

## NON-PAPER

### Medicines and the implementation of the Protocol on Ireland and Northern Ireland

#### Issue

1. Pursuant to the Protocol on Ireland / Northern Ireland (“the Protocol”), medicines placed on the market in Northern Ireland (NI) must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the UK for NI in applying the Union legislation for medicinal products listed in Section 20 of Annex 2 to the Protocol (UK national authorisations).
2. The implementation issues that have been identified in the various talks to date between the UK Government and the European Commission solely concern **medicines covered by national marketing authorisations**. There are two possible UK national authorisation routes: purely UK national authorisations (“NI-only authorisations”), which concern medicines that are made available in NI only, and UK national authorisations granted via the Mutual Recognition or Decentralised Procedures (MRP/DCP), which is mandatory<sup>1</sup>.
3. 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 undisrupted supply of medicines to NI and those EU Member States (Cyprus, Ireland and Malta) that have been historically dependent on medicines supply from or through GB.<sup>3</sup>
4. 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 undisrupted supply of medicines and a high level of public health protection.
5. However, adapting supply chains to the new situation is still particularly challenging (in particular for suppliers of generics and over the counter medicines). Specifically, in relation to the implementation of the Protocol, it is proving too costly for certain operators currently based in GB to move relevant regulatory compliance functions (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible for batch testing and release and for pharmacovigilance) to NI or the EU in respect of UK nationally authorised products for NI, as required by the Protocol.

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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, NI participates in these two procedures but the UK cannot have the leading role.

<sup>2</sup> Commission Notice of 25 January 2021 on the application of the Union’s pharmaceutical acquis in markets [CY, IE, MT, NI] 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 Joint Committee meeting of 17.12.2020.

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

6. This non-paper sets out the EU's proposed solutions to provide a long-term perspective for uninterrupted medicines supply to NI for the benefit of patients in NI.

### **Proposed solution**

7. **Regulatory compliance functions may exceptionally be located in UK (GB)** in respect of medicines covered by any national authorisations issued by the UK authorities in respect of NI, provided that the following **conditions** are met:

- a. the UK fully applies the relevant Union legislation on medicines: on quality, safety, efficacy, pharmacovigilance and batch testing and release when issuing national marketing authorisations in respect to NI;
- b. the marketing authorisation contains a legal prohibition of sale (resale) outside its geographical scope: medicines with an authorisation for UK(NI) cannot be legally sold anywhere else in the EU and the specific authorisation code for NI is stamped on each pack;
- c. the safety features required under applicable Union law are placed on each pack ensuring that medicines can only be sold in conformity with a valid marketing authorisation in NI;
- d. the UK ensures and demonstrates the correct implementation/application of the Falsified Medicines Directive in respect of NI. The EU end-to-end verification system must generate an alert if a medicine specifically authorised for NI is scanned elsewhere in the EU Internal Market;
- e. enforcement and supervision by the UK competent authorities on economic operators and regulatory compliance activities located in GB are carried out in accordance with applicable Union law.

8. This needs to be accompanied by **enhanced enforcement** by the UK competent authorities **on the NI market** to prevent that the medicines concerned are further distributed in the EU Internal Market as follows:

- a. the UK notifies the Commission the list of medicines covered by all national authorisations (NI-only authorisations and those issued under the MRP/DCP), the references of the corresponding authorisation codes that will be stamped on the medicine packs. The UK also establishes a publicly available database with this list that will be regularly updated;
- b. the UK ensures effective supervision of wholesalers in GB and NI and pharmacists and other points of sale in NI, the affixing of the unique identifier on the medicine packs supplied to NI and that the verification by the person entitled to supply to the public in NI will be carried out in compliance with the requirements of EU legislation on falsified medicines;
- c. the UK ensures effective supervision of operators importing medicines from GB into NI by the UK competent authorities after the end of the current grace period in those cases where the marketing authorisation holder is based in GB.
- d. The Commission, with the support of the EU Member States, will regularly carry out inspections to verify compliance of the marketing authorisations

issued by the UK in respect to NI with relevant Union legislation and the specific conditions set out above.

9. **The MRP/DCP is the mandatory authorisation route for NI market whenever the medicinal product concerned is also placed on the market of one or more EU Member States.** Any changes to the original marketing authorisation will continue to be processed solely through the EU Reference Member State. The UK will recognise those assessments and adapt its corresponding national authorisations accordingly, so as to ensure they remain fully in compliance with Union law. The UK competent authorities will need to work together with the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh) and align their implementation and application of Union legislation on medicines to ensure this in practice. Relevant guidance to stakeholders will also need to be aligned accordingly

10. As regards the implementation of the Falsified Medicines Directive in the UK in respect to NI, the proposed solution is to amend an amendment Commission Delegated Regulation (EU) 2016/161 to provide for:

- a derogation from decommissioning at export for UK single- and multi-market packs;
- identification of UK single- and multi-market packs when they are verified in the EU repository system.

11. 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.

12. The proposed solution outlined in the above paragraphs will require legislative action on the EU side. The European Commission is working on a legislative proposal to that effect that will be sent to the Council and the European Parliament as soon as possible on the basis of a clear commitment from the UK to put in place the safeguards referred to in paragraphs 7 - 10.

13. The Union act giving effect to the legislative amendment will be added to the list of Union legislation on medicinal products in Section 20 of Annex 2 to the Protocol and therefore apply to and in the UK in respect of NI pursuant to Article 5(4) of the Protocol.

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