



Benefits and Challenges of Reliance Pathways

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Benefits of Reliance Pathways

- **Enable efficient and effective use of manpower**
 - Reduce work duplication among NRAs
 - Releases limited resources of NRAs to focus on the critical, added-value activities that can benefit local population
 - Pharmacovigilance
 - Quality assurance along local supply chain
- **Improve robustness of regulatory decision-making: predictability, consistency and timelines**
 - May help reduce application backlog for NRAs
 - Supports evidence-based decision making by NRAs
 - Facilitates supply chain planning for companies
- **Encourage global alignment and convergence of regulatory requirements**
 - Reduce burden of fulfilling country-specific requirements by companies

Accelerate global access to medicines



Challenges of Reliance Pathways

- **Lack of systematic, internationally-recognised framework for adoption of reliance pathway by NRAs**
 - Type of reliance model to adopt and what information is needed?
 - The areas that reviewers should evaluate and to what depth?
- **Need to comply with the existing legal system of the country**
 - Is participation in international cooperation and exchange of information with external parties allowed under the local legislation?
- **Availability of the relevant post-approval systems by the NRA to mitigate the risks of reliance**
 - Is there a robust pharmacovigilance system in-place to monitor the safety signals of approved products in the local population?
- **Management of stakeholders' confidence in the quality of decision made using reliance pathway**
 - Are there SOPs to ensure that the sovereignty of the NRA's decision-making process and outcomes are retained in a reliance model?
 - Are there sufficient safeguards to address potential uncertainties, assumptions and risks associated with reliance model?
- **Competency and operational readiness**
 - E.g. Difficulty of access to un-redacted assessment reports from reference agencies



Thank you