



Date: 26 July 2022

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### **Scottish Lifesciences Association response to Government consultation on future strategy for testing and release of imported medicines**

After discussions at the Qualified Person (QP) Special Interest Group within the Scottish LifeSciences Association we feel it appropriate to respond directly on the recent consultation document on the future strategy on batch testing of medicinal products being imported into Great Britain. We feel that the preferred option going forward would be to implement Mutual Recognition Agreements with our key partners where we have equivalent regulatory standards in the field of medicinal manufacture, testing and control. We feel that this provides greater flexibility than the “list” approach described in the consultation, whilst also being better recognised internationally.

However, as the consultation was limited to the four options provided, we looked into those in detail and our conclusion is that none of the four options are optimal in isolation. We would suggest that the best approach, using the 4 options available would be a hybrid of option B and option D, where lower risk medicines from lower risk locations would go onto an Option B list, and medicines which are higher risk and/or from higher risk locations would go on to an Option D list. It is felt that this approach would enable the smooth flow of medicines into Great Britain, whilst also providing for an increased level of control over medicines that have a higher risk of being problematic. Option A provides insufficient control over medicines coming into Great Britain, and we simply do not have the testing infrastructure to implement Option C.

One further point to note is that Options B, C and D all place an additional burden on GB QPs and the likelihood that GB will need more QPs to implement either of these options well. Many companies are already struggling to recruit the required number of QPs and an increased requirement for QPs, without an equivalent increase in the number of QPs will be problematic, leading to delays in the supply of medicines in GB.

### **Scottish LifeSciences Association (SLA)**

With over 130 member life sciences companies and organisations of all types and sizes, the Scottish Lifesciences Association is the voice of Scotland’s vibrant life sciences industries to investors, NHSScotland, the Scottish and UK Governments, and the wider community. We are member driven through 16 Special Interest Groups and 4 sub-groups. We deliver on every aspect of members’

businesses, helping each other to attract investment and increase business activity, and engaging with the NHS and Government to grow the life sciences sector in Scotland and the UK.

Best regards

A handwritten signature in black ink, appearing to be 'SJ', with a long horizontal stroke extending to the right.

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