

## PROTOCOL ON IRELAND AND NORTHERN IRELAND

### NON-PAPER

### MEDICINES

#### 1) Issue

1. Adapting supply chains to the new situation created by the United Kingdom (UK)'s withdrawal from the European Union (EU) and the application of the Protocol on Ireland / Northern Ireland ("the Protocol") remains challenging in the pharmaceutical sector, in particular for suppliers of generics and over the counter **medicines covered by national authorisations issued by the UK in respect of Northern Ireland**.
2. Specifically, it appears to be too costly for certain operators currently based in Great Britain to move regulatory compliance functions and related logistics and testing facilities (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible for batch testing and release and for pharmacovigilance) to Northern Ireland or the EU, as well as to comply with the importation requirements, such as the manufacturing import authorisation, as required by the Protocol. As a result, some companies may decide no longer to supply medicines to the Northern Irish market, which might create a public health risk.
3. Stakeholders have also requested that the UK national authorisation procedures for Great Britain (governed by UK domestic law) and for Northern Ireland (governed by EU law), which are under the responsibility of the same UK regulatory authority, should be operated and coordinated in such a way as to permit the continued use of a single pack and a single leaflet for patient information for the whole UK market.
4. This non-paper sets out the EU's proposed solution to provide a long-term perspective for uninterrupted **medicines supply from or through Great Britain to Northern Ireland** for the benefit of patients in Northern Ireland. It updates and replaces the non-paper published on 26 July 2021.

#### 2) Framework

5. Pursuant to Article 5(4) of the Protocol, the provisions of Union law listed in Annex 2 to the Protocol apply to and in the UK in respect of Northern Ireland from 1 January 2021 (i.e. as from the end of the transition period, cf. Article 185 of the Withdrawal Agreement). Accordingly, medicines placed on the market in Northern Ireland must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the UK for Northern Ireland in applying the EU legislation for medicinal products listed in Section 20 of Annex 2 to the Protocol (UK national authorisations).
6. There are two possible UK national authorisation routes in accordance with the Protocol: purely UK national authorisations ("Northern Ireland-only authorisations"), which concern medicines that are made available in Northern Ireland but nowhere else in the EU, and UK national authorisations granted via the Mutual Recognition or Decentralised Procedures (MRP/DCP), which apply when a medicine is also made available in one or more Member States.<sup>1</sup> The

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<sup>1</sup> Under these procedures, a Member State takes the lead in the assessment ("Reference Member State") and issues the first authorisation, on the basis of which identical national authorisations are then issued by the other "Concerned Member States". Pursuant to the Protocol, Northern Ireland participates in these two procedures but the UK cannot have the leading role.

implementation issues that have been identified in the various talks to date between the UK Government and the European Commission and with both UK and EU stakeholders solely concern **medicines covered by UK national marketing authorisations**.

7. The Commission Notice of 25 January 2021<sup>2</sup> provides for a grace period of one year (until end-December 2021) for maintaining batch testing and manufacturing / logistics in Great Britain (GB) to ensure uninterrupted supply of medicines to Northern Ireland and those EU Member States (Cyprus, Ireland and Malta) that have been historically dependent on medicines supply from or through Great Britain.<sup>3</sup>
8. The grace period aimed to give all relevant stakeholders sufficient time to adapt to the UK's withdrawal and to establish new supply routes where necessary, while providing for uninterrupted supply of medicines and a high level of public health protection.

### 3) Possible solutions

#### Localisation of regulatory compliance functions

9. The proposed solution would provide, as a permanent derogation from the relevant provisions of Directive 2001/83/EC (framework directive for medicinal products for human use) that regulatory compliance functions for medicines supplied to the Northern Ireland market only, pursuant to national authorisations issued by the UK in accordance with the Protocol, may be located in Great Britain. In addition, no manufacturing import authorisation would be required for bringing medicines into Northern Ireland from or through Great Britain.
10. This should greatly facilitate the operations of pharmaceutical companies in Great Britain and thus ensure medicines supply. The companies concerned would not need to relocate infrastructure (including testing facilities) or regulatory compliance functions to Northern Ireland or the EU and could therefore continue to supply the whole UK market, including Northern Ireland, from where their infrastructure and regulatory functions are currently located.
11. The following **conditions** would apply:
  - a. the UK should fully apply the relevant Union legislation on medicines - on quality, safety, efficacy, pharmacovigilance and batch testing and release - when issuing national marketing authorisations in respect of Northern Ireland;
  - b. the marketing authorisation should contain a legal prohibition of sale (resale) outside its geographical scope: medicines with an authorisation for Northern Ireland cannot be legally sold anywhere else in the EU and the specific authorisation code for Northern Ireland should be stamped on each pack;

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<sup>2</sup> Commission Notice of 25 January 2021 on the application of the Union's pharmaceutical acquis in markets [Northern Ireland, Cyprus, Ireland, Malta, Northern Ireland] historically dependent on medicines supply from or through Great Britain after the end of the transition period, [OJ C 27, 25.1.2021, p. 11](#). The Commission Notice implements the EU's unilateral declaration on medicinal products made in the meeting of the Joint Committee of the EU-UK Withdrawal Agreement of 17.12.2020.

<sup>3</sup> The current flexibilities allow: (i) wholesale distributors in Northern Ireland, Cyprus, Ireland and Malta to place medicinal products imported from Great Britain without the manufacturing authorisation required for imports from third countries; (ii) batch testing normally required to be carried out in the EU (or Northern Ireland pursuant to the Protocol) before placing medicinal products on the market to take place in Great Britain; (iii) derogations relating to the placement of the unique identifier for prescription medicines for human use.

- c. the safety features for required under applicable EU law should be placed on each pack ensuring that medicines can only be sold in conformity with a valid marketing authorisation in Northern Ireland;
  - d. the UK should ensure and demonstrate the correct implementation/application of the Falsified Medicines Directive in respect of Northern Ireland. The EU end-to-end verification system must generate an alert if a medicine specifically authorised for Northern Ireland is scanned elsewhere in the EU Internal Market (see further under paragraphs 20 and 21 below);
  - e. as regards the derogation from the manufacturing import authorisation requirement, the person importing medicines into Northern Ireland should nonetheless hold a wholesale distribution authorisation issued in accordance with EU law. In addition, the relevant checks normally performed by the manufacturing authorisation holder should be performed either in the EU (as per para. 12 below) or in Great Britain applying equivalent standards to those in Union law;
  - f. enforcement and supervision by the UK competent authorities on economic operators and regulatory compliance activities located in Great Britain should be carried out in accordance with applicable EU law.
12. If batch testing has been carried out in the EU, it would not be necessary to repeat it for medicines which are exported to Great Britain from a Member State in view of subsequent importation into Northern Ireland. This would be on condition that the batches concerned have undergone the necessary controls in a Member State and are accompanied by the control reports signed by the qualified person meeting the legal requirements.
13. **Enhanced enforcement** by the UK competent authorities **on the Northern Ireland market** would be required **to ensure that the medicines concerned remain in Northern Ireland and are not further distributed in the EU Internal Market**, as follows:
- a. the UK should notify to the Commission the list of medicines covered by all national authorisations (Northern Ireland-only authorisations and those issued under the MRP/DCP) as well as the references of the corresponding authorisation codes that will be stamped on the medicine packs. The UK should also establish a publicly available database with this list that will be regularly updated;
  - b. the UK should ensure effective supervision of wholesalers in Great Britain and Northern Ireland and pharmacists and other points of sale in Northern Ireland, the affixing of the unique identifier on the medicine packs supplied to Northern Ireland and that the verification by the person entitled to supply to the public in Northern Ireland will be carried out in compliance with the requirements of EU legislation on falsified medicines;
  - c. the UK should ensure effective supervision of operators importing medicines from Great Britain into Northern Ireland by the UK competent authorities after the end of the current grace period in those cases where the marketing authorisation holder is based in Great Britain.
14. The marketing authorisation holders will always be entirely responsible for ensuring the quality, safety and efficacy of the medicinal products placed on the Northern Ireland market independently of any derogations provided.
15. The Commission, with the support of the EU Member States, will carry out inspections to verify compliance of the marketing authorisations issued by the UK in respect of Northern Ireland with relevant EU legislation and the specific conditions set out above.

### **Operation of the MRP/DCP in respect of Northern Ireland**

16. As regards UK national authorisations issued pursuant to the **MRP/DCP**, the Commission stands ready to continue discussing with the UK and stakeholders how to ensure in practice that the UK national authorisation procedures for Great Britain (governed by UK domestic law) and for Northern Ireland (governed by EU law) are operated and coordinated in such a way as to ensure the continued use of a single medicine pack and a single leaflet for patient information for the whole UK market, in order to address the concerns raised by stakeholders in this regard.
17. After a marketing authorisation for Northern Ireland has been issued pursuant to the MRP/DCP route, any changes would continue to be processed through the EU Reference Member State. The UK should recognise those assessments and adapt its corresponding national authorisation for Northern Ireland accordingly, so as to ensure they remain fully in compliance with EU law.
18. The UK competent authorities and the EU Coordination Group for Mutual Recognition and Decentralised Procedures should work together to ensure consistency in relevant guidance issued to stakeholders.

### ***Investigational medicinal products***

19. The proposed solution would provide a derogation from the manufacturing import authorisation requirement to allow clinical trial sites or sponsors in Northern Ireland to continue to use investigational medicinal products supplied from or through Great Britain provided the conditions set out in para. 11 above are complied with.

### ***Requirements relating to the safety features for medicinal products for human use***

20. In order to provide further flexibility with respect to compliance with the safety features (namely, an anti-tampering device and unique identifier) that are mandatory for prescription medicinal products for human use pursuant to applicable EU legislation, the proposed solution consists of a further three-year derogation from the obligation to decommission the unique identifier when medicines are exported from the EU to the UK in respect of both single- and multi-market packs.
21. In order to ensure that medicines made available to Northern Ireland (or Cyprus, Malta and Ireland, which may also benefit from the same flexibility<sup>4</sup>) are not placed on the market elsewhere in the EU, the EU repository system should be adapted so as to ensure that an alert is generated when the medicine is verified for sale outside these markets.

### ***Veterinary medicines***

22. The Commission stands ready to continue discussions with the UK and stakeholders to identify any outstanding implementation issue with a view to finding the most appropriate way forward for ensuring continuity of veterinary medicines supply to Northern Ireland.

### ***Implementation of the proposed solutions***

23. The proposed solutions set out in the above paragraphs would be implemented through:
  - a targeted legislative amendment of the relevant legal acts in the EU pharmaceutical legislation, namely Directive 2001/83/EC (framework directive for medicinal products for

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<sup>4</sup> Pending the development of longer-term policy or legislative initiatives, a temporary time-limited derogation on sourcing medicines for Cyprus, Malta and Ireland from the UK could be considered on the basis of justified public health reasons.

human use) and Directive 2001/20/EC and Regulation (EU) No 536/2014 (good clinical practice in the conduct of clinical trials on medicinal products for human use);

- an amendment of Commission Delegated Regulation (EU) 2016/161 on safety features appearing on the packaging of medicinal products for human use.
24. The EU acts implementing the proposed solutions would be added to the list of EU legislation on medicinal products in Section 20 of Annex 2 to the Protocol and therefore apply to and in the UK in respect of Northern Ireland pursuant to Article 5(4) of the Protocol.
25. The Commission is very mindful of the need to provide business with the necessary predictability and legal certainty, pending the completion of the procedures necessary for implementing the envisaged solutions for human medicines and discussions on a way forward for veterinary medicines, in view of the fact that the grace period provided for in the Commission Notice of 25 January 2021 expires at the end of this year.

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