Explanatory Memorandum for COM(2025) 1023 - Proposal for a Regulation of the European Parliament and of the Council 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

SUBJECT MATTER

1. The European Commission published the draft proposal on the 16th December 2025, following the launch of a targeted evaluation of the existing legislation in 2024, which has informed the proposals. The evaluation is being finalised alongside these proposals but indicates that although the Regulations are achieving their aims by strengthening device safety and performance and increasing transparency, this is at the expense of high and often disproportionate compliance costs and delays, in part due to regulatory complexity. The European Commission identified that the current regulations have also affected the competitiveness of EU manufacturers, particularly Small and Medium-sized Enterprises (SMEs) and hindered innovation in the sector.

2. Therefore, a need was identified to simplify and to reduce burden relating to the implementation of the EU Medical Devices Regulation (Regulation (EU) 2017/745) and the In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746) without undermining their main objectives. A key aim of these reforms is to ensure the smooth functioning of the EU market, taking as a base a high level of protection of health for patients and users, and recognising that SMEs are active in this sector.

3. The EU Medical Device Regulation (EU MDR) and In Vitro Diagnostic Medical Devices Regulation (EU IVDR) are referenced in Annex 2 of the Windsor Framework (WF). Therefore, these amendments will apply in Northern Ireland (NI) in accordance with Article 13(3) of the Windsor Framework. The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for implementing EU MDR and EU IVDR in NI.

4. The proposals make a wide range of amendments designed to streamline processes, reduce the burden on businesses and consider new technologies and developments. There are eight broad areas of change: increased simplification and proportionality; reduction of administrative burden; innovation; cost-efficiency of certification; coordination; digitalisation; international cooperation and interactions with other legislation. The proposals broadly bring the EU's legislation in closer alignment with our current policy in Great Britain (GB). The section on policy and legal implications will go into further detail.

SCRUTINY HISTORY

5. No UK parliamentary scrutiny has yet taken place on these specific measures. Scrutiny has taken place on COM (2024) 43 Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of EUDAMED, information obligation in case of interruption of supply and

the transitional provisions for certain in vitro diagnostic medical devices. An Explanatory Memorandum was submitted for this on the 14th May 2024.

MINISTERIAL RESPONSIBILITY

6. Medical devices, in-vitro diagnostic devices and the Windsor Framework are the responsibility of the Parliamentary Under-Secretary of State for Health Innovation and Safety.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

7. The regulation of medical devices and in vitro diagnostic devices are a reserved matter, and the MHRA is the competent authority across the UK. The UK Government will continue to discuss matters where relevant with each of the devolved governments.

LEGAL AND PROCEDURAL ISSUES

8. The adoption of the Regulation by the EU is expected for Q2 2027.

9. This Regulation is applicable under Article 13(3) of the Windsor Framework.

10. The legal basis for the proposal is the same as that in the Regulations to be amended, namely Article 114 and Article 168(4) point (c) of the Treaty on the Functioning of the European Union. The voting procedure for this is qualified majority voting.

POLICY AND LEGAL IMPLICATIONS

11. The Medical Devices Regulations 2002 (MDR 2002) apply in GB. Under EU Exit transitional arrangements, CE marked medical devices (that have been certified under EU legislation) are recognised in GB without additional checks until June 2030. A public consultation on the indefinite recognition of CE marking in GB was launched in February 2026 and will conclude on the 10th April 2026.

12. The government intends to introduce ‘pre-market’ regulations which will introduce additional measures that must be taken before a device can be put on the market with a UKCA mark. These amendments are necessary to strengthen patient safety and access, drive growth and innovation in the MedTech sector, and ensure alignment with international best practices. Reforms to these regulations are intended to enable faster, safer access to medical products through streamlined, risk-based regulatory pathways.

13. The pre-market statutory instrument (SI) will amend provisions in MDR 2002. However, it broadly aligns with harmonised International Medical Device Regulators Forum principles for medical device regulation, which the EU devices regulations also broadly align to.

14. For all proposals discussed below, any changes brought about for NI may also be realised in GB if CE marked medical devices are indefinitely recognised on the GB market. The medical devices market is pan-European and the vast majority of devices are supplied to both the UK and the EU.

Simplification and Proportionality

Person Responsible for Regulatory Compliance (PRRC)

15. The PRRC is a mandatory role for device manufacturers under EU MDR and requires them to have a range of responsibilities in relation to the conformity of devices, both before and after the device is released on the market e.g. ensuring technical documentation is drawn up. Under the current regulations, the PRRC is required to have either a formal qualification or four years' experience in regulatory affairs or quality management systems in relation to medical devices. The proposed revisions remove the specific criteria for PRRCs and instead call for "requisite expertise in the field of medical devices" which will make it easier for companies to have a PRRC.

16. The current regulations also require that SMEs, whilst not required to have a permanent PRRC within their organisation, must have such a person permanently and continuously at their disposal. The proposed revisions remove the permanent and continuous aspect, so SMEs will now only be required to have access to a PRRC.

17. Overall, the changes to PRRCs will reduce divergence between NI and GB, as there is no similar provision in GB within MDR 2002 or the pre-market SI. They also reduce regulatory burden on businesses, particularly SMEs.

Certificates of conformity

18. Under the current regulations, certificates of conformity, which are issued by notified bodies, are valid up to a maximum of five years. The proposed revision makes it so certificates will not generally be time limited, unless the notified body considers it necessary to do so on justified grounds, in which case the validity period will be indicated on the certificate. Risk-based periodic reviews and audits will still be carried out by the notified body, but there will be no requirement for mandatory recertification. Notified bodies will still have the power to suspend or withdraw certificates where the requirements of EU MDR/EU IVDR are not being met or may impose conditions like limiting the intended purpose of the device.

19. This will make it easier, and less expensive, for manufacturers to supply devices within NI and the EU. It is less stringent than the requirements within GB, where UKCA certificates will still have a maximum validity of five years. The MHRA are considering this policy and intend to conduct stakeholder engagement before any public consultation to implement a similar proposal.

Data sources

20. The range of acceptable clinical data sources that can be used as part of the device assessment process is to be broadened, promoting non-clinical data and introducing flexibility for equivalent device data. Currently, it is possible to demonstrate a device's safety and performance based on non-clinical data alone, but the proposals expand this further. "New Approach Methodologies", which are any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment to avoid the use of animal testing, are promoted where possible.

21. These changes may reduce the need for clinical investigation studies of medical devices and performance evaluation studies of IVD devices in NI and the EU, reducing cost and time to market in NI and the EU. This policy is more flexible than the current requirements in GB, though the pre-market SI will also make the recognition of equivalent devices

easier which is more in line with the EU's proposals. The MHRA are considering this policy and would need to conduct stakeholder engagement before a public consultation to implement a similar proposal in GB. The MHRA is actively considering the inclusion of new forms of clinical data, such as in silico data (computational modelling and simulation) and real-world data.

"Well-Established Technologies"

22. The proposals introduce a definition for "Well-Established Technologies". This replaces a range of lists in the current MD Regulation and covers any device that belongs to a generic device group and is considered simple, stable and has a long history on the EU market, amongst other criteria. Devices belonging to this definition, for example sutures and dental fillings, are exempt from more onerous requirements in the proposed revisions e.g. requiring an implant card to be produced for and supplied with the device. This is intended to simplify conformity assessments and adapted clinical evidence requirements in NI and the EU, reducing the cost and time to market in NI and the EU for qualifying devices.

23. This policy is more flexible than the existing GB requirements and the pre-market SI. There is further work needed by MHRA to understand whether a definition for "Well-Established Technologies" rather than a list could lead to differing interpretations. The MHRA would need to conduct stakeholder engagement before any subsequent public consultation to implement a similar proposal for GB.

Repackaging

24. The current EU regulations require that, where a device is repackaged or relabelled after being placed on the market, a notified body certificate must be obtained and provide at least 28 days' notice to the manufacturer and the competent authority of the relevant Member State of this intention. The proposal removes these requirements, which will make it easier, and less expensive, for manufacturers to supply impacted devices within NI and the EU. This proposal reduces divergence between NI and GB because it is removing an additional burden which was faced in NI, in comparison to GB where there is no similar provision within MDR 2002 or the pre-market SI.

Classification changes

25. The proposals update the classification of certain devices, such as reusable surgical instruments and accessories to active implantable devices and software, moving these to a lower risk class, meaning that they will be subject to less stringent requirements and standards. This will reduce the level of oversight making it less burdensome, and less expensive, for manufacturers to supply impacted devices within NI and the EU. The proposed changes bring NI and the EU into greater alignment with the provisions in the pre-market SI, thus reducing divergence between NI and GB.

Reduction of Administrative Burden

Single submission of summary of safety and clinical performance

26. The current regulation requires that manufacturers provide a draft summary of safety and (clinical) performance (SS(C)P) for implantable devices and class III devices (other than custom-made or investigational devices) to the relevant notified body as part of the broader assessment documentation. Manufacturers are additionally required to provide

an additional SS(C)P for validation separately by the notified body. The revisions remove the requirement to provide this second SS(C)P. Instead, only the draft version will be required as part of the certification process, unless the device is required to undergo a technical documentation assessment by the notified body.

27. These changes will make it easier, and less expensive, for manufacturers to supply impacted devices within NI and the EU. Overall, this proposal reduces divergence and improves consistency between NI and GB because it is removing an additional burden which was faced in NI that does not exist in GB.

Post-market surveillance

28. The current regulations require manufacturers to provide Periodic Safety Update Reports (PSUR) which summarise post market surveillance data, benefit-risk determinations of the device and sales and usage data. For manufacturers of medium-high risk (class IIb) and high risk (class III) devices this is currently required annually. The revisions reduce the update frequency for the first year after the certificate is issued, then every two years thereafter unless there is a significant change in the benefit-risk determination if undesirable side effects are identified. For manufacturers of medium risk (class IIa) PSURs are required at least every two years, or when necessary, and will be reduced to only when considered necessary.

29. A reduction in PSUR reporting frequency for some devices is intended to make it easier, and less expensive, for manufacturers to supply such devices within NI and the EU. This policy would be less stringent than the requirements within GB which still requires PSUR reporting every 2 years for class IIa devices and annual reporting for class IIb and class III devices and would add complexity for manufacturers of devices which are both UKCA and CE-marked to comply with both sets of requirements. To determine the suitability for introducing similar changes in GB, a further detailed assessment of the underlying objectives is needed.

Serious incident reporting

30. Where serious incidents are identified in the vigilance framework, manufacturers currently have 15 days to report this to the relevant competent authority; more stringent deadlines apply where there is a public health threat (immediately and not later than 2 days after they become aware) or in the event of death / serious deterioration of health (immediately and not later than 10 days after they become aware). The proposal would leave the latter two deadlines unchanged, but allow manufacturers more time for less serious threats, increasing this from 15 to 30 days. This increase means that it will take longer to identify these incidents in NI and the EU.

31. This policy would be less stringent than the requirements within GB, which is 15 days, and would add some complexity for manufacturers of devices which are both UKCA and CE marked to comply with both sets of reporting requirements. The MHRA are considering this policy in combination with the above post-market surveillance proposal and would need to conduct stakeholder engagement before a public consultation to implement a similar proposal in GB.

Predetermined changes to devices

32. The revisions require notified bodies to distinguish between changes regarding the quality management system or the approved device that manufacturers can implement without prior notification, prior approval or only after approval by the notified body. This is intended to allow manufacturers to seek authorisation to implement planned changes to devices that are expected to undergo regular changes once on the market, such as software, to ensure the continued safety and effectiveness of their medical device.

33. This is intended to make it less expensive for manufacturers to update impacted devices within NI and the EU and brings NI and the EU into greater alignment with the provisions in the pre-market SI. The draft provisions for predetermined change control plans in GB will apply to software only, whereas the EU proposal applies to any medical device or IVD that undergoes assessment by a notified body, where appropriate. Overall, this proposal reduces divergence between NI and GB because it is reducing an additional burden which was faced in NI, in comparison to the draft provisions for GB.

Samples for performance studies

34. EU IVDR currently requires that, where a performance study is being conducted, prior authorisation is needed from the relevant competent authority where a sample is taken. The proposed updates would remove the need for authorisation, where only a routine blood draw is done.

35. If a study involving a companion diagnostic device is undertaken using left-over samples, the competent authority currently has to be notified. The proposals will remove this requirement. Both changes will bring NI and the EU into greater alignment with current approaches for performance studies under MDR 2002. Overall, this proposal reduces divergence between NI and GB because it is removing an additional burden which was faced in NI, in comparison to GB.

Innovation and Availability

In-house devices

36. The current regulation states that, beyond the general safety and performance requirements, in-house devices (i.e., devices designed, manufactured or modified for use within the same health institution) are not subject to the other provisions of the regulations. This is as long as they are not transferred to another legal entity, that there is no equivalent device already available on the market, amongst other criteria. The revisions increase the flexibility of conditions for the manufacture and use of such in-house devices, for example, the transfer of in-house devices is allowed if in the interest of patient safety or public health. For EU IVDR only, the condition that there is no equivalent device on the market is removed.

37. The proposed changes will make it easier for organisations to be able to supply products or provide services under the exemption, though all in-house devices will still be required to meet the general safety and performance requirements of EU MDR/EU IVDR. This policy is more flexible than the criteria for applying the health institution exemption in GB. The MHRA are considering this policy in the context of the NHS and wider health system in the UK and are conducting stakeholder engagement on this topic following a call for evidence in 2025. The MHRA would need to conduct a public consultation to implement a similar proposal in GB.

Reporting supply disruption

38. The revisions provide for the EU Commission to establish a central IT tool to be used in reporting instances of supply interruption or discontinuation, to be provided for in EUDAMED or be interoperable with it. Manufacturers are already required to report this to the relevant competent authority, who will then inform other competent authorities and the EU Commission. The European Medicines Agency (EMA) will also be tasked with developing a methodology to identify devices falling within the scope of the reporting obligation and draw up a list of these devices.

39. The proposals would make it easier for manufacturers and economic operators to comply with this requirement under EU MDR and EU IVDR. This would also enhance the MHRA's ability to monitor and manage supply-related risks associated with certain CE-marked products on the NI market.

Assessing breakthrough devices

40. The revisions will introduce a new conformity assessment procedure for breakthrough or orphan devices, which are devices that are novel, offer significant clinical benefit and have insufficient available alternatives. An expert panel will be required to designate devices as such, which will then enable them to benefit from priority and rolling reviews. Manufacturers of these devices will also be able to access advice from the expert panel. Further details of how the procedure for the conformity assessment of breakthrough or orphan devices set out may be introduced in an implementing act.

41. The proposal is more supportive of manufacturers of innovative devices than the MDR 2002 and the pre-market SI, however the MHRA's upcoming early access service will aim to provide conditional access to innovative medical devices (i.e. breakthrough devices) that address unmet clinical needs in GB. The early access service will provide a similar level of support and access to innovative medical devices as the proposed changes in the EU. Overall, this proposal reduces divergence between NI and GB.

Regulatory sandboxes

42. The revisions allow for the establishing of regulatory sandboxes at national level, either upon a Member States' own initiative or by substantiated request from a manufacturer. They may only be set up for a device if it is expected to address unmet medical needs or to provide a significant clinical benefit to patients or the health system compared with similar existing alternatives or the state of the art, or if the usual processes and assessments would impede or significantly delay the development of the device. These proposals align with MHRA's approach to regulatory sandboxes.

Single-use devices

43. For single-use devices (SUDs), the revisions require manufacturers to provide a justification as to why their device is single-use, setting out how the device would be unable to meet the relevant safety and performance requirements when reused in accordance with its intended purpose even after appropriate reprocessing. This will increase the re-use of devices, wherever possible, for economic and environmental reasons.

44. This policy is more stringent than the requirements in GB, as MDR 2002 is silent on reprocessing/remanufacturing of SUDs and does not require a justification. This is also not in the pre-market SI, though MHRA has produced guidance on this area. However, the intention aligns with sustainability aims within DHSC initiatives like 'Design for Life'. The MHRA are considering this policy and would need to conduct stakeholder engagement before a public consultation to implement a similar proposal in GB.

Predictability and Cost-Efficiency

Dialogue

45. The revisions introduce a legal basis for pre- and post-submission dialogue between manufacturers and notified bodies. This is intended to increase engagement between the notified body undertaking conformity assessment and the manufacturer through the process, for example through scientific advice meetings.

46. Further details on the underlined procedures will be required to assess the practical impact of these proposals. This approach appears to move closer to the model used by the US FDA, which industry has consistently supported, characterised by greater structured engagement between the regulator and the manufacturer throughout the assessment process (for example, through scientific advice meetings).

47. This would contrast with current EU and GB practice, where notified bodies and approved bodies typically do not provide substantive advice to manufacturers on their submissions. It is likely that manufacturers will advocate for the same policy in GB if it is taken forward in the EU. The MHRA are already discussing this with approved bodies to support them offering a similar service.

Notified body assessment

48. For low to medium risk devices (Class IIa, IIb medical devices, Class A sterile, B and C IVD devices) the revisions reduce the level of involvement of notified bodies. This means that for such devices, technical documentation can be assessed for one representative device for a generic device group, category or for the entire portfolio, rather than on an individual basis. For class A sterile IVD devices, a notified body will no longer be involved in assessing their conformity, due to their extensive standardisation and long-standing safe use of such instruments across healthcare settings.

49. The proposed policy to reduce the involvement of notified bodies in the conformity assessment of lower and medium risk devices is generally less stringent than the requirements within GB. This is except for Class B IVD devices, which the pre-market SI will amend the conformity routes to market for in GB, to remove the involvement of approved bodies). The MHRA are considering this policy and would need to conduct stakeholder engagement before a public consultation to implement a similar proposal in GB.

Surveillance audits of manufacturers

50. There will also be increased flexibility in how notified bodies undertake surveillance audits. Currently, these are done on-site only, but the proposals will allow for remote audits to be conducted where appropriate. The frequency of surveillance audits to be

reduced to every two years, rather than current annual requirement, where justified due to absence of safety issues.

51. These and other changes, such as the removal of the requirement for an unannounced audit once per certification cycle to for-cause only, will reduce burden within the EU and NI, and mean requirements are more stringent under the current MDR 2002 and proposals in the pre-market SI. The MHRA will consider the details of this policy and engage with stakeholders to assess the feasibility of similar policies in GB.

Substances of Human Origin (SoHO)

52. The proposal includes requiring notified bodies to consult with a SoHO competent authority (established under the 2024 EU SoHO Regulation) rather than with a human tissues and cells competent authority (established under the 2004 EU Tissue Directive). It requires the SoHO competent authority to provide an opinion within 90 days (reducing it from the current 120 days), though allows a 30 day extension where justified. It is anticipated that it will streamline timelines for notified bodies in the EU and NI, which may reduce administrative burden and costs.

53. In GB, there is currently no requirement for devices that incorporate derivatives of SoHO to meet requirements in addition to those set out in MDR 2002, which won't change under the pre-market SI so there will continue to be different requirements in this area for NI and GB, but no increase in divergence. Work is ongoing on SoHO in GB more broadly, following our commitment in 2024 to commence the SoHO Regulation Review Programme, with one of the key commitments being to maintain a compatible set of high standards of safety and quality to protect public health and support the movement of SoHO across the UK.

54. In the case of devices incorporating a medicinal substance, the notified body is required to consult with a competent authority or the European Medicines Agency. Currently, the relevant authority has 210 days to provide its opinion to the notified body. This will be reduced to 90 days under the new proposals (which may be extended once for a further 30 days on justified grounds). If the medicinal substance has not previously been authorised in the EU, the relevant authority will have 180 days to provide its opinion. It is anticipated this will streamline timelines for notified bodies in the EU and NI, which may reduce administrative costs.

55. The timelines in GB will remain at 210 days in the MDR 2002. This is a service in GB with minimal demand and the MHRA will consider, including through stakeholder engagement, whether changes to the GB policy are appropriate.

Notified body fees

56. Currently, there are no restrictions on the fees of notified bodies, just that such fees must be publicly available, fair, reasonable, and take into account the interests of SMEs. The proposed revision will empower the EU Commission to set levels and structures for notified body fees. It will also require notified bodies to apply at least a 50% fee reduction for micro-enterprises and at least 25% fee reduction for small enterprises, as well as at least 50% reduction for conformity assessment of orphan devices.

57. These changes are expected to benefit small businesses and start-ups looking to place products on the NI market. The MHRA cannot prescribe the UK Approved Bodies fee structure because these organisations operate independently as commercial entities. Consequently, their fees cannot be specified within legislation beyond the current requirements in MDR 2002 which ensure that any fees fairly reflect the cost incurred plus a reasonable profit.

Coordination and Governance

Management of notified bodies

58. The designation and monitoring of notified bodies by the relevant competent authority is being streamlined under the revised regulations. Currently, it is competent authorities who designate notified bodies, but this is being expanded to include joint assessment teams composed of the competent authority responsible for notified bodies, experts nominated by the European Commission and experts nominated from other Member States. These joint assessment teams will be involved in the monitoring of notified bodies after they have been designated, with this taking place at least every two years. The current requirement for the full reassessment of notified bodies every five years will also be removed. The European Commission will also have powers to set the level and structure of fees and recoverable costs for the designation and monitoring of notified bodies.

59. These changes will not have impacts on GB or NI, as the MHRA have not yet had an application for an NI-based notified body. The MHRA are already engaging with Approved Bodies about how to streamline these processes.

Dispute resolution and external expertise

60. Where there are disputes between manufacturers and notified bodies, the revised regulations will now require the competent authority responsible for notified bodies to have a designated ‘ombudsperson’ role to help resolve these issues. As there is currently no designated notified body in NI, this is no impact on NI and the MHRA as a result of this proposal.

61. The role of external expertise, such as expert panels, will have an enhanced role under the revised regulations. Such groups will be involved in a wider range of tasks including determining the regulatory status of products and the classification of devices. Expert panels already provide scientific, technical, clinical and regulatory advice to the Commission and Medical Devices Coordination Group (MDCG) but this is extended to Member States, notified bodies and in certain cases to manufacturers under the proposals. The EMA will continue to be the secretariat for the expert panels.

62. As the MHRA does not take part in coordinated groups, there are expected to be minimal impacts on NI as a result of this proposal.

Digitalisation

Digitalisation of compliance

63. The revisions will increase the situations where digital rather than physical elements can be used in regard to compliance tools. This means that declarations, labelling, and instructions for use may be used electronically, subject to future implementing legislation. Where information is submitted in relation to the regulations, this will be required to be

done electronically. These changes may reduce costs for manufacturers in NI and the EU.

64. This policy is more flexible than the MDR 2002 and the pre-market SI. The MHRA are intending to implement this policy in the future but would need to conduct stakeholder engagement before a public consultation to implement a similar proposal in GB.

*Eudamed (**Eu**ropean **Da**tabase for **Med**ical Devices)*

65. The revisions clarify how unique device identifiers (UDI) are assigned to devices and registered on Eudamed, which is the EU's database for medical devices, as well as expanding digital data requirements and interoperability with national systems outside Eudamed. These changes do not pose any significant changes to the intended traceability aspect of the UDI system but add minor requirements for digital contacts and some clarifications of using Basic UDI when registering, so it is not anticipated to be any impacts on NI arising from this.

66. The proposals for interoperability with national systems, like that operated by the MRHA, would have positive benefit for NI.

International cooperation

International cooperation

67. The revisions introduce an article that sets out how the European Commission will pursue international cooperation, focusing on promoting global standards and guidance for safety and performance, amongst other things, by participating in relevant international fora. It also references that the European Commission may sign administrative arrangements with authorities of third countries or international organisations to exchange best practice, do joint or coordinated inspections and coordinate actions on safety issues. This will have no impact on divergence or alignment between GB and NI, as it relates to steps the European Commission will undertake rather than changes to regulation, however it may increase the opportunities for engagement between the EU, notified bodies, EMA MHRA.

Reliance mechanisms

68. The proposals introduce an article that enables the European Commission to participate in bilateral or multilateral reliance mechanisms or programmes to enable assessments, inspections, and other regulatory decisions carried out or taken by regulatory authorities of third countries or international organisations or international bodies. This is provided there is equivalence in health and safety provisions to EU MDR/EU IVDR, and some arrangements for mutual exchange of information and oversight, but more specific criteria may follow in an implementing act. This will have no impact on divergence or alignment between GB and NI, as it relates to steps the European Commission will undertake rather than changes to regulation. This may however provide opportunity for the UK to cooperate more closely with the EU on the regulation and assessment of devices.

Interactions with other EU legislation

69. The revisions reference various changes to text that cross-reference other pieces of EU legislation. What these entail, and their applicability under the Windsor Framework, are set out as follows:

- There is a change to combined studies that involve medical products, medical devices and/or IVD devices that enable the clinical trial sponsor to submit a single application for a coordinated assessment, rather than multiple applications. This in turn signposts the Clinical Trials Regulation (Regulation (EU) No 536/2014). However, this section is not part of EU MDR/EU IVDR Chapter IX, which is the only part of the Regulation that is in Annex 2 of the Windsor Framework, therefore this change will have no impact on NI.

- The proposal amends the Artificial Intelligence Act (Regulation (EU) 2024/1689 also known as the EU AI Act) so that EU MDR and EU IVDR are moved from Section A to Section B in Annex 1. This move significantly reduces the obligations applicable to medical or in vitro diagnostic devices that are also high-risk AI systems. Products in scope of Section B are subject to bespoke requirements at sectoral level, and only if those are introduced in sectoral legislation; products in scope of Section A, by contrast, are subject to specific requirements set out in the AI Act itself, such as technical documentation, risk management systems and human oversight. However, and importantly, it should be noted that with the exception of limited provisions which amend existing EU law in Annex 2 to the Windsor Framework under Article 13(3), the EU AI Act does **not** apply under the Windsor Framework. The UK has been notified by the EU under Article 13(4) that the EU considers the Act in scope of the Windsor Framework insofar as it includes provisions which contain conditions and specifications for the placing on the market of products or relate to the provision of services that may affect the free movement of products. It would only apply following an agreement at the Withdrawal Agreement Joint Committee, which would be subject to mechanisms in Schedule 6B to the Northern Ireland Act 1998. The EU and UK are currently undertaking technical engagement.

- The revisions include new articles that add additional reporting obligations where cybersecurity is concerned, in addition to existing EU MDR and EU IVDR incident reporting. This cross-references the Cyber Resilience Act (Regulation (EU) 2024/2847) where “actively exploited vulnerability” and severe incidents are defined; if these occur, even if they do not meet the threshold of serious incidents under EU MDR/EU IVDR, the manufacturer will still be required to report this to the relevant national computer security incident response team (CSIRT) and to the European Union Agency for Cybersecurity (ENISA) through Eudamed. Cybersecurity will also be explicitly included in Annex I of EU MDR/EU IVDR in the general safety and performance requirements. The Cyber Resilience Act does not apply in NI beyond limited provisions which amend existing EU law in Annex 2 of the WF under Article 13(3). As with the AI Act, the EU has notified the UK under Article 13(4) of the Windsor Framework, but no decision has been made.

- The Regulation reinforcing the role of the European Medicines Agency in monitoring shortages of critical medicines and medical devices during public health crises (Regulation (EU) 2022/123) is also being amended, to align with the changes to the provisions on expert panels in EU MDR. As this Regulation is not in Annex 2 of the Windsor Framework, this will have no impact on NI.

CONSULTATION

70. The European Commission conducted a targeted evaluation of the Regulations including a consultation and a call for evidence with industry and key stakeholders on the existing EU MDR and EU IVDR at the end of 2025. The consultation provided stakeholders with the opportunity to express their views on how the current rules are performing and to highlight possible shortcomings. The MHRA contributed to this public consultation to present our assessment of the impact that the current rules have on NI.

71. The MHRA will continue to engage with stakeholders impacted by the proposals to facilitate their implementation in NI.

FINANCIAL IMPLICATIONS

72. According to the analysis conducted by the European Commission (SWD(2025)1050, Annex II), the suggested proposals are expected to save between 2 and 5 billion euros per year in the EU. This in turn is expected to reduce the financial burden of placing medical devices on the market in NI and to stimulate growth and innovation within the MedTech sector.

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