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From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	COM(2023) 122
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland - Opinion of the European Social and Security Committee

Delegations will find attached the European Social and Security Committee's opinion regarding the above proposal. Other language versions are available on the following link:

Specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland | European Economic and Social Committee (europa.eu)

ANNEX

OPINION

European Economic and Social Committee

Specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland

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Proposal for a

Regulation of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland

[COM(2023) 122 final – 2023/0064 (COD)]

REX/574

Rapporteur-General: **Jack O'CONNOR**

Referral	Council, 09/03/2023 European Parliament, 13/03/2023
Legal basis	Articles 114 and 304 of the Treaty on the Functioning of the European Union
Section responsible	Section for External Relations
Adopted at plenary	27/04/2023
Plenary session No	578
Outcome of vote (for/against/abstentions)	154/0/0

1. **Conclusions and recommendations**

1.1 The EESC agrees that a regulation is the appropriate instrument to give effect to the jointly agreed solutions and welcomes the timeliness with which the Commission has come forward with the proposed regulation.

1.2 The EESC agrees that:

- the provisions of the proposed regulation are appropriately limited to the relevant policy area and that no assessment of consistency with other Union policies is necessary;
- the proposal uses as a legal basis the provisions of Article 114 of the Treaty on the Functioning of the European Union;
- the measures envisaged are proportionate to the objectives to be met;
- the proposal also contains adequate safeguard mechanisms to ensure the protection of the EU single market;
- the proposed regulation is exempt from impact assessment, given the urgency and sensitivity of the situation.

1.3 The EESC supports the adoption and early implementation of the proposed regulation, which would ensure continuity of supply of medicinal products for human use in Northern Ireland and enhance the prospects for implementation of the Protocol on Ireland/Northern Ireland, as well as contribute to the protection of the Belfast/Good Friday Agreement.

1.4 Articles 9 and 10 of the proposed regulation enable suspension of the specific rules by the Commission in the event of the UK's non-compliance. The EESC agrees that such a provision is essential. However, the EESC emphasises the importance of the consultation with the UK envisaged in 9(3), as well as with the experts designated by each Member State in 10(4), prior to any such suspension.

1.5 The EESC encourages ongoing consultation with key stakeholders to help ensure timely implementation, as well as monitoring for any future risks to the delivery of the objectives of the proposed regulation. In this regard, the European institutions should also be updated periodically on the progress of implementation ahead of January 2025.

2. **General comments**

2.1 The proposed regulation arises in the context of the solutions agreed between the EU and the UK in the Windsor Framework.

2.2 The proposed regulation arises in the context of a comprehensive set of joint solutions agreed between the EU and the UK to address the concerns listed in the proposed regulation's Explanatory Memorandum. It concerns the adoption of specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland in accordance with Article 6 of Directive 2001/83/EC. These are intended to provide for specific rules to the provisions listed in Annex 2 of the Protocol on Ireland/Northern Ireland (Protocol), which regulate activity in the medicinal products sector.

2.3 The difficulties that the proposed regulation aims to address arose practically at the entry into force of the Protocol on 1 January 2021. They continued even after the expiry of the transition period set out in the EU-UK Withdrawal Agreement, particularly around the availability of GB-manufactured medicinal products in Northern Ireland, due to the complex new regulatory environment. To ensure the uninterrupted supply of medicines from Great Britain to Northern Ireland, the EU adopted Directive (EU) 2022/642 on 12 April 2022, providing derogations from certain obligations concerning certain medicinal products for human use made available in the UK in respect of Northern Ireland.

2.4 Essentially, these allowed UK manufacturers to maintain batch testing and regulatory functions in parts of the UK other than Northern Ireland. They also facilitated the supply of novel medicines by allowing the competent UK authorities to authorise for a limited period of time such a supply to patients in Northern Ireland, even though they would not yet have approval in the EU.

2.5 Subsequent experience revealed certain practical problems with these solutions. The requirement to provide separate packs and information leaflets for Great Britain and Northern Ireland would impose a significant economic burden on manufacturers in the context of the small size of the Northern Ireland market. Concerns were also raised that the coexistence of potentially divergent marketing authorisations for Great Britain and Northern Ireland for the same medicine would create legal uncertainty relating to the applicable rules for medicines. Other issues concerned the complexity of regulations applying to the export and reimportation of medicines, which the Commission addressed in Delegated Regulation (EU) 2022/315, providing for a three-year derogation for wholesalers.

2.6 The subsequent joint solutions agreed between the EU and UK are designed to provide a sustainable solution to these issues. They provide that:

- new and innovative medicines lawfully placed on the market in Northern Ireland are only to be covered by a valid marketing authorisation issued by the UK;
- EU safety features will not appear on packs of medicines in Northern Ireland;
- medicines placed on the market in Northern Ireland will not be made available in any EU Member State;
- UK packs will carry a "UK Only" label;
- UK authorities will continuously monitor activity in the market to ensure compliance;
- the Commission can unilaterally suspend the new rules in the event of UK non-compliance with its obligations.

2.7 The proposal is designed to give legislative effect to this set of joint solutions.

2.8 The EESC agrees that a regulation is the appropriate instrument to give effect to the jointly agreed solutions and welcomes the timeliness with which the Commission has come forward with the proposed regulation.

2.9 The EESC agrees that:

- the provisions of the proposed regulation are appropriately limited to the relevant policy area and that no assessment of consistency with other Union policies is necessary;
- the proposal uses as a legal basis the provisions of Article 114 of the Treaty on the Functioning of the European Union;
- the measures envisaged are proportionate to the objectives to be met;
- the proposal also contains adequate safeguard mechanisms to ensure the protection of the EU single market;
- the proposed regulation is exempt from impact assessment, given the urgency and sensitivity of the situation.

2.10 Given that extensive consultations with industry associations and other stakeholders preceded the discussions with the UK before the adoption of the first set of solutions in April 2022 and that this additional set of joint solutions responds to only a few additional issues that have arisen in the meantime, the EESC agrees that there is no requirement for an open public consultation prior to adoption. However, the EESC encourages ongoing consultation with key stakeholders to help ensure timely implementation, as well as monitoring for any possible future risks to the delivery of the objectives of the proposed regulation. In this regard, the EU institutions should also be updated periodically on progress on implementation ahead of January 2025.

2.11 The EESC supports the adoption and early implementation of the proposed regulation, which would ensure continuity of supply of medicinal products for human use in Northern Ireland and enhance the prospects for implementation of the Protocol on Ireland/Northern Ireland, as well as contribute to the protection of the Belfast (Good Friday) Agreement.

Brussels, 27 April 2023

Oliver RÖPKE

The president of the European Economic and Social Committee