EUROPEAN
COMMISSION

Brussels, 17.12.2021
C(2021) 9668 final

COMMUNICATION TO THE COMMISSION

Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland

COMMUNICATION TO THE COMMISSION

Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland

On 25 January 2021 the Commission adopted a Notice explaining how it would apply, until 31 December 2021, the EU's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland[1] (i.e. Cyprus, Ireland, Malta and Northern Ireland).

That Commission Notice was intended to facilitate the application of the EU's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland by indicating the manner in which the Commission would apply to this specific situation the relevant provisions of Directives 2001/82/EC[2], 2001/83/EC[3] and 2001/20/EC[4] and Commission Delegated Regulation (EU) 2016/161[5].

On 1 February 2020, the United Kingdom withdrew from the European Union. The Withdrawal Agreement[6] provides for a transition period which ended on 31 December 2020. At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst the Protocol on Ireland and Northern Ireland ('the IE/NI Protocol'), which forms an integral part of the Withdrawal Agreement, became applicable. In accordance with Article 5(4) of and point 20 of Annex 2 to the IE/NI Protocol, the pharmaceutical *acquis* of the Union including the abovementioned legal acts, as well as legal acts of the Union implementing, amending or replacing those legal acts apply to and in the United Kingdom in respect of Northern Ireland.

The period covered by the above Commission Notice is now coming to an end, but it remains challenging for operators in Cyprus, Ireland, Malta and Northern Ireland to fully comply with Union law.

In order to address this situation, and with the aim of preventing shortages of medicines and ensuring a high level of public health protection, with regard to medicinal products for human

---

1 Commission Notice – Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period, 2021/C 27/08, OJ C 27, 25.1. 2021, p. 11.

2 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1.

3 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

4 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

5 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

6 Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7) ('Withdrawal Agreement').

use, the Commission intends to adopt on 17 December 2021 two legislative proposals amending the relevant provisions of Directive 2001/83/EC, Directive 2001/20/EC[7] and Regulation (EU) 536/2014[8], as well as a Commission Delegated Regulation amending Commission Delegated Regulation (EU) 2016/161[9].

It is necessary to bridge the gap between 31 December 2021 and the entry into force of these amendments. In addition, as regards medicinal products for veterinary use, more time is needed for companies to adjust to the changes brought about by the end of the transition period and the provisions of the IE/NI Protocol referred to above.

The Commission is therefore called upon to approve the content of a draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland, at the same time as it will adopt the two Commission legislative proposals and the Delegated Regulation, on 17 December 2021.

The draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland will be formally adopted by the Commission later, when all language versions are available. It is only from that moment that the Notice will be applicable. The intention is to adopt the Notice before 31 December 2021. The text of the draft Commission Notice is enclosed as Annex to this Communication.

---

7 Commission proposal for a Directive of the European Parliament and of the Councilamending Directive 2001/83/EC and Directive 2001/20/EC as regards derogations from certain obligations concerning certain nationally authorised medicinal products for human use made available in the United Kingdom in respect of Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)997)

8 Commission proposal for a Regulation (EU) of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards derogations from certain obligations concerning investigational medicinal products made available in United Kingdom in respect to Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)998)

9 Commission Delegated Regulation (EU) of 17/12/2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom (C(2021) 9700)