COM/2025/1023 Proposal for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

1. **How would the application of the proposed EU act impact divergence between Great Britain and Northern Ireland in this policy area? What are the potential consequences of this e.g. for the supply of medical devices and in vitro diagnostic medical devices from GB to NI?**

Northern Ireland (NI) remains aligned to EU Regulation 2017/745, on medical devices (MDR) and Regulation 2017/746 in vitro diagnostic medical devices (IVDR). In Great Britain (GB) medical devices are regulated under the UK Medical Devices Regulations 2002. The regulations will remain broadly aligned.

The EU proposals intend to reduce the regulatory burden and administrative activities and therefore mitigate this risk as it may be easier for GB companies to obtain CE accreditation and thus supply NI. The Department of Health (DoH) and the Department of Health and Social Care (DHSC) will continue monitoring any supply risk to address these supply risks appropriately.

2. **How many companies in Northern Ireland manufacture medical devices and in vitro diagnostic medical devices?**

DoH does not hold this information. The Medicines and Healthcare products Regulatory Agency (MHRA) have provided the following information from their Devices Online Registration Database that has 72 manufacturers, of which:

- 59 manufacture General Medical Devices and systems & procedure packs
- 13 manufacture IVDs

3. **What engagement has the Department of Health and/or the Medicines and Healthcare products Regulatory Agency carried out with stakeholders on the proposed EU act? What views have been expressed on the current regulatory framework and the impact of the proposed changes?**

As these are relatively new proposals DoH has not had any stakeholder engagement on them. DoH continues to engage with the Department for the Economy (DfE), DHSC and the MHRA to fully understand the objectives of these proposals and any potential impacts.

4. Do you have any concerns about the removal or reduction of some of the requirements in the current regulatory framework?

We do not anticipate any adverse impacts for public health or patient safety standards. We also understand that MHRA will consider similar simplifications in GB.

We understand the EU's intention is to reduce the administrative burden and lower their compliance-related costs. If this intent is realised it may be beneficial to businesses and the health sector more broadly through improved access to medical devices and in vitro medical devices. For example, it allows for a wider range of clinical data sources to be used as part of device authorisation processes, therefore encouraging swifter progress between development of devices and placing on the market. The amendments also increase the length of validity of certificates of compliance, reducing costs for businesses to continue to place devices on the market.

5. Recently, the MHRA launched a consultation on indefinite recognition of CE-marked medical devices and has set out plans for future regulation in this area. How do the proposed UK and EU legislative changes compare? Would this lead to greater alignment or divergence between GB and NI? How would that impact the supply of medical devices and in vitro diagnostic medical devices from Great Britain to Northern Ireland?

The MHRA's consultation on indefinite recognition of the CE mark is currently live and the DoH cannot provide comment at this time.

DoH cannot comment on the level of alignment between the proposed amendments and the upcoming changes to the UK MDR, as this is a reserved matter and the statutory instrument is not yet published. However, we understand from engagement with DHSC and MHRA that it will align us more closely in some respects.

With regards the impact to supplies, as outlined in question 1 these changes may make it easier for GB companies to obtain CE accreditation and thus supply NI. More broadly, the medical device market is typically international and indeed pan-European in nature. In GB, well over 90% of medical devices on the market are CE marked. Therefore, in the vast majority of cases, the same medical devices can be supplied across the whole of the UK.

6. Can you provide more information about the Department's engagement with the UK Government on the proposed EU act?

DoH has regular and frequent meetings with the MHRA and DHSC in respect of medical device and in vitro diagnostic regulations with a view to ensuring patient safety, management of the risk to supply of devices and providing guidance to key stakeholders in respect of the application of the current EU MDR & IVDR, in NI.

7. The Department states that its current understanding is that there may be impacts in relation to non-application of the proposed amendments, if a separate regulatory framework had to be taken forward for Northern Ireland. Why would a separate framework be required?

Should these amendments, once finalised and adopted, not be applied in NI, the current EU MDR/IVDR regulatory frameworks would continue to apply in NI under the Windsor Framework, independent of the revised EU MDR/IVDR that would apply in the EU. As the amendments by and large simplify processes to reduce business burden, this would mean that businesses placing products on the NI market may face higher burdens.

8. What are the implications of potential 'trivergence' in this policy area if the proposed EU act were not applied, i.e. if Northern Ireland, the UK and Ireland/the EU had three different regulatory frameworks?

"Trivergence" in this policy area has the potential to create separate regulatory frameworks for placing a product on the NI market when compared to the EU or GB. The current EU MDR/IVDR framework would continue as the NI set of regulations. Medical device and IVD manufacturers would need to comply with the new regulations to export their product to the EU (which will have simplified processes to reduce business burden).

Similarly, EU manufacturers would have to comply with the current NI regulatory regime in addition to EU and GB specific requirements. It would add a layer of regulatory burden to manufacturers in NI and outside wishing to supply the NI market. It could have an impact on supplies of medical devices and IVDs as manufacturers would have to adjust accordingly.

9. How would the non-application of the proposed EU act affect relevant businesses in Northern Ireland? For example, could this restrict their exports to the EU or put these businesses at a competitive disadvantage?

Businesses must follow the relevant regulatory regime for the market they wish to place their products. Non-application of the EU proposals will mean NI is subject to a different regulatory framework than both GB and the EU. NI access to the EU single market and UK internal market could continue as long as businesses comply with applicable regulations, this would include more burdensome requirements to supply the NI market.