EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

C(2021) 251 final

Commission Delegated Regulation (EU) 5371/21 of 13.1.2021 amending Delegated Regulation (EU) 2016/161 as regards a derogation from the obligation of wholesalers to decommission the unique identifier of products exported to the United Kingdom

Submitted by the Department of Health and Social Care - 16/02/2021

SUBJECT MATTER

Directive 2011/62/EU (the Falsified Medicines Directive) sets out the Union's legal framework for preventing falsified medicines from entering the legal supply chain and reaching patients. Under Article 54a(2) of Directive 2001/83/EC (as amended by Directive 2011/62/EU), Delegated Regulation (EU) 2016/161 supplements the rules in Directive 2001/83/EC by setting out detailed rules for the safety features appearing on the packaging of medicinal products for human use. These safety features include the affixing of a UI which allows medicinal products to be verified throughout the supply chain, and the addition of a tamper-evident device on each pack of medicines that can be prescribed. When a product is being exported to any third country, Article 22 of Delegated Regulation (EU) 2016/161 provides that wholesalers must verify and decommission any UI previously affixed to a pack before it is exported.

EU Commission Delegated Regulation of 13 January 2021 amends Article 22 of Delegated Regulation (EU) 2016/161, waiving the requirement for wholesalers to decommission the unique identifier (UI) on packs of medicinal products entering the UK from the EU market, for a period of 12 months from 1 January 2021 to 31 December 2022. This Delegated Regulation sets out one element of what was previously agreed by the UK and EU at the Withdrawal Agreement Joint Committee (WAJC) for the smooth implementation of the Northern Ireland Protocol.

Given that the UK is now a third country, the Falsified Medicines Directive (FMD) no longer applies. However, under the terms of the Northern Ireland Protocol (NIP), the Directive continues to apply in the UK in respect of Northern Ireland (NI). This means that medicines with a marketing authorisation valid in Northern Ireland will require a unique identifier and a tamper evident device on each pack.

Through industry engagement in 2020 we determined that the immediate application of rules on unique identifiers and tamper evident devices could disrupt the flow of medicines to NI due to the structure of the market, with most NI medicines arriving from Great Britain (GB): 98% of medicines are transported to GB via NI ports, and the majority of those are distributed through the UK wholesalers' networks. Packs of medicinal product imported into GB from the EEA were to be decommissioned upon export, but there would be an obligation to affix a replacement UI on the packs before they could be placed on the market in NI. Where medicinal products are supplied through GB to NI, there is no capability in GB for importers (Wholesale Distribution Authorisation holders) to affix an active UI to medicinal products

destined for the NI market. This would make compliance by 1 Jan 2021 very challenging, thereby presenting a risk to medicines supply to NI after the end of the transition period, during the ongoing Covid-19 response.

The UK and the EU agreed a pragmatic approach to implementation, including a one year time-limited approach to the application of the regulatory requirements for imports and the 'safety feature' elements discussed above, through the WAJC in December 2020, following provisional agreement in November 2020 at the Ireland/Northern Ireland Specialised Committee. This Delegated Regulation puts the safety feature element of this agreement into European law.

The practical effect will be that all medicinal products entering the UK from the EU will continue to have a UI affixed, to ensure the presence of this UI in NI, so that all packs entering NI comply with the safety feature requirement. This is a continuation of the system that was previously in place so does not present any risks to patient safety.

SCRUTINY HISTORY

This Delegated Regulation references Directive 2001/83/EC. Scrutiny has previously been conducted on "COM(99)315: Proposal for a Directive of the European Parliament and of the council on the community code relating to medicinal products for human use." The Department of Health Submitted an EM on this document on 26 July 1999. This completed scrutiny through the European Scrutiny Committee on 20 October 1999 without a substantive report to the House (Report 28,98/99). It completed scrutiny through the European Union Committee at Sift 1006 on 16 September 1999.

This Delegated Regulation also references the Commission Delegated Regulation (EU) 2016/161. This was the subject of proposal 11804/15; Commission Delegated Regulation (EU) No …/..of... XXX supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for safety features appearing on the packaging of medicinal products for human use. This was not required to be deposited for scrutiny under the consultation arrangements between the Government and the Committees.

MINISTERIAL RESPONSIBILITY

Minister of State for Health – **Edward Argar MP**

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Northern Ireland Ministers have an interest because medicines regulation is devolved to Northern Ireland (although the MHRA continues to regulate medicines on a cross-UK basis, as it has done for many years.)

Northern Ireland Executive Ministers have an interest in the 12-month regulatory flexibility that this Regulation sets out, because of their role in protecting the supply of medicines to Northern Ireland which are transported via the rest of the UK. The Northern Ireland Executive has been consulted in the preparation of this EM and we have incorporated their concerns in the consideration of policy implications section below.

LEGAL AND PROCEDURAL ISSUES

There are no legal or procedural issues. This is not a proposal for legislation. The United Kingdom has withdrawn from the EU and is now a third country. Following the terms of the Withdrawal Agreement, as of 1 January 2021, union law no longer applies to the United Kingdom. However, under the terms of the Northern Ireland Protocol (NIP), the EU procedures and rules in respect of medicinal products stipulated in Annex 2 are to continue to apply to medicinal products in Northern Ireland, but not in the rest of the UK.

Given that the UK is now a third country, the Falsified Medicines Directive (FMD) no longer applies subject to the following. Under the terms of the NIP, Directive 2001/83/EC continues to apply in the United Kingdom in respect of Northern Ireland. As a result, the safety feature requirements laid down in Article 54(o) and 54a(1) of Directive 2001/83/EC apply to medicinal products on the market in NI meaning that medicines with a marketing authorisation valid in Northern Ireland will require a unique identifier and a tamper evident device on each pack.

POLICY IMPLICATIONS

Under the terms of the Northern Ireland Protocol, this Delegated Regulation applies to Northern Ireland. However, it does not apply to Great Britain (the rest of the UK) because of its status as a third country.

In line with the agreement reached with the EU at the Joint Committee, the government considers that this Delegated Regulation provides a workable solution to the problem outlined above.

The practical effect will be that all medicinal products entering the UK from the EU will continue to have a UI affixed, to ensure the presence of this UI in NI. This is a continuation of the system that was previously in place so does not present any risks to patient safety, nor immediate changes to UK government policy. This also means that any medicines being exported from NI to GB would not need to be decommissioned and would move as they did before the end of the Transition Period, therefore we do not expect any impact to medicines being exported from NI to GB. At the end of the agreed 12-month phased implementation period the regulatory important requirements and the ‘safety feature’ elements (referred to in this document under ‘subject matter’) will apply in full. The government will support the pharmaceutical industry in using that time to make the changes it needs so supply chains will be fully compliant, such as support for the delivery of additional warehousing capacity in Northern Ireland, if appropriate. Where relevant, these arrangements will also apply to the important supply of veterinary medicines and investigational medicinal products.

Since the end of the Transition Period, a number of pressing problems with the operation of the NI Protocol have become apparent. Recognising the urgency of these issues, the UK government is now engaging with the EU to resolve these as quickly as possible. In a letter to the Vice President of the European Commission, the Chancellor of the Duchy of Lancaster also proposed another year’s extension to the 12-month phased implementation period to give industry time to adapt to the Protocol. We are continuing to engage with the EU on a number of issues relating to medicines in NI including, and relevant to this delegated regulation, an extension to the 12-month phased implementation period.

CONSULTATION

The government worked closely with industry throughout the development of the proposal.

FINANCIAL IMPLICATIONS

The legislation provides for the continuation of the system that was previously in place, so does not give rise to financial implications.

EDWARD ARGAR MP – MINISTER OF STATE FOR HEALTH