Access Consortium Statement on Good Manufacturing Practice (GMP) Inspections Reliance and Recognition

Good Manufacturing Practice (GMP) ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use or as required for marketing authorisation. In alignment with the Access Consortium's[1] strategic objective to expand and maximise collaboration throughout the product lifecycle, this collective statement[2] issued by the Access Heads of Agencies serves to solidify the Consortium's commitment to demonstrate greater inspection reliance and accept GMP inspection outcomes. The reliance on inspection outcomes will be based on the review of inspection reports or other documentary evidence for GMP inspections conducted by Access members within their territory, in lieu of conducting another GMP inspection. This reduces the regulatory burden on stakeholders and could facilitate our populations' timely access to high quality, safe and effective pharmaceutical products.

Our Commitment to Reliance and Recognition Arrangement in GMP Inspections

GMP Inspection reliance arrangements and formal mutual recognition arrangements are highly effective tools that can help regulatory authorities manage increasing complexity in the manufacturing and supply chain of medicines in a timely manner. Establishing such arrangements reduces duplication of GMP inspections and allows for more efficient use of each authority's resources, allowing these to be channelled to areas where most needed.

As Participating Authorities of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the Consortium members will commit to accept GMP inspection reports issued by Access members for GMP inspections conducted within their territory, in lieu of conducting another

[1] 1 The Access Consortium was formed in 2007 by 'like-minded' regulatory authorities to promote greater regulatory collaboration and alignment of regulatory requirements. The Consortium was initially formed by the regulatory authorities from Australia (Therapeutic Goods Administration), Canada (Health Canada), Singapore (Health Sciences Authority), and Switzerland (Swissmedic). More recently, the United Kingdom's Medicines and Healthcare products Regulatory Agency joined the Consortium. Its goal is to maximise international cooperation, reduce duplication, and increase each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products.

[2] This statement reflects the intention of the Consortium members. It is not intended to create legal obligations of any nature, either in domestic or international law. This statement is not intended to diminish or otherwise affect the authority of the Consortium members to carry out their responsibilities and regulatory programmes or restricting a Consortium member from conducting its own inspection of a product manufacturing facility which may have already been inspected by another Consortium member when deemed necessary.

GMP inspection. The Consortium will maximise the existing GMP Inspection reliance and mutual recognition agreements in place and work closely together to expand their use wherever possible for products undergoing evaluation.

The Access Consortium will continue to explore opportunities for information and work-sharing initiatives, to better align the regulatory systems, reduce unnecessary duplication and facilitate convergence. For more information on the Access Consortium and its work, please refer to the related links below.

Related links: *(Access members to link to these documents on their respective website)*

Access Strategic Plan 2021-2024

Access Terms of Reference