5139/23, COM(23)10

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

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Submitted by the Department of Health and Social Care on 10 February 2023.

SUBJECT MATTER

On 11 January 2023, the EU Commission published a Proposal for a Regulation that would amend the EU Medical Devices Regulation (Regulation (EU) 2017/745) ("EU MDR") and the EU *in vitro* Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746) ("EU IVDR"). In particular, the proposed Regulation would amend the transitional provisions in place for certain medical devices and would remove the current 'sell-off' provisions for both medical devices and *in vitro* diagnostic medical devices (IVDs - which are tests that analyse samples that have been taken from the human body, such as blood, tissue, urine, sweat and breath).

The EU MDR and EU IVDR establish a reinforced regulatory framework for medical devices and IVDs and supersede three EU Directives that were previously in place.[1] The EU MDR and EU IVDR have fully applied in the EU and in Northern Ireland (under the terms of the Northern Ireland Protocol) since 26 May 2021 and 26 May 2022 respectively. The Regulations contain transitional provisions that allow certain medical devices and IVDs, that were certified under the preceding EU Directives, to continue to be placed on the EU market for specified periods, providing that they meet certain criteria.

In January 2022, the European Parliament and the Council adopted a staggered extension of the IVDR's transition period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

The transition period provided for in Article 120(3) of the EU MDR will end on 26 May 2024. An additional 'sell-off' provision allows for the further making available until 27 May 2025 of medical devices which are placed on the market before or during the transition period and which are still in the supply chain when the transition period has ended.

The EU Commission has identified a need to extend the EU MDR's transition period due to concerns about the overall capacity of conformity assessment bodies (notified bodies) to assess and certify medical devices under the Regulation. After the expiry of the certificates issued under the Directives and without a valid EU MDR certificate, manufacturers are no

[1] Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
Directive 93/42/EEC on medical devices (EU MDD)
Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

longer allowed to place these medical devices on the EU market. This is threatening the availability of medical devices on the EU market and may cause shortages.

The Proposal seeks to avert the risk of shortages of medical devices across the EU by providing a staggered and conditional extension of the EU MDR transitional period. This would:

- Extend the validity of certificates issued under Council Directives 90/385/EEC or 93/42/EEC that were valid on the day of the EU MDR's date of application (26 May 2021) and have not been withdrawn by a notified body.
- Extend the transitional period for higher-risk devices (Class III and certain Class IIb implantables)[2] from 26 May 2024 until 31 December 2027, subject to certain conditions (including requirements for market surveillance, quality management systems, and engagement with notified bodies).
- Extend the transitional period for medium and lower-risk devices (other Class IIb devices, Class IIa, Class Im, Is and Ir devices)[3] until 31 December 2028, subject to certain conditions (including requirements for market surveillance, quality management systems, and engagement with notified bodies).
- Extend the validity of certificates that have already expired since 26 May 2021, subject to certain conditions (such as a requirement to have contracted a notified body at the point of certificate expiry, or for a derogation to have been granted).
- Remove the 'sell-off' date set out in the EU MDR and EU IVDR, allowing devices and IVDs placed on the market before or during the transitional period to continue to be made available without time limitation (i.e., they will be able to continue to circulate until they reach their end user).
- Introduce a transition period for Class III custom made implantable devices, which are not currently covered by the EU MDR's transitional provisions. This would allow such devices to be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body, provided that the manufacturer, or their authorised representative has lodged a formal application with a notified body by 26 May 2024.

SCRUTINY HISTORY

None for this proposal. However:

- Regulation 2017/745: EUR-Lex - 32017R0745 - EN - EUR-Lex (europa.eu) was subject to scrutiny as EU document 14493/12, COM(12)542.
- Regulation 2017/746: EUR-Lex - 32017R0746 - EN - EUR-Lex (europa.eu) was subject to scrutiny as EU document 14499/12, COM(12)541. The proposal as regards transitional provisions for Regulation 2017/746 was subject to scrutiny as EU document 12884/21, COM(21)627 on which DHSC submitted an EM dated 11 November 2021. The proposal was drawn to the attention of the House of Lords European Affairs Committee' NI Protocol Sub-Committee (Sift 10, 18 November

[2] The highest risk classes for medical devices, which include products such as pacemakers and breast implants.

[3] Class Im means Class I devices with a measuring function; Class Is means Class I devices that are placed on the market in sterile condition; Class Ir means Class I devices that are reusable surgical instruments.

2021). The House of Commons European Scrutiny Committee did not report substantively on the proposal, completing scrutiny on 1 December 2021 (Report 13, 21/22).

MINISTERIAL RESPONSIBILITY

The Secretary of State for Health and Social Care has overall responsibility for the regulation of medical devices in the United Kingdom. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Secretary of State and is the UK regulator for medical devices. For the purposes of EU law relating to medical devices, the MHRA is the competent authority in respect of Northern Ireland.

INTEREST OF THE DEVOLVED GOVERNMENTS

Medical devices regulation relates to reserved matters under the UK's devolution settlements. Under the terms of the Northern Ireland Protocol, the EU MDR and the EU IVDR are directly applicable in Northern Ireland, where they have fully applied from 26 May 2021 and 26 May 2022 respectively. The Department of Health (Northern Ireland) has been notified of these implementing regulations. The MHRA continues to actively engage with Devolved Governments in its work to develop the future regulatory framework for medical devices in the UK.

LEGAL AND PROCEDURAL ISSUES

i. **Legal Base**

The proposal is based on Articles 114 and 168(4), point (c), of the Treaty on the Functioning of the European Union (TFEU).

ii. **Voting Procedure**

The proposed Regulation would be via the ordinary legislative procedure.

iii. **Timetable for adoption and implementation**

The Proposal's preamble sets out that the adoption of the Regulation takes place due to exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. It notes that it is necessary for the Regulation to enter into force as soon as possible and it is also considered appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

Should it be adopted, the Regulation shall enter into force on the day of its publication in the Official Journal of the European Union.

POLICY IMPLICATIONS

The EU MDR and EU IVDR are listed in Annex 2 to the Northern Ireland Protocol and have applied in Northern Ireland since 26 May 2021 and 26 May 2022 respectively. These Regulations have no direct application in Great Britain.

The Government recognises that the timetable for implementation of the EU MDR and EU IVDR has been adversely impacted by insufficient notified body capacity to undertake mandatory third-party conformity assessment, coupled with insufficient preparedness among manufacturers; factors that have been further exacerbated by the COVID-19 pandemic. It also recognises the importance of having an ongoing safe supply of medical devices to the UK market, and therefore welcomes the proposals outlined in this EU Commission document.

Regarding the impact of these regulations:

- There may be some concern that the Proposal would delay full compliance with the higher regulatory standards provided for in the EU MDR and EU IVDR, Regulations that are designed to improve the scrutiny and safety of devices placed on the EU (and, by extension, Northern Ireland) market. However, as outlined in the EU Commission document, the proposed EU action is necessary to avert the possible risk of shortages of medical devices across the EU.
- The changes that this Proposal would introduce are designed to manage the demand for EU notified body capacity and address manufacturer preparedness, which we consider will ultimately benefit UK manufacturers seeking third party conformity assessment for medical devices (for the purposes of CE marking).
- On 25 October 2022, the UK Government announced its intention to introduce a 12-month extension to the implementation of the future Medical Device Regulations.[4] This will mean that CE marked medical devices will be accepted on the Great Britain market until 30 June 2024. The EU MDR transitional provisions currently run until 26 May 2024. Therefore, the EU Commission's Proposal to extend the transitional provisions may serve to support the supply of medical devices to the UK market during the extended period of CE marking recognition.

As outlined in its response to the consultation on the regulation of medical devices in the UK on 26 June 2022, the UK Government plans to strengthen future regulation of medical devices in Great Britain. As part of this work, the UK Government intends to put in place a suite of transitional arrangements to allow sufficient time to adapt to new requirements. The Government will take account of the concerns identified in the EU Commission Proposal as the Government develops its regulatory framework.

It should be noted that the Government introduced the Northern Ireland Protocol Bill on 13 June 2022. The Government's overriding priority is preserving political stability in Northern Ireland.

The situation as it stands with the Protocol is undermining the balance established by the

[4] Implementation of the future regulation of medical devices and extension of standstill period - GOV.UK (www.gov.uk)

Belfast (Good Friday) Agreement and power sharing, and with it political stability in Northern Ireland. It is the Government's preference to resolve this through talks and the Government is engaging in constructive dialogue with the EU to find solutions to these problems. One such issue is that there are currently no structures for UK or Northern Ireland representatives to allow meaningful input on EU rules that are being developed. However, the Northern Ireland Protocol Bill aims to fix the practical problems the Protocol has created in Northern Ireland if a solution cannot be found with the EU.

CONSULTATION

No consultation or impact assessment of this specific Proposal has taken place, and none is planned. The draft Proposal has been shared with Devolved Governments for comment. Of the Devolved Governments, comments were received from the Northern Ireland Executive only. It was noted that no detrimental economic impacts to trade between Northern Ireland, Great Britain and the EU were envisaged, as this measure relates to extending the transitional provisions under the EU MDR and EU IVDR, which will apply in Northern Ireland, giving more time for manufacturers in the EU, Northern Ireland and Great Britain to comply with requirements for the EU and Northern Ireland markets. It was also noted that the potential impacts of the proposed changes would need to be closely monitored and that ongoing support and guidance would be needed from the MHRA.

FINANCIAL IMPLICATIONS

The proposed action has no financial implications. This is also noted in the EU Commission's proposal.

MINISTERIAL NAME AND SIGNATURE

Will Quince

Minister of State for Health and Secondary Care
Department for Health and Social Care