Brexit: DG SANTE prepared for a new relationship with the UK / Key arrangements put in place ahead of Brexit

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(https://ec.europa.eu/newsroom/sante/picture.cfm?id=59595&src=0&universe=674)

Director for Crisis preparedness in food, animals and plants, in charge of the Brexit files for DG SANTE, Bernard Van Goethem lays out the preparatory work carried out by DG SANTE ahead of 1 January 2021.

‘New beginnings for old friends’ as President Von der Leyen stated last month is how we begin this year following the end of the Transition Period on 31 December, marking the end of the United Kingdom’s application of the European Union’s regulatory framework. The Commission has been laying the groundwork for this moment and the EU is well prepared.

In particular, DG SANTE has finalised any outstanding issues in the areas of sanitary, phytosanitary (SPS) and pharmaceuticals policy under the Protocol on Ireland and Northern Ireland (https://ec.europa.eu/commission/sites/beta-political/files/revised_withdrawal_agreement_including_protocol_on_ireland_and_nothern_ireland.pdf) (NI) (‘the IE/NI Protocol’). Under the terms of the IE/NI Protocol, in force since 1 January 2021, Northern Ireland will remain in the EU single market for the SPS area, requiring border checks on animals, plants and their products entering NI from GB.

The Commission has closely monitored UK SPS legislation to assess if the UK can be allowed to import into the EU and to ensure Member States can continue to export all categories of animals and goods to the GB market. Furthermore, certification and control will gradually be implemented by GB between January and July 2021.

The Commission has assisted in the preparations undertaken by the Member States most impacted by Brexit, such as Ireland, France, Belgium and the Netherlands, in the construction and extension of their border control posts (BCPs). These posts are now operational, while BCPs on the British side will be operational as from July 2021.

In December, the Commission amended relevant legislation to list the UK amongst the third countries authorised to export animals and animal products to the EU. We also amended the Delegated Act on transit (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32019R2124) to ensure Ireland unrestricted access to the internal market.

EU representatives will be present in NI during official controls, especially at the border posts, in order to ensure that EU legislation is implemented in compliance with the Protocol.

The IE/NI Protocol also covers the area of medicinal products. The Commission has intensively prepared, in cooperation with our relevant authorities, the European Medicines Agency (EMA) and national authorities, to ensure that all medicinal products placed in the EU or Northern Ireland are in compliance with the regulatory requirements laid down in the Union law so that the supply chain is protected across Member States.

Despite the good level of preparedness, the Commission published a notice on 22 December 2020 (https://ec.europa.eu/health/sites/health/files/human-use/docs/c_2020_9264_en.pdf) that aims to provide solutions to avoid medicine shortages in small markets that have historically relied on the supply of hundreds of various medicinal products from Great Britain, namely in Ireland, Northern Ireland, Cyprus and Malta. Although companies have not been making the investments to support the necessary regulatory changes for those small markets, the Commission has strived to ensure that patients are not deprived of critical medicines post-Brexit.

This notice will also allow the pharmaceutical industry further time to adapt their marketing authorisation processes to the consequences of Brexit, namely in manufacturing authorisation and batch release testing for medicinal products for human and veterinary use as well as medicinal products used in clinical trials. The notice also covers measures to fight medicine falsification.

The UK and EU have agreed, through the Annex on pharmaceuticals, to ensuring mutual recognition of our Good manufacturing practice (GMP) certificates. This agreement will allow the EU to save on inspection resources. The EU will continue to recognise GMP certificates issued by UK for UK sites as well as for third countries.

In practice, the annex will offer the advantages of other mutual recognition agreements for broad scope product inspections, comparable to a similar arrangement with Switzerland.

We have been working intensively for the past four years to prepare for this eventuality. The Commission will endeavour to see that Member States, businesses and citizens continue to function effectively now that the UK has left the EU.
