



IFPMA



Advancing GMP inspection reliance – from pilots to practice

Introduction

Around the world, National Regulatory Agencies (NRAs) face mounting pressure to ensure access to and availability of high-quality medicinal products while confronted with an increasing number of sites to inspect, a demand driven by a need to strengthen supply resilience and manage limited inspection resources.

According to the World Health Organization (WHO) and International Coalition of Medicines Regulatory Authorities (ICMRA), “reliance” can be defined as, “*The act by which a regulatory authority takes into account and gives significant weight to an inspection outcome or report conducted by another trusted regulatory authority when making its own regulatory decisions*”¹. Informed reliance is gaining more traction in the modern regulatory toolbox, facilitating smart, risk-based, and efficient regulation of medicinal products. Good Manufacturing Practices (GMP) Inspection Reliance is one of the tools available to NRAs that is already operational and legally feasible – one that reduces redundancy, enhances regulatory efficiency, and sustains global supply of medicinal products.

This position paper represents the views of the research-based biopharmaceutical industry on GMP inspection alliance and provides an overview of the key enablers supporting implementation:

- Convergence of GMP standards
- International collaboration and pilot evidence
- Inspectorate networks – Pharmaceutical Inspection Co-operation Scheme (PIC/S), WHO Listed Authorities (WLA)
- Legal frameworks.

In addition, we provide practical recommendations that can foster the implementation of GMP inspection reliance:

- Use evidence of GMP compliance from trusted mature NRAs (based on WLA status and/or PIC/S membership) as the basis for reliance
- When necessary, advocate for adequate legislation and/or adapt guidelines to enable reliance
- Encourage reliance through collaboration and remote tools.

Benefits of regulatory reliance

Exercising reliance is a way of “in-sourcing” knowledge without “outsourcing” decision-making. In the recent EFPIA inspection survey, it was found that 80% of inspections² at the same site result in redundant findings, with no added benefit to patient safety.

Reliance has the potential to bring benefits to all stakeholders involved in the life cycle of a medicinal product – from patients to NRAs and industry. Such benefits have been widely described in literature^{3,4,5}. While manufacturing or distribution sites outside an NRA’s jurisdiction may sometimes be perceived as a regulatory risk, reliance on assessments from trusted mature NRAs (PIC/S and / or WLA) provides an opportunity to broaden knowledge about these sites, strengthening oversight rather than diminishing it. Reliance-based inspection procedures focus on risk for patients, enabling inspectors to prioritize novel or high-risk technologies, products, or sites.

Applying reliance approaches may:

- Accelerate time to market new products and the processing of post-approval changes
- Eliminate duplicative GMP inspections and optimize the use of resources
- Improve supply resilience, as it facilitates access to compliance data from additional manufacturing sites, diversifying supply and mitigating risk of shortages.
- Facilitate capacity building, leveraging and learning from trusted sources to make timely, informed, risk-based decisions at a national level.

Key enablers of GMP inspection reliance

The successful implementation of GMP inspection reliance depends on the establishment and reinforcement of critical enablers. Key enablers and considerations for GMP inspection reliance are:



Convergence of GMP standards

Most NRAs already apply harmonized GMP principles as laid down in PIC/S, ICH Q7, and ICH Q10 frameworks, creating a solid basis for reliance. Fostering convergence of regulatory frameworks, aligned with international standards, facilitates reliance as the rationale behind a decision is based on the same or equivalent requirements. However, it is important to note that reliance efforts can progress in parallel, without needing full harmonization to be in place.



International collaboration and pilot evidence

Multiple initiatives have demonstrated operational feasibility, including unilateral reliance: EMA GMP Inspectors Working Group (IWG), ICMRA Collaborative Hybrid Inspection Pilot (CHIP), PIC/S pilots, and ACCESS Consortium. Industry stakeholders believe that a significant amount of evidence has already been gathered through these different pilot programs. This accumulated evidence should enable us to move from pilots to standard practice, incorporating lessons learned into established regulatory pathways.

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Inspectorate networks (PIC/S, WLA)

PIC/S has more than 50 participating authorities, while the WHO has officially designated 39 NRAs as WLAs⁶, a status granted to NRAs that meet the highest international regulatory standards for medical products. These initiatives hold significant potential for expansion and further realization of their benefits, as more PIC/S participating authorities could rely on each other’s assessments through a reliance-based process (i.e. desk-reviews).

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Legal frameworks

While legislation is often framed as an obstacle, a conducive legislative framework is essential to enable both unilateral and mutual reliance arrangements. Many NRAs still conduct their own inspections abroad, even when facilities have been inspected by trusted mature NRAs (PIC/S or WLAs countries). This often reflects legal constraints rather than quality concerns.

Legal tools such as Confidentiality Agreements (CA), Memoranda of Understanding (MoUs), and Mutual Recognition Agreements (MRAs) enable reliance approaches. This facilitates secure information sharing and formal recognition of inspection results. These mutual recognition instruments (MRI) are already successfully used among WLAs and regional groups like the Association of Southeast Asian Nations (ASEAN), the Gulf Cooperation Council (GCC) and the European Union (EU). An illustration of the different levels of legal frameworks for empowering reliance is captured in figure 1. MRAs are the highest level of this framework, with most pharmaceutical MRAs being standalone agreements between two trade partners. Additional types of MRIs exist such as arrangements amongst assessment bodies, which should be further explored, especially considering the potential of PIC/s and its mission.

Without a clear legal basis for reliance, NRAs may find it difficult to make use of inspection results from trusted authorities. However, efforts should still be made to implement reliance within the current frameworks rather than postponing it until an ideal legal structure is in place.

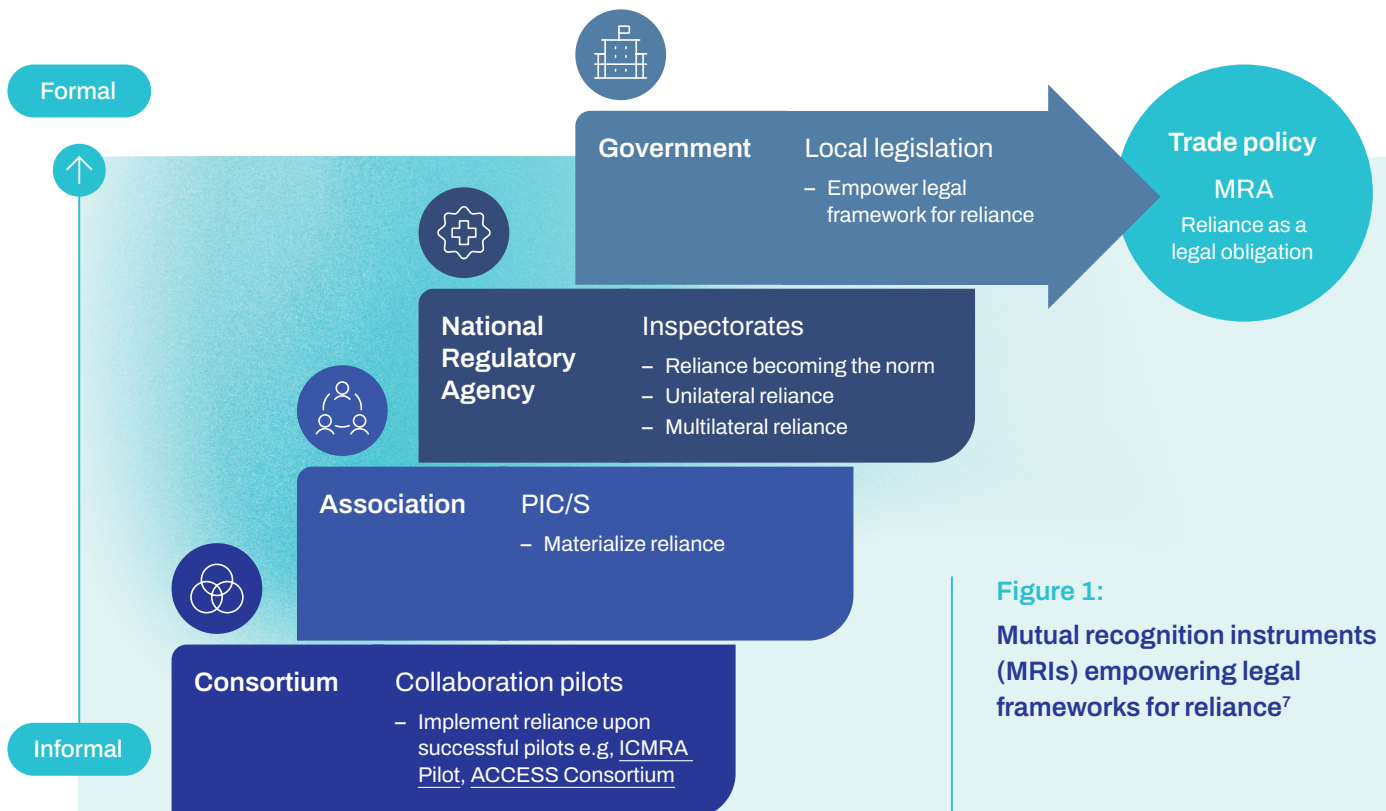


Figure 1: Mutual recognition instruments (MRIs) empowering legal frameworks for reliance⁷

Practical recommendation to facilitate GMP inspection reliance

The following practical recommendations reflect the perspective of the pharmaceutical industry and are informed by our experience to date with GMP reliance procedures and pilots. They are intended to support NRAs in establishing GMP reliance processes that are effective, efficient, and workable for both NRAs and industry.



Use evidence of GMP compliance from trusted mature NRAs as the basis for reliance

Evidence of GMP compliance (e.g. GMP certificate or equivalent, like the US-FDA Establishment Inspection Report) from a mature NRA (e.g WLA), covering the equivalent scope as needed, should be sufficient and allow for reliance by replacing the need for a GMP inspection. This approach aligns with PIC/S's GMP Inspection Reliance Guidance (PI 048-1)⁸, which offers a framework for desktop assessment based on other regulators' inspection outcomes and with IFPMA's Best Practices for Unilateral Reliance⁹. The decision to approve a new marketing authorization, manufacturing license, or post-approval change remains with the respective NRA, who fully retains their independence and sovereignty.



When necessary, support the development of adequate legislation and/or adapt guidelines to enable reliance

Adapting national laws and/or regulatory guidelines to allow recognizing "evidence of GMP Compliance" from a WLAs / PIC/S participating authorities can foster GMP inspection reliance. Promoting familiarity with international frameworks such as PIC/S and WHO's WLA program and institutionalizing reliance within NRA-level processes (e.g., quality management systems) can accelerate uptake and implementation.



Encourage reliance through collaboration and remote tools

Building on existing models like the ACCESS Consortium and Mutual Recognition Agreements (e.g., EU and 3rd countries, ASDEAN, GCC) facilitates acceptance of inspection reports across jurisdictions and enhance regulatory efficiency. NRAs can also adopt alternative modes such as hybrid and remote inspection modalities, a practice effectively applied during crisis situations, e.g. the COVID-19 pandemic, to support timely and informed reliance decisions. The remote inspection model can also be used for observed inspection by other NRAs and/or to clarify site related compliance questions emerging during a regulatory filing. Ultimately, compliance could be verified by assessing current GMP certificates and/or latest inspections reports only. This represents an efficient alternative to an on-site inspection, removing the need for travel and the associated operational downtime.

Figure 2 below illustrates a high-level, generic process that NRAs may follow when operationalizing GMP inspection reliance. It outlines progressive steps starting with some baseline of convergence all the way to allowing systematic reliance on a trusted domestic inspectorate to ideally have only one inspection per site per year. This shows that reliance is not a single action but a structured, maturing process that enables NRAs to confidently use trusted inspection outcomes while maintaining full regulatory sovereignty.

Figure 2:

A stepwise process to implement GMP inspection reliance



Conclusion

The time is now

Experience gathered at a global level has shown that GMP inspection reliance works. The tools, data, and frameworks needed for implementation are already in place through PIC/S guidance, facilitated by ICMRA collaboration and by WLA initiative. Successful pilots between trusted NRAs have proven that reliance can deliver efficiency without compromising quality or sovereignty. The next step is to move from pilots to practice and embed reliance principles into national systems and modern GMP frameworks across more NRAs.

With its network of 50+ inspectorates, PIC/S is uniquely positioned to lead this next phase. By aligning processes, sharing best practices, and fostering political and policy-level commitment, PIC/S can help make reliance a routine, sustainable reality that builds confidence among participants while fully preserving national authority in decision-making.

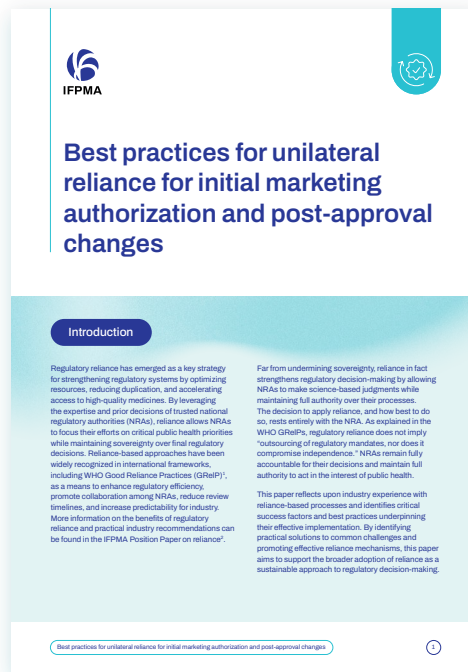
IFPMA and its members are ready to support this process by sharing data, case studies, and technical expertise. We remain committed to providing practical pathways for implementation and showcasing success stories from ongoing collaboration efforts. Together, we can foster global implementation of GMP inspection, building efficient, resilient, and sustainable regulatory systems that accelerate patient access to quality medicines and vaccines worldwide.

Endnotes

1. [Technical Report Series, No.1033, Annex 10: Good reliance practices in the regulation of medical products: high level principles and considerations, WHO, 2021.](#)
2. [EFPIA, Annual Regulatory GMP/GDP Inspection Survey 2023 Data, 2024](#)
3. Danks L, Alshammari TM, Habib A, Bakshi R, Almandil NB, Aljadeed R, et al. [Evaluation of the impact of reliance on the regulatory review timeline.](#) *Front Med.* 2023;10:1134503.
4. Xu M, Velásquez G, Røttingen J-A, Wiktor S. [Regulatory reliance to improve access to quality-assured medical products: a global health perspective.](#) *BMJ Glob Health.* 2022;7:e009002.
5. Doerr P. [Reliance: a smarter way of regulating medical products.](#) *Regul Rapporteur.* 2021;18(7/8):8–12.
6. WHO, [List of WHO Listed Authorities WLAs, 2025](#)
7. [EFPIA, Annual Regulatory GMP/GDP Inspection Survey 2023 Data, 2024](#)
8. PIC/S, [Guidance on GMP Inspection Reliance, 2018](#)
9. IFPMA, [Best practices for unilateral reliance for initial marketing authorization and post-approval changes, 2025](#)



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