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

12884/21

COM(2021) 627

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices

Submitted by the Department of Health and Social Care on 11/11/2021

SUBJECT MATTER

1. On 15 October 2021 the EU Commission shared the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 (EU IVDR) as regards transitional provisions for certain in vitro diagnostic medical devices (IVDs) and deferred application of requirements for in-house devices.

2. The proposal is to amend the EU IVDR to extend the transitional periods, introduce additional transitional provisions, and defer the application of its provisions concerning in-house devices. It is not looking to impose new requirements. It aims to address concerns that a shortage of notified body capacity could lead to disruption in supply of IVDs, and to ensure parties are in a position to implement EU IVDR, taking into account the magnitude of the COVID-19 pandemic.

3. As the proposal sets out, the EU IVDR establishes a new regulatory framework for IVDs, such as HIV tests, pregnancy tests and COVID-19 tests. The EU IVDR increase the types of *in vitro* diagnostic medical devices (IVDs) requiring assessment by independent conformity assessment bodies (designated as "notified bodies") before they are placed on the market. The EU IVDR will apply in Northern Ireland from 26 May 2022 but will not apply in Great Britain.

4. The proposal sets out that, given the challenges presented by the COVID-19 pandemic and associated public health crisis and lack of notified bodies capacity, it is very likely relevant actors will not be ready or able to implement EU IVDR on time. The European Commission anticipates that, unaddressed, this situation

would lead to a significant disruption in the supply of IVDs on the market.

5. Recognising the need to ensure both high levels of safety and performance of these devices and their availability on the market, and to provide certainty to avoid market disruption, the proposal aims to:

    a. extend the existing transitional period for devices covered by a certificate issued under Directive 98/79/EC to 26 May 2025, and

    b. introduce tailored transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time under EU IVDR.

6. The proposal also recognises that many health institutions have had to focus their efforts on COVID-19 and this has impacted on their capacity to work towards new requirements under the EU IVDR. It proposes delaying the application of certain new requirements for devices manufactured and used within the same health institution. This is to give health institutions extra time to comply with the new requirements and ensure in-house tests can continue to be developed in clinical laboratories.

7. More specifically, the proposal notes that:

    a. as the main challenge to market readiness is the limited independent conformity assessment body capacity, the number of devices that need to undergo a conformity assessment involving a notified body should be spread over a longer period, allowing for a gradual phasing-in of the EU IVDR's requirements while prioritising high-risk in vitro diagnostics. This can be achieved by amending Article 110 of the Regulation on transitional provisions, providing a period for existing higher risk class devices that is shorter than the one for existing lower risk class devices, and

    b. at the same time, the existing transitional period for devices covered by notified body certificates issued under Directive 98/79/EC should be extended by 1 year until 26 May 2025 which will lessen the strain on Member States' competent authorities, independent conformity assessment bodies, manufacturers, health institutions and other actors who deal with both medical devices and in vitro diagnostics.

SCRUTINY HISTORY

8. None for this document, however there has been scrutiny on 14499/12, COM(12)541: Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices
9. The Department of Health submitted an EM on 11 December 2012. The response from the Committees was as follows:
   - Commons ESC: The Committee reported extensively on the proposal as raising issues of political importance in 14 reports to the House completing scrutiny in report 10, 16/17 on 7 September 2016
   - Lords EUC: The proposal was examined by the then sub-committee F and was subject to extensive correspondence with Ministers which concluded on 14 September 2016.

MINISTERIAL RESPONSIBILITY

The Secretary of State for Health and Social Care has overall responsibility for medical devices regulation.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Medical Devices regulation relates to reserved matters under the UK's devolution settlements. The EU IVDR will take automatic effect in Northern Ireland on 26 May 2022 and the Northern Ireland Health Department has been notified of this proposed EU amendment. The MHRA continues to actively engage with Devolved Administrations in its work to develop a future regulatory framework for medical devices in the UK.

LEGAL AND PROCEDURAL ISSUES

i. Legal Base

The legal base for the proposal is Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

ii. Voting Procedure

The proposed amending regulations would be via the ordinary legislative procedure.

iii. Timetable for adoption and implementation

The proposed amendments are to take effect from the day they are published in the Official Journal of the European Union. The timeframe for finalising, adoption and implementation of the proposed amendments is not clear but the European Commission's proposal states that it should enter into force as a matter of urgency.

POLICY IMPLICATIONS

The EU IVDR is listed in Annex 2 to the Northern Ireland Protocol and will fully apply (as replaced or amended) in Northern Ireland from 26 May 2022. A short statutory instrument will also be required to make provision for any national flexibilities the UK elects to exercise under the Regulation and to make provision for supplementary matters such as fees and enforcement. This will follow in Spring 2022 and will be laid using standard Parliamentary processes. This proposed EU amendment to the IVDR has no impact on the timeline to the delivery of the future regulation of medical devices, which will be delivered via separate legislation.

The Government recognises the importance of ensuring that there are sufficient, safe and effective IVDs on the UK market. It recognises also that the market's ability to implement the EU IVDR has been impacted by COVID-19 and the shortage in independent conformity assessment body capacity. It therefore welcomes the extension of time periods for the market to implement the EU IVDR requirements that this proposal sets out.

The Government is seeking a new balance to the Northern Ireland Protocol. As set out in its Command Paper of July 2021, the Government has proposed a dual regulatory regime in Northern Ireland, where goods that meet either UK or EU rules could circulate within Northern Ireland. In this scenario, the EU IVDR would only be applicable to those IVDs sold in Northern Ireland under EU rules and UKCA marked products regulated under the Medical Devices Regulations 2002 could also be available on the Northern Ireland market not subject to the EU IVDR.

CONSULTATION

No consultation or impact assessment of this proposal has taken place, and none is planned. The Government has been working closely with the medical devices industry during the COVID-19 pandemic and has invited views from a wide range of stakeholders in its consultation on the future regulation of medical devices in the UK, including IVDs, which closes on 25 November 2021.

FINANCIAL IMPLICATIONS

No additional financial implications identified by this proposed change.

MINISTERIAL NAME AND SIGNATURE

Lord Kamall

Parliamentary Under Secretary of State (Minister for Technology, Innovation and Life Sciences) Department for Health and Social Care