Response to consultation on the future strategy for batch testing of medicinal products in Great Britain

July 2022

UK BioIndustry Association

The BIA welcomes the opportunity to respond to the Department of Health and Social Care consultation on the future strategy for batch testing of medicines in Great Britain. The consolidated BIA response was developed with input from our Regulatory Affairs Advisory Committee. We also encouraged individual responses from BIA member companies so that they can give their specific views on the future batch testing policy.

It is important that the consultation outcome supports the ambitions of the Life Sciences Vision and ensures that the UK retains and grows its reputation as a world-leading base for innovation and investment in R&D, while protecting patient safety and access to medicines, and maintaining globally harmonised standards.

We have provided below the BIA feedback on the four policy options proposed in the consultation document with regards to medicines imported from a third country with which the UK does not have a mutual recognition agreement (MRA) on batch testing.

Option A: No import testing or UK QP certification or release for medicines imported from countries on the approved list

In our view, **option A will have a favourable impact on the continued supply and patient access to medicines** because:

- The current measures that were put in place at the end of the transition period work well and provide long term certainty with no additional costs, allowing life sciences companies to focus their resources on R&D of innovative medicines in the UK.

- This option avoids setting up duplicative and unnecessary testing operations, with no delays to bringing medicines to the UK market.

- There will be no environmental impacts – this option avoids unnecessary transport of samples, as well as use of additional testing equipment and reagents and production of waste due to duplicate testing.

- The EU/EEA countries have been deemed to be of equivalent regulatory standards to the UK. The UK will remain aligned to ICH guidelines. Any future countries to be included on the approved list will be countries with equivalent standards to the UK, aligned with ICH guidelines.

- The MHRA will remain responsible and accountable for the quality, safety and efficacy of medicines on the UK market but can rely on the testing and release performed under the jurisdiction of other trusted regulators to facilitate timely patient access to medicines in the UK.

Therefore, option A is the BIA's preferred policy option.

<u>Option B</u>: No import testing but implementing UK QP certification and release for countries on the approved list

We believe option B will negatively impact on the supply chain and add unnecessary regulatory duplication and costs:

- **Delays to the supply and access to medicines**: This option requires additional time and resources to implement the requirement for QP certification/release in the UK. There is concern that this option will lengthen the time to release a product on the UK market, which will impact on shelf-life, and cause delays to the supply of essential medicines to GB patients.

- **Unnecessary regulatory burden**: Many companies do not carry out their manufacturing and batch release operations in the UK and will therefore have to apply for a Manufacture and Importing Authorisation (MIA) and recruit UK QPs for certification/release. This option will remove the role of the Responsible Person (import) (RPi) which was created in 2021 and can be perceived as a wasteful activity by companies. In addition, marketing authorisation holders will need to apply for a variation to their licences to add the UK batch certification site. Moreover, MHRA will need to have capacity to process all these applications for regulatory changes, including conducting GMP inspections in the context of the MIA applications. Such an approach also stands in contrast to the progressive efforts of regulatory science leadership to move towards addressing the quality management system, rather than relying on testing at the end of the process.

- **Non-value-added activities and increased costs**: Our member companies do not see this option as adding value to UK life sciences. They have concerns regarding the current QP resources in the UK and the need to train new QPs which will take many years. The cost of bringing medicines to GB patients will rise because of the addition of this unnecessary step to the release process for medicines.

Therefore, option B is not supported.

<u>Option C</u>: full quality control batch testing and implementing UK QP certification and release for all non-MRA countries

We believe **option C would introduce the greatest additional burden on suppliers and likely result in shortages and delays to the supply of medicines to the UK market and could have a significant impact on continuity of patient care**:

- As for option B, a large number of companies importing medicines from such countries will require the MIA and GMP certificate and recruit UK QPs for certification and release of the batch. All marketing authorisation holders will need to apply for a variation to their licences to add the UK batch certification site and the UK quality control testing site.

- As for option B, MHRA will need to have capacity to process all these applications for regulatory changes, including conducting GMP inspections in the context of the MIA applications. Additional variation applications for changes in testing methods may also need to be processed, due to unforeseen problems with transfer of testing methods from EU sites to UK laboratories – this will result in further workload for the MHRA.

- A lack of in-house testing facilities may require new facilities to be built, resulting in significant delays, increased costs and resource issues. There is also a need to assess the availability and suitability of UK contract laboratories and their capacity given the increase in demand.

- This duplicative batch testing provides no added value for GB patients. It is worth noting that products tested and released at EU registered GMP manufacturing sites meet the required quality standards. As noted above, it also stands in clear contrast with the direction of travel in regulatory science leadership to move away from end testing towards a more sophisticated review of quality management systems.

- The requirement for full batch testing and release on all medicinal products will make the UK a hugely costly and far less attractive market for medicinal product supply and R&D investment. This will result in shortages and delays in the supply of medicines to the GB market and have a negative impact on shelf-life and costs of medicines.

- The additional costs, time and resources required for testing and release may also impact on the availability of new, innovative medicines to UK patients. This may be prohibitive for the supply of orphan medicines to a small number of GB patients.

- The significant increase in transporting testing samples to laboratories, use of reagents and their disposal strategies will have environmental impacts.

Therefore, option C is not supported.

<u>Option D:</u> reduced number of import tests and implementing UK QP certification and release for all listed countries

We believe **option D is expected to have a similar impact as option C**. Therefore, reference is made to the comments above regarding option C.

It is not clear to us how this policy option supports the Government's aims in the Life Sciences Vision. This duplicative batch testing provides no added value for GB patients.

Therefore, option D is not supported.

About the BIA

The UK BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK, representing over 500 member companies including start-ups, emerging and more established biotech companies, pharmaceutical companies, academic, research and philanthropic organisations, and service providers to the life sciences sector. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

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