Reflection Paper on the role and value of reliance in the UK medicines regulatory framework

June 2022

UK BioIndustry Association

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has a long history as a valued contributor to the global regulatory ecosystem. This contribution has been realised not only through advancements in regulatory science, but also through acting as **a point of reference** for the regulatory decision-making of other regulators and by leveraging outcomes from trusted partners in the system to deliver regulatory decisions and facilitate access to innovative medicines for UK patients. **This balance of acting as a reference and recognising expert outputs from others is now widely accepted as standard practice and can in fact be seen as a measure of regulatory maturity**. We believe that this balance should be retained as a central part of the MHRA's operating model moving forward.

Regulatory reliance is a mechanism which supports agile management of resources whilst simultaneously allowing focus on core and innovative national activities. The MHRA played a central role in pioneering and advancing reliance in the evolution of the European regulatory network, and this regulatory innovative practice is one of the most important global legacies for medicines regulation. The current recommendations on reliance from the International Conference of Drug Regulatory Authorities, in which MHRA plays an important role, are to "Explore approaches to utilise concepts of reliance and collaborative decision-making to increase timely access to safe and effective medical products".

Regulators remain responsible and accountable for all decisions taken but can rely on the decisions and assessments of other trusted regulators to facilitate timely assessment of medicines and healthcare products for early patient access in their respective territories. Reliance is not about becoming deferential or dependent on other regulators but advancing good regulatory practice and international networks to allow for a better division of resources and potentially specialisation. Reliance allows regulators to focus increasingly pressured regulatory staff and resources on the most valuable tasks of protecting public health and supporting innovation, and to maintain timelines and quality standards for all procedures.[1]

Reliance-based regulatory procedures can be utilised across all stages in the product lifecycle. New products can be approved through reliance-based regulatory procedures, but also post-approval changes can be managed utilising the same approach. The pandemic has underscored the value of reliance to address the significant workloads of regulators as well as the urgent need to deliver new and established treatments for patients globally.

[1] MHRA publishes metrics on licensing performance: Medicines: licensing time-based performance measures - GOV.UK (www.gov.uk). These figures illustrate experiences BIA members have witnessed, as pressures to meet timelines increase for MHRA. Without the reliance route, one could anticipate even more serious delays and pressures on staff.

A list of accepted reference regulatory authorities can be a living document to recognise the evolution of partnerships over time. The MHRA can build upon the current recognition pathways in place – such as the EC Decision Reliance Procedure (ECDRP), and international work-sharing through the Access Consortium and Project Orbis – and consider how these concepts can offer additional opportunities for agile ways of working with other regulators around the globe. This also includes opportunities for the UK to act as a reference agency for other regulators globally and to help develop reliance capabilities across the MHRA's growing global regulatory network.

We believe that it is imperative for the MHRA to leverage its strong history of active participation in reliance practices to confirm this reliance pathway for the future. This would enrich the regulatory offerings for UK regulatory procedures as well as advance the MHRA's role as a global regulatory leader, as an exemplar for best practices in balancing a successful portfolio of innovative pathways, work-sharing and reliance that delivers high performance and resource optimisation.

If the MHRA departed from certain regulatory approaches, sufficient time and engagement with stakeholders would be required to allow for smooth transitions to new ways of working. Horizon scanning is important not only for regulators but for the regulated industry, to be able to anticipate and plan in light of proposed regulatory change. Suspending the reliance pathway at the end of 2022 without a short notice prolongation will be highly disruptive for BIA member companies and for UK patients, as filing plans are very likely to be substantially delayed. Moreover, our member companies would need assurances that the MHRA would have sufficient resources to deal with an increased volume of national licensing applications in a timely fashion without the reliance route being a potential option.