



EU-UK relations: Commission delivers on promise to ensure continued supply of medicines to Northern Ireland, as well as Cyprus, Ireland and Malta

Brussels, 17 December 2021

The Commission has today put forward proposals 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. In the context of the Protocol on Ireland/Northern Ireland, this means that the same medicines will continue to be available in Northern Ireland at the same time as in the rest of the United Kingdom, while specific conditions ensure that UK-authorised medicines do not enter the Single Market.

Throughout this year, the Commission has been engaging intensively with citizens, industry and other business representatives in the EU and the UK on the issue of medicines. The European Commission and the UK government have conducted extensive talks to find a long-lasting solution. 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, and takes into account the concerns raised by stakeholders during the Commission's extensive outreach.

Vice-President Šefčovič said: *"I promised to do whatever it takes to ensure the continued supply of medicines to Northern Ireland, even more so in light of these challenging times of the pandemic. Today, we are turning this genuine commitment to the people of Northern Ireland into a lasting solution, based on our extensive outreach to all relevant stakeholders. I am convinced that the issue of medicines shows that the EU and the UK can work together for stability and prosperity of all communities in Northern Ireland. It also shows that the Protocol has the flexibility to work on the ground. To strengthen its opportunities, we must now carry this momentum into the other areas of discussion."*

Stella Kyriakides, European Commissioner for Health and Food Safety, said: *"We all know how crucial the continuous supply of medicines are for hundreds of thousands of patients in Northern Ireland, but also in Cyprus, Ireland and Malta, whose markets are historically dependent on medicines from the UK. In the past months, we have remained committed to finding a solution which would work for all citizens. Our objective is to ensure that they can continue to get the medicines they need, at all times. Now we have to act swiftly to see these proposals adopted and I call on the European Parliament and the Council to adopt them as soon as possible."*

In detail

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 will amend its own legislation on medicines to ensure that:

- **Generic medicines** (such as paracetamol) **can be authorised** under national UK procedures, in compliance with EU rules on medicines. People in Northern Ireland will have access to these medicines at the same time as people in the rest of the UK.
- People in Northern Ireland will also have **access to innovative life-saving medicines** (including **new cancer medicines**) at the same time as any other person in 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. This 'bridging solution' is in addition to the existing compassionate and emergency use mechanisms under EU law.
- **All regulatory functions can remain** in the UK if they are currently located there.
- **For medicines brought into Northern Ireland from the rest of the UK, batch testing** does not need to be repeated if it has already been carried out in Great Britain or the EU.
- **No manufacturing authorisation or import licenses are needed** for medicines supplied

from Great Britain to Northern Ireland, subject to certain conditions.

- Authorisation by the UK regulator can allow companies located in Great Britain to use **a single pack and leaflet** when supplying markets in Great Britain and Northern Ireland. There would be no need for separate packaging.
- **Malta, Cyprus and Ireland** 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. 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 proposals also require the UK to respect certain conditions:

- The proposal provides for packaging requirements to ensure that UK-authorised medicines **do not enter the Single Market**.
- The UK assumes sole responsibility for authorising medicines for Northern Ireland. This is contingent on the **UK complying substantively with EU law on quality, safety and efficacy of human medicines** when issuing market authorisations for Northern Ireland. This **reduces risks for the EU Single Market**.

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 and the three Member States concerned.

In order to ensure 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 continue. This will last until the end of 2022 unless the legislative procedure is finalised sooner.

For More Information

[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](#)

[Questions & Answers](#)

[Relations with the United Kingdom](#)

IP/21/6911

Press contacts:

[Daniel FERRIE](#) (+32 2 298 65 00)

[Sinéad MEEHAN - VAN DRUTEN](#) (+ 32 2 298 40 94)

General public inquiries: [Europe Direct](#) by phone [00 800 67 89 10 11](#) or by [email](#)

Related media

 [Visit of Theresa May, British Prime Minister, to the EC](#)