Council of the European Union

Brussels, 28 February 2022
(OR. en)

6693/22

Interinstitutional Files:
2021/0431(COD)
2021/0432(COD)

UK 27
PHARM 29
SAN 118
MI 153
COMPET 127
CODEC 219

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	COM(2021) 997 final COM(2021) 998 final
Subject:	OPINION of the European Economic and Social Committee - Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain 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 final - 2021/0431 (COD)] - Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta [COM(2021) 998 final - 2021/0432 (COD)]

Delegations will find attached the abovementioned opinion. Other language versions will become available on the following website:

https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/medicinal-products-human-and-investigational-use-derogations

European Economic and Social Committee

OPINION

European Economic and Social Committee

Medicinal products for human and investigational use/derogation

a) Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain 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 final – 2021/0431 (COD)]

b) Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta
[COM(2021) 998 final – 2021/0432 (COD)]

INT/975

Rapporteur: **Martin SCHAFFENRATH**

www.eesc.europa.eu

EN

www.eesc.europa.eu/facebook www.eesc.europa.eu/twitter www.eesc.europa.eu/linkedin www.eesc.europa.eu/instagram

Referral	a) European Parliament, 20/01/2022 a) Council, 03/02/2022 b) European Parliament, 20/01/2022 b) Council, 03/02/2022
Legal basis	a) Article 114 of the Treaty on the Functioning of the European Union b) Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted in section	03/02/2022
Date adopted in plenary	24/02/2022
Plenary session No	567
Outcome of vote (for/against/abstentions)	176/0/4

1. Conclusions and recommendations

1.1 The continued supply of high-quality, effective and safe medicinal products for human use is key to ensuring access to healthcare for patients. The European Economic and Social Committee (EESC) therefore welcomes the package of measures presented by the European Commission on 17 December 2021 aimed, on the one hand, at ensuring the long-term uninterrupted supply of medicinal products from the UK to Northern Ireland and, on the other hand, at addressing in a timely manner the remaining supply shortages in Cyprus, Ireland and Malta resulting in part from the UK's withdrawal from the European Union.

1.2 The EESC recognises that the smaller EU Member States of Cyprus, Ireland and Malta in particular are historically heavily dependent on the supply of medicinal products and investigational medicinal products from the UK.

1.3 The EESC believes that the amendments in the package of measures introducing derogations from certain obligations concerning medicinal products and investigational medicinal products made available in the UK in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta, are appropriate due to the UK's withdrawal from the EU and the related framework conditions, and the EESC therefore fully supports them.

1.4 The EESC stresses in particular the central role of a functioning, fair and efficient single market. The top priority must be compliance with EU legislation relevant to medicinal products and investigational medicinal products, in particular with regard to the quality and safety of the products concerned. At the same time, the EESC also welcomes the packaging requirements for UK products included in the package, in order to avoid additional repackaging, which could lead to the withdrawal of medicines from the Northern Ireland market due to the additional costs entailed and the complexity of the process.

1.5 However, with regard to the temporary derogations for Cyprus, Ireland and Malta, the EESC draws attention to the need for a timely and sustainable solution, which should be developed within the framework of the Pharmaceutical Strategy for Europe, in order to ensure the long-term supply of medicinal products authorised in the EU to patients in the aforementioned Member States.

2. Context of the Commission's proposals

2.1 In accordance with the Protocol on Ireland/Northern Ireland to the UK Withdrawal Agreement[1], medicinal products placed on the market in Northern Ireland must hold a valid marketing authorisation granted by the Commission (EU marketing authorisations) or the UK for Northern Ireland. These national authorisations must comply with EU legislation on medicinal products. The importation of investigational medicinal products from third countries into the EU or Northern Ireland is also subject to the possession of a manufacturing and import licence. These must comply with the requirements of established EU law on clinical trials.

[1] OJ L 29, 31.1.2020, p. 7.

2.2 Cyprus, Ireland, Malta and Northern Ireland have always depended on the supply of medicinal products, including investigational medicinal products, from or through parts of the UK other than Northern Ireland, and the supply chains for these markets have not yet been fully aligned with EU law and the altered situation following the UK's withdrawal from the European Union.

2.3 The Commission Notice of 25 January 2021[2] provides for a grace period of one year (until the end of December 2021) for the maintenance of batch testing and manufacturing/logistics in parts of the UK other than Northern Ireland, in order to ensure the uninterrupted supply of medicinal products to Northern Ireland, Cyprus, Ireland and Malta. This Notice also applies to import requirements for investigational medicinal products, in order to ensure their uninterrupted supply to Northern Ireland, Cyprus, Ireland and Malta.

2.4 Despite the transition period, it is still very difficult for certain economic operators currently established in parts of the UK other than Northern Ireland to adapt to the requirements of the Protocol. The main reasons for this are the high costs of such adaptation relative to the small size of the Northern Ireland market, which represents 3% of the total UK market, and the complex logistics, for which no viable alternative logistical hubs have been identified in Northern Ireland.

2.5 The aim of these proposals is, firstly, to solve the problems regarding medicinal products for human use, to avoid shortages of medicinal products and to ensure adequate protection of public health in Northern Ireland, Cyprus, Ireland and Malta. In addition, the problems relating to investigational medicinal products also need to be addressed in order to prevent an adverse impact on their supply and, as a result, on the carrying out of clinical trials authorised under Regulation (EU) No 536/2014[3] in Northern Ireland, Cyprus, Ireland and Malta.

---

[2] 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).

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

3. **General comments**

3.1 The EESC therefore welcomes this package of measures. Ensuring the supply of medicines and protecting public health are fundamental concerns of the Committee.

3.2 The EESC considers the UK's withdrawal from the EU to be a very complex and difficult exercise. It is true that the EU-UK Trade and Cooperation Agreement[4] and its Protocol on Ireland/Northern Ireland[5] govern most of the future relationship between the two parties. As the one-year transition period provided for has proved insufficient to adapt to the new requirements in order to ensure the uninterrupted supply of medicinal products and investigational medicinal products to Northern Ireland, Cyprus, Ireland and Malta, swift and targeted action is now needed in order to mitigate the economic and health impacts.

3.3 The EESC believes that the following key elements of the package should be highlighted in particular:

- uninterrupted supply of medicinal products from the UK to Northern Ireland, provided they comply with EU legislation;
- further recognition of batch testing by a qualified person who is established in a part of the UK other than Northern Ireland and is responsible for batch testing and pharmacovigilance, in order to avoid duplication of work in the future;
- maintaining the possibility of retaining packaging for Northern Ireland and the UK and at the same time being able to apply for a marketing authorisation through the decentralised or national authorisation procedure;
- appropriate measures to adapt the requirements of Directive 2011/62/EU ("Falsified Medicines Directive")[6] to further ensure the safety of medicinal products in Northern Ireland and to prevent them being distributed to the rest of the EU.

3.4 In the context of the EU single market, the EESC stresses that, when implementing the package of measures, it must in all circumstances be ensured that the relevant medicinal products and investigational medicinal products from the UK remain in Northern Ireland and are not marketed in other parts of the single market, unless they have been authorised by a national competent authority in accordance with EU legislation. The same applies for the transitional period of three years for Cyprus, Ireland and Malta. The overriding principle here must be that these medicinal products and investigational medicinal products serve only to supply patients resident in those countries.

3.5 In this connection, the EESC also particularly welcomes the principle of transparency through the requirement for the competent authorities in Northern Ireland and the EU Member States concerned to draw up and publish a list of relevant medicinal products and investigational medicinal products, in order to ensure the protection of health in the EU and to prevent those medicinal products from entering other Member States.

---

4 Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the One Part, and the United Kingdom of Great Britain and Northern Ireland, of the Other Part, OJ L 444, 31.12.2020, p. 14.

5 OJ L 29, 31.1.2020, p. 7.

6 OJ L 174, 1.7.2011, p. 74.

3.6 The EESC also supports in particular the proposed derogations from Directive 2011/62/EU ("Falsified Medicines Directive"), which aim to allow manufacturers to maintain the unique identifiers required for the EU for medicinal products, even if they are imported into Northern Ireland by other EU Member States via the UK, and for a period of three years into Cyprus, Ireland and Malta. The EESC also supports the proposed mechanism whereby pharmacists and hospitals in the EU (except Northern Ireland, Cyprus, Ireland and Malta) are informed via the European Medicines Verification System as soon as a medicinal product authorised in the UK for Northern Ireland is scanned. This will clearly indicate to end-users that such a package of medicinal products may not be intended for supply in the EU.

3.7 With regard to possible transitional solutions to ensure that patients in Northern Ireland are on the same footing as those in the rest of the UK, the EESC also welcomes the proposed derogation for the temporary importation of new patented medicinal products authorised in the UK until the EU has also granted a marketing authorisation.

4. Specific comments

4.1 In the EESC's view, all concerns of the affected stakeholders have been fully taken into account with a view to ensuring the uninterrupted supply of medicinal products and investigational medicinal products to Northern Ireland and other smaller, similarly affected Member States. However, the EESC proposes a few clarifications below, which could be included in the accompanying guidelines.

4.2 Of particular note is recital 7 of the proposal for a Directive, which provides an important clarification regarding the retention of the regulatory requirements for batch testing and pharmacovigilance in the UK for exports to Northern Ireland. It is important to clarify that any regulatory function carried out in a part of the UK other than Northern Ireland in the context of authorisation for marketing in the UK in Northern Ireland can be used for both current and future national marketing authorisations and for marketing authorisations via the decentralised procedure and/or the mutual recognition procedure. This must be firmly embedded both in the proposal for a Directive and in the corresponding guidelines.

4.3 The EESC draws particular attention to Article 2 of the proposal for a Directive (introducing an Article 5a into Directive 2001/83/EC), as proposed by the European Commission, concerning exemptions from certain obligations for certain medicinal products for human use made available in the UK. In all circumstances, it must be ensured that affected medicines exported from the UK to Northern Ireland (and for the three-year transition period to Cyprus, Ireland and Malta) remain in these markets and do not end up on the market in other parts of the single market.

4.4 The EESC considers that further clarification is needed as regards the quality control testing provided for in Article 2(4) of the proposal for a Directive (amendment of Article 20 of Directive 2001/83/EC) for medicinal products authorised through the EU's centralised procedure but manufactured in the UK (other than in Northern Ireland) instead of in an EU Member State and from there imported directly into Northern Ireland.

4.5 The EESC also recommends further clarification with regard to Article 2(5) of the proposal for a Directive (amendment of Article 40 of Directive 2001/83/EC) concerning the need for an undertaking established in a part of the UK other than Northern Ireland to have a wholesale distribution authorisation in order to export/import to Northern Ireland. It should be noted that it should continue to be possible to import medicinal products from a facility in the UK to Northern Ireland with a wholesale distribution authorisation issued by a UK authority.

4.6 The Committee also supports Article 2(9), which makes it possible for the qualified person responsible for batch testing and pharmacovigilance in a company to continue to be located in parts of the UK other than Northern Ireland. However, the EESC calls for further clarification, where appropriate in appended guidelines, on the actual implementation of this rule in practice.

4.7 Finally, the EESC stresses that it is particularly important to make a clear distinction between the Commission Notice of 25 January 2021[7], which temporarily allows the economic operators concerned to continue to supply medicinal products and investigational medicinal products in Northern Ireland, and the provisions of this package of measures. The EU is requested to ensure a high level of legal certainty for marketing authorisation holders, wholesalers and pharmacists during this transition period between the aforementioned derogation and the adoption and implementation of the amendments through the proposal for a Directive and the proposal for a Regulation.

Brussels, 24 February 2022

Christa Schweng
The president of the European Economic and Social Committee

[7] 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).