CIRS Centre for Innovation in Regulatory Science

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CIRS R&D Briefing 94

The Value of Reference Agency Assessment Reports in Enabling Regulatory Reliance

CIRS Centre for Innovation in Regulatory Science

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Infographic summary

Access to information, including the assessment documents of reference national regulatory agencies (NRAs), is a key enabler of regulatory risk-based decision making (e.g. reliance).

CIRS undertook a study to better understand the provision of regulatory review documents and reports, including what type of documents are requested, how often and how they are being used for reliance decision making.

Two surveys were conducted to gather the perceptions of companies and NRAs on the use and importance of non-public documents (e.g. full assessment reports), and public documents (e.g. public assessment reports) during a reliance review.

The results highlighted the importance of non-public documents for evaluating sameness and understanding reference NRA decision making, however, NRAs varied in their reliance assessment practices. Better ways of sharing non-public assessment reports, improved communication channels, secure platforms and best practices for the content and evaluation of reference NRA reports may be needed.

Public documents were not utilised as the only source of information for reliance by most of the NRAs studied. Limitations regarding i.e. public assessment reports (PARs) are identified and need to be addressed to ensure their utilisation, for example by standardising the content of PARs and providing education on how to utilise them for the purpose of reliance.

The next major challenge highlighted by NRAs was changing the mindsets of reviewers to ensure reliance is undertaken in practice; this may require cultural transformation within NRAs.

Summary of key outcomes

Access to information, including the assessment documents of reference national regulatory agencies (NRA), is a key enabler of regulatory risk-based decision making. It promotes an understanding of what was reviewed by the reference NRA, provides a rationale for decision making and promotes confidence and trust.

The goal of this study was to better understand the provision of regulatory review documents and reports - what type of documents are requested, how often and how they are being used for risk-based decision making (e.g. reliance). An additional objective was to understand perspectives and the interpretation of unredacted assessment reports (UAR) in order to determine if a better terminology for UARs may be appropriate. The study, which comprised of two perception surveys, one of companies and the other one of relying NRAs, focused on evaluating the use and importance of non-public documents (e.g. full assessment reports), as well as public documents (e.g. public assessment reports) during a reliance review. Responses were received from 11 major pharmaceutical companies and 10 NRAs globally. Due to a relatively low response rate, the below findings may therefore not always reflect the overall landscape.

Based on findings from these surveys - non-public documents are seen as key for the purpose of reliance, primarily to enable evaluation of product sameness and to understand NRA decision making. Non-public documents were mostly provided by the applicant and submitted as "unredacted". However, some degree of redaction occurs in most cases, such as personal identifier data from the reviewers, which is often based on the laws and regulations of the NRA that are beyond the control of the sponsor (for example, see for EMA). Therefore, it may be helpful to move away from the term 'unredacted assessment report' and instead refer to the documents as 'non-public assessment reports' (NPARs), where the company or the reference NRA could further specify what information was redacted.

Challenges exist regarding the provision of non-public documents and need to be addressed to ensure an efficient risk-based review processes, including reliance. For example, better transparency on the documentation requirements and rationale, more timely provision of high quality and complete non-public documents, improved and secure communication channels for sharing the documents and efforts to build trust among stakeholders are needed. The development of best practices on what reference NRA assessment reports should contain could also be helpful, to not only existing reference NRAs but also future ones.

In addition, it appears that NRAs vary in their processes, depth and extent of review of the reference NRA non-public documents for the purpose of reliance. The NRAs also differ in terms of what is assessed for the purpose of sameness evaluation and what, according to the NRA, needs to be identical vs. can be different. Harmonisation/convergence of requirements, processes and guidances across NRAs, as well as minimisation of local requirements could ensure best practice across NRAs. This could enable more efficient submission by companies, processes by NRAs, and ultimately enable timely approval of medicines through reliance.

The study also uncovered that public documents alone are generally not required or utilised by the NRAs for the purpose of reliance. However, companies still generally submit them to the NRAs undertaking a reliance review. Their availability as well as completeness and quality was highlighted as a challenge by NRAs, whereas the use of PARs is being promoted by the World Health Organisation (WHO) to enable timely reliance. This gap needs to be addressed to ensure that PARs meet their evolving purpose and can support reliance review. Participating NRAs suggested for example that the introduction of internationally agreed best practices on the content of PARs, more timely availability of PARs for different application types, as well as best practices and training on utilising PARs for the purpose of reliance, could support consistency and transparency of risk-based decision making.

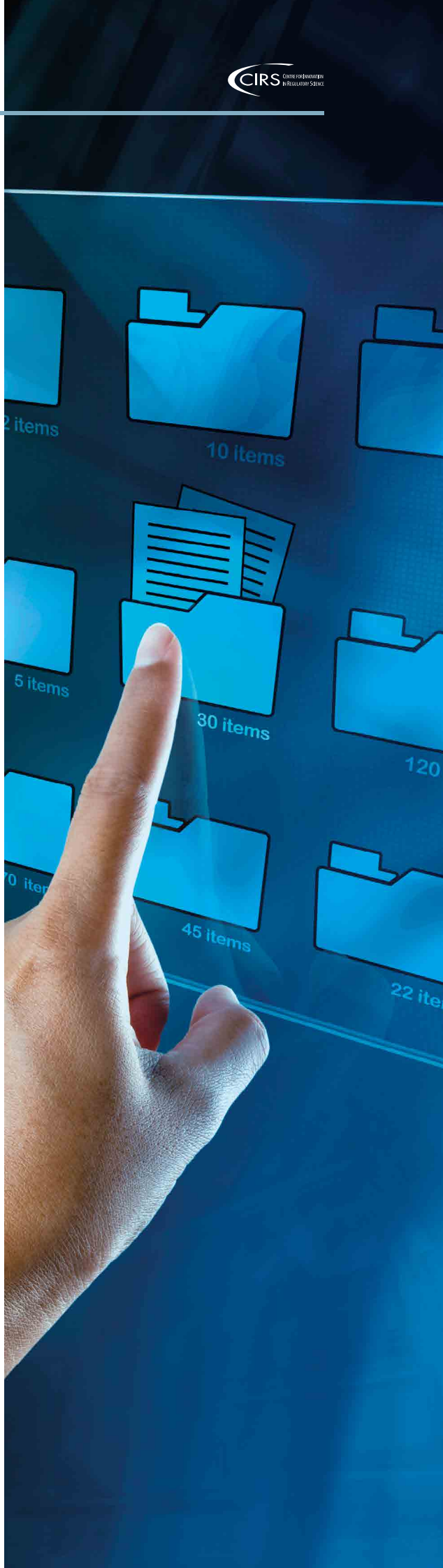
Background

Regulatory reliance is occurring globally to ensure timely approval of medicines. It is regarded as a 21st century regulatory tool and there is no longer a question of 'if' but 'how' NRAs should implement it. NRAs are encouraged to implement WHO Good Reliance Practices, which are anchored in overall Good Regulatory Practices (GRP). The principles of GRP – legality, consistency, independence, impartiality, proportionality, flexibility, clarity, efficiency and transparency – are relevant to all authorities responsible for the regulation of medical products, irrespective of their resources, sophistication or regulatory model. Furthermore, the WHO Global Benchmarking Tool (GBT) advocates that a reliance procedure should be part of an NRA's toolkit. Therefore, reliance procedures should be in place to ensure compliance with the WHO GBT.

Based on a 2022 survey of 29 global regulatory authorities, access to assessment reports was identified as the main challenge to implementing reliance (83% of NRAs in Africa, Latam, Asia and Middle East). Reliance guidances from regulatory NRAs often request "unredacted assessment reports (UARs)", however, in many cases, the guidance does not specify what is categorised under this term and could include documents such as non-public scientific advice, questions and company responses, and Advisory Committee meeting documents. It is also not clear how these documents are being used for a risk-based review and if so, which specific parts are being used that may not necessarily be in the publicly available information.

Requirements for UARs, although common and aimed at ensuring transparency and understanding of decision making, could also, at times, be a barrier, particularly where access to these reports is problematic due to the confidential nature of the information. On the other hand, WHO recommends that NRAs use public assessment reports (PARs) as the primary source of information for risk-based assessments. However, it is not certain how these documents are currently perceived or utilised by relying NRAs, and there remains a question of how well these documents support reliance reviews.

To better understand the provision and use of public (e.g. public assessment reports) and non-public (e.g. full assessment reports) regulatory review documents, CIRS undertook a perception study of companies and relying NRAs to find out what type of documents are requested, how often and how they are being used for risk-based decision making.



Objectives

- Evaluate the types of documents that are being utilised for a reliance review
- Assess the consistency, rationale and strategy for utilising public as well as non-public documents
- Better understand the use of public and non-public regulatory review documents to inform external advocacy on this topic with regulators
- Determine if a better terminology for UARs may be appropriate.

Approach

This study was undertaken in two phases:

Phase 1: Industry perception survey	
11 pharmaceutical companies (from IFPMA)	Q3 2023

Phase 2: NRA perception survey	
10 national regulatory agencies globally	Q1 2024

About this R&D Briefing

This R&D Briefing summarises the key findings from the stakeholder surveys to better understand the provision and utilisation of regulatory review documents, with a focus on non-public assessment reports.

Study 1: Industry perception and strategy: information submitted to support a reliance review

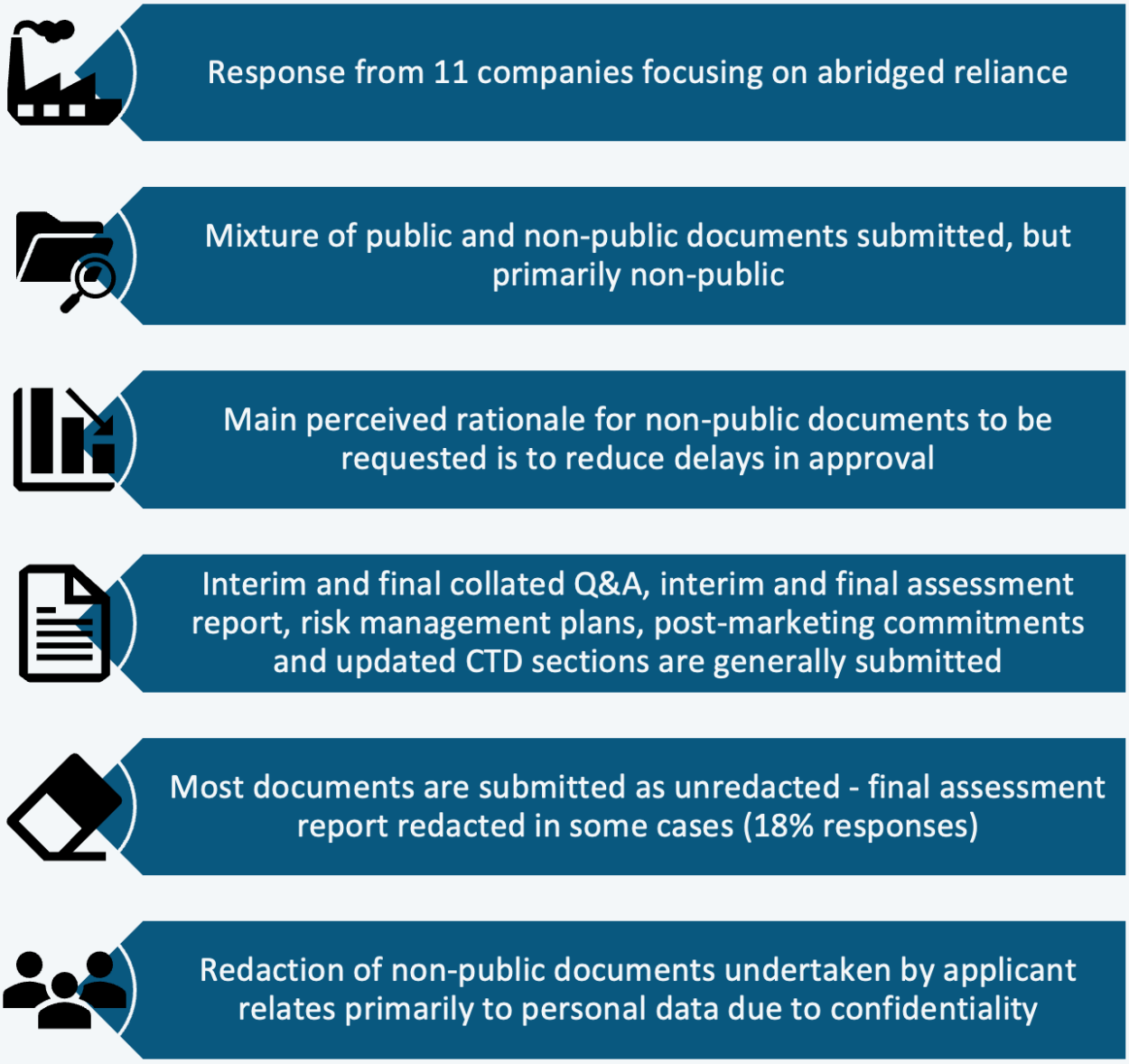
Background

In the first phase of the study, in order to understand the landscape regarding the use of assessment reports to support reliance, a perception survey was conducted across members of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The responses from this survey were utilised to design the second study, namely the NRA survey. Companies provided responses across 24 relying authorities (see Appendix), relating to either new active substances (NASs) or clinical line extensions (CLEs) submitted to the country between 2020-2023 using a unilateral reliance procedure for granting a national approval *(act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority; including verification or abridged pathways).*

Key results

- 11 companies (IFPMA members) provided responses to the survey.
- Authorities where industry provided the most responses (>50% of the 11 companies) were Brazil, Colombia, Egypt, Indonesia, Jordan, Malaysia, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan, Tanzania and Thailand.
- For the majority of the 24 authorities, a mixture of public and non-public reference NRA documents were submitted to support reliance decision making. For Jordan, the majority of companies submitted only publicly available documentation.
- The focus of this study, and the follow-on findings, was where non-public reference NRA documents were submitted as part of reliance. Countries for which at least three companies confirmed that non-public documents were submitted as part of reliance were Brazil, Canada, Egypt, Indonesia, Israel, Kenya, Malaysia, Nigeria, Philippines, Saudi Arabia, Singapore and Thailand.
- The information that was submitted to support a reliance review by most companies (>50%) were: interim and final collated questions /queries and responses, interim and final assessment reports, risk management plans, post-marketing commitments and updated Common Technical Document (CTD) sections. The information was mostly submitted as unredacted.
- The rationale for NRAs to request non-public documents was perceived as multifactorial by industry. Most commonly, companies felt that NRAs do this to reduce delays in the approval process, but also to confirm sameness of the product and to understand reference NRA decision making.
- The type of information that was generally redacted from the documents (mainly the final assessment report; 18% of responses) was personal information, such as identifiers of the assessors. The rationale for redacting was mixed, but generally related to confidentiality, for example personal identifier data from the reviewers, and this is often based on the laws and regulations in the country of the NRA.
- The stakeholder responsible for redacting information from non-public documents was mainly the applicant. The redaction of the information was generally acceptable to the relying regulator.

Summary of industry perception survey



Study 2: NRA approach and rationale for requesting documents to support an abridged reliance review

Background

A survey of regulatory authorities was conducted, where authorities provided responses about their abridged reliance procedure (product has been registered by a 'reference' NRA and the scientific assessment is carried out in relation to its use under local conditions).

Results

Part 1: Overall results

- **Response rate:** 10 authorities provided responses to the survey out of 21 approached.
- **Reliance pathway:** 9 of the 10 NRAs that provided a response have a reliance abridged procedure in place as noted in the table below.

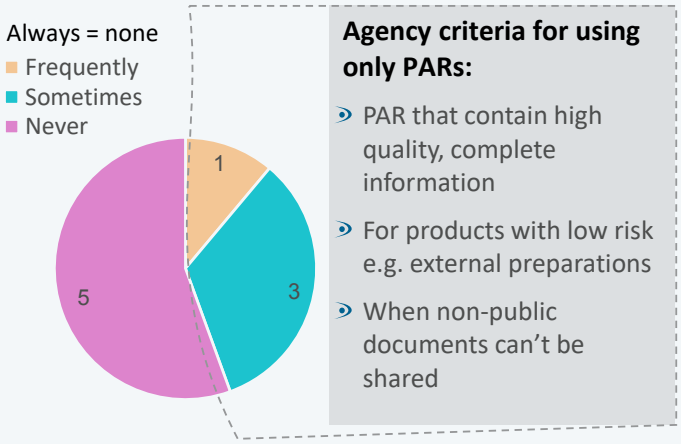
Country	Reliance procedure
Australia	Comparable Overseas Regulator (COR)
Brazil	RDC 750/2022 and OS45/2018
Canada	No abridged procedure in place
Ghana	SRA, WHO Prequalified Route, WAHO route
Jordan	Fast Track Registration
Malaysia	Facilitated Registration Pathway
Saudi Arabia	Registration According to Verification and Abridged
Singapore	Verification evaluation route
South Africa	Abridged review pathway
Tanzania	(i). WHO-Collaborative Registration Procedure (ii). SRA-Collaborative Registration Procedure

- Application and product type: The abridged reliance pathway is used by all the NRAs for new active substances, and by the majority of NRAs (5) for clinical line extensions and post-marketing changes. It is used for many different product types including small molecules, biologics (by all 9 NRAs), as well as biotech products (8), biosimilars (8) and vaccines (6).

Part 2: Public documents

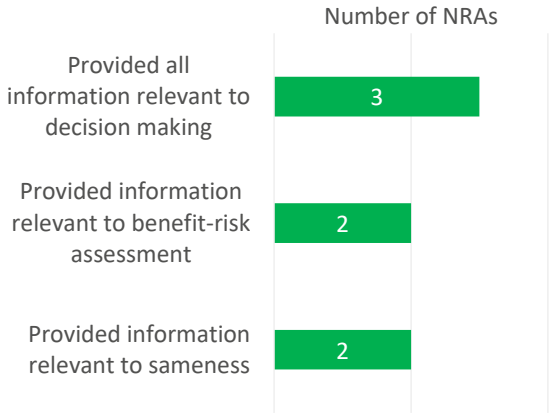
- **PAR utilisation:** 5 of 9 NRAs never utilise PARs as the sole source of information for an abridged reliance review, and some NRAs (1 frequently, and 3 sometimes) utilise only PARs for a reliance review. Where NRAs utilise only PARs, they have specific criteria for those cases, either relating to the quality and availability of documents as well as the level of risk. This information suggests that PARs are generally not utilised as the only source of evidence during a reliance review, and this may be because challenges remain around their format, completeness and availability.

Question: Does your agency utilise only publicly available documents to undertake abridged reliance review?



n = 9 NRAs
Question 8

Question: How have PARs benefitted your agency?



n = 3 NRAs
Question 8

- **PAR benefit:** However, those NRAs that utilised PARs reported benefits such as the provision of all information relevant to decision making.
- **Challenges** on PARs were highlighted e.g. limited access to PARs, their quality and completeness, as noted in the table below.
- **Solutions** were suggested e.g. ensuring timely posting of PARs, as well as use of structured and standardised PAR templates, as described below.

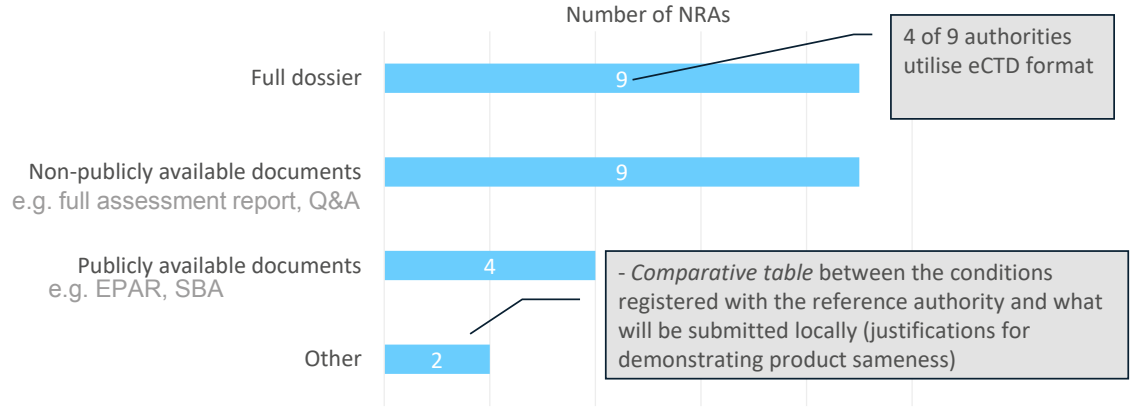
Responses from NRAs regarding public documents	
Challenges	***Solutions***
Limited availability *of publicly available documents/reports (PARs)*	• *Reference NRAs: Ensure PARs are* ***posted*** *on a platform in a short timeframe following approval* • *Reference NRAs: Ensure PARs are* ***published for different application types*** *including e.g. major line extensions* • *Where PARs are not available - enable better* ***communication and secure sharing of non-public information between regulators*** *through confidentiality agreements and* ***Memoranda of Understanding (MoUs)*** *in order to protect commercially sensitive information and personal data*
Quality of reports, completeness *of information, redaction (e.g. CMC)*	• *Advocate for and develop best practices on what a reference agency PAR should contain* • *Reference NRAs: Determine if certain important* ***technical information*** *like detailed specifications* ***could be added*** *to a reference NRA PAR e.g. to better enable sameness assessment. Share the full assessment report where non-public data are required.* • *Relying NRAs: Develop clear and comprehensive* ***criteria for accepting*** *public documents for a reliance review e.g. whether the PAR is complete and of sufficiently high quality or based on a lower level of risk for that product.*
Clarity on ***utilising PARs***	• *Develop a Standard Operating Procedure (****SOP)/training for utilising*** *and evaluating PARs during a reliance review by an NRA*

Number of NRAs = 7

Part 3: Non-public documents

- **NRA requirements:** Provision of non-public documents is a regulatory requirement for reliance for 5 of 9 NRAs, compared to a legal requirement (4 of 9), where the former may provide more flexibility and be easier to modify as needed by the NRA. The non-public documents are generally requested at the time of submission, for all products (7 of 9 NRAs).
- **Document requirements:** All NRAs require the full dossier and non-public documents (e.g. assessment reports) to undertake the reliance review as shown below.

Question: What documents are required by authorities to undertake an abridged reliance procedure:

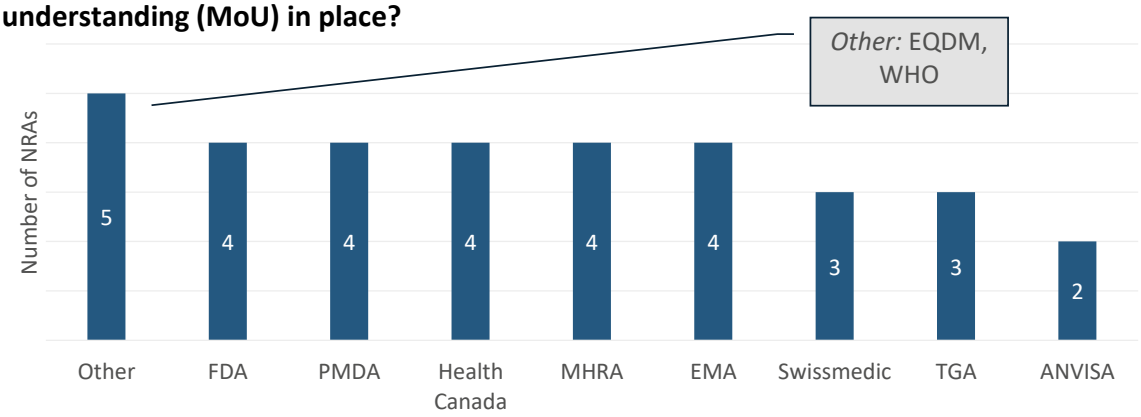


n= 9 NRAs

Question 6, 7

- **Reference NRA:** The choice of reference NRAs and the establishment of MoUs are mixed across the NRAs – but EMA and WHO are most frequently selected as shown in the figures below.

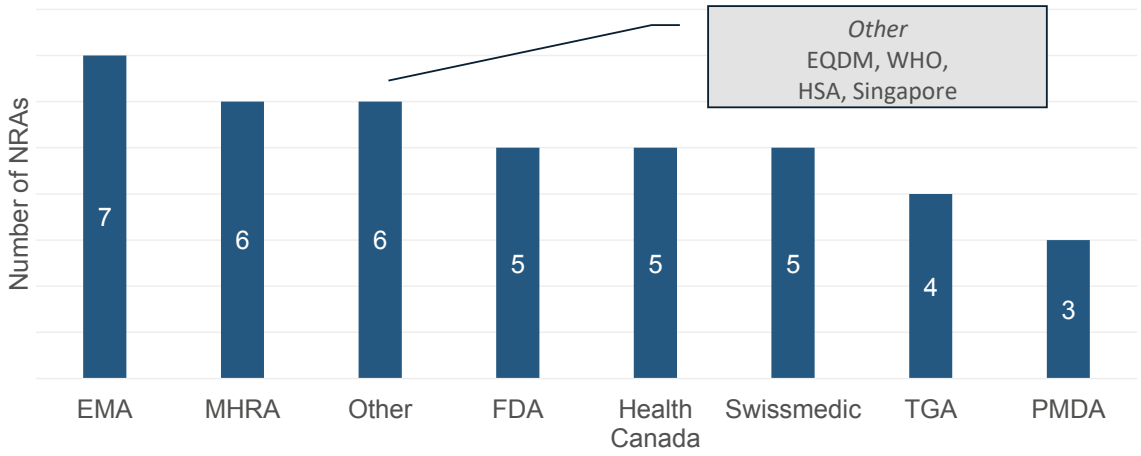
Question: With which reference agencies does your agency have a memorandum of understanding (MoU) in place?



n = 8 NRAs

Question 17

Question: From which regulatory authority do the non-public documents come from?

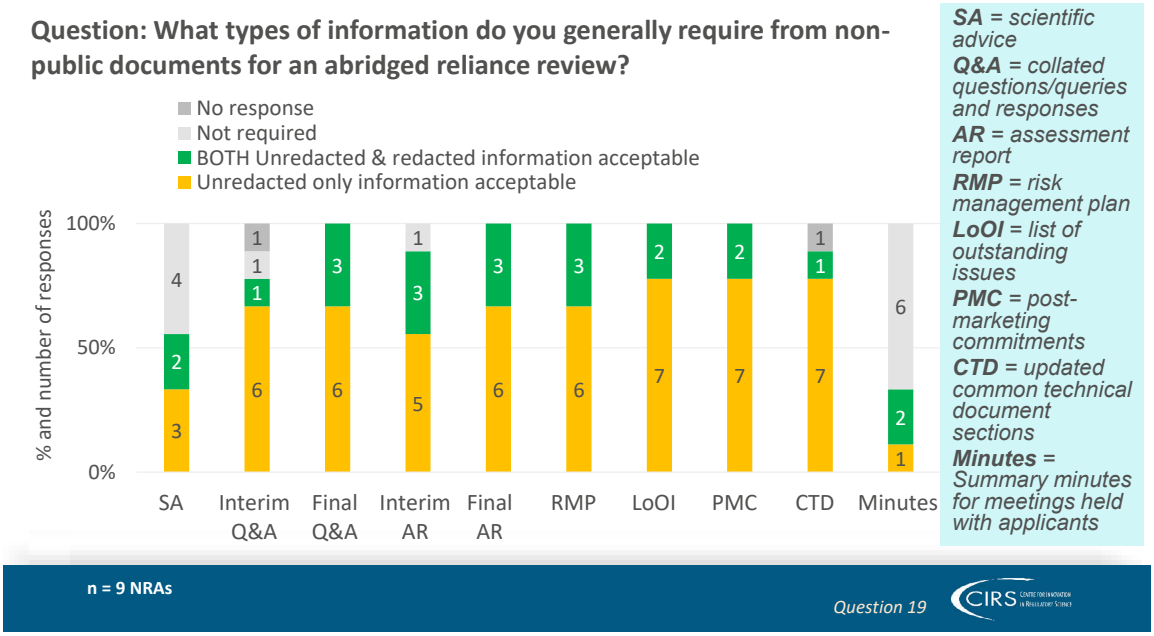


n = 8 NRAs

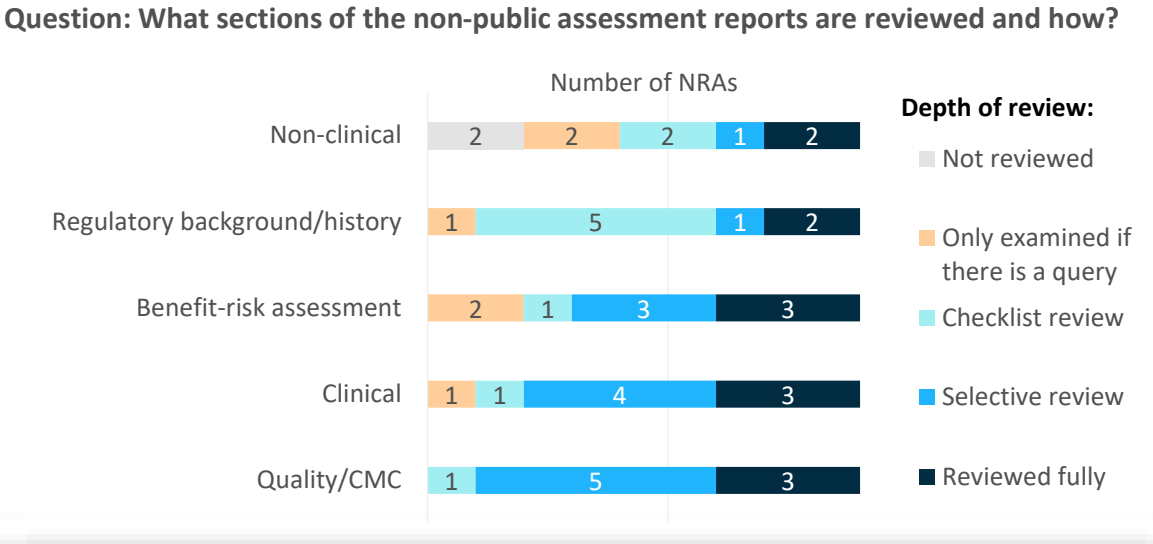
Question 10, 12

EQDM: European Directorate for the Quality of Medicines & HealthCare; WHO: World Health Organisation; FDA: Food and Drug Administration, USA; PMDA: Pharmaceuticals and Medical Devices Agency, Japan; MHRA: Medicines and Healthcare products Regulatory Agency, UK; EMA: European Medicines Agency; TGA: Therapeutic Goods Administration, Australia; ANVISA: Brazilian Health Regulatory Agency; HSA: Health Sciences Authority, Singapore.

- **Authentication** of non-public documents is generally not a requirement.
- **Sharing:** Documents are primarily obtained through an electronic platform and are provided by the applicant.
- **Documents required:** The documents required by the majority of the authorities (>50%) are: interim and final collated Q&A, interim and final assessment reports, risk management plans, list of outstanding issues, post-marketing commitments and updated CTD sections. This information was generally required to be submitted as unredacted, as shown in the graph below.

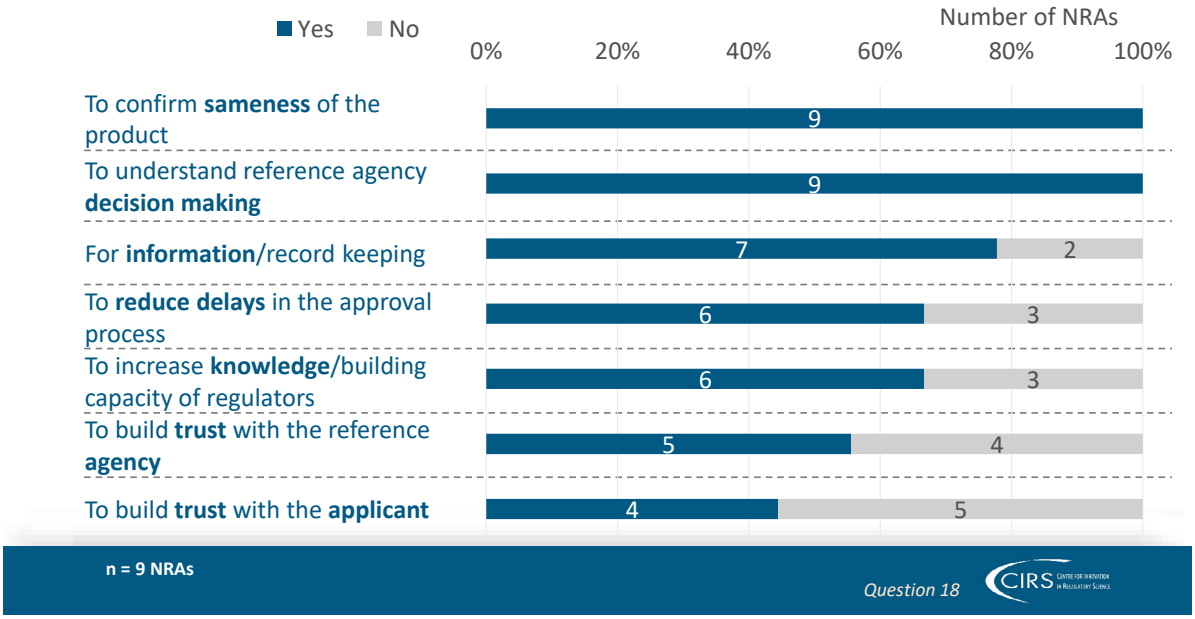


- **The type and depth of review of information within non-public documents** during a reliance review is mixed across NRAs as demonstrated below. In general, clinical, benefit risk and quality/CMC sections are reviewed fully/selectively, whereas non-clinical is either not reviewed or only reviewed if there is a query.

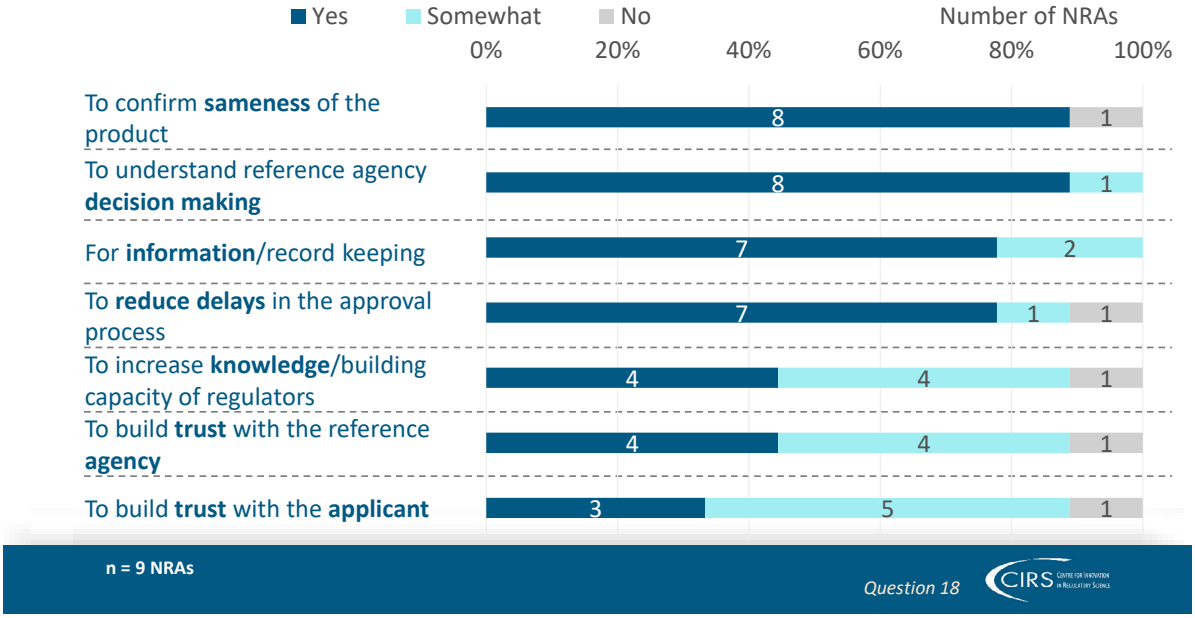


- **The rationale for NRAs to request** non-public documents was multifactorial, most commonly to confirm sameness of the product and to understand reference NRA decision making. The perception is that the non-public documents help to meet those main goals.

Agency rationale for requesting non-public documents



Do the non-public documents help to meet this goal?



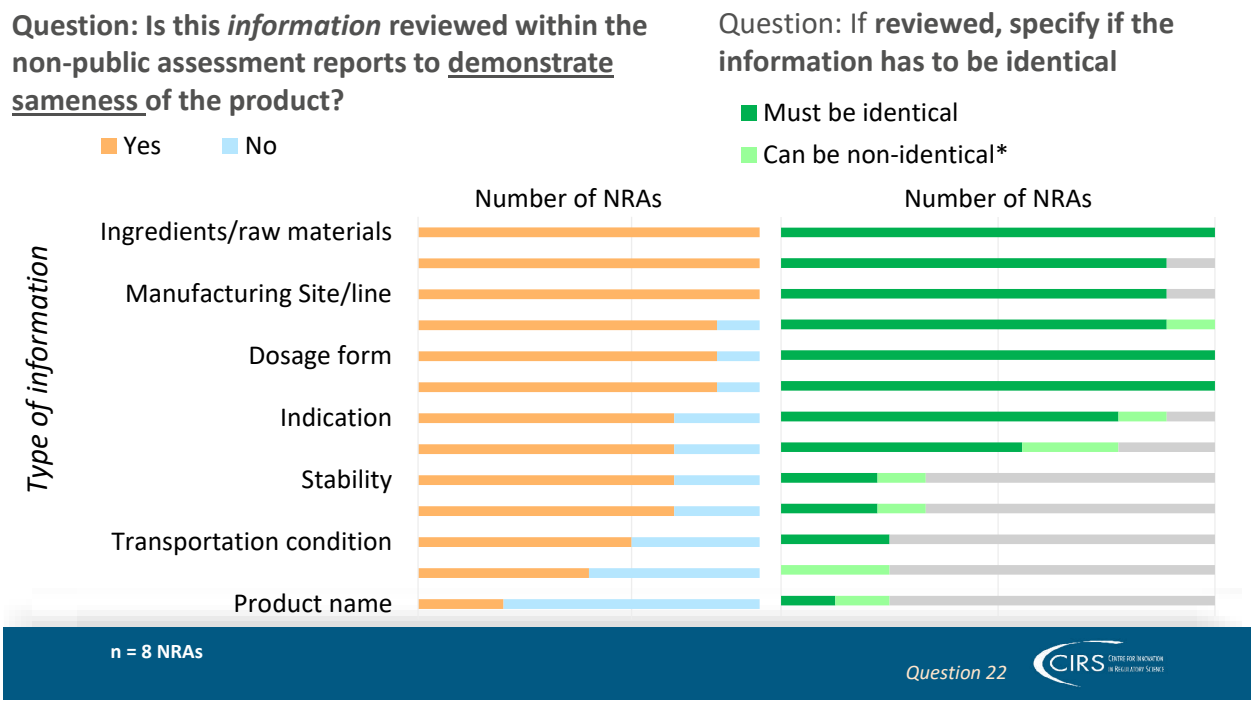
- **Challenges and solutions for the use of non-public documents** were proposed by the authorities as outlined below.

Responses from NRAs regarding non-public documents	
Challenges	**Solutions**
Difficulty in obtaining all the relevant non-public documents in a timely manner	• **Implement efficient and streamlined processes** for the submission and retrieval of documents • Relying NRAs to **establish MoUs/confidentiality agreements** with reference authorities • Relying NRAs to request documents earlier in review process • Applicant to authorise reference NRAs to share reports with the relying authority or provide them by default as part of the submission
Lack of communication channels to enable secure sharing of confidential non-public information	• Develop **secure platforms, databases and protocols** for handling and sharing non-public documents • **Increase dialogue** among regulators
Lack of clear and harmonised standards, templates for documents and **criteria** for accepting non-public documents	• Advocate and develop **best practices on the content** of reference NRA assessment reports, or a harmonised PAR template • Define **clear and standardised** criteria for accepting non-public documents and guidelines on how to assess those documents
Differences in product (and the challenge to assess sameness) **or in the dossier**	• Ensure the **dossier is as similar as possible** (except for country-specific requirements) • Any **differences** in dossier or product need to be clearly **stated and justified**
Lack of support for relying NRAs to **become a reference NRA**	• Regulatory system **strengthening** to build capacity • **Clarify criteria** for becoming a reference NRA

Number of NRAs = 7

Part 4: Focus on sameness

- **Evaluation of product sameness** was highlighted as a challenge by the authorities.
- **Information reviewed to demonstrate sameness** within non-public documents varied across the NRAs - those selected by all NRAs were: ingredients/raw materials, finished product and the manufacturing site/line as shown below.
- **The information that needs to be identical** compared to the reference product for the purpose of reliance are: indication, dose, dosage form, strength, ingredients/raw materials, manufacturing site/line, finished product and warnings and precautions as demonstrated in the following graph.



*Can be non-identical but sameness needs to be justified

- **Challenges and solutions regarding the evaluation of the sameness of product** were proposed by the authorities as outlined below.

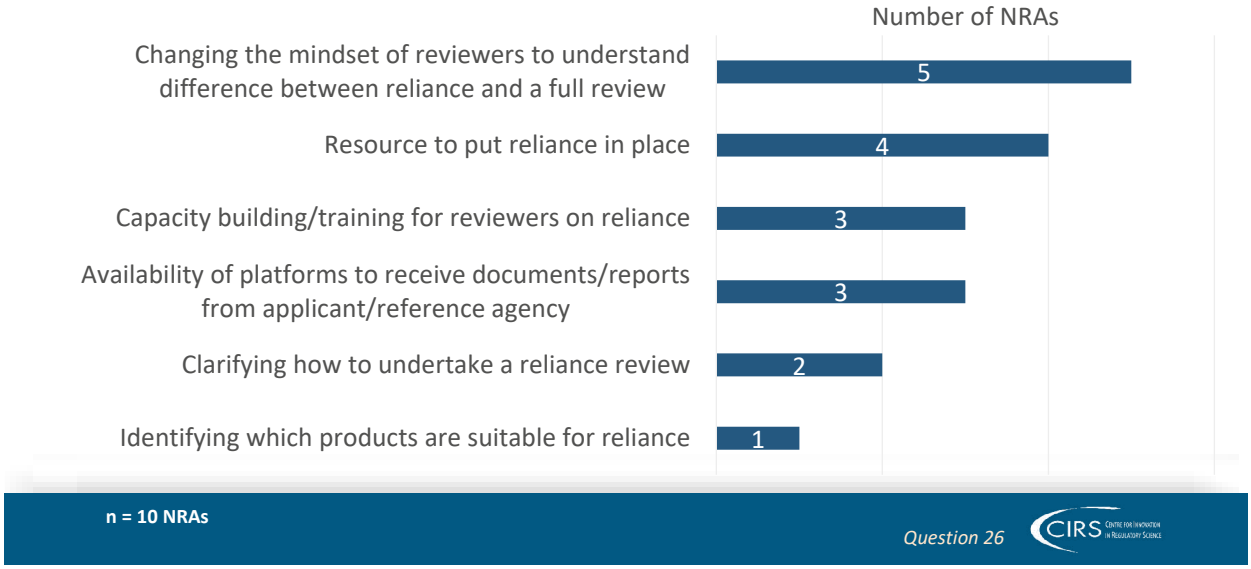
Responses from NRAs regarding sameness evaluation	
Challenges	**Solutions**
Differences relating to local conditions, in terms of: • reference product e.g. Manufacturing site, Container, SmPC, CMC variations, indications, dosage, PI • dossier: Different CTD format (e.g. ASEAN), different information included in submitted dossier (e.g. if additional evidence has been generated)	• **Applicant should ensure the submitted dossier and product is aligned** with the reference product, and the dossier information is aligned e.g. aligning CTD format as needed. The applicant should clearly **state and justify differences** compared to the reference product and note any differences in the submission. • **Relying authority: Differences should be reviewed** by the relying authority. Relying authority may introduce time limit on submission to limit product differences from the reference application.
Demonstration and assessment of sameness e.g. • lack of clarity on how to undertake the evaluation of sameness • uncertainty when a different decision is made by different reference authorities • lack of detailed submitted information needed to review sameness e.g. just lists the tests conducted without including the specifications for each test • reviewers may be resistant and proceed with full review of dossier • need for additional activities like local stability testing	• **Ensure use of clear guidelines, processes, SOPs and criteria** for assessment of sameness • **Enable a continuous dialogue and communication between NRAs** to ensure understanding of decision making and therefore trust building • **Non-public reference NRA assessment reports to also include** the specifications for each test e.g. drug substance, drug product, in-process control etc. • **Relying NRA to consider local population** and needs in benefit-risk decision making when assessing sameness • **Relying NRA to change reviewer mindset** on what to review through training
Standards, terminology and interpretation e.g. • lack of definition/interpretation of what is sameness • lack of best practice and global guidance on assessing sameness of product • lack of clarity on distinguishing between identical and equivalent products • lack of global harmonisation on essential characteristics	• **Develop standardised and clear definitions, standards and terminology** relating to sameness and essential characteristics globally – this could be done through ongoing international discussions

Number of NRAs = 9

Part 5: Additional challenges and solutions

- **Other challenges regarding the implementation of reliance**, beyond the availability of assessment reports/documents, were selected by authorities. The main challenge was regarding how to change the mindset of reviewers to ensure that a reliance review is being undertaken in practice.

Other challenges: What other major challenges does your agency face with regards to implementation of reliance in addition to the availability of documents/assessment reports?



- **Final solutions raised by NRAs were**
  - *Facilitate a cultural transformation* at the NRA through training and capacity building; this could be joint training with reference authorities and an exchange of reviewers
  - *Increase collaboration*, coordination and information sharing (e.g. reviews) between relying and reference authorities to build trust in reviews as well as reviewers
  - *Implement a sharing platform* for exchanging documents and information, and direct *communication* channels with reference NRA
  - *Ensure there are clear, consistent criteria* for which products are/are not suitable for reliance
  - *Enable convergence* of global reliance practices and definitions.

Conclusion

This study aimed to understand the provision of regulatory review documents and reports for risk-based decision making. It should be noted however that the number of responses was relatively low and these may not reflect the landscape as a whole.

Non-public documents are mostly provided by the applicant and submitted as "unredacted". However, some degree of redaction occurs in most cases, such as personal identifier data from the reviewers. This type of redaction does not remove technical information that is relevant for the reliance review, however it still means that the report is 'redacted', which this may be misleading to the relying NRAs. Therefore, it may be helpful to move away from the term 'unredacted assessment report' and instead refer to the documents as 'non-public assessment reports' (NPARs), where the company or the reference NRA could further specify what information was redacted. Alternatively, a grading/coding system for the redaction could be developed and applied e.g. 1 = personal data only removed, 2 = commercially confidential information removed etc. This could provide clarity to all stakeholders on what information is removed and build transparency and trust in the process.

Based on the cohort of NRAs included in the study, the results highlight the current importance of non-public documents for evaluating sameness and understanding reference NRA decision making. However NRAs differ in terms of reliance assessment practice i.e. what is requested and what is reviewed within those documents. Better ways of sharing the non-public assessment reports, improved communication channels, secure platforms as well as ensuring the development of best practices for the content and evaluation of reference NRA reports, including a common template on how to demonstrate and assess sameness, were highlighted.

Public documents are not utilised as the only source of information for reliance by most of the NRAs studied, although WHO does support their use as the primary source of information for reliance. Limitations regarding PARs were found based on NRA perception and need to be addressed to ensure their utilisation, for example by developing best practices on what a PAR should contain, ensuring that PARs are complete, of high quality and produced in a timely manner for different application types. This will help support today's reference NRAs but also new reference NRAs as they mature to WHO-listed status and start producing PARs. Furthermore, training and education on how information contained in PARs be used for reliance could be helpful.

The next major challenge relating to reliance highlighted by the NRAs (in addition to those relating to assessment reports) was changing the mindsets of reviewers to ensure a reliance review is undertaken in practice. A cultural transformation within the NRA was proposed as a solution to ensure the implementation of reliance.

Appendix

Scope – NRAs included in the industry survey

Country	NRA name
Argentina	ANMAT
Australia	TGA
Brazil	ANVISA
Canada	Health Canada
Colombia	INVIMA
Egypt	EDA
Ghana	Ghana FDA
Indonesia	BPOM
Israel	MoH
Jordan	JFDA
Kenya	PPB
Malaysia	NPRA
Mexico	COFEPRIS
Nigeria	NAFDAC
Philippines	Philippines FDA
Saudi Arabia	SFDA
Singapore	HSA
South Africa	SAHPRA
South Korea	MFDS
Switzerland	Swissmedic
Taiwan	Taiwan FDA
Tanzania	TMDA
Thailand	Thai FDA
Turkey	TITCK

Questionnaires

Copies of the questionnaires used can be found on the CIRS website:

- Industry questionnaire: https://cirsci.org/wp-content/uploads/2024/06/IFPMA-UAR-survey_FINAL_industry.docx
- Agency questionnaire: https://cirsci.org/wp-content/uploads/2024/06/UAR-survey_agency_final_for-send-out.docx

Definitions

Clinical line extension (CLE): A clinical line extension is a modification to an authorised medicinal product licence, where new clinical data submitted have a significant impact on the quality, safety or efficacy of a medicinal product, and the change is sufficiently great that is considered a major variation to the original product for a new therapeutic indication.

New active substance: A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans. The term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available
- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure through changes to the nature of source material or manufacturing process and which will require clinical investigation
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Applications that are excluded from the study:

- Vaccines
- Biosimilars
- Any other application, where new clinical data were submitted
- Generic applications
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company
- Applications for a new or additional name, or a change of name, for an existing compound (i.e., a 'cloned' application)
- Emergency use or Special authorisations derived from an emergency (e.g. COVID-19 pandemic).

Non-public documents: Evidence from an authority that is not available in the public domain that is used to inform another NRA decision making related to the assessment of the medicine. Excluded are standard ancillaries used routinely and historically e.g. CPP, GMP. Included are for example interim and final reports, Q&A, advisory committee meetings, scientific advice.

Unilateral reliance: 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. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Reliance abridged review: The pre-requisite here is that the product has been registered by a 'reference' NRA and scientific assessment is carried out in relation to its use under local conditions and regulatory requirements.

Reliance verification review: NRA verifies an authorisation by a 'reference' or 'benchmark NRA'. The process is to validate the status of the product and ensure that the product for local marketing conforms to the authorised product.

Relying country: Authority that is taking into account and is giving significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.

Redaction: The act whereby an NRA or applicant removes confidential information from texts before making them available to the public or a relying agency, respectively.

About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. CIRS provides an international forum for industry, regulators, health technology assessment (HTA) and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy through the innovative application of regulatory science and to facilitate access to pharmaceutical products. 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, special projects and grants.

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