Chapter 14: Routes to market

Section 72 - MDSAP and Domestic Assurance

Background

72.1 The MHRA is considering introducing routes to the UK market which can be utilised by manufacturers with a Medical Device Single Audit Programme (MDSAP) certificate, or with an approval from certain other international regulators. Manufacturers entering through these alternative routes could apply for an abridged assessment with an Approved Body. Introducing alternative routes to market could have a number of benefits for example in enhancing the supply of devices to the UK market and in supporting MHRA's ambition for medical devices regulation to become globally harmonised. Patient safety will remain a priority, and the MHRA has carefully considered how these routes can be introduced with appropriate levels of scrutiny applied to medical devices to ensure they are safe and that they perform as intended.

Possible Changes and Questions

MDSAP

72.2 A Medical Device Single Audit Programme (MDSAP) has been developed that allows a single regulatory audit of a medical device manufacturer's Quality Management System (QMS) (see Chapter 3, Section 11) that would meet the requirements of multiple regulatory jurisdictions. Countries involved in MDSAP are USA, Canada, Brazil, Japan, and Australia with the European Union (EU), Argentina, South Korea and Singapore acting as affiliate members. The UK (MHRA) was granted observer status in March 2021. MDSAP assessments are carried out by 'Auditing Organisations' (AOs), these are recognised by the participating regulatory authorities once they have successfully completed the application process to become AOs.

72.3 The new regulatory system for the UK could make provision to take MDSAP assessments into account. It is expected that the UK Approved Bodies will also be AOs under MDSAP and in most cases this should be a seamless process. However, there will be some AOs who do not have an affiliation to a UK Approved Body. In such cases the manufacturer would need to appoint a UK Approved Body who would need to review outputs from the AO's MDSAP audit and review device technical documentation prior to issuing their own UK certification.

72.4 Consideration should also be given for the UK Approved Bodies to undertake their own unannounced audits of manufacturers if these are not already being undertaken under other schemes.

Domestic Assurance

72.5 The MHRA could accept approvals from other international medical device regulators. Devices with approvals accepted by the MHRA could be subject to a domestic assurance process in which UK Approved Bodies could perform an abridged assessment of the device with appropriate levels of scrutiny to ensure that it meets the requirements of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), as well as an assessment of the manufacturer's QMS. The MHRA will need to consider which regulatory approvals it could accept, and the appropriate level of domestic assurance required to accept the device onto the UK market.

Other Considerations – MDSAP and Domestic Assurance

72.6 For all domestic assurance and MDSAP routes, defined contractual provisions between the client and the UK Approved Body would allow for contact between the Approved Body, MHRA and the international regulators. This would allow for information sharing for Market Surveillance perspectives should the need arise.

72.7 Domestic assurance would not be relevant for clients of EU Notified Bodies who also have designation as a UK Approved Body. Such clients could be offered a 'CE plus UKCA' route which would result in certification for both the UK and EU markets.

72.8 It should also be noted that there is a move towards a global technical document review process in which, hopefully, MHRA will be fully involved in its development and, once public consultation has taken place, it can be incorporated in the UK Regulations once it has been implemented. This will have a positive impact on the level of domestic assurance required in future.

72.9 All manufacturers who utilise the MDSAP or Domestic Assurance approach would need to register with MHRA and appoint a UK Responsible Person where they are based outside of the UK.

Q72.1 Do you think the MHRA should introduce an alternative route to market which utilises Medical Device Single Audit Programme (MDSAP) certificates? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q72.2 Please explain your answer to question 72.1 and, if applicable, please outline any further considerations/requirements that should be in place for accepting MDSAP certificates.

Q72.3 Do you think the MHRA should introduce an alternative route to market which utilises approvals from other countries (domestic assurance route)? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q72.4 Please explain your answer to question 72.3 and, if applicable, please outline any further considerations/requirements that should be in place for the domestic assurance route.

Section 73 - Pathway for Innovative MedTech

Background

73.1 The MHRA is considering an alternative pathway to market for devices that meet certain criteria. These criteria are likely to include factors such as:

a. size of patient population – rare conditions / small patient groups
b. scale of innovation – devices that will be 'game changers' for end users
c. size of manufacturer – targeting small and medium sized enterprises (SMEs).

Possible Changes and Questions

73.2 We would create a structured pathway for devices meeting the criteria we establish (such as those set out in paragraph 73.1). This would include MHRA setting up a hub for innovation, through which we would support manufacturers' research and data gathering activities, alleviating some of the cost and capacity obstacles faced by SMEs in getting innovative products to market.

73.3 This would work as an alternative route to the 'traditional route' whereby a manufacturer obtains a Certificate of Conformity from a UK Approved Body and places a UKCA marking on their device(s). Under the proposed alternative pathway, the MHRA would be granting approval for the manufacturer to make the device available on the market prior to obtaining a UKCA marking. This would be limited to specific circumstances, e.g. for use on certain groups of patients and/or within specific healthcare institutions where there is an identified need.

73.4 We plan to partner with the National Institute for Health and Care Excellence (NICE) and other key healthcare partners as it will be critical to establish end to end oversight.

73.5 Following the pre-market approval phase – manufacturers using the alternative pathway would then be required to switch over to the mainstream Approved Body route for UKCA marking and post market surveillance etc. This would avoid potential 'conflict of interest' issues.

Q73.1 Do you think the MHRA should introduce a pre-market approvals route to place innovative medical devices into service for a specified time period and for specific use cases? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q73.2 Do you think the MHRA should have powers to conduct conformity assessments and issue approvals in certain scenarios, such as the one outlined in paragraph 73.3? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q73.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 72.1-73.2, including any impacts on you or other stakeholder groups and/or any other general comments on how this could be implemented, including potential timeframes and specified uses.