Asia Perspectives On Regulatory Reliance, Experiences and Value of Reliance

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17 December 2025

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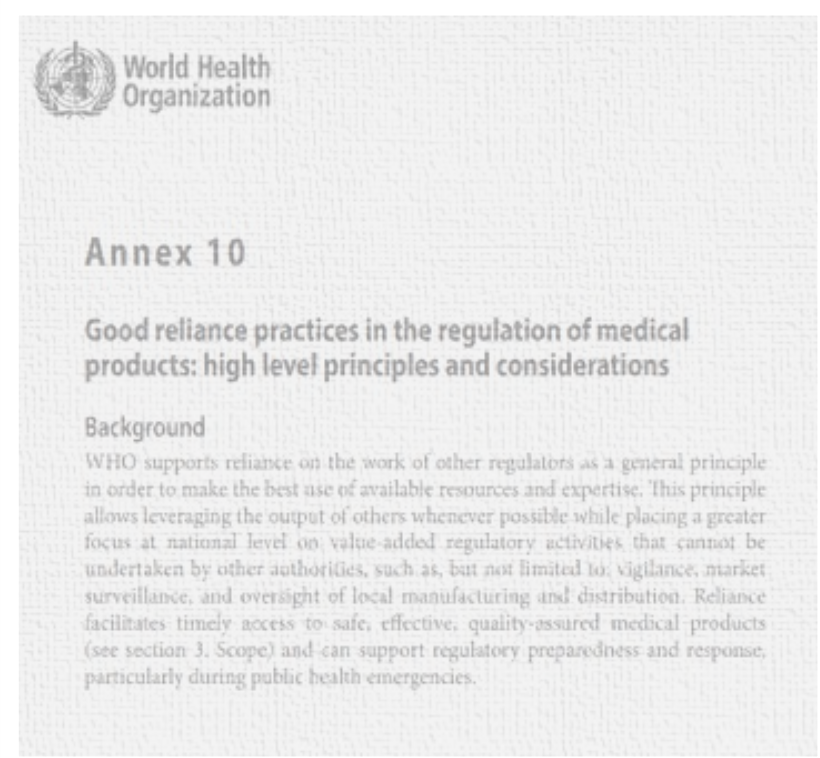
Agenda

- Regulatory Reliance in Asia & ASEAN
- Good Registration Management – Good Submission Practice
- Value of Regulatory Reliance - time and resources

Regulatory Reliance


World Health Organization

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to, vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance facilitates timely access to safe, effective, quality-assured medical products (see section 3, Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

WHO - Good reliance practices in regulatory decision-making for medical products: high-level principles and considerations (Annex 10)

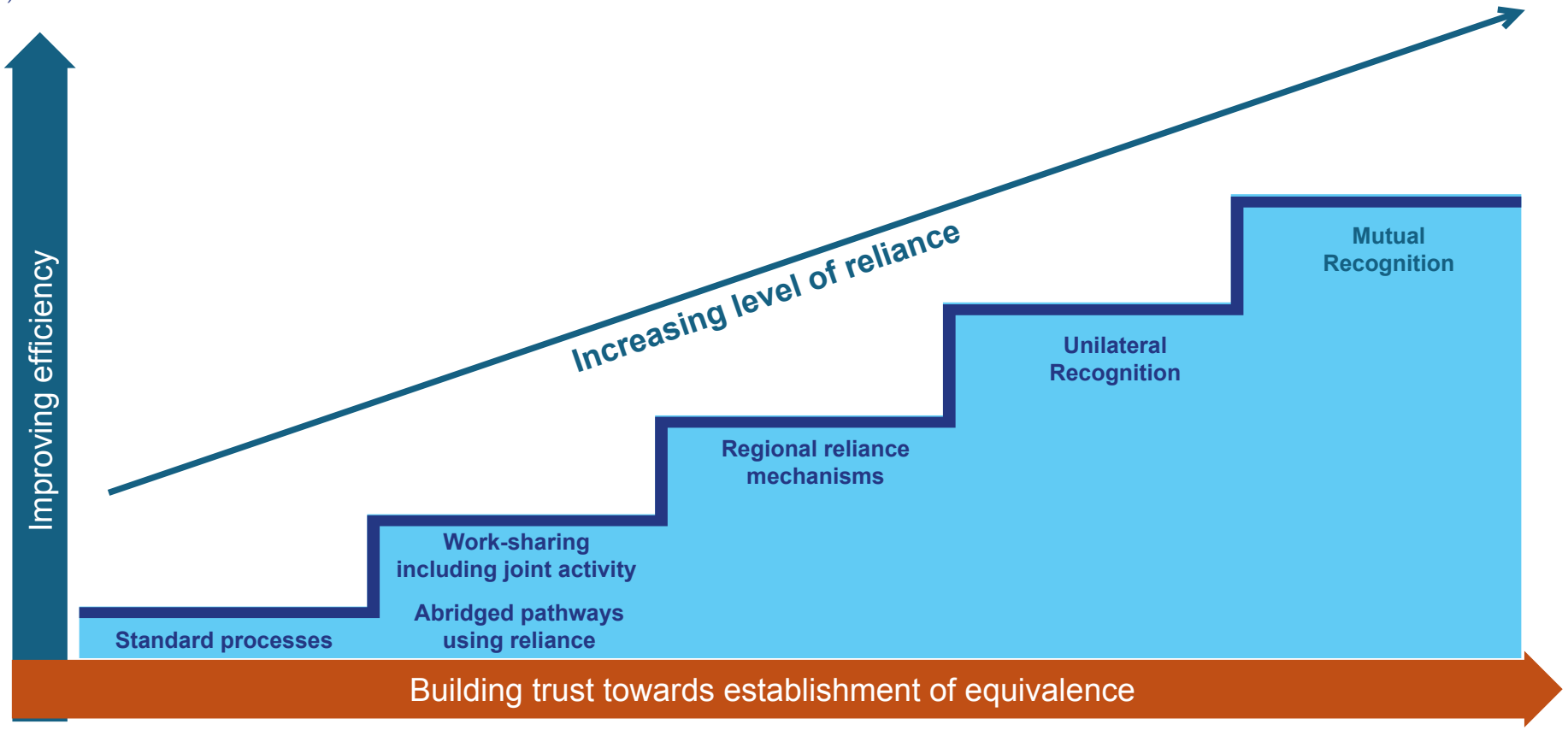
Takes into account and gives significant weight to:

- Assessments **performed by another regulatory authority or trusted institution**
- Any other authoritative information in reaching its own decision

- Relying authority remains independent, responsible and accountable for decisions

Can be limited to a discreet regulatory process or include the entire **LCM of a medical product**

Adapted from: World Health Organization (WHO), 2021. Good reliance practices in the regulation of medical products: high level principles and considerations. TRS 1033 (Annex 10)



Independent decisions
Based on its own reviews and/or inspections

Leveraging regulatory work
Performed by other competent and trusted authorities to reduce the workload, with independent final decision-making

Regional reliance mechanisms
Centralized evaluation conducted for a group of countries

Unilateral or mutual recognition
Based on treaties or equivalent, providing maximal benefits

AP – Regulatory Reliance

Dedicated Regulatory Reliance Pathway

- Australia (2019)
- Indonesia (2019)
- Malaysia (2019)
- Pakistan (2021)
- Philippines (2022)
- Singapore (2004)
- Sri Lanka (2025)
- Taiwan (2011)
- Thailand (2017)
- Vietnam (2025)

ASEAN Reliance Pathways

Country	Std Pathway	Reliance Pathway	Conditions for Reliance Pathway	Reference Agency
Indonesia	300 wd	120 wd	• 1 ref agency • Approval by ref agency <5yr • Assessment Report • Sameness	USFDA, EMA, TGA, HC, UKMHRA, PMDA
Malaysia	210 wd	Abr: 90 wd Ver: 20 wd	• 1 ref agency • Approval by ref agency <3 yr • Assessment Report • Sameness	USFDA, EMA, HC, PMDA, Swissmedic, TGA, UKMHRA, WHO CRP-SRA & PreQ, ASEAN JA
Philippines	180 wd	Abr: 45 wd Ver: 30 wd	Abr: 1 ref agency Ver: 2 ref agency • Approval by ref agency <3yr • Assessment Report • Sameness	USFDA, EMA, HC, TGA, FAMHP, ANSM, BfARM, PEI, AIFA, PMDA, MEB, HSA, Swissmedic, UKMHRA

ASEAN Reliance Pathways

Country	Std Pathway	Reliance Pathway	Conditions for Reliance Pathway	Reference Agency
Singapore	Abr: 180 wd	Ver: 60 wd	• 2 ref agency • Approval by ref agency <3yr • Assessment Report • Sameness	USFDA, EMA, TGA, HC, UKMHRA, Swissmedic
Thailand	NDA: 220 wd Biologic: 160 wd	NDA Abr:154 wd WHO PQ CRP: 90 wd SRA CRP: 90 wd Biologic Abr: 110 wd WHO PQ CRP: 90 wd SRA CRP: 90 wd	• 1 ref agency • Approval by ref agency <3 yr • Assessment Report • Sameness	USFDA, EMA, HC, PMDA, Swissmedic, TGA, UKMHRA, WHO CRP-SRA & PreQ

International Work-sharing & Collaboration

ACCESS Consortium

- Australia
- Singapore

US FDA Project Orbis

- Australia
- Singapore

EMA OPEN Pathway

- Australia,
- Japan
- South Korea

ACCESS Consortium

- The Access Consortium is a coalition of like-minded regulatory authorities that work together to promote greater regulatory collaboration and alignment of regulatory requirements.
- The original consortium, formed in 2007 and known as “ACSS”, comprised the national regulatory authorities of Australia, Canada, Singapore and Switzerland. In October 2020, the UK joined, and the group’s name was changed to “Access”. The UK’s Medicines and Healthcare products Regulatory Agency started participating in work-sharing initiatives with consortium partners from 1 January 2021.

Source: https://accessconsortium.info/

Project Orbis

- The FDA Oncology Center of Excellence (OCE) initiated Project Orbis in May 2019 to provide a framework for concurrent submission and review of oncology products among international partners.

- This initiative aims to facilitate earlier access to cancer treatments for patients by allowing regulatory authorities from different countries to collaborate on the review process.

Source: https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis

Project Orbis

A framework for concurrent submission and review of oncology products

Content current as of:
11/06/2025

Regulated Product(s)
Drugs
Oncology

The FDA Oncology Center of Excellence (OCE) initiated Project Orbis in May 2019 to provide a framework for concurrent submission and review of oncology products among international partners.

Collaboration among international regulators may allow patients with cancer to receive earlier access to products in other countries where there may be significant delays in regulatory submissions, regardless of whether the product has received FDA approval. Pivotal clinical trials in oncology are commonly conducted internationally and these global trials are increasingly important for investigating the safety and effectiveness of cancer drugs for approval in the United States. Future drug development may benefit by establishing a greater uniformity of new global standards of treatment, leading to the optimal design of these important trials.

EMA OPEN Pathway

Several regulators can evaluate a medicine in parallel with EMA, remaining scientifically and procedurally independent from one another while sharing information, expertise and approaches during the evaluation.

The OPEN framework on permanent confidentiality arrangements between EMA and medicine regulators outside the EU, who are known as OPEN partners.

Australia, Japan and South Korea are OPEN partners.

Source from EMA. https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/opening-procedures-ema-non-eu-authorities-open-framework

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ASEAN Joint Assessment

- ASEAN Joint Assessment Procedure: A formal procedure in which the same application is simultaneously submitted to all participating ASEAN. Assessment work is then carried out together by all participating NRAs utilizing reference agency AR and a joint assessment report is prepared. At the end of the process, the final decision on the application is then taken, within established timelines, by each individual NRA through their normal decision-making process based on the joint assessment report and, where applicable, nationally-relevant considerations.
- ASEAN Member States: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

ASEAN Sectoral MRA on BA/BE

- ASEAN Sectoral MRA on BA/BE: A formal procedure to enable the mutual recognition of BE Study Reports of generic medicinal products, issued by Listed BE Centres located in the territory of Member States in order to facilitate the movement of generic medicinal products within ASEAN

- ASEAN Member States: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

ASEAN Sectoral MRA on GMP

- ASEAN Sectoral MRA on GMP: A formal procedure for Good Manufacturing Practice (GMP) inspections of medicinal products signed by ASEAN member states in 2009. Its purpose is to facilitate the movement of medicines in ASEAN by having countries accept each other's GMP inspection reports and certificates, thereby avoiding duplicate inspections

- ASEAN Member States: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam

APAC
Asia Partnership Conference of Pharmaceutical Associations

Chong et al. AAPS Open (2024) 10:14
https://doi.org/10.1186/s41120-024-00102-2

AAPS Open

RESEARCH Open Access

Advancements in regulatory agility, regional collaboration, and digital transformation: insights from the Asia Partnership Conference of Pharmaceutical Associations (APAC)

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Abstract

Purpose The Asia Partnership Conference of Pharmaceutical Associations (APAC) examines recent developments in regulatory practices across Asia, focusing on regulatory agility, regional collaboration, and digital transformation. The paper identifies key improvements made by national regulatory authorities (NRAs) in adopting regulatory agilities over a two-year span. It also suggests optimizing regional reliance pathways and recommends best practices for implementing e-submission, real-world evidence (RWE), decentralized clinical trials (DCTs), and paperless e-labelling.

Methods APAC surveyed all 14 member associations to track progress in regulatory agility implemented by our NRAs from 2022 through April 2024. Additionally, APAC assessed the uptake of regional reliance pathways and the implementation levels of e-submission, RWE, DCTs, and paperless e-labelling. Through the analysis of case studies and survey results, the paper aims to identify key trends, challenges, and opportunities in the regulatory landscape.

Results Nine of twelve NRAs have advanced in regulatory agility, with Thai FDA leading with a 36% improvement and ranking 7th in the number of best practices implemented. e-Labeling adoption rose by 50%, and there was a 17% increase in the use of multiple sites under one license, good reliance practices, and acceptance of electronic Certificates of Pharmaceutical Product (eCPP) and Good Manufacturing Practice (eGMP). Perceived issues with the ASEAN Joint Assessment (JA) procedure include timeline constraints, limited flexibility in choosing participating NRAs, and country-specific requirements. NRAs have achieved 100% adoption of e-submissions and 50% for paperless e-labeling. Additionally, 67% accept data from DCTs and RWE using good reliance practices. However, 42% still require paper documents in e-submissions, and 50% continue to accept dossier format different from the International Council for Harmonisation Electronic Common Technical Document (ICH CTD).

Conclusions APAC supports adopting agility best practices to reduce country-specific requirements, optimizing the ASEAN JA procedure. APAC also values strategic partnerships with NRAs, as demonstrated by the case studies of Vietnam and India. The shift towards digital transformation is evident, with 50% adoption of paperless e-labeling and 100% adoption of e-submissions, though not all processes are paperless with the use of ICH CTD dossier format.

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- APAC 2nd Paper published online via AAPS Open on Dec 17, 2024
- Survey to 12 APAC member associations between December 2021 and April 2024

Reference and link to article: https://aapsopen.springeropen.com/articles/10.1186/s41120-024-00102-2

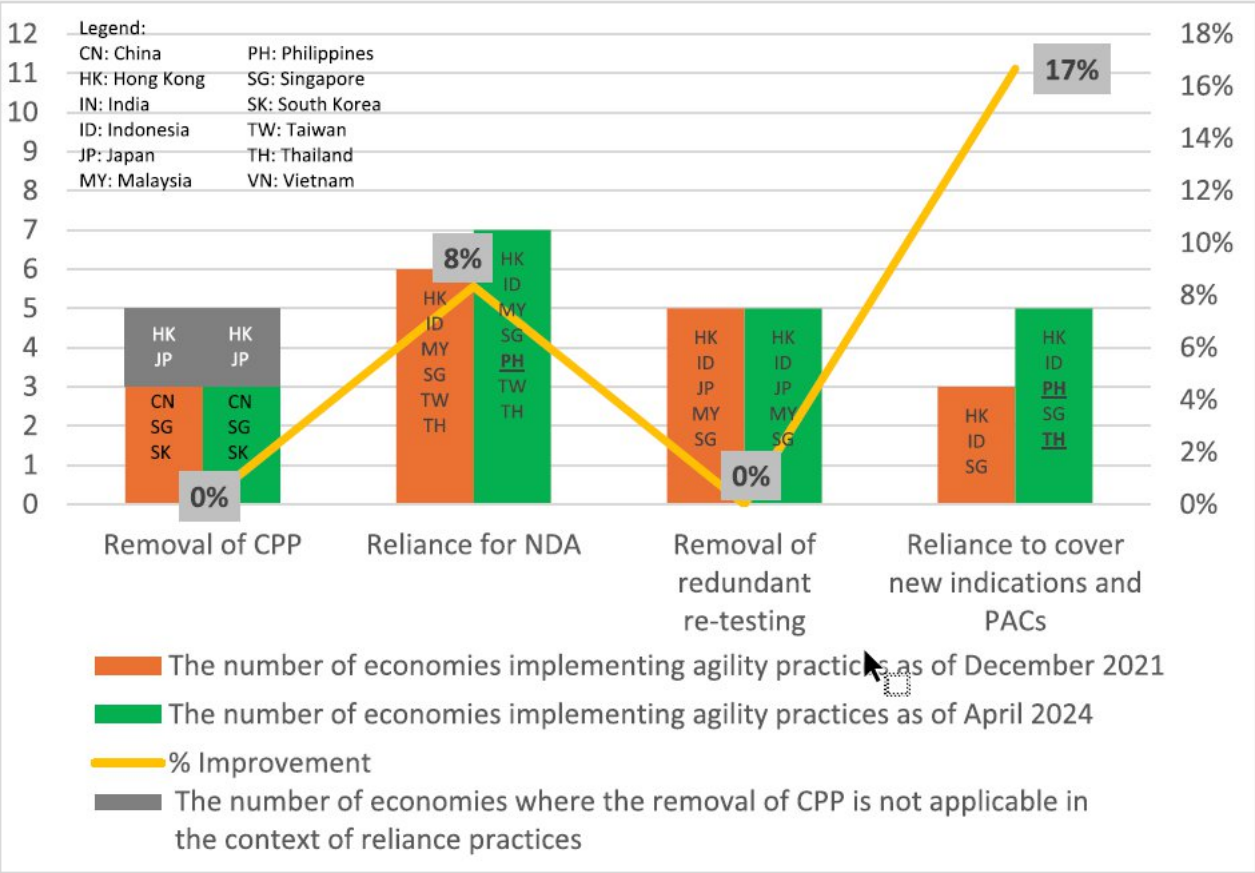


Fig. 1a Adoption of good reliance practices improved by 17% for new indications and PACs, and by 8% for NDAs

Source: https://aapsopen.springeropen.com/articles/10.1186/s41120-024-00102-2

An increased number of reliance pathways for New Drug Applications (NDAs), new indications and Post-Approval Changes (PACs)

ASEAN JA Challenges & Opportunities

Asia Partnership Conference of Pharmaceutical Associations

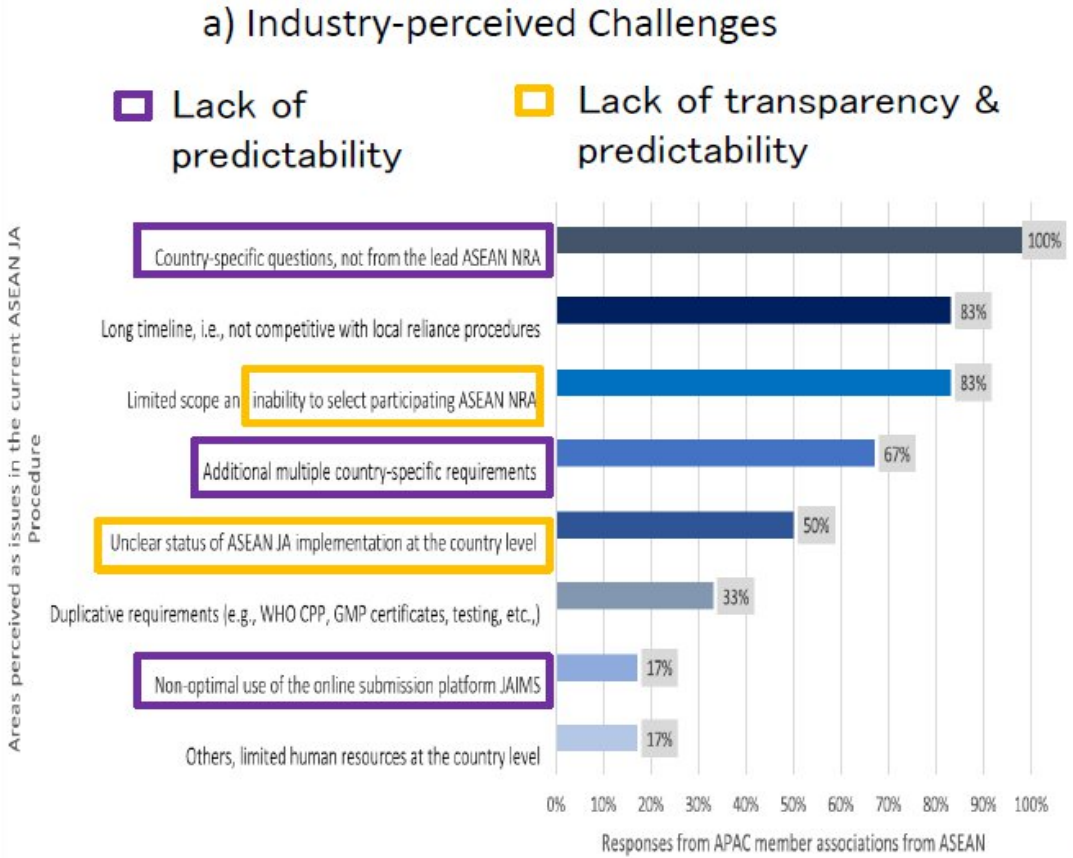


Figure 3: More than 80% of APAC member associations from ASEAN perceived country specific-requirements, timelines, scope and lack of flexibility to select participating NRAS as major challenges

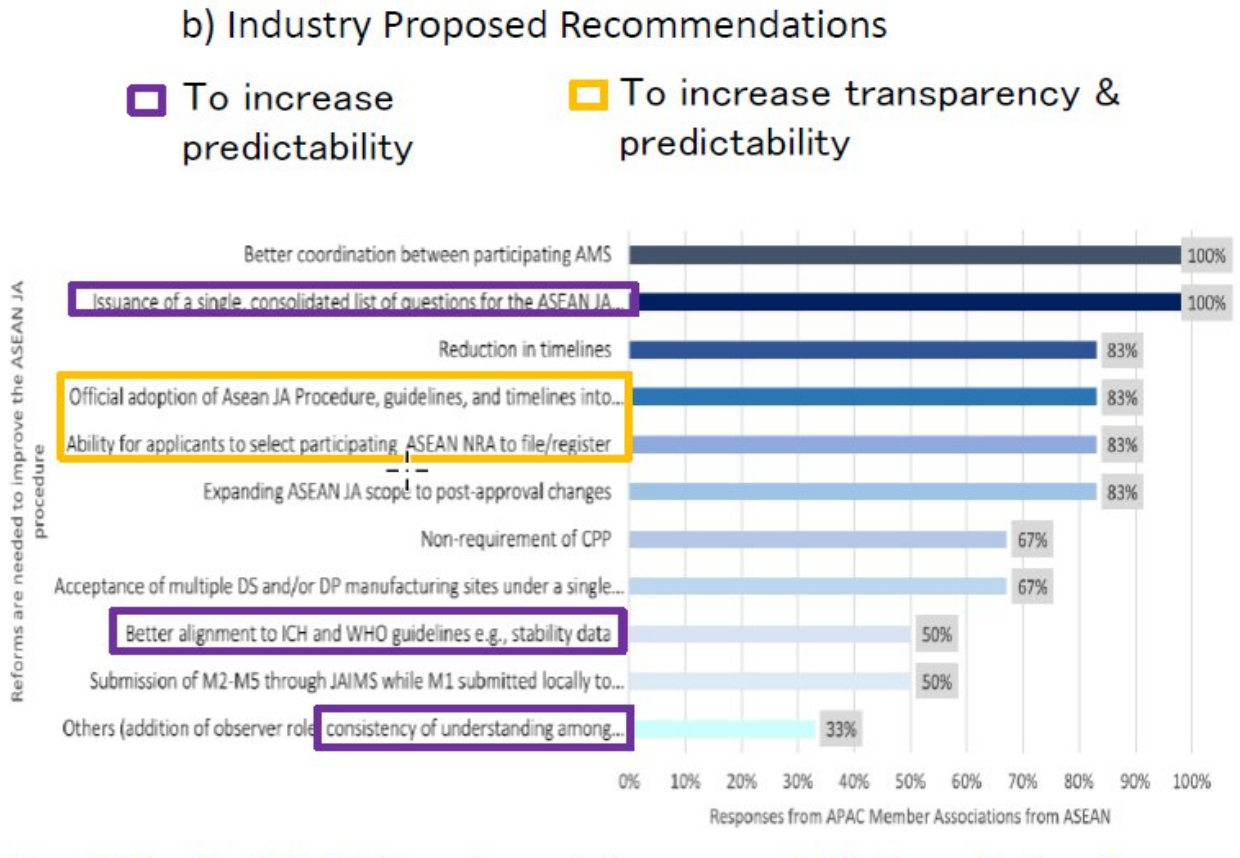


Figure 4: More than 80% of APAC member associations recommended better coordination with issuance of a single list of questions, reduction in timelines, national adoption, PAC, flexibility to select participating NRAs, CPP removal, and multiple sites in a license as top reforms to improve the current ASEAN JA procedures

Source: Predictability and Transparency to facilitate Reliance Schemes: APAC Insights; https://apac-asia.com/images/achievements/pdf/14th/06_Presentation%20from%20Helene%20Sou(SAPI)%20and%20Huyen%20Do(PGVN).pdf

Good Review Practices (GRevP)

To help **achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality** in the content and management of reviews

Good Submission Practice (GSubP)

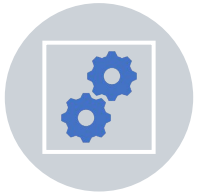
To **enhance the quality and efficiency of the medical product registration process** by improving the quality and management of submission

Source: https://apac-asia.com/groups/ra/task_a.html

Observations: Best Practice In Implementing Reliance

Establish a clear and transparent framework

Establish clear communication process



Leveraging reliance to streamline process

Optimising tools for reliance

Capacity building and training

Monitoring and continuous improvement

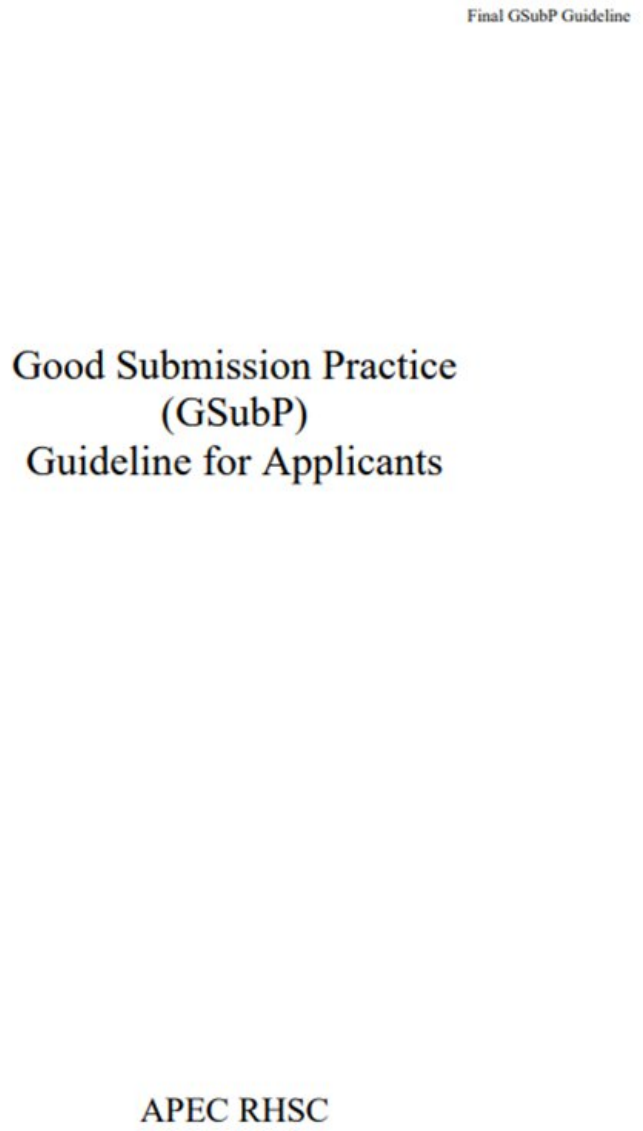
Adaptation from: Best practices for predictability & transparency to facilitate reliance; Siti Noor Haryani Ismail. https://apac-asia.com/images/achievements/pdf/14th/07_Presentation%20from%20Siti%20Noor%20Haryani%20binti%20Ismail,%20NPRA.pdf

Leveraging Reference Agency AR

QUALITY (CMC)

NON-CLINICAL STUDIES

CLINICAL STUDIES

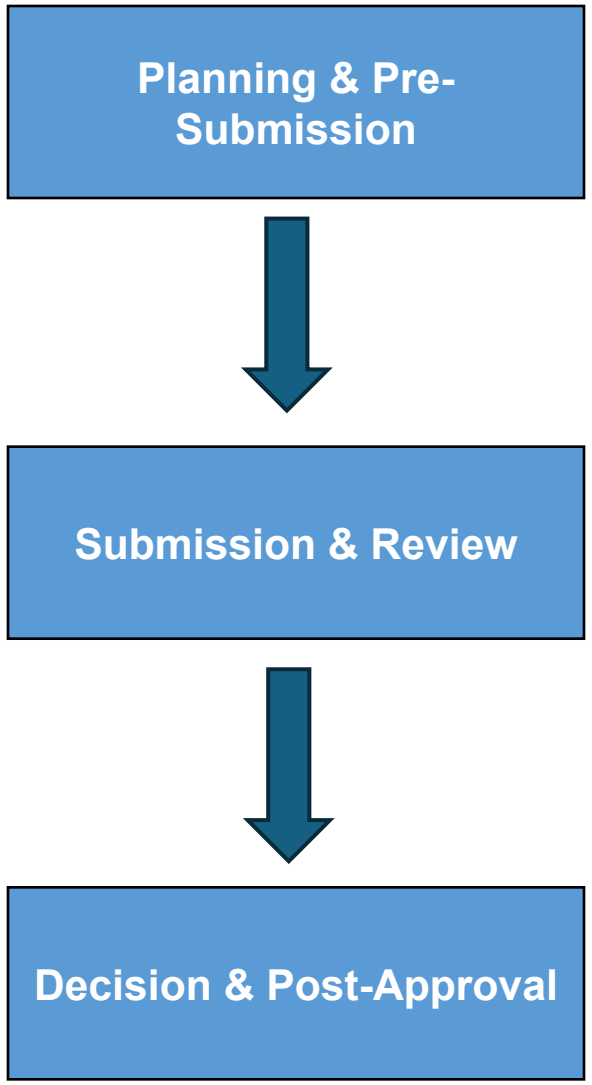


Principles of Good Submission

- STRONG SCIENTIFIC RATIONALE AND ROBUST DATA WITH CLARIFICATION OF BENEFIT-RISK PROFILE
- COMPLIANCE TO UP-TO-DATE REGULATORY REQUIREMENTS
- WELL-STRUCTURED SUBMISSION DOSSIER WITH APPROPRIATE CROSS-REFERENCES
- RELIABILITY, QUALITY, INTEGRITY AND TRACEABILITY OF SUBMISSION DOCUMENTS AND SOURCE DATA
- EFFECTIVE AND EFFICIENT COMMUNICATIONS

Source: https://apac-asia.com/images/ra/pdf/GSubP%20Guideline%20for%20Appllicants.pdf

Regulatory Reliance NDA Submission Process



- Identify Eligibility
- Gather Documentation
- Pre-submission Consultation

- Formal Submission
- Screening & Verification
- Abridged Review
- Q&A and Clarifications

- Independent Decision
- Approval/Rejection
- Post-Market Surveillance

Planning & Pre-submission

- Identify Eligibility
  - Coordination with global submission office on the product and submission pathway
  - Check for product meeting the prescribed NRA reliance pathway requirements (e.g. type of product, reliance pathway, choice of Ref Agency, product approved within X years of Ref Agency approval)

- Prepare documentations required for reliance submission*
  - SRA/Reference Agency Assessment report
  - Product sameness declaration
  - NRA submission checklist
  - Prepare the submission package based on the pre-submission consultation discussion (if happened) using the appropriate pathway

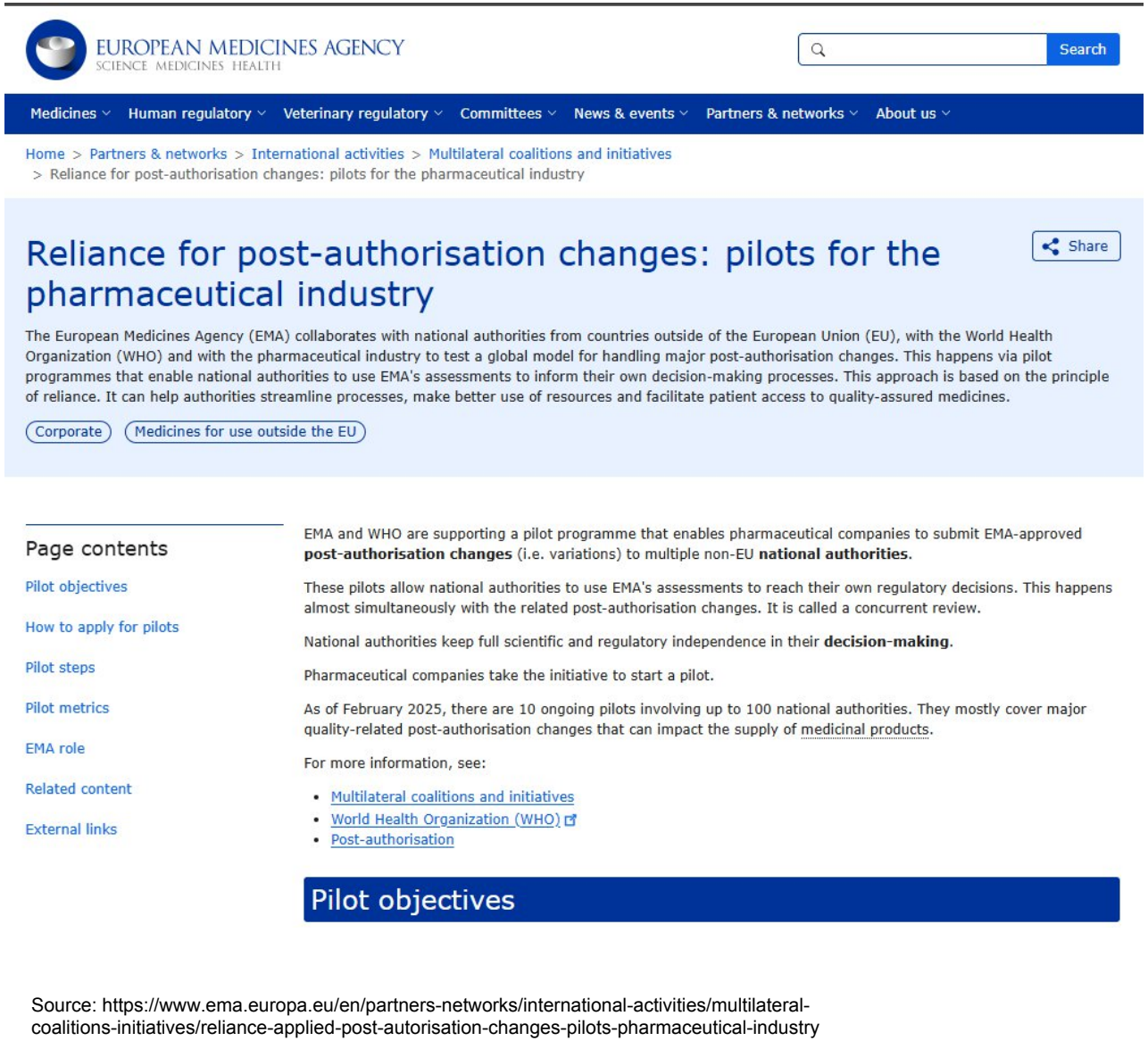
- Pre-submission Consultation
  - Consult with NRA if necessary to get clarity on the proposed product and pathway suitability
  - Prepare quality meeting materials

* In-addition to normal dossier & documentations

Value of Regulatory Reliance & Efforts by Regulatory Authorities

- Strengthen regulatory capacity, to improve health systems nationally and internationally, to increase the availability of medicines, to save financial resources and to use human resources more strategically.
- Reliance is built on trust between regulators and can be unilateral or mutual.
- Regulatory processes can be optimized and duplication of efforts can be minimized through reliance.
- Scientific expertise can be leveraged, leading to more fruitful and robust decision making, and enhancing the capacity of regulators.
- Allow efficient allocation of resources by NRAs and improve access to medicines.

Source: https://icmra.info/drupal/strategicinitatives/reliance/statement



Source: https://www.ema.europa.eu/en/partners-networks/international-activities/multilateral-coalitions-initiatives/reliance-applied-post-autorisation-changes-pilots-pharmaceutical-industry

Reliance in Post Approval Changes (PAC)

- EMA and WHO are supporting a pilot programme that enables pharmaceutical companies to submit EMA-approved post-authorisation changes (i.e. variations) to multiple non-EU national authorities.
- These pilots allow national authorities to use EMA's assessments to reach their own regulatory decisions. This happens almost simultaneously with the related post-authorisation changes. It is called a concurrent review.

Reliance in PAC

Therapeutic Innovation & Regulatory Science
https://doi.org/10.1007/s43441-024-00677-8

DIA

ANALYSIS

Unleashing the Power of Reliance for Post-Approval Changes: A Journey with 48 National Regulatory Authorities

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Received: 26 April 2024 / Accepted: 18 July 2024
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Abstract

Post-approval changes (PACs) to marketed products are routinely introduced to continuously enhance the product lifecycle management. However, bringing a chemistry, manufacturing and control (CMC) change through the global health authorities can be a complex and lengthy process taking up to several years, therefore negatively impacting supply continuity. In order to accelerate the review and approval of regulatory submissions and ensure continuous supply to patients, the World Health Organization (WHO) is strongly supporting the implementation of reliance among National Regulatory Authorities (NRAs). While some promising developments have been made with the use of reliance pathways for initial marketing authorizations, reliance is still not widely used for PACs. With the support of the European Medicines Agency (EMA) and WHO, Roche launched a reliance pilot based on EMA approval to file a supply critical variation for a monoclonal antibody. The variation constitutes major changes to the approved manufacturing process. Sameness of the product is ensured by submitting to all participants the same variation package as in the EU. The objectives of the pilot are to ensure continuous supply of this critical medicine by targeting global approval in 6.5 months, to promote regulatory convergence by waiving country specific requirements, and enhance greater transparency by sharing EMA Committee for Medicinal Products for Human Use (CHMP) final assessment report and Q&As to participating NRAs. Globally 48 NRAs have agreed to join the pilot. This article outlines the process of establishing the pilot project, including a planning phase and an engagement phase with the EMA, WHO and the participating NRAs.

PDA Journal
of Pharmaceutical Science and Technology

PDA Parenteral Drug Association

Worldwide Regulatory Reliance: Results of an Executed Chemistry, Manufacturing, and Control Post-Approval Change Pilot

Cynthia Ban, Jamie Graham, Lyne Le Palaire, et al.

PDA J Pharm Sci and Tech **2025**, *79* 295-302
Access the most recent version at doi:10.5731/pdajpst.2024-003023.1

RESEARCH

Worldwide Regulatory Reliance: Results of an Executed Chemistry, Manufacturing, and Control Post-Approval Change Pilot

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ABSTRACT: Post-approval changes (PACs) are integral to pharmaceutical product life cycle management, ensuring that the product remains safe, effective, and compliant with evolving standards. However, managing these changes across multiple regulatory jurisdictions remains a challenging endeavor due to diverse regulatory requirements and timelines across national regulatory authorities (NRAs). This results in delays in obtaining approval from NRAs, impacting global supply chains and ultimately jeopardizing timely access to essential medical products by patients. In 2021, the World Health Organization issued the Good Reliance Practices (GReIP) guidance to encourage streamlined PAC review and approval process while maintaining access to quality-assured, safe, and effective medicinal products. NRAs are encouraged to rely on the assessment completed by a reference authority that agrees to provide the outcomes of its regulatory expertise. The ultimate objective of this guidance is to accelerate the overall process for PACs, ultimately fostering more equitable and timely access to medical products by the populations who need them. This approach was tested in a chemistry, manufacturing, and control PAC pilot to determine the feasibility of using the principles of regulatory reliance based on the recommendations outlined in the GReIP with the goal of establishing a predictable, 6-month approval timeframe across multiple NRAs. The design and management of this pilot is described in Gastineau et al. This paper describes the outcomes of the pilot, which demonstrated that regulatory reliance is feasible. Of the 21 NRAs that agreed to participate, 55% were able to complete the review within 6 months; within 10 months, 95% of

Sources:

https://pubmed.ncbi.nlm.nih.gov/39048766/

PD-JPST250028 295..302

Therapeutic Innovation & Regulatory Science (2025) 59:1032–1041
https://doi.org/10.1007/s43441-025-00824-9

DIA

REVIEW

Reliance into Action

Understanding EMA Documents to Streamline Reliance for Marketing Authorization Applications

Isabelle Colmagne Poulard[1] · Susanne Ausborn[2] · Martin Harvey Allchurch[3] · Victoria Palmi[3] · Alberto Ganan[3] · Angelika Joos[4] · Andrew Deavin[5] · Corentin Beauchesne[6] · Priti Shah[7] · Jyothsna Krishnan[8] · Chaima Askri[9]

Received: 30 January 2025 / Accepted: 17 June 2025 / Published online: 28 June 2025
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Abstract
According to data gathered from across EU pharmaceutical trade associations, the European Medicines Agency (EMA) is one of the most frequently selected reference regulatory authority (RRA) for reliance procedures due its transparency, detailed decision-making reflected on its public assessment reports and easy access to information related to the assessment of medicines. This review discusses the implementation of unilateral reliance pathways for marketing authorization applications (MAAs) based on EMA assessment. The EMA established a focus group dedicated to reliance in 2022, with the primary aim of understanding the opportunities and hurdles encountered by European industry when using the EMA as RRA in global regulatory filings. A survey conducted among industry stakeholders revealed significant benefits of reliance pathways, including reduced approval timelines and decreased inquiries from relying authorities. However, the survey also highlighted persistent hurdles that hinder the benefits of unilateral reliance pathway, such as variability in documentation requirements and a lack of consistency across the documents requested by each national regulatory authority (NRA) when relying on EMA assessment. The findings highlight the need for collaboration between regulatory authorities and industry to streamline reliance processes and data requirements to make informed reliance decisions ultimately improving global access to safe, effective, and quality-assured medical products.

Keywords EMA · Manufacturing authorization application · Reliance · Regulatory convergence · CPP/eCPP

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Springer

Source: s43441-025-00824-9.pdf

Table 1 Benefits of using reliance

	% of positive responses	Number of responses
Reduction of timelines to approval	95%	40
Reduction of number of questions from the relying agency	86%	36
Aligned PI (Product Information)	67%	28
Predictable review/approval timelines	64%	27
Reduction of country specific requirements and/or harmonization with SRA	48%	20
Capacity building (review and/or resources) amongst regulators	41%	17
Perceived reduced resource requirements for industry	41%	17
Other	2%	1

Table 2 Perceived hurdles when using reliance

	% of positive responses	Number of responses
Additional administrative requirements/ documents including local M1 and other local documents	66%	27
Unredacted assessment report	54%	22
No clear reliance guideline or reliance not practiced	51%	21
Strict interpretation of product sameness	44%	18
No regulatory framework allowing reliance	41%	17
No Confidentiality Agreement or Memorandum of Understanding between reference authority and relying authority	34%	14
No clear understanding of reliance definition or no acceleration of timelines	24%	10
Not enough Reference Authorities to apply reliance or restricted scope	17%	7
Long submission lag time	15%	6
Difficulties in accepting eCPP	7%	3
None of the above or other	2%	1

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DIA

REVIEW

Reliance into Action

Understanding EMA Documents to Streamline Reliance for Marketing Authorization Applications

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Received: 30 January 2025 / Accepted: 17 June 2025 / Published online: 28 June 2025
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Abstract

According to data gathered from across EU pharmaceutical trade associations, the European Medicines Agency (EMA) is one of the most frequently selected reference regulatory authority (RRA) for reliance procedures due its transparency, detailed decision-making reflected on its public assessment reports and easy access to information related to the assessment of medicines. This review discusses the implementation of unilateral reliance pathways for marketing authorization applications (MAAs) based on EMA assessment. The EMA established a focus group dedicated to reliance in 2022, with the primary aim of understanding the opportunities and hurdles encountered by European industry when using the EMA as RRA in global regulatory filings. A survey conducted among industry stakeholders revealed significant benefits of reliance pathways, including reduced approval timelines and decreased inquiries from relying authorities. However, the survey also highlighted persistent hurdles that hinder the benefits of unilateral reliance pathway, such as variability in documentation requirements and a lack of consistency across the documents requested by each national regulatory authority (NRA) when relying on EMA assessment. The findings highlight the need for collaboration between regulatory authorities and industry to streamline reliance processes and data requirements to make informed reliance decisions ultimately improving global access to safe, effective, and quality-assured medical products.

Keywords EMA · Manufacturing authorization application · Reliance · Regulatory convergence · CPP/eCPP

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Springer

Source: s43441-025-00824-9.pdf

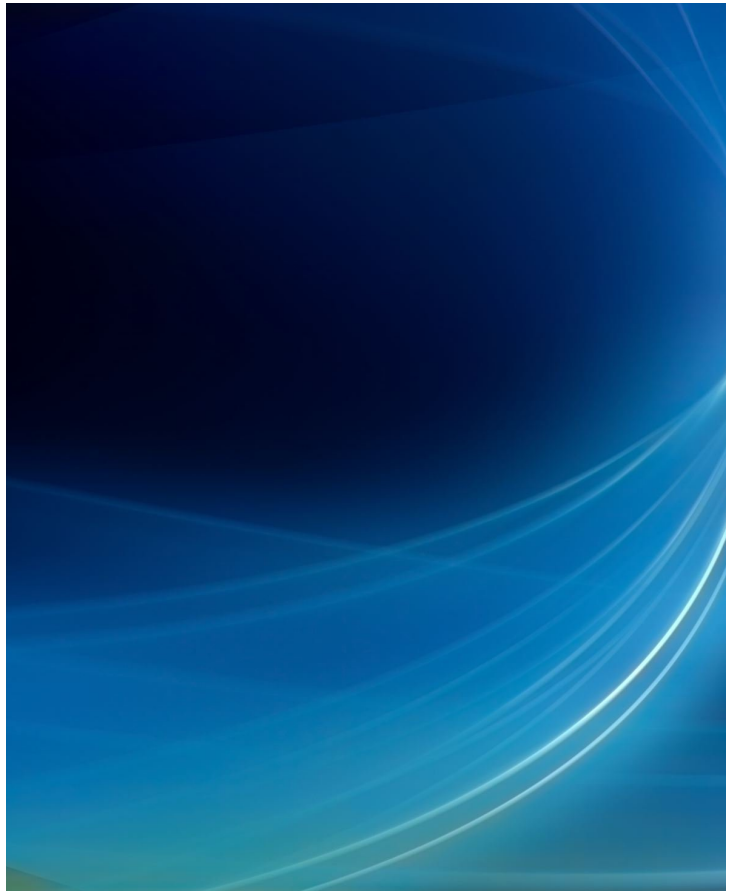
- Flexibility and agility are key for smart implementation of reliance pathways.
- Extending scope of reliance to other areas in need: post-approval changes, clinical trials oversight, regulatory inspection, lot release/import and laboratory testing.
- Accelerating timelines for approval is one of the key components of reliance pathways but other important aspects to be considered include promoting alignment of requirements, capacity building and collaboration between authorities and ultimately improving access to quality-assured medical products and potentially reducing the risk of shortages when applied to post-approval changes.

Australia CoR A & B : Reliance Pathway

CIRS R&D Briefing 91 reported two abridged reliance review pathways from the Australian TGA; CoR A and CoR B are associated with faster review timelines compared to the full review

The review timelines for the abridged pathway were also more predictable compared to the full review pathway

Analysis shows that a reliance review can speed up the regulatory review, thereby ensuring an efficient process and thereby increasing the timely availability of medicines.



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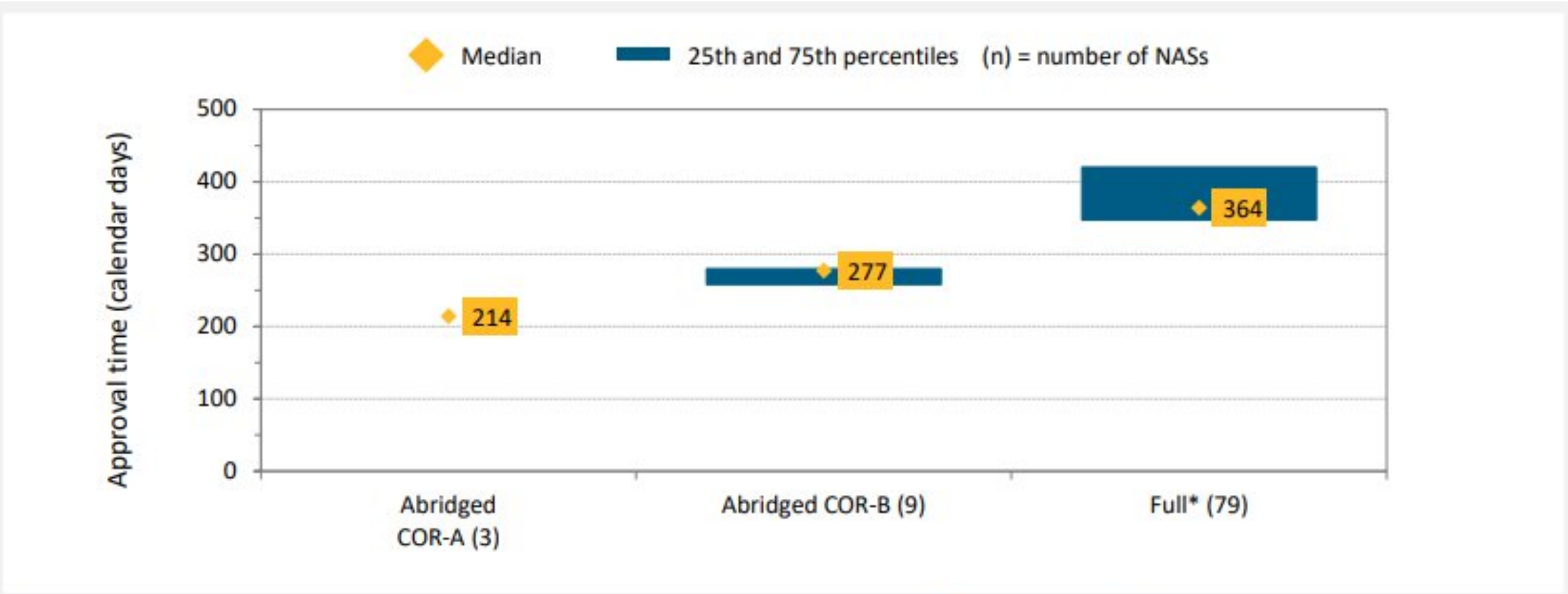

Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. For COR A no variance (25–75th percentiles) are shown as there are <5 NASs

**Standard = non-COR-A or COR-B approvals*

Source: CIRS 6 agency Briefing 88; data obtained from the public domain

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SAHPRA
South African Health Products Regulatory Authority

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Backlog Clearance Project

The South African Health Products Regulatory Authority (SAHPRA) Medical Products Backlog Clearance Strategy

One of the critical priorities of the South African Health Products Regulatory Authority (SAHPRA), since its launch in February 2018, has been the clearance of its medical products backlog. SAHPRA has developed a detailed strategy to clear this "inherited backlog", defined as all applications (including new registrations, variations, duplicates, clones, multiple doses and different dosage forms) submitted which are yet to receive final

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- South Africa Health Product Regulatory Authority (SAHPRA) Backlog Clearance Project (BCP) initiated in 2018 and went live on Aug 2019
- Huge backlog appx.16000 applications. 8 years to clear assuming no new applications
- Re-engineered regulatory process: Applied Reliance Review (Abridged Review with Assessment Report of RRA) and risk-based
- Project completed in Dec 2022 with complete backlog clearance

Source: https://www.sahpra.org.za/backlog/
Source: MEDIA-RELEASE-Backlog-Clearance-02-December-2022.pdf

Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities

- Methods: Abridged review outcomes were examined for New Chemical Entity (NCE) and generic applications to the South African Health Products Regulatory Authority (SAHPRA) in Chemistry, Manufacturing and Controls (CMC) and clinical/ bioequivalence (BE), as well as overall NCE authorization times.
- Results: SAHPRA NCE CMC review time was 91 days (abridged) vs. 179 days (full), applicant response time was 34 vs. 105 days, respectively, and there was a >2- fold time reduction for abridged vs. full CMC review (125 vs. 284 days). There was a 99-day decrease in clinical approval time through an abridged review (230 vs. 329 days) and a decrease in marketing authorization time for NCE abridged assessment (446 vs. 619 days). SAHPRA review time for generic applications was 97 days (abridged) vs. 191 days (full); applicant response time was 26 days (abridged) vs. 81 days (full) and there was a >2-fold time reduction for CMC and BE abridged vs. full review (122 vs. 272 days).
- Conclusion: These results clearly support World Health Organization recommendations for the use of reliance-based regulatory review to expedite the worldwide availability of safe, effective and needed medications.

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TYPE Original Research
PUBLISHED 23 October 2023
DOI 10.3389/fmed.2023.1265058

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OPEN ACCESS

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RECEIVED 21 July 2023
ACCEPTED 11 October 2023
PUBLISHED 23 October 2023

CITATION
Danks L, Semete-Makokotlela B, Otwombe K, Parag Y, Walker S and Salek S (2023) Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities.
Front. Med. 10:1265058.
doi: 10.3389/fmed.2023.1265058

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Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities

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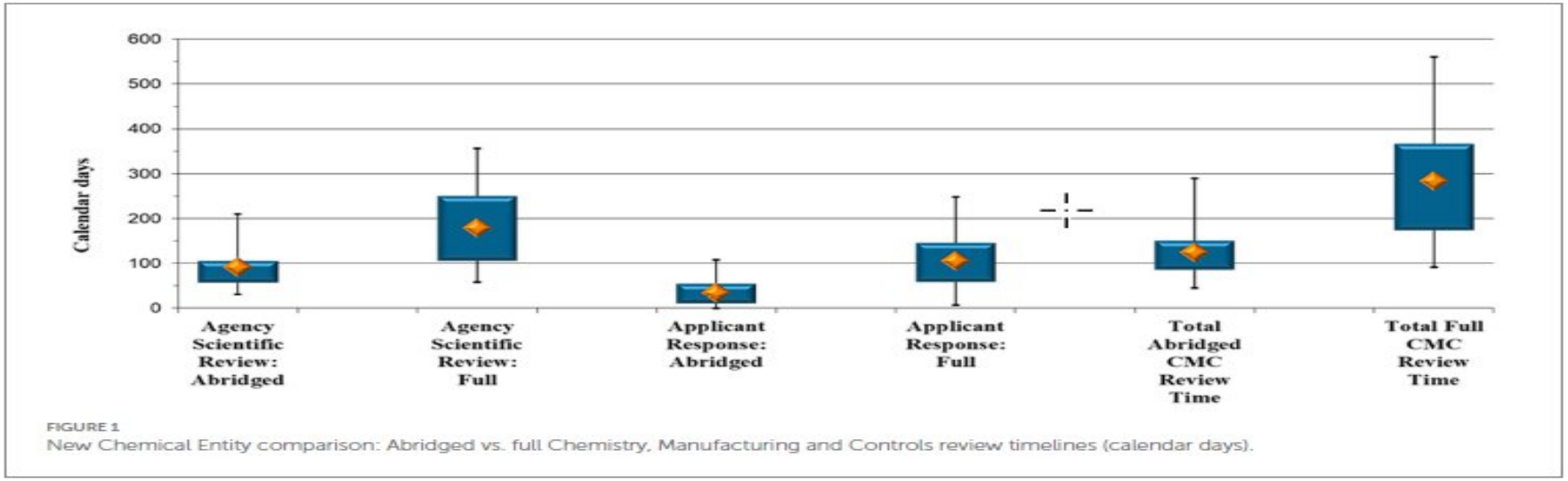

FIGURE 1
New Chemical Entity comparison: Abridged vs. full Chemistry, Manufacturing and Controls review timelines (calendar days).

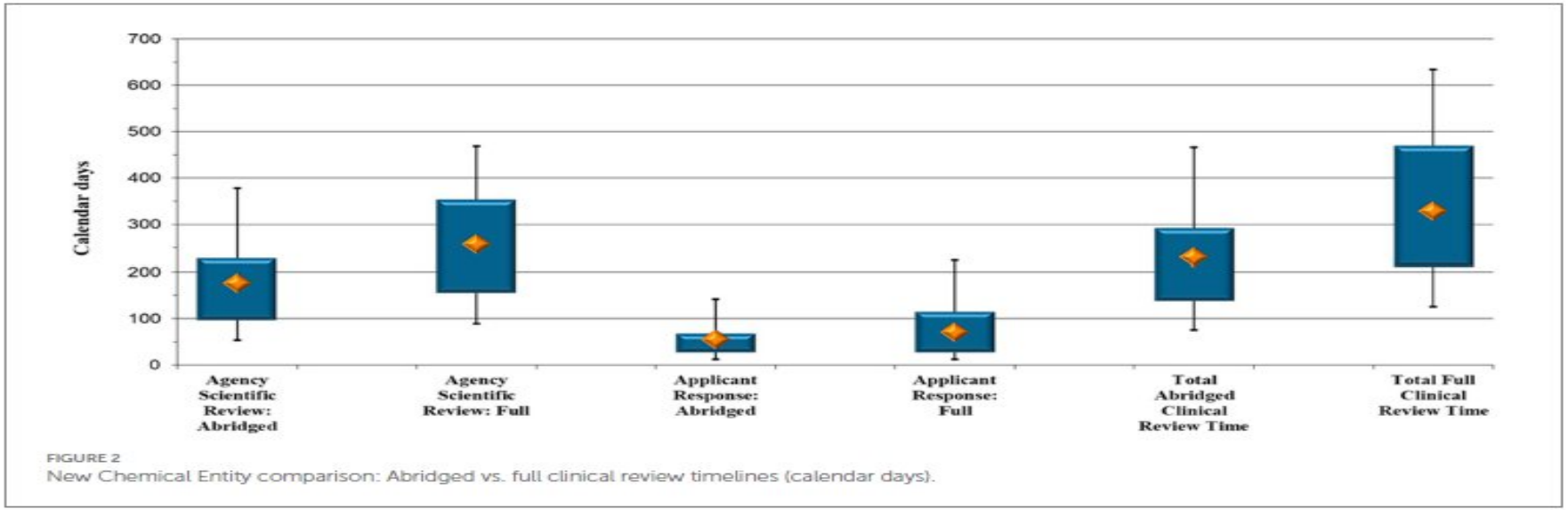

FIGURE 2
New Chemical Entity comparison: Abridged vs. full clinical review timelines (calendar days).

Source: Frontiers | Evaluation of the impact of reliance on the regulatory performance in the South African Health Products Regulatory Authority: implications for African regulatory authorities

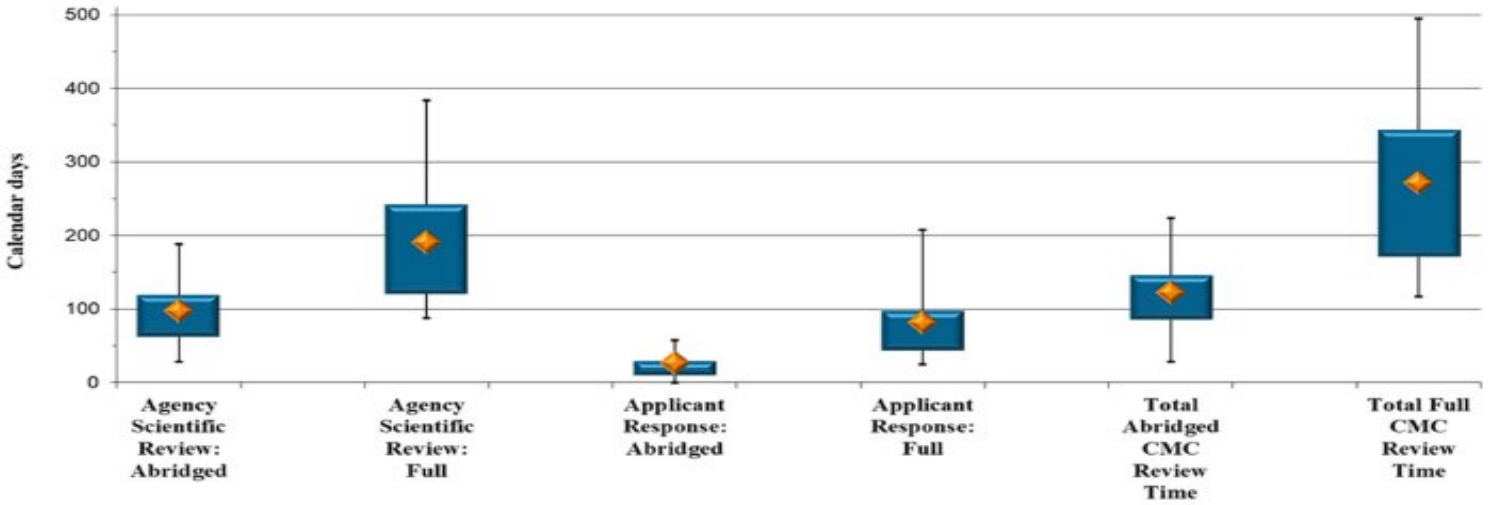

FIGURE 3
Generic comparison: Abridged vs. full Chemistry, Manufacturing and Controls review timelines (calendar days).

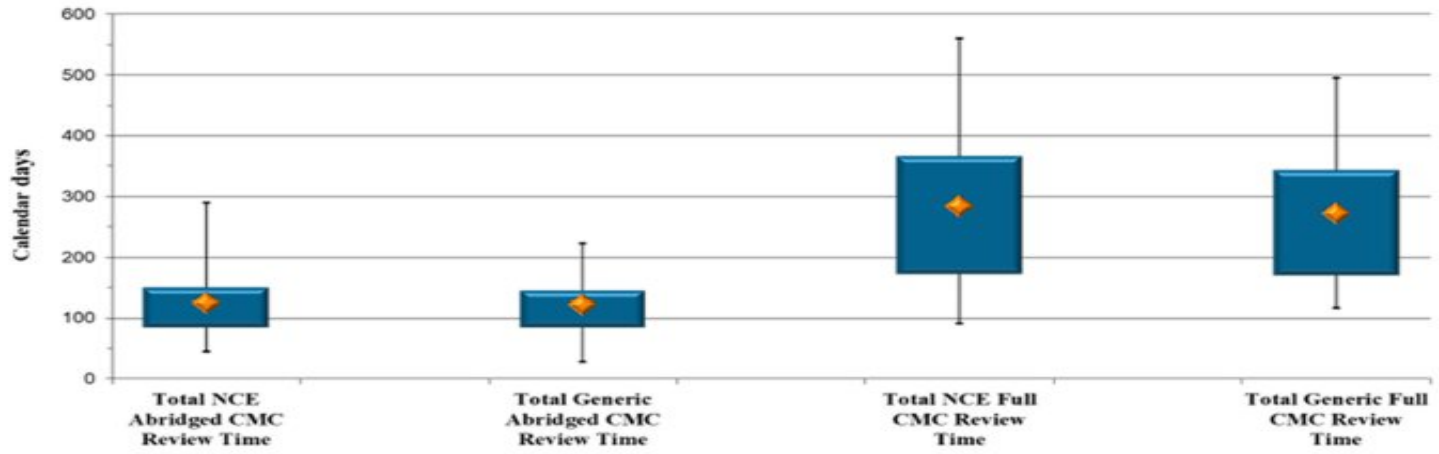

FIGURE 4
Comparison between the abridged and full Chemistry, Manufacturing and Controls evaluation timelines for New Chemical Entity and generic product applications, respectively.

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Reflecting on the outcome of the Backlog Clearance Project the following recommendations should be considered:

- **Cultural transformation** – Ensure that reviewers have subscribed to the concept of reliance, especially with regard to clinical assessment, as this necessitates a change in their mindset
- **Risk-based review** – Create a priority evaluation process, differentiating medicine applications to the model of review, which in turn will lead to operational efficiency
- **Reference agency assessment report** – Agencies implementing reliance should engage with the WHO-listed authorities by developing Memoranda of Understanding (MoUs) in order to gain access to unredacted assessment reports
- **Information management system** – It should be incumbent upon the agencies to establish robust electronic tracking systems in order to measure and monitor regulatory performance which in turn would underpin the success of reliance initiatives

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TYPE Original Research
PUBLISHED 23 October 2023
DOI 10.3389/fmed.2023.1265058

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OPEN ACCESS

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Reliance Saves Time and Resources

- The Economic Impact of Reliance on an African Medicines Regulatory Authority; published on 10 February 2025 in Pharmaceutical Medicine Journal.
- Research aimed at determining the economic impact of reliance on national regulatory authorities (NRAs) in terms of lower assessors' costs, especially to offset the financial efforts required to attain a higher World Health Organization (WHO) maturity level and understanding the way fees can sustain NRA activities.

Pharmaceutical Medicine
https://doi.org/10.1007/s40290-025-00553-2

ORIGINAL RESEARCH ARTICLE

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The Economic Impact of Reliance on an African Medicines Regulatory Authority

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Accepted: 10 February 2025
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Abstract

Background and Objectives The inherited backlog of 16,000 medicines applications of the South African Health Products Regulatory Authority (SAHPRA) was cleared through facilitated review pathways that included reliance on prior work by trusted regulators. This research aimed at determining the economic impact of reliance on national regulatory authorities (NRAs) in terms of lower assessors' costs, especially to offset the financial efforts required to attain a higher World Health Organization (WHO) maturity level and understanding the way fees can sustain NRA activities.

Methods To this end, the assessor costs associated with reliance and full review applications were calculated and compared. A high-level review of African NRA fee structures was also carried out and pharmaceutical industry input was solicited regarding the feasibility of alternative tariff modalities for low- and middle-income (LMIC) NRAs.

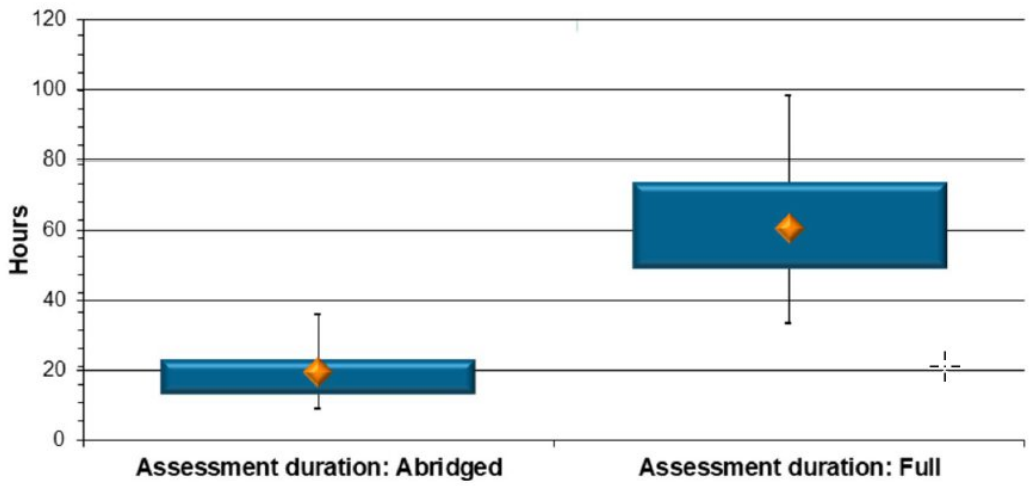
Results The investigation showed a marked reduction in time spent in reliance assessments compared to full reviews, with an associated decrease in reviewers' costs; SAHPRA conserved US$277,413 across the 188 applications applying reliance principles. The NRA fee structure review revealed outdated fees with little differentiation between full and reliance assessment. NRAs lack the financial resources to strengthen regulatory systems; WHO Global Benchmarking Tool activities are not directly covered by levied fees. Overall, the pharmaceutical industry was supportive of advancing the maturity of African NRAs and was willing to pay increased fees for reliance reviews when authorities adhere to published timelines. More expensive fast-track services were cited, making an argument for higher fees for reliance assessment when this enables medicines to reach markets quicker.

Conclusions Reliance is a tool to safeguard NRA resources and support regulatory and information systems strengthening. The study illustrates the return on investment of reliance for NRAs and, if optimally implemented, the benefits for patients.

Source: https://www.sahpra.org.za/wp-content/uploads/2025/03/The-Economic-Impact-of-Reliance-on-an-African-Medicines-Regulatory-Feb-2025.pdf

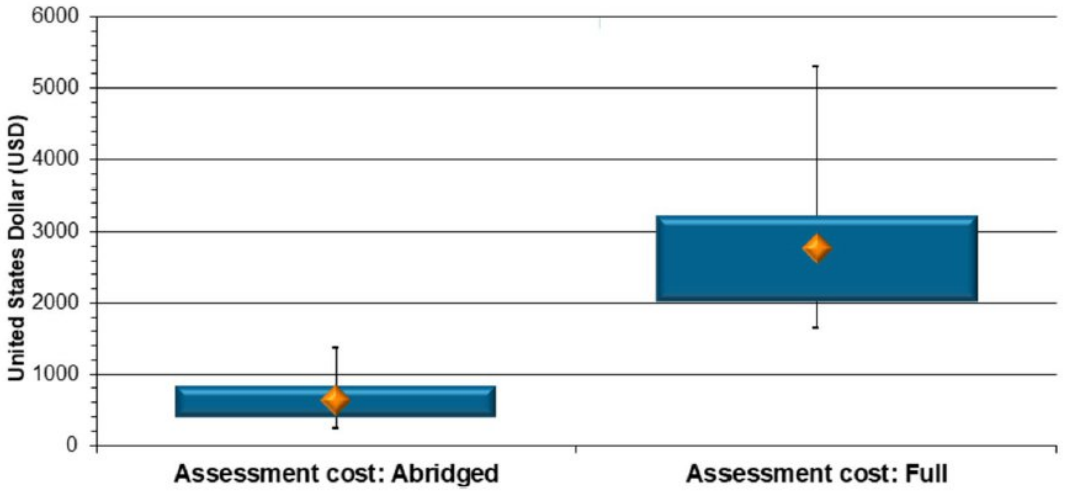
NCE CMC Data Assessment Abridged Review vs Full

Fig. 3 New chemical entity product comparison: duration of abridged versus full review of chemistry, manufacturing and controls data (hours)



- Assessment Duration
- Abridged require 33% (1/3) of time

Fig. 4 New chemical entity product comparison (2019–2022): assessors' costs for abridged versus full review of chemistry, manufacturing and controls data (United States dollars)



- Assessment Cost
- Abridged review 77% decrease

Source: https://www.sahpra.org.za/wp-content/uploads/2025/03/The-Economic-Impact-of-Reliance-on-an-African-Medicines-Regulatory-Feb-2025.pdf

Generic CMC and BE Data Assessment: Abridged Review vs Full

Fig. 5 Generic product comparison: duration of abridged versus full review of chemistry, manufacturing and controls and/or bioequivalence data (hours)

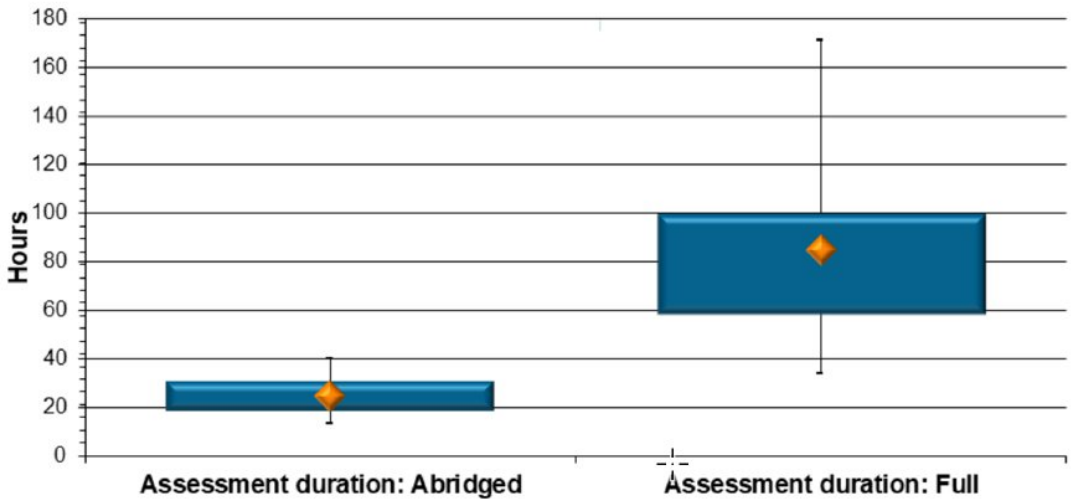
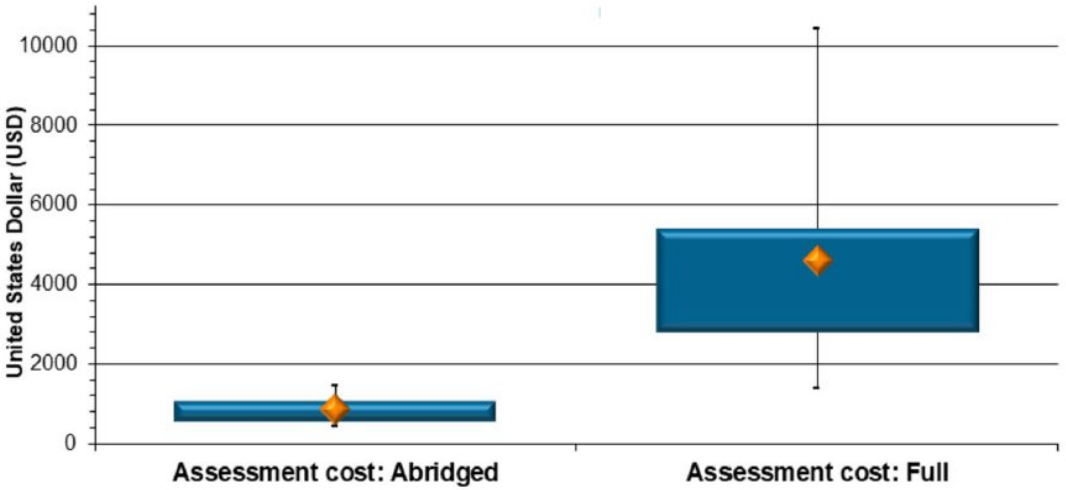


Fig. 6 Generic product comparison (2019–2022): assessors' costs for abridged versus full review of chemistry, manufacturing and controls and/or bioequivalence data (United States dollars)



- Assessment Duration
- Abridged Review require 30% of time

- Assessment Costs
- Abridged review 81% decrease

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- Results showed a marked reduction in time and decrease in costs for reliance assessments

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Summary

- Regulatory reliance: Strengthen regulatory capacity, to improve health systems nationally and internationally, to increase the availability of medicines, to save financial resources and to use human resources more strategically.
- Clear regulatory framework is important supported with risk-based and information management system. Regulatory processes can be optimized and duplication of efforts can be minimized through reliance. Applicable to both NDA, PAC, regulatory inspection, lot release and import testing.
- Allow efficient allocation of resources by NRAs and improve access to medicines.
- Further collaboration between industry and NRAs to enhance efficiency and convergence in implementing regulatory reliance in country and region.
- Reliance saves resources and time.

Thank You

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