APPLICATION OF UNION LAW RELATED TO MEDICINAL PRODUCTS IN RESPECT OF NORTHERN IRELAND AFTER THE END OF THE TRANSITION PERIOD

UNILATERAL DECLARATION BY THE EUROPEAN UNION IN THE JOINT COMMITTEE

The full and proper implementation of the Protocol on Ireland and Northern Ireland is an essential element in the Union's relationship with the United Kingdom.

As regards the supply of medicines, this Protocol provides for the application of the Union's pharmaceutical acquis in respect of Northern Ireland after the transition period. We also note that Northern Ireland faces particular challenges in this regard, due to the withdrawal of the United Kingdom from the Union.

The Union is determined to ensure not only the high level of public health protection guaranteed by applicable Union law, but also an undisrupted supply of medicines to Northern Ireland and other small markets historically dependent on medicines supply from or through Great Britain. These considerations are of particular importance given the exceptional circumstances of the Covid-19 pandemic.

In order to achieve these objectives, and under due consideration of Northern Ireland's particular challenges, the Union suggests a practice in the application of the Union's pharmaceutical acquis in respect of Northern Ireland which includes the following three elements:

1. A temporary removal of the obligation to decommission safety features applied to medicinal products supplied to the United Kingdom by a manufacturer, importer or wholesaler in the Union.
2. A consideration of small markets historically dependent on medicines supply from or through Great Britain as "justifiable cases" allowing for quality control testing in Great Britain during a limited time

3. An abstention from sanctioning certain breaches of Union law arising due to the absence of manufacturing authorisation holders in Northern Ireland

These three elements will apply to human and veterinary medicinal products, including investigational medicines where relevant.

By applying this approach for a period of up to twelve months after the end of the transition period, the Union aims to give all relevant stakeholders sufficient time to adapt to the United Kingdom's withdrawal and to establish new supply routes where necessary, while providing for undisrupted supply of medicines and a high level of public health protection.

The same approach to the application of Union law related to medicinal products supplied through Great Britain during the first 12 months after the transition period will also be set out in detail in a Commission Notice (to be published shortly) on the supply of medicinal products to small markets historically dependent on medicines supply from or through Great Britain (Cyprus, Ireland and Malta) in accordance with the Union's pharmaceutical acquis after the end of the transition period in detail.

UNILATERAL DECLARATION BY THE UNITED KINGDOM IN THE JOINT COMMITTEE

The United Kingdom takes note of the European Union's declaration setting out its approach to the application of Union law on pharmaceuticals in respect of Northern Ireland for a period of up to twelve months after the end of the transition period.