Position Paper

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Considerations for effective regulatory reliance – an Industry perspective

Regulatory reliance is increasingly being used by National Regulatory Authorities (NRAs) of all maturities with different regulatory systems. This concept is actively promoted by organisations such as World Health Organization (WHO)[1], the Pan American Health Organization (PAHO)[1] and the European Medicines Agency[2] as a mechanism for NRAs to better manage resource capacity issues whilst simultaneously strengthening regulatory systems. This allows them to focus on core national activities and is a key exemplar of a risk-based review system[3]. This is evidenced in the recent recommendations from the International Conference of Drug Regulatory Authorities[4] to NRAs to "*Explore approaches to utilize concept of reliance and collaborative decision-making to increase timely access to safe and effective medical products*".

The World Health Organisation (WHO) defines regulatory reliance as "*The act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others*[5]."

The IFPMA recognises that regulatory reliance offers opportunities for all stakeholders impacted by regulatory systems:

- **Patients & healthcare providers** - Timely access to safe, effective and quality medical products.
- **National Regulatory Authorities** - Efficient utilisation of resources by avoiding duplication of work and providing opportunities to strengthen the regulatory system, while maintaining sovereignty over decision-making.
- **Industry** – Streamlined management of regulatory submissions and global supply systems as well as predictable, timely approvals.

In this paper, IFPMA outlines key elements for NRAs to consider when establishing and implementing effective regulatory reliance mechanisms.

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[1]PAHO (2018), Regulatory Reliance Principles: concept note and recommendations

[2]Luigetti (EMA) et al. (2016). Collaboration, not competition: developing new reliance models. *WHO Drug Information Vol. 30, No. 4*.

[3] WHO (2019), Annex 6: Good practices of national regulatory authorities in implementing the collaborative registration procedures for medical products

[4] WHO (2018), 18th ICDRA Recommendations

[5] WHO (2016), Good Regulatory Practices Guidance

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Practical considerations for successful implementation of regulatory reliance

- Regulatory reliance should be considered by NRAs regardless of their resource or capacity level and independent of their maturity. In fact, streamlined processes for handling regulatory reliance can be seen as an exemplar of maturity.
- Clear public health priorities based on medical needs and regulatory capacity should guide NRAs approaches to regulatory reliance.
- Regulatory reliance should result in a reduction of regulatory burden and offer an opportunity for faster and more predictable approvals.
    - Regulatory reliance provides an opportunity to more efficiently utilise available capacity within NRAs. When regulatory reliance is implemented effectively, reducing the effort for both NRA and Industry, applicants will be more likely to use reliance-based regulatory procedures ahead of standard registration pathways.
- The timeline from reference country approval to submission of dossiers in a reliance-based regulatory procedure should be flexible. Country filing decisions are based on multiple factors - not only regulatory considerations. Reliance-based regulatory procedures that require submissions within a defined time of reference country approval may limit the usefulness of the procedure.
- Pilot programs for reliance-based regulatory procedures will provide initial practical experience for NRAs and applicants. Robust evaluation of results from these programs, including feedback and dialogue between NRA and Industry users, could swiftly capture opportunities to improve processes and procedures leading to increased trust and acceptability by all stakeholders.
- Reliance-based regulatory procedures can be implemented at many stages in the product life-cycle.
- When products are approved through reliance-based regulatory procedures, then post-approval changes should also be managed through reliance-based procedures.

- Other practical factors to be considered when implementing regulatory reliance:
    - Publishing a list of accepted reference NRA countries.
    - Providing guidance on what documents are required and how they are used for the assessment. Clarity on who is providing which documents (e.g. reference NRA vs applicant) should also be given and confidentiality should be assured.
    - Reliance-based regulatory procedures should be based on assessments from one reference NRA, and not upon 2 or more reference NRA countries.
    - Transparent, predictable and faster approvals compared to standard pathways to increase attractiveness of use.

Opportunities in implementing regulatory reliance

- Regulatory harmonization across different jurisdictions will foster regulatory reliance
    - NRAs should consider implementing regulatory reliance approaches within their existing legal framework and take into account regulatory convergence and harmonisation opportunities through implementing WHO and ICH guidance. Changes to regulatory and legal frameworks should also be considered, when needed, to leverage the benefits of regulatory reliance in the longer term.
- Regulatory reliance supports capability building
    - Different forms of regulatory reliance have different objectives. In cases where regulatory reliance is used to fill a capability gap, the learning and experience-sharing aspect of regulatory reliance will allow NRAs to address these gaps in the longer term. Regulatory reliance can support NRAs in developing capabilities to do independent dossier reviews.
- Strengthening trust between stakeholders
    - Collaboration and dialogue between all stakeholders participating in regulatory reliance activities will help to create and build trust, which is the foundation of regulatory reliance.

Conclusion

The IFPMA is supportive of strengthening regulatory systems and increasing their efficiency through the implementation of regulatory reliance. We are confident that the effective implementation of regulatory reliance will benefit patients, healthcare providers, regulatory authorities and Industry. Factors for a successful implementation of regulatory reliance have been described in this paper and the IFPMA is open to discuss these with NRAs and other stakeholders