

Medicines and Medical Devices Act 2021 Assessment

Under section 45(3) of the Medicines and Medical Devices Act 2021 the Secretary of State must, when exercising the power to make regulations for medical devices under section 15 of the Act, provide a summary of an assessment of the overarching objective of safeguarding public health and, in considering whether the 'overarching objective' is being met by the proposed regulations, have regard to:

- the **safety** of medical devices
- the **availability** of medical devices
- the likelihood of the UK being seen as a **favourable place** in which to carry out research relating to medical devices, develop medical devices, and manufacture or supply medical devices.

We are exploring ways to update the regulation of medical devices (including *in vitro* Diagnostics medical devices (IVDs)) placed on the UK market to enhance patient safety, protect the supply of devices to the UK market, provide access to devices, unlock innovation, and establish new international collaborations. This has real potential to improve the safeguarding of public health by better assuring the safety and quality of devices placed on our market, and the transparency of information about devices.

We have had regard to the factors set out above. An initial summary of key possible changes and possible implications for these three factors are summarised below.

However, the MHRA is considering the potential impacts of policy proposals on these three factors in more detail and is seeking views and evidence from stakeholders and consultees to inform these assessments.

1. **Scope and classification of general medical devices**: we recognise that changes in the classification of medical devices and the extent of devices regulated as medical devices could mean that a greater number of devices are subject to more proportionate scrutiny before, and once, they are placed on the market.

Safety: We believe these changes could ultimately deliver significant and meaningful improvements in the safety of medical devices being provided to patients by increasing the classification of certain devices, such as surgical mesh and bringing certain other products, such as coloured contact lenses and all dermal fillers, into scope of the Regulations where there is a need to do so to ensure much better protection of patients and consumers.

Availability We recognise that this increased regulation could also increase the demand for conformity assessment capacity – which if unmet, could detract from device availability. We continue to work with organisations who have expressed an interest in becoming designated as a UK Approved Body to maximise conformity assessment capacity in the lead up to 1 July 2023.

Favourability: We recognise that this approach could add to the compliance burden on manufacturers, that could detract from the favourability of the UK as a medical device market and therefore upon the availability of devices. However, the changes that may be

taken forward will be in line with international best practice and bring the UK broadly into alignment with regulatory requirements already in place in other international regulators' jurisdictions.

- 2. Economic operator, UDI and registration requirements:** key changes we are considering include requiring unique device identifiers (UDI) to be issued and an expansion of the information manufacturers (or their representatives) are required to submit when registering a device with MHRA. We are also considering setting out further requirements that could apply to manufacturers and other economic operators and to the manufacture and modification of devices in healthcare settings.

Safety: There are significant potential patient safety gains to be made by introduction of a UDI, by enhancing MHRA's ability to trace and identify specific devices back to manufacturers, as well as strengthening adverse incident reporting. We consider that moving 'in-house' manufacture from guidance into regulation could also ensure greater, more consistent safety standards across the sector.

Availability: UDI systems are advantageous because they allow the tracing of particular devices and more targeted field safety actions. This means UDIs could help avoid mass recalls of devices in case concerns arise, avoiding major disruptions to the availability of devices and unnecessary disruption to patients.

Favourability: We recognise the possibility that some of these proposals could increase the compliance burden on manufacturers. This in turn could reduce the favourability of the UK as a medical device market - and we would therefore look to ensure that any changes are proportionate. For example, we could closely align ourselves with UDI systems already deployed internationally to maximise the potential of interoperability of systems across global regulators.

- 3. Approved Body and conformity assessment requirements:** the key changes we are considering are to strengthen the processes by which devices are assessed before they are placed on the UK market, and the role of Approved Bodies in undertaking these assessments.

Safety: These changes could provide significant improvements in the safe provision and use of medical devices through higher standards of oversight, accountability, and assessments. It is vital that we consider options to ensure all appropriate steps are taken to ensure those benefitting from medical devices do so safely.

Availability: In combination with other changes that could lead to an increased volume of assessments, changing the way Approved Bodies are regulated needs careful consideration to avoid negatively impacting availability. This could be achieved through transitional arrangements, including possible automatic roll-over of Approved Body status.

Favourability: We recognise that adding to these requirements could place a greater burden on those subject to, and undertaking, these assessments - which could impact on the favourability of the UK as a destination market for medical devices. We are seeking to make proportionate changes that balance the need to enhance the safety of devices placed on our market with the accessibility of that market.

4. **Clinical evaluations and performance studies:** We are consulting on new ways to ensure that medical device manufacturers conduct effective clinical evaluations in a consistent, comprehensive, and systematic way, protecting the health and welfare of any study participants.

Safety: Effective clinical evaluations and performance evaluations are critical to ensuring the safety and efficacy of medical devices. Possible changes outlined in Chapter 7 could deliver substantial improvements through a consistent approach to clinical evaluations and performance evaluations.

Availability: It is possible that amended requirements for clinical investigations and performance studies may put strain on the capacity of manufacturers and industry experts to assess and review evidence, and therefore the availability of those devices. However, many in the sector already perform robust clinical and performance evaluations that already would meet any new requirements. New requirements should also be viewed in light of having much greater confidence in the safety of devices available.

Favourability: It is possible that some new requirements for clinical investigations and performance studies may be perceived as burdensome, and therefore impact on the likelihood of the UK to be seen as a favourable place to develop and manufacture devices. However, they will also level the playing field by raising standards across the MedTech and diagnostics sector, in line with the many outstanding examples of industry practice already seen globally. These possible changes offer much greater clarity to manufacturers and sponsors of investigations of what will be expected, furthering the adoption of international standardisation.

5. **Post market surveillance, vigilance and market surveillance:** key changes we are considering include increasing the monitoring and scrutiny of devices on the UK market.

Safety: It is critical that we have robust oversight of the safe and effective use of the devices available to patients and the public. It is important for manufacturers and the MHRA to be able to identify and respond to emerging issues. The possible changes outlined in this consultation provide an opportunity to significantly improve surveillance and vigilance of devices, with considerable potential benefits to patient safety. For example, clearer and more timely reporting of serious incidents could ensure that clinicians and industry are better equipped to provide the necessary support to patients.

Availability: We do not anticipate that the proposals outlined for post-market surveillance, vigilance and market surveillance will have a direct impact on the availability of medical devices. However, impacts on favourability might affect availability in turn.

Favourability: While we recognise that some changes in the post-market surveillance, vigilance and market surveillance could increase the compliance burden on manufacturers and therefore how favourably they view the UK as a destination to supply devices, they also offer the potential to provide critical improvements in the safe use of devices. We are committed to ensuring that proposals reflect a proportionate means of safeguarding the safety of medical devices on our market.

6. **Product-specific changes, including IVDs and software as a medical device:** we recognise the fast pace of change in technology surrounding medical devices and the need to ensure our regulations keep pace with this - and that the scrutiny these devices receive should be commensurate with their risk.

Safety: We see real potential for changes in these areas to increase the safety of devices placed on our market and will carefully consider any additional compliance burdens that might arise for industry. For instance, we believe there is significant opportunity to strengthen scrutiny of implantable devices to ensure greater safeguards are in place to protect patients receiving such devices. Chapter 12 also sets out options which could improve the safe use of single-use devices, by enhancing the requirements on persons re-manufacturing single-use devices on behalf of healthcare institutions. Equally, we recognise that under current arrangements around 80% of IVDs are placed on the market without requiring a third-party conformity assessment, and that increasing the scrutiny applied to IVDs will drive an important step-change in the safety of such products.

Availability: We are considering the potential implications of these proposals for the availability of medical devices. Up-classifying IVDs, for example, could adversely impact their availability and result in greater demand for conformity assessments in the near to mid-term.

Favourability: The MHRA has made clear its commitment to supporting a thriving and dynamic MedTech sector, and we believe the proposals on implantable devices, re-use of devices, and IVDs provide an important opportunity to ensure that the UK remains a favourable place to research, develop, manufacture and supply medical devices. While new regulatory requirements might increase the burden on manufacturers, in the case of re-use, this would move areas of guidance into regulations. We recognise the progress seen in the use of software as a medical device, and the huge potential this offers for patients and the life sciences industry in the UK. Proposals to ensure the regulation of Software as a Medical Device (SaMD) will ensure we support responsible innovation in digital health, and lay the framework for a dynamic, thriving market which attracts innovative manufacturers and developers to the UK.

7. **New routes to market:** We are considering introducing new pathways for medical devices to be placed on the market in the UK. This could include dovetailing with approvals pathways utilised by comparable regulators in other countries, or enabling our approvals process to consider international Quality Management System accreditation programmes such as the Medical Device Single Audit Programme, (MDSAP). We are also considering creating a new pathway for innovative devices, for example those which would be serving rare conditions or which could be 'game changers' for end users.

Safety: We would be considering the domestic assurance/MDSAP approvals routes only for those regulatory systems that have demonstrated their patient safety credentials. Furthermore, should this proposal be implemented, it would be supplemented by additional UK regulatory requirements, tailored to the route, to ensure that devices reaching the market through this route, meet relevant safety standards. For the innovative access pathway, partnering with the National Institute for Health and Care Excellence (NICE) and key healthcare partners would ensure end to end oversight of patient safety considerations.

Availability: New routes to market could further the availability of medical devices by improving the speed at which new products might be placed on the UK market - through leveraging work carried out by trusted international regulators and avoiding duplication of efforts for manufacturers.

Favourability: These proposals have the potential to streamline access to our market, making the UK a more favourable market for manufacturers. However, any new approvals pathways would need to be developed in a way that assures relevant standards are met and patient safety is not compromised.