Impact Statement
UK-EU Trade and cooperation agreement January 2021

The summary of this document which was published by the UK Government in late December 2020. The full document was later discussed and approved by the UK parliament on Dec 30, 2020. We note that the summary refers to an Annex on medicinal products.

This Annex aims to facilitate availability of medicines, promote public health, and protect high levels of consumer and environmental protection in respect of medicinal products. It provides for mutual recognition of Good Manufacturing Practice (GMP) inspections and certificates, meaning that manufacturing facilities do not need to undergo separate UK and EU inspections, as well as ongoing co-operation.

See: -summary page 9 point 22

Also, within the same summary we note the following important points in Chapter 5–Regulatory framework - Section 2 -Mutual recognition of professional qualifications

Point 50. The UK and the EU have agreed a framework for the recognition of qualifications between the Parties which is based on the EU's recent Free Trade Agreements (FTA) agreements. It makes improvements on those agreements, which are designed to make the system more flexible and easier for regulatory authorities to use.

Point 51. This approach will allow the UK and its regulators to maintain standards of professional competence. From early 2021, the government will provide help and guidance to UK regulatory authorities and professional bodies to help them benefit from these provisions as well as other recognition paths.

Point 52. The Agreement clarifies that the provisions on professional qualifications are without prejudice to alternative arrangements that the UK may agree with the EU, allowing for improved mechanisms to be agreed in future. Agreements will be negotiated on a profession-by-profession basis.

The text of the full agreement has now been published and can be viewed at full agreement

The medicines annex (TBT-2 MEDICINAL PRODUCTS) is on pages 492-503

Overall, the outcome appears to be positive in terms of ongoing trade in Medicines between the UK and The EU. However, the text appears to fall short of the text of Mutual Recognition Agreements (MRAs) between the EU and other countries. For instance, no mention is made of testing and release of imports. This may well mean that the EU will continue to treat the UK as a 3rd country and require such testing and release of UK manufactured medicines on import to the EU. We will need to wait for further clarification on this and other issues. For imports from the EU and existing MRA partners into the UK the situation is clearer and such testing will not currently be required as detailed in the Human Medicines Regulations. See:-Importing medicines to Great Britain or Northern Ireland

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