EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND WINDSOR FRAMEWORK

COM(2023)192 Final, plus annexes 1-8

SWD(2023)191

SWD(2023)192 Parts 1 and 2

SWD(2023)193 Parts 1 and 2

COM(2023)193 Final, plus annexes 1-5

SWD(2023)192 Parts 1 and 2

SWD(2023)193 Parts 1 and 2

SWD(2023)194

Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC; and

Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Submitted by the Department of Health and Social Care

10/07/2023

SUBJECT MATTER

1. This package consists of two legislative proposals which revise and replace the existing general pharmaceutical legislation. The proposed reforms represent the largest reform of the EU's pharmaceutical legislation in over 20 years and aim to address challenges such as equitable access to medicines across EU Member States, gaps in addressing unmet medical needs, or shortages of medicines, as well as promoting innovation and competitiveness**.**
2. These proposals are:
    i. a new **Directive** which contains all the requirements for authorisation, monitoring, labelling, placing on the market and other regulatory procedures for all medicines authorised at EU and national level.

ii. a new **Regulation** which sets specific rules for medicines authorised at EU level, in particular the most innovative ones. This includes the rules that govern the European Medicines Agency (EMA).

3. These draft reforms apply to medicinal products for human use, including those for the treatment of rare diseases and for children. The overarching aims of these proposed reforms are to provide patients across the EU with timely and equitable access to medicines, and to support innovation and boost the competitiveness and attractiveness of the EU pharmaceutical industry, while promoting higher environmental standards.
4. The proposal seeks to achieve this by:
    i. Harmonising the EU Single Market for medicines, ensuring equitable and timely access across the EU to safe, effective, and affordable medicines.
    ii. Continuing to offer an attractive and innovation-friendly framework for research, development, and production of medicines in Europe.
    iii. Reducing administrative burden by speeding up procedures such as authorisation times for medicines, so that they reach patients faster.
    iv. Introducing a modulated system of data protection incentives that rewards companies that fulfil important public health objectives.
    v. Addressing antimicrobial resistance (AMR) and the presence of pharmaceuticals in the environment through a One Health approach.
    vi. Making medicines more environmentally sustainable, by updating existing frameworks to adapt to scientific and technological changes, to reduce the environmental impact of medicinal products.
    vii. Enhancing security of supply through stronger obligations on marketing authorisation holders to notify potential or actual shortages and marketing withdrawals, cessations, and suspensions in advance of a foreseen interruption to continued supply of a medicinal product to the EU market.

SCRUTINY HISTORY

5. Relevant scrutiny history includes the Explanatory Memorandum of 17 April 2023 submitted by the Foreign, Commonwealth and Development Office regarding “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). The Commons European Scrutiny Committee and Lords Northern Ireland Protocol Sub-Committee are both in correspondence with FCDO Ministers on matters arising from that proposal.

MINISTERIAL RESPONSIBILITY

6. The UK Secretary of State for Health and Social Care and the Northern Ireland Minister of Health are responsible for the grant, renewal, variation, suspension and revocation of licences and authorisations under the Human Medicine Regulations 2012.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

7. The subject matter of this explanatory memorandum relates to medicines, which is a transferred matter in Northern Ireland and a reserved matter in the rest of the UK. The MHRA is the regulator for the whole UK.
8. This EM has been shared with officials in the Northern Ireland Executive and no comments have been received.

LEGAL AND PROCEDURAL ISSUES

9. When the proposed EU Regulation comes into force, it will take effect in relation to Northern Ireland automatically under the terms of the Windsor Framework and Section 7A of the EU Withdrawal Act.
10. When the new proposals are adopted by the EU, the UK will amend its Human Medicines Regulations 2012 to implement the new Directive in relation to Northern Ireland.
11. The Directive will impose a deadline for this to occur. The proposal contains an implementation deadline of 18 months from when the Directive comes into force.

i. **Legal Base:** Articles 114(1) and 168(4), point (c), of the Treaty on the Functioning of the European Union (TFEU) provide the legal basis for this Directive and Regulation.

ii. **Voting Procedure:** Ordinary legislative procedure.

iii. **Timetable for Adoption and Implementation:** Both legislative acts would enter into force 20 days after they are published in the Official Journal of the EU (which is the final step of the EU legislative process). The new Regulation would apply 18 months after that (on the same day as the new Directive). The new Directive is subject to transposition requirements which must be met by member states 18 months after it enters into force. The Commission, having adopted the proposals for new legislative acts, has triggered the start of the process for adopting new EU laws. Typically, the proposals would be reviewed by the European Parliament and Council of the EU; they would then be the subject of trialogue negotiations between those institutions and the Commission. Once the process is completed, the laws will be adopted. Adoption is likely to be between 2026-2027, and not before 2025.

POLICY IMPLICATIONS

Northern Ireland

12. At present, manufacture and supply of medicines for the Northern Ireland market must follow the EU acquis in accordance with Annex 2 of the Windsor Framework. Following negotiations with the EU, amendments were made to the current EU Directive on human medicines in April 2022, and medicines can be supplied from the Great Britain market to Northern Ireland without requiring additional regulatory importation controls. Medicines from Northern Ireland can also be supplied to the EEA, provided they are appropriately licensed.
13. New or innovative medicines for the Northern Ireland market must be authorised by the European Commission on the recommendation of the European Medicines Agency (EMA).
14. Generic medicines for the Northern Ireland market are licensed on a national basis by its national regulatory body, the MHRA. This means that generic medicines licensed by the MHRA for the UK, or centrally authorised products licenced by the EU, can be supplied to Northern Ireland. In some rare occurrences, generic medicines licensed on a Northern Ireland-only basis can be supplied, as part of the EU mutual recognition and/or decentralised procedure. All generic medicines entering Northern Ireland must be licensed in compliance with EU law.
15. The proposed changes would have implications for the independent batch testing (OCABR) that is performed by EU labs for vaccines and blood products for the EU market. We will continue to assess the impact of this for Northern Ireland as proposal are developed.
16. In February 2023, the UK and the EU agreed the Windsor Framework, which will introduce significant regulatory changes to help ensure the supply of medicines to Northern Ireland. The EU have published their draft proposal implementing these measures and UK Parliamentary Scrutiny Committees have considered. This was adopted on 30 May 2023 and is currently awaiting approval at a session of the Joint Committee, under Article 13.4 procedures of the Windsor Framework.
17. The Windsor Framework sets out a long-term solution to safeguard the supply of medicines into Northern Ireland: the EU's centralised licensing procedure will no longer apply in Northern Ireland, allowing for the supply of UK-wide licensed novel medicines.
18. The medicines provisions outlined in the Windsor Framework are expected to come into effect on 1 January 2025. The implementation of the Windsor Framework will mean that the proposals relating to new and innovative medicines, as well as EMA processes, will no longer apply to Northern Ireland[1].

[1] Guidance can be found at: The Windsor Framework - further detail and publications - GOV.UK (www.gov.uk)

19. The Windsor Framework makes no changes to the regulation of generic medicines in Northern Ireland, which can already be licenced on a UK-wide basis.
20. DHSC and the Medicines and Healthcare Regulatory Agency (MHRA) are currently scoping potential interactions between the EU proposals and the Windsor Framework, but further analysis will be required as details of the proposals emerge.
21. Moreover, the proposal contains suggested amendments to the regulation of paediatric medicines, including more detail on paediatric investigation plans. The extent of the impact of these proposals on Northern Ireland is also being considered in the above package of work.
22. These measures are currently in draft and are subject to change. Under the terms of the Windsor Framework, the EU and the UK Government intend to organise regular meetings between joint bodies. The Joint Consultative Working Group may provide for the exchange of views on any future legislation regarding goods of relevance to the operation of the Windsor Framework.

UK Supply Resilience

23. The draft proposals include several measures aimed at ensuring the security of supply of medicinal products for the EU market. Given the UK market is heavily supplied by pharmaceutical manufacturers that are based in the EU, or have an EU touchpoint in their supply chain, changes that strengthen security of supply for EU member states may have indirect impacts on UK supply resilience. The measures aimed at strengthening security of supply, as currently drafted, will not impact GB to NI supply and are not expected to have differential impacts on NI.
24. These measures could provide benefits to the UK by increasing the overall level of resilience held by medicinal product suppliers, encouraging them to improve their business continuity plans and capability to respond to disruption to supply.
25. However, there may be negative impacts on UK supply resilience if these measures lead suppliers to prioritise the EU market over the UK.
26. As the EU proposals develop further and the detail of the implementation becomes clear, greater scrutiny can be given to the potential impacts on UK supply resilience.

CONSULTATION

27. The draft proposal is currently in an eight-week feedback process. This period is being extended every day until the proposal is available in all EU languages. All feedback received will be summarised by the European Commission and presented to the European Parliament and Council with the aim of feeding into the legislative debate.
28. The UK Government is not planning a public consultation on this Directive and regulation. We are interested in industry/stakeholder views and targeted

engagement will take place in due course, when the draft measures are more finalised

FINANCIAL IMPLICATIONS

29. There may be financial implications for the medicinal products industry to meet some of the requirements placed on them to ensure security of supply. For example, the proposed measures being considered in relation to contingency stock of critical medicines and/or ingredients will lead to increased costs for companies that do not already have these in place.

MINISTERIAL NAME AND SIGNATURE

WILL QUINCE

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