Questions and Answers on Commission Proposal to ensure continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta

Brussels, 17 December 2021

What has the Commission adopted today?

The Commission has today put forward a package of measures to ensure the continued long-term supply of medicines from Great Britain to Northern Ireland and to address outstanding supply concerns in Cyprus, Ireland and Malta – markets that have been historically supplied through or by Great Britain.

The European Commission and the UK government have conducted extensive talks to find a long-lasting solution on medicines. The proposed bespoke solution reflects the outcome of substantial discussions between European Commission Vice-President for Interinstitutional Relations and Foresight Maroš **Šefčovič**, and the United Kingdom Cabinet Office Minister, David Frost. It also takes into account the concerns raised by stakeholders, following our extensive outreach to citizens, industry and other business representatives in the EU and the UK on the issue of medicines.

With today's proposed solution, the Commission is delivering on its intention to facilitate the implementation of the Protocol on Ireland/Northern Ireland on the ground, in line with the package of far-reaching solutions for Northern Ireland tabled on 13 October 2021.

The EU has continuously engaged in good faith with the UK to find pragmatic solutions to help minimise disruption caused by Brexit and to help facilitate the everyday life of communities in Northern Ireland.

What is your solution as regards Northern Ireland?

The Commission has proposed to change EU rules to ensure that the same medicines are available in Northern Ireland at the same time as they are in the rest of the United Kingdom.

On Generic Medicines (e.g. Paracetamol)

Generic medicines will be authorised under national UK procedures, in compliance with EU substantive rules on medicinal products. Pharmaceutical companies will have the option of choosing either the UK authorisation process or an EU Member State procedure. If companies opt for the UK national procedure, the UK regulator will not have to agree the terms of the authorisation with Member State authorities and will be solely in charge. In such a scenario, authorisation by the UK regulator could allow companies located in Great Britain to use a single pack and single leaflet when supplying markets in Great Britain and Northern Ireland. There would be no need for separate packaging.

All regulatory functions will remain wherever they are now in the UK. This means that there is no need to relocate any regulatory functions or testing facilities from Great Britain to Northern Ireland. Batch testing carried out in the EU does not need to be repeated when medicines are brought into Northern Ireland through Great Britain.

On life-saving Innovative Medicines (e.g. new cancer medicines)

People in Northern Ireland will continue to have access to novel, innovative life-saving medicines at the same time as people in other parts of the UK. A 'bridging solution' will allow any new medicine authorised in the UK to be supplied to Northern Ireland, until the relevant authorisation is also given in the EU. Those temporary authorisations should be time limited and cease once a decision on the medicinal product is taken at EU level. Today's solution covers any medicine that may need to undergo assessment by the European Medicines Agency and be authorised by the European Commission. This 'bridging solution' is in addition to the existing compassionate and emergency use early access mechanisms under EU law.

On procedures for the supply of medicines from Great Britain to Northern Ireland

(applicable to all medicines)

No manufacturing authorisation or import license will be required for bringing medicines into Northern Ireland from the rest of the United Kingdom. In addition, EU medicine unique identifiers – that ensure prescription medicines are genuine – will not need to be removed from prescription medicines that transit through Great Britain to Northern Ireland for another three years. This is a derogation from the rule that unique identifiers must be removed when prescription medicines leave the EU and are exported to a third country. This will avoid the need for affixing a new identifier when those medicines enter Northern Ireland from the rest of the United Kingdom and will allow more time for industry to adapt.

Why are you also addressing the situation in Cyprus, Ireland and Malta?

Historically, many medicines in Cyprus, Ireland and Malta have been supplied through or from Great Britain. The UK's withdrawal from the EU has made it challenging for operators in these Member States to comply fully with EU law. In order to address this situation, prevent shortages of medicine, and ensure a high level of public health protection, Cyprus, Ireland and Malta will benefit from certain derogations for a three-year period. For example, during this period in these three countries, importers of medicines from the UK will not need to hold manufacturing authorisations, nor will these medicines need to be batch tested again if they have already been tested in the UK. In addition, Cyprus and Malta will be able, under certain conditions, and for justified public health reasons, to authorise the placing on their national market of a medicine authorised in the UK. This will give operators more time to adapt. Work on a long-term permanent solution is ongoing in the context of the EU's Pharmaceutical Strategy.

Today's notice requires the competent authorities in the UK and the Member States concerned to publish a list of the medicines in question. This is a way to increase transparency about the operation of the bespoke solution for Northern Ireland and the specific derogations for Cyprus, Ireland and Malta, with the ultimate aim of protecting public health in the EU and ensure that those medicines are not further distributed to other parts of the Single Market.

What will happen in the interim?

For the sake of stability and predictability, there will be an extension of the Commission's interpretive note to ensure a continuation of the supply of medicines to Northern Ireland as well as Cyprus, Ireland and Malta. Existing arrangements will therefore last until the end of 2022, unless the legislative procedure is finalised sooner.

Does today's package cover veterinary medicines?

Today's legislative proposals do not cover veterinary medicines. Discussions on veterinary medicines will continue over the next months in order to gather information, identify any outstanding implementation issues and find the most appropriate way forward to ensure long-term continuity of veterinary medicines supply to Northern Ireland, as well as Cyprus, Ireland and Malta.

For the short term, however, the extension of the Commission's interpretive notice includes veterinary medicines. Existing arrangements in this area will continue until the end of 2022.

What are the next steps?

Today's legislative proposals will be sent to the European Parliament and the Council as soon as all linguistic versions are available. The Commission urges the co-legislators to start work on these proposals as soon as possible, in the interests of the people and businesses of Northern Ireland.

For More Information

Press release

Press Statement by Vice-President Maroš Šefčovič on the state of play of discussions with the United Kingdom on the implementation of the Protocol on Ireland / Northern Ireland

Commission proposal to ensure continued supply of medicines to Northern Ireland, As well as Cyprus, Ireland and Malta

Relations with the United Kingdom

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