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

C(2022)8626 (with Annex)
COMMISSION IMPLEMENTING REGULATION (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

C(2022)8638
COMMISSION IMPLEMENTING REGULATION (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose

Submitted by the Department for Health and Social Care on 25 January 2022.

SUBJECT MATTER

This memorandum concerns two EU Commission implementing regulations made under Regulation (EU) 2017/745 on medical devices (EU MDR).

The EU Commission Implementing Regulation (EU) 2022/2346 and accompanying Annex sets out specifications that must be met by certain groups of products without an intended medical purpose in scope of (Annex 16 of) EU MDR before they are placed on the market, made available on the market, or put into service in the EU. Though these products are not medical devices, from the date of application of these common specifications, the EU MDR will apply to these products. These requirements will apply from 6 months after the Regulation comes into force (20 days after its publication in the Official Journal of the European Union (OJEU) on 2 December 2022. It sets out transitional measures for products already on the market at the time the regulation applies.

The EU Commission Implementing Regulation (EU) 2022/2347 reclassifies certain groups of active products without an intended medical purpose that are within scope of Annex 16 of the EU MDR. The effect of the reclassification means that certain products, for example liposuction equipment, will need to be conformity assessed by a notified body before the manufacturer can declare that the product is in conformity with the EU MDR and affix the CE mark. These changes took effect on 22 December 2022.

SCRUTINY HISTORY

None for these implementing regulations. However, the EU MDR itself was subject to scrutiny as EU document 14493/12, COM(12)542. The Government submitted an EM dated 11 October 2012. The House of Commons reported that the proposal raised issues of political importance on 14 occasions with the last report completing scrutiny on 7 September 2016 (Report 10, 16/17). The proposal was considered by the then European Union Committee's sub-committee F and scrutiny was completed on 10 December 2014.

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 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 (including its coverage of products without an intended medical purpose), the MHRA is the competent authority in respect of Northern Ireland.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

Medical Devices regulation is a reserved matter under the UK's devolution settlements. Under the Northern Ireland Protocol, the EU MDR is directly applicable and has fully applied in Northern Ireland from 26 May 2021 and the Northern Ireland Health Department 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 legal basis for these regulations is:

- Commission Implementing Regulation (EU) 2022/2346: Article 1(2) and 9(1) of the EU MDR (Regulation (EU) 2017/745)
- Commission Implementing Regulation (EU) 2022/2347: Article 51(3)(b) of the EU MDR (Regulation (EU) 2017/745)

ii. **Voting Procedure**

Both regulations were subject to the examination procedure under Article 5 of Regulation (EU) 182/2011.

iii. **Timetable for adoption and implementation**

These regulations were adopted by the Commission on 1 December 2022 and published in the OJEU on 2 December 2022. Commission Implementing Regulation (EU) 2022/2346 will fully apply from 22 June 2023 and from this date the EU MDR will apply to the products listed in Annex 16 of that Regulation. Commission Implementing Regulation (EU) 2022/2347 came into force on 22 December 2022 and has fully applied since that date. Both of these implementing regulations are directly applicable in Member States and Northern Ireland. Domestic legislation is not required for their implementation.

POLICY IMPLICATIONS

As outlined above:

1. **The EU Commission Implementing Regulation (EU) 2022/2346** and accompanying Annex specifications that must be met by certain groups of products without an intended medical purpose in scope of (Annex 16 of) EU MDR (such as coloured contact lenses) before they are placed on the market, made available on the market, or put into service in the EU. Though these products are not medical devices, from the date of application of these common specifications, the EU MDR will apply to these products. These requirements will apply from 6 months after the Regulation comes into force (20 days after its publication in the Official Journal of the European Union (OJEU) on 02 December 2022. It sets out transitional measures for products already on the market at the time the regulation applies.

2. **The EU Commission Implementing Regulation (EU) 2022/2347** reclassifies certain groups of active products without an intended medical purpose that are within scope of Annex 16 of the EU MDR. The effect of the reclassification means that certain products, for example liposuction equipment, will need to be conformity assessed by a notified body before the manufacturer can declare that the product is in conformity with the EU MDR and affix the CE mark. These changes took effect on 22 December 2022.

The specifications being introduced for these products, and changes to how they are classified, for the purpose of the EU MDR apply to products being placed on the EU market. Under the terms of the Northern Ireland Protocol (NIP), these regulations will apply in Northern Ireland (NI). They have no direct application for placing products on the Great Britain market.

Further regarding the impacts of these regulations:

- There may be some concern this would deter devices without an intended medical purpose in scope of these implementing regulations being placed on the NI market. However, that the EU intended to issue specifications for these products has been widely communicated without substantive supply issues being raised with MHRA or DHSC.

- Notably, through the principles of mutual recognition and non-discrimination, the UK Internal Market (UKIM) Act 2020 delivers unfettered access for qualifying Northern Ireland goods moving from Northern Ireland to Great Britain. The UKIM Act will allow the products without a medical purpose that are qualifying Northern Ireland goods and that comply with the amended EU requirements to continue to be able to be placed on the market in Great Britain. These products are not currently regulated as medical devices in Great Britain so this will mean those NI products that can be placed on the Great Britain market due to UKIM provisions will be subject to more stringent requirements than similar products on the Great Britain market.

- The changes these requirements introduce are expected to increase demand for EU notified body capacity as there is now a larger number of products which require notified body approval before they can be placed on the market.

The implementing regulations create regulatory divergence between the EU and Great Britain. As a result of the legislation, certain groups of products now fall within scope of the EU's MDR and therefore need to meet certain requirements if placed on the NI market. Whereas the same products placed on the Great Britain market, do not need to comply with the UK's medical devices regulations (MDR).

As outlined in its response to the consultation on the regulation of medical devices in the UK in June 2022, the Government plans to strengthen future regulation of medical devices in Great Britain. It plans to bring certain devices without a medical purpose, but which are similar to medical devices in terms of their functioning and risk profile, in scope of medical device regulations. We anticipate the planned reforms would reduce the divergence that the EU medical devices regulations and these EU implementing regulations bring to how devices without a medical purpose are regulated in Northern Ireland and Great Britain.

Regarding the NIP, the overriding priority is preserving political stability in Northern Ireland. The situation as it stands with the Protocol is undermining the balance established by the Belfast (Good Friday) Agreement and power sharing, and with it political stability in Northern Ireland. It is our preference to resolve this through talks and the Government is engaging in constructive dialogue with the EU to find solutions to these problems. However, the Northern Ireland Protocol Bill will fix the practical problems the Protocol has created in Northern Ireland, if we can't find a solution with the EU. The Bill includes proposals for a dual regulatory regime for manufactured goods, including medical devices, in Northern Ireland. A dual regulatory regime would mean that goods that meet either EU or UK rules will be accepted on the market in Northern Ireland.

CONSULTATION

No consultation or impact assessment of these specific implementing regulations has taken place, and none is planned. Devolved governments were consulted in the production of this EM. Of the devolved governments comments were received from the Northern Ireland Executive (NIE) only. Comments from NIE have noted the divergence these regulations create by introducing requirements to placing products on the Northern Ireland market which do not apply in Great Britain and potential for it to disincentivise placing products on the Northern Ireland market. They also noted the importance of communications about these requirements.

FINANCIAL IMPLICATIONS

Those placing devices without a medical purpose on the NI market will incur the costs of familiarising themselves with and meeting these new requirements, including conformity assessment costs if required – a cost that won't apply to placing the same types of goods on the Great Britain market. There will also be regulator costs incurred associated with the enforcement of the regulations applicable to these devices being placed on the market in NI.

MINISTERIAL NAME AND SIGNATURE

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