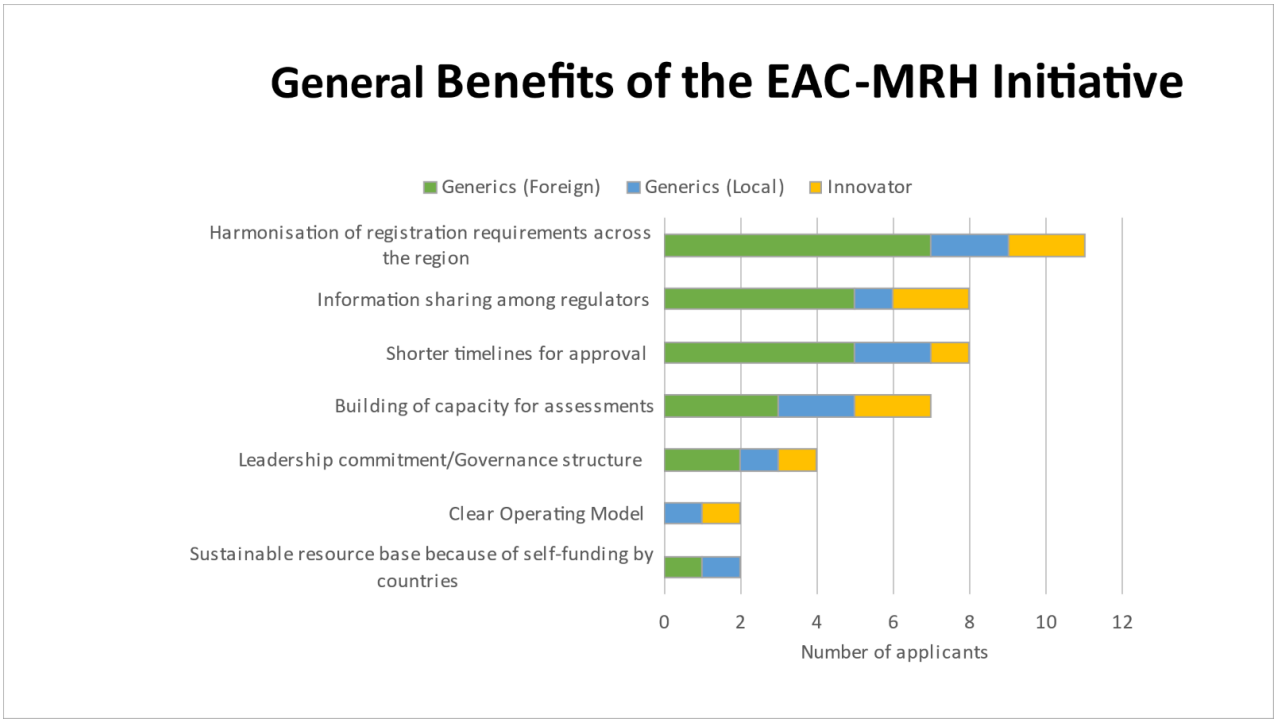
The aim of this study was to evaluate the effectiveness and efficiency of the EAC-MRH initiative from the applicants' perspective, identifying strengths and weakness, challenges and possible opportunities for improvement, as well as determining strategies for moving forwards. Of the 25 eligible applicants, there were 14 responses. The Process Effectiveness and Efficiency Rating questionnaire was used to conduct the study.

*Benefits*

Study participants identified harmonisation of registration requirements across the region, improved information sharing among regulators, shorter timelines for approval and capacity building for assessments as the top four benefits of the EAC-MRH (see below).

In terms of specific benefits to applicants, the initiative was seen to reduce burden, including time and resources, as applicants only compile one submission and receive the same list of questions from multiple countries. Simultaneous access to various markets and shorter timelines for approval compared to that of individual countries were also identified as benefits to applicants.

In terms of benefits to patients, the initiative was seen to accelerate access to quality-assured medicines and increase availability of medicines. However, reduced prices of medicines was not believed to be an outcome for patients yet.




*Challenges*

Study participants highlighted a lack of ability to mandate central registration, along with a lack of detailed information on the process for applicants, as key challenges of the EAC-MRH. Other challenges faced by national regulatory agencies that were identified included lack of structured mechanisms for execution of joint assessment procedures and differing application requirements in some countries, for example, labelling requirements.

*Improving effectiveness and efficiency*

Several ways to improve the effectiveness and efficiency of the EAC-MRH were identified in the study. Most study participants indicated that improving effectiveness would entail minimising requirements for country-specific documents. To improve efficiency, most participants felt that compliance with target timelines by measuring and monitoring each milestone in the review process was key.

**Addressing the challenges**

Based on this study, the following recommendations have been made:

- The EAC-MRH Secretariat should closely track national marketing authorisations, and good manufacturing practice assessments after a positive joint assessment, to ensure that each country implements registration within an appropriate timeframe
- Financial incentives should be given to follow the joint evaluation pathways, with the fees per country being lower for joint assessments compared with those of single-country assessments
- There is a need for engagement with industry and a clear registration procedure for the EAC process
- Clear guidance should be implemented based on established harmonised regulations and procedures across the whole region, and adhered to at the national level
- Stronger mutual recognition is needed between member states.
- Establishment of the EAC regional medicines agency would be the best strategy for improved performance.

**Summary**

A recent study determined the effectiveness and efficiency of the EAC-MRH work-sharing initiative based on views of 14 applicants. Perceived benefits included the harmonisation of registration requirements across the region, improved information sharing among regulators and shorter timelines for approval. Key challenges were the lack of ability to mandate central registration and lack of detailed information on the process for applicants. Recommendations for improvement include introducing incentives for joint evaluation pathways, better engagement with industry and establishing an EAC regional medicines agency.

**References**

[1] Ngum N, Mashingia J, Ndomondo-Sigonda M, Walker S and Salek S (2022) Evaluation of the Effectiveness and Efficiency of the East African Community Joint Assessment Procedure by Member Countries: The Way Forward. Front. Pharmacol. 13:891506. doi: 10.33

## Current regional initiatives, how are these developing to meet both regional and individual country needs?

## Regional Initiative 3: Economic Community of West African States (ECOWAS) - What are the key challenges?

**Mercy Owusu-Asante**, Head, Drug Industrial Support Dept, Food and Drugs Authority, Ghana

The West African Medicines Regulatory Harmonisation (WA-MRH) project was launched in July 2017 to improve availability of quality, safe, and effective medicines and vaccines in the Economic Community of West African States (ECOWAS) region. Two years later, a joint assessment procedure for the registration of medicines was developed; seven national medicines regulatory agencies (NMRAs) have participated in joint assessments. The outcome of joint assessments is taken as a basis for regulatory decisions in all 15 NMRAs in the ECOWAS region.

**Joint assessment: benefits and challenges**

A study was conducted in November 2021 to identify ways to enhance the effectiveness and efficiency of the WA-MRH joint assessment by obtaining the views of participating NMRAs. Of the seven countries who are active participants, five responses were received (Sierra Leone, Burkina Faso, Cote d'Ivoire, Nigeria, and Ghana). The study questionnaire aimed to identify benefits and challenges, as well as identify ways of improving the performance of the work-sharing programme, and future strategies for the WA-MRH initiative.

Study participants identified several key benefits of the WA-MRH initiative, including a clear operating model, shorter approval timelines, enhanced information sharing amongst regulators and harmonisation of registration across the region. In addition, participants felt that the initiative enabled high standards of assessment to be applied, regardless of country size or maturity of the regulatory agency.

Participants were also asked about challenges facing the WA-MRH initiative; a summary of these is provided over the page.

### Key Challenges - Summary

| Section | Top three Challenges |
|---|---|
| The WA-MRH Initiative | 1. Low or decreasing number of applications for assessment<br>2. Unequal workload among Partner States<br>3. Lack of centralised submission and tracking system |
| Assessing WA-MRH products | 1. Inadequate human resources<br>2. Lack of priority review for WA-MRH products<br>3. Unpredictable schedule of Committee meetings |
| Submission of applications by manufacturers | 1. WA-MRH process being more stringent than some country processes<br>2. Differing labelling requirements in participating countries<br>3. Lack of information on country and WA-MRH websites about the process, milestones, timelines, pending and approved products |

The following were identified by study participants as potential ways to improve effectiveness and efficiency of the WA-MRH initiative:

- Ensure the decision-making process is transparent by publishing public assessment reports
- Make publicly available any information that may help applicants manage their submissions
- Ensure consistency in applying guidelines
- Publish a list of approved products
- Minimise the need for country-specific documents
- Ensure specific and clear requirements are easily available to applicants
- Employ robust IT systems
- Improve central tracking of WA-MRH products

**Addressing the challenges**

The study identified two key strategies to help move the WA-MRH initiative forward. A regional administrative body should be established, which can centrally receive and track applications, and have responsibility for allocating work. This body should apportion application fees to countries and communicate with applicants. An alternative is to continue with the current WA-MRH operating model, but with provision of full information on the process, including timelines and milestones. A list of approved products should also be available on every participating country's website and on the WA-MRH website.

**Summary**

The WA-MRH project developed a joint assessment procedure for registration of medicines within the ECOWAS region. Key challenges for joint assessment include a lack of detailed information on the process, unequal workloads amongst partner states, lack of centralised submission and tracking, and failure by manufacturers to adhere to deadlines for response to questions. To move forward with the initiative, transparency of the current operating model must be improved and establishment of a regional administrative body should be considered.

# Session 3: Panel discussions

## How does the Africa regional model fit into an agency toolkit from a country perspective? Are these fit for purpose and what advantages do Heads of Agencies see for their patients?

### West Africa

**Prof Christianah Mojisola Adeyeye,** Head, Nigeria National Agency for Food & Drug Administration

- Incorporating regional approval with national regulatory processes has several benefits, such as enhancing regulatory collaboration and harmonisation, capacity building, and globalisation of pharmaceutical production. There is room for efficient use of resources through work-sharing
- Critical issues need to be addressed for efficient and effective regional activities, including poor legislation and governance structures, inefficient communication and knowledge gaps in conducting regulatory activities
- Individual national regulatory agencies must be strengthened enough to be able to collaborate, and effectively contribute to the regional initiative.

### East Africa

**Yonah Hebron,** Tanzania Medicines & Medical Devices Authority

- Key benefits of regional models are pooling resources to address common problems and sharing of technical knowledge. For patients, benefits include improved access to medicines resulting from accelerated market access, with reduction in approval timelines by about 60% for some essential medicines
- There are challenges with disparity between countries, delays in implementation resolutions and the lack of a body to compel member states to implement agreed resolutions.
- Regional models should evolve by focusing on common and complex agendas and issues
- In relation to the African Medicines Agency (AMA), regional initiatives act as a platform to elevate common regional issues and uplift capacity within their region.

### Company perspective

**Nevena Miletic,** Regulatory Policy Lead, F.Hoffmann-La Roche, Switzerland

- With the evolution of the African regulatory ecosystem, there are a wealth of opportunities for filings, but it is challenging for companies to choose the optimal route. An offered pathway must have a distinct advantage for companies to use it

- Key learnings from using national vs regional procedures relate to harmonisation of requirements, clear guidance and adherence, resource stability, scope, transparency, administrative burden and digitalisation
- For AMA to be successful, there must be clear distinction of scopes, roles and responsibilities among national, regional and continental authorities, as well as defined ways of working.

# Session 4: Future perspectives – How should collaborative models evolve and how should they fit into the regulatory toolkit?

## Key stakeholders' future perspective on the benefits and weaknesses of regional models and how these should evolve

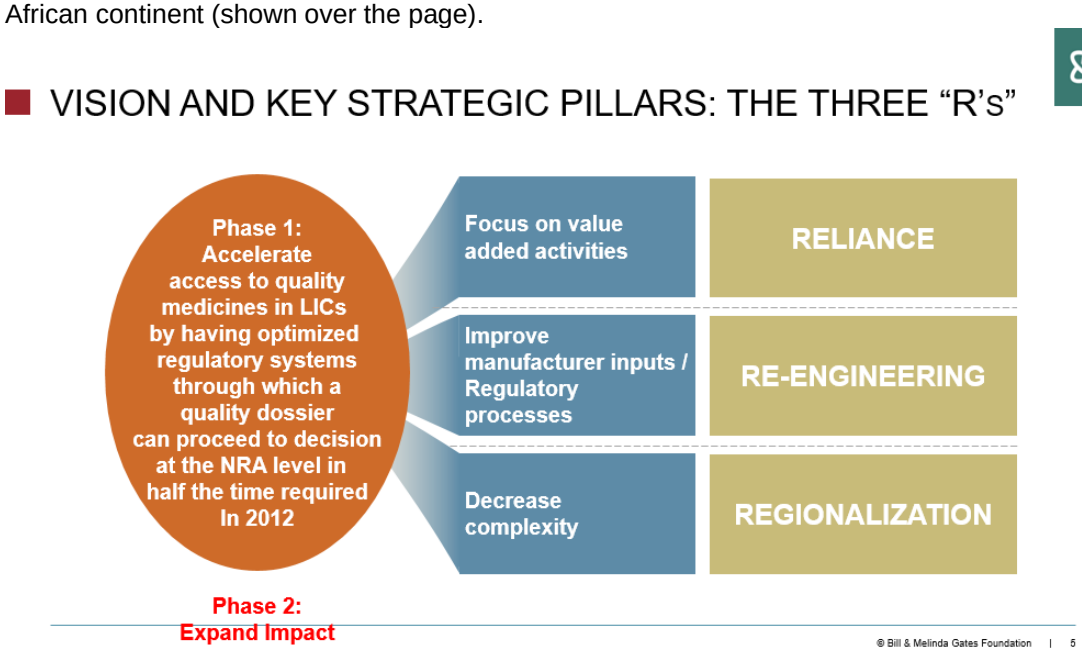
### Funder viewpoint

**Dr David Mukanga,** Senior Program Officer Regulatory Affairs, Africa Systems, Bill and Melinda Gates Foundation

**Why did the Bill and Melinda Gates Foundation invest in regional regulatory platforms in Africa?**

If a product is available for a life-threatening disease, especially with accelerated access, millions of lives can be saved, but the opposite is true if market entry is delayed. Lives are lost and suffering is imposed on patients and their families. At the Foundation, we have the mantra that all lives have equal value. Lives in country A compared to country B are the same, but access could be delayed by years between those two countries, and this has real public health impact (called the 'drug lag').

With this in mind, the Foundation put together a vision and strategy hinged on three Rs, to optimise processes to accelerate access to quality medicines in low- and middle-income countries on the African continent (shown over the page).




**What have these regional platforms delivered?**

There are now harmonised regulatory requirements, processes and standard operating procedures across several regional economic communities in Africa. Joint assessments for over 500 products have been carried out through these harmonisation initiatives, as well as joint inspections of manufacturing sites.

Capacity and trust building with regulatory staff have been important, including training and 'learning-by-doing'. Ensuring financial sustainability has also been key, with the Economic Community of West

African States being the first region to align on a regional fee schedule (though there is ongoing discussion as to whether these fees are too high).

**How could these regional platforms improve?**

One area for improvement is transparency and publication of timelines. Regional platforms can improve by demonstrating the impact they have on 'drug lag' i.e., by showing whether products are becoming available, faster than they would have otherwise, and whether coverage across the market is changing.

Another area for improvement is sustainability, which must be optimised by ensuring the right fees for the service are charged, with fees linked to value. This includes both public health value and commercial value to companies.

There is also a need for more efficient translation from regional recommendations to national authorisation, as well as for improved communication to different stakeholders, particularly to industry. Using channels like websites or webinars could help to improve industry's awareness of regional procedures.

**What is the untapped potential of these regional platforms?**

There are several areas of untapped potential for these regional platforms, including linking regional recommended products to regional and national procurement decisions; use of indirect reliance between regional economic communities; use of regional registration databases, particularly by countries without registration systems; embedding regional and continental procedures into 'business as usual' within national agencies; and use of incentives to enable access to products that would otherwise not reach certain markets e.g. priority review with conditionality to market in these countries.
The regions will also be important contributors to the African Medicines Agency (AMA), acting as levers for trust building with national authorities and as platforms for coordinating national authority nominations for AMA assessments. They will also help to drive uptake of AMA decisions/opinions by national authorities.

**Summary**

Regional platforms in Africa have delivered progress in terms of harmonisation of requirements, standardisation of procedures, joint assessment, post-approval changes, capacity strengthening and trust building. Challenges remain relating to transparency of timelines, fee systems, transition of regional recommendations to national authorisations, and limited industry awareness of regional models. Going forward, there are opportunities to link regional recommended products to regional and national procurement decisions, conduct inter-regional reliance, establish regional registration databases and create incentives to enable greater access.

## Key stakeholders' future perspective on the benefits and weaknesses of regional models and how these should evolve

### Procurer's viewpoint

**Robert Matiru,** Director, Programme Division, UNITAID, Switzerland

UNITAID is a development and financing agency, created in 2006 to accelerate access to health innovations, tests, treatments, and preventive medicines associated with HIV, tuberculosis (TB), malaria, and co-infections. UNITAID has since expanded to cover reproductive maternal, newborn and child health and, during the last two years, has supported the COVID response.

UNITAID's model is designed to achieve impact at three critical moments:

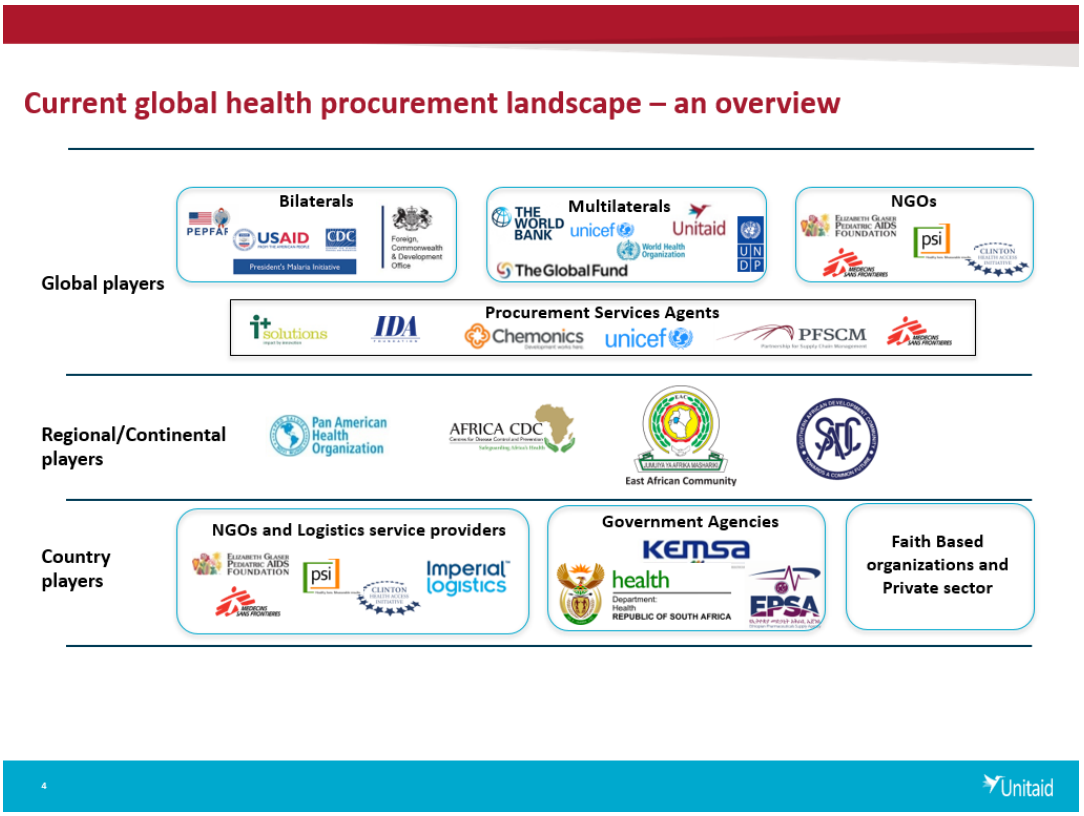
1. Product is available – development and innovation of products in the pipeline, including thinking about sustainable regulatory pathways and approval processes
2. Product is adopted – catalysing equitable access, with critical barriers removed to ensure scalability, including regulation issues (at global, regional and in-country levels)
3. Product is scaled up – to maximise effectiveness of the global health response to major diseases.

**Partnerships with global stakeholders**

UNITAID works closely with major procurers, such as the Intercept Supply Division, the Global Fund, the United States government bilateral programme, and the Pan American Health Organisation (PAHO) Strategic Fund in Latin America. Collaborations between global procurers and entities such as UNITAID position new innovations to enter the market, both in terms of market shaping and quality assurance. For example, UNITAID were involved in joint negotiations to achieve price reductions for rifapentine, a preventive medicine for TB, and has supported therapeutics and diagnostics work undertaken by the World Health Organisation Prequalification programme over the last ten years.

**Current global health procurement landscape**

The image over the page provides an overview of the current global health procurement landscape, covering some of the major players at global, regional and country-specific levels.




**UNITAID'S evolving perspective**

UNITAID supports a differentiated approach to procurement and regulation of key health products and technologies, across national, regional and continental regulators – so that regulators at each level have different focuses (as shown below). There is a subset of essential medicines and diagnostics that national regulators should be supported to regulate using reliance. Then, there are classes of medications and diagnostics that regional regulatory mechanisms are well placed to deal with. Finally, very complex novel health products, such as biologics or complex medical devices, would fall within the continental remit, for example, of the African Medicines Agency or other continental regulatory mechanisms.

## Panel Discussion (Session 4): Future development of global risk-based approaches

Each panellist was asked to provide their thoughts on the following:

- How can we build on current initiatives? Can today's models be expanded to other agencies or provide a basis for other agencies to consider?
- What does the future evolution of the regulatory tool kit look like and what direction should agencies consider: collaborative, work-sharing, regional models or a mixture of fit-for-purpose routes? What frameworks need to be in place?
- Recommend possible research areas for CIRS and other groups to undertake to support /inform/enable future optimisation or expansion of collaborative, work-sharing or regional models.

### WHO perspective

**Marie Valentin,** Technical Officer, World Health Organisation (WHO)

We can build on:

- The WHO Regulatory System Strengthening Programme, including use of the WHO Global Benchmarking Tool, Good Regulatory Practices and Good Reliance Practices
- Lessons learned from the COVID-19 pandemic in relation to collaboration, work-sharing and regulatory agilities
- Improving transparency towards the public, patients and professionals, but also between regulators.

Future evolution of the regulatory toolkit should involve:

- Making best use of global regulatory resources by being collaborative and using reliance; the WHO-listed authorities framework will help to inform regulators where to use and which authority to use as a reference
- Using real-world data/evidence in decision making, modernising electronic records and finding new methods of digital monitoring in clinical trials
- Continuing to listen to the patient voice across the medical product life cycle.

Further guidance and research are needed around:

- Reliance:
    - Verification of product sameness
    - Changing mindsets – what makes the change successful?
    - Focusing on pilot projects and gradual changes
    - Developing a successful model for national regulatory agencies (NRAs) while recognising that there is no 'one-size-fits-all' model.
- Innovation:
    - Early alignment to fit new types of innovation into the current legal and regulatory framework – science always moves faster than legislation
- Product information and transparency:
    - Sharing best practices across NRAs
    - Involving patients
    - Communication of clear and relevant information for safe and efficacious use of medical products.

### Regulatory agency perspective

**Dr Evelyn Soo,** Director, Bureau of Gastroenterology, Infection and Viral Diseases, Health Canada

We can build on:

- Ensuring current practices can quickly adapt to address emerging needs, making use of collaborative, parallel and work-sharing approaches
- Aligning timelines and requirements across jurisdictions to reduce burden
- Understanding infrastructure and coordination requirements, such as document storage and coordination of meetings
- Risk-based prioritisation i.e., based on public health emergencies and unmet medical needs.
- Alignment with HTA agencies to help accelerate patient access
- Improving communication and transparency, including reducing misinformation by ensuring regulators' decisions are well communicated
- Always considering the cost-effective perspective, both for industry and the regulator.

Future evolution of the regulatory toolkit should involve:

- Ensuring regulatory toolkits are fit for purpose and flexible, while balancing earlier access and cost-effectiveness of the process
- Focusing on public health priorities, using models that enable faster and higher-quality decisions when there is an emergency public health need
- Collaboration with industry, especially when there are multiple submissions at once, looking at ways to reduce burden.

Further guidance and research are needed around:

- Assessment of successes and barriers associated with different collaboration models
- Impact of collaboration on regulatory decision making, including speed of decision making balanced with quality of decisions
- Transparency and communication, including public perception of how regulators work together
- Work to dispel misinformation, particularly around vaccines and vaccine hesitancy
- Understanding current infrastructure and what needs to change
- Resource requirements – every regulator has different constraints and priorities
- Change management – enhancing trust, managing organisational culture, and collaborative working.

### Regulatory agency perspective

**Dr Suchart Chongprasert,** Director, Medicines Regulation Division, Thailand Food and Drug Administration

We can build on:

- Encouraging use of WHO guidelines i.e., Good Regulatory Practices, Good Reliance Practices etc.
- Establishing similar infrastructures / regulatory systems to facilitate working together
- Considering how existing models can be used throughout the life cycle of products
- Promoting reliance models to authorities who have never used them
- Practical implementation of reliance e.g., understanding the sameness of product dossiers.

Future evolution of the regulatory toolkit should:

- Include a wide range of models, as there is no one-size-fits-all solution. Agencies must be able to mix and match.

Future guidance and research should:

- Focus on qualitative measures of regulatory processes, including:
  - Quality of collaborative reviews – infrastructure requirements and practical implementation
- Step-by-step advice for authorities wanting to get involved in reliance or collaborative models
- Build trust and confidence.

### Company perspective

**Judith Macdonald**, Senior Director, Global Regulatory Policy Development, Pfizer, UK

We can build on:

- Ensuring there are multiple risk-based options, because one size does not fit all.
- Providing regulators with practical guidance on how to get started.
- Considering the company perspective i.e., by appreciating that company regulatory representatives need to get internal buy-in to use a particular procedure for a particular asset and aiming to design the features of the procedure with this perspective in mind to ensure the reliance process is used by industry.
- Ensuring expansion is thoughtful; not just by adding more countries, but to include more complex products like gene therapy.
- Building trust, which requires improved understanding and an agreed common pathway forward, particularly in terms of unredacted assessment reports and sameness of product.
- Regulatory systems strengthening, including wider sharing of data, which requires stronger, more secure IT platforms.

Future evolution of the regulatory toolkit should involve:

- Next-level collaboration, meaning both work sharing within a submission and regional work sharing across submissions e,g., regional networks could develop that specialise in particular types of products or activities and there could be reliance between these networks.
- Fewer duplicative submissions – submission to agile regional networks.
- Technology to unlock efficiencies:
  - A cloud-based system for sharing information will allow instantaneous data updates.
  - Libraries of previous questions and answers can increase knowledge management and review efficiency.
- Secure data sharing platforms – these need to be more secure than in the past (i.e., cloud-based) to provide greater confidence and trust in sharing data more widely with appropriate controls.
- Maintenance of national-only capabilities for certain activities i.e., national-only generics review, local company inspections, pharmacovigilance. Reliance frees up resources to support essential aspects that need to remain national.

More guidance and research are needed around the following:

- Public assessment reports: which countries produce public assessment reports in English on regulatory decisions? This is an important indicator for transparency and should be increasing as WHO GBT/WLA rolls out.
- Unredacted assessment reports: what are regulators' expectations / interpretations? The term itself is a barrier to developing shared understanding as there are different assessment formats and laws on redactions per country and the term is being applied broadly to any form of regulatory assessment information. We need research to document the range of materials typically included under this term to build mutual trust and a more constructive way forward.
- Features and capabilities of data-sharing platforms. Research on what features and capabilities future state data-sharing platforms should have would be useful.
- Collaborate with WHO to assess the impact of the WHO-listed authorities' system on reliance / work sharing and procurement to baseline prior to introduction and then see whether the introduction of WLA's catalyses a greater use of reliance procedures over time.

### Academic perspective

**Dr James Leong,** Assistant Professor, Head, Health Products & Regulatory Science, CoRE, Singapore

There are currently gaps in:

- Understanding the principles of risk-based approaches
- Infrastructure and capabilities to mitigate risks taken
- Implementation and change management
- Staff-level training and education – how do these affect organisational capacity and capabilities?
- Platforms for industry and regulators to explore regional collaborations and share global best practices.

Regulator training should focus on:

- Technical competency:
    - Regulatory joint decision making (joint assessment and work-sharing)
    - Evaluation using regulatory reliance
    - Ensuring local regulatory capabilities are already in place, including pharmacovigilance and post-market activities.
- Change management:
    - Process review
    - Allocation of manpower
    - Communication (internal and external).

Further research should focus on:

- Defining and achieving consensus on when to choose a risk-based approach
    - i.e., what are the considerations of the local healthcare system and public health needs? What are the operational concerns of the agency and their needs?
- Validating measures of successful implementation of risk-based approaches.

# *Summary of panel discussion: Future development of global risk-based approaches*

## We can build on:

- Lessons from COVID-19
- Transparency and communication
- Using WHO guidance documents
- Understanding and aligning infrastructure requirements
- Considering cost-effectiveness
- Practical guidance and implementation for agencies
- Sameness of product dossier
- Using existing models across the product lifecycle
- Improving IT and data-sharing platforms
- Ensuring there are multiple risk-based options available
- Considering the company perspective
- Building trust and confidence

## Future evolution of regulatory toolkit should involve:

- Ensuring a wide range of models that are flexible and fit-for-purpose
- A focus on public health priorities
- Improving technology capabilities, including data-sharing, IT, electronic records, etc
- Making best use of global regulatory resources, like WHO guidance documents
- Listening to the patient voice
- Collaborating with industry to reduce burden, i.e. fewer duplicative reviews
- Maintaining some national capabilities
- Focus training on technical competency and change management

## Guidance and research required:

- Transparency, communication and dispelling misinformation
- Alignment on how to fit new innovations within existing legislative frameworks
- Assessment of barriers and successes of current models
- Change management / mindset
- Considerations for choosing a risk-based approach
- Qualitative measures of collaborative reviews
- Expectations and interpretations unredacted assessment reports
- Understanding local infrastructure and what needs to change
- Impact of regulatory decision-making – speed vs. quality of decisions
- Validating measures of successful implementation

## Appendix: Workshop attendees

*Affiliations are stated as they were at the time of the meeting 5th and 6th July 2022.*

| | | |
|---|---|---|
| **Dr Alia Seoud Abdalla** | Head of Regulatory Affairs – ELI Cluster | Pfizer. Egypt |
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| **Pei Chen Lin** | Associate Reviewer | Taiwan Food and Drug Administration, Chinese Taipei |
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