Medicines and Healthcare products Regulatory Agency

15 December 2017

IMPLEMENTATION OF EU LEGISLATION FOR MEDICAL DEVICES AND IVDS

Issue/ Purpose: To provide an update on progress with implementing the new legislation at a UK and EU level.

Summary: The MHRA continue to implement the new Regulations at a UK level. This has involved implementing an operational programme plan, engaging industry and health institutions, drafting guidance documents and position papers, and publishing communication tools.

We have also been engaged with implementation work at a European level, as members of the Implementation Taskforce (who are tasked with ensuring working groups deliver on their work plans) and the Transition Subgroup (concerned with interpreting the complex phasing out of existing legislation and phasing in of the new Regulations).

Resource implications: We anticipate a requirement for significant additional resourcing due to the impact that the new market surveillance requirements will have on the Devices Division.

EU Referendum implications: Elements of the new regulations have been applied directly in UK law since May, meaning devices can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements. As it stands, the EU (Withdrawal) Bill would maintain this position beyond March 2019.

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Which of the five themes in the Corporate Plan 2013/2018 does the paper support?

Theme 2: Bringing innovation safely to market
Theme 5: Achieving excellence – a well-run, efficient and effective organisation

If relevant, which Business Plan strategic activity does it support?

Aim 2: Enabling innovation
Aim 3: Vigilance
Aim 4: Secure global supply chains

CET Sponsor: John Wilkinson

Implementation of new EU Regulations for medical devices and *in vitro* diagnostic (IVD) devices

Purpose

1. We continue to implement the new EU Regulations for medical devices (MDR) and *in vitro* diagnostic devices (IVDR), which entered into force on 25 May 2017. This paper provides an update on progress made with UK and EU implementation, as well as highlighting the need for additional resources within the Agency to meet the range of additional obligations placed on competent authorities by the Regulations.

Brexit

2. The Government's top priority for life sciences during the negotiations is to protect the safety of patients and ensure the integrity of cross-European public health systems. The Government will seek a mutually beneficial future partnership between the UK and EU that is in the interests of both sides, which builds on the convergence between our regulatory systems and gives business the maximum freedom to trade with and operate within European markets.

3. As stated by Lord O'Shaughnessy at an ABHI conference in September, elements of the new regulations have been applied directly in UK law since May, meaning devices can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements. As it stands, the EU (Withdrawal) Bill would maintain this position beyond March 2019.

UK Implementation

4. We continue to implement the Devices operational programme plan to ensure that we meet the legislative obligations under the new Regulations. Key 'Work Stream Leads', who are responsible for ensuring the delivery of certain activities, meet with the Project Manager on a fortnightly basis to ensure that the plan is on track.

5. We have been engaging external stakeholders in a number of ways. This includes providing updates during formal meetings (such as the MDR/IVDR External Strategy Group, Devolved Administrations Strategy Group, and the Medical Devices Industry Liaison Group) and speaking at industry conferences.

6. We are consulting industry in several policy areas. For example, we have produced a detailed guidance document for implementing the new health institution exemption requirements. This guidance document will go out for informal consultation at the end of the year. We have also drafted position papers, which will be taken to European working groups for endorsement.

7. We are working closely with NHS Improvement and the NHS Confederation in order to develop plans to communicate with health institutions about the changes that will occur as a result of the MDR and IVDR, and any actions that the Trusts will be required to implement. As part of this engagement, we will be asking for volunteer Trusts to trial the processes set out in the health institution guidance document. We have also been working closely with NHS eProcurement's Scan4Safety programme, which will be implementing traceability requirements for medical devices entering the NHS supply chain ahead of the timescales set out in the Regulations.

8. Part of the implementation work has involved updating our current online guidance. Certain guidance documents, such as guidance on custom-made and 3D printed devices, will be updated following discussions at a European and international level (where we are involved in the International Medical Device Regulators Forum work package for personalised medical devices).

9. At the end of August, we published our high level 'Introductory Guide to the MDR and IVDR', which provides succinct information on the key steps to getting a device on the market under the new Regulations. Our initial campaign targeted around 6,000 manufacturers, and, since its publication, the Guide has been downloaded over 4,000 times. We received positive feedback from industry and the Commission on the usefulness of the Guide and we continue to promote the Guide as part of our ongoing communications work.

10. In order to raise awareness amongst the new stakeholder groups (in particular, SMEs and manufacturers of Annex XVI, substance-based and software devices who are not regulated under the current Directives) we will be conducting extensive communications campaigns.

11. We anticipate a requirement for significant additional resourcing due to the impact that the new market surveillance requirements will have on the Devices Division.

European Implementation

12. We have played a leading role in the coordination of European implementation activities. The Taskforce has published a list of implementation priorities on the Competent Authorities for Medical Devices (CAMD) website, and through formal engagement with European stakeholders and working group chairs, has created a single European Implementation Roadmap which all parts of the system can sign up to. This will ensure the best utilisation of resource and expertise as well as creating a consistent approach to implementation across Member States. The MHRA have stepped down as chair of this Taskforce as it moves into the second phase of its work, which involves ensuring that working groups devise and deliver work plans to implement these priorities.

13. We are also a member of the CAMD's Transition Subgroup, which has been tasked with interpreting the transition-related provisions. This includes identifying areas with the potential for inconsistent application, providing recommendations on interpretation, and, where appropriate, seeking legal input to underpin proposals. The Subgroup aim to publish the first results from discussions by the end of the year.

14. The inaugural Medical Device Coordination Group (MDCG) meeting took place on 28 November. Whilst much of the discussion related to the remit and functioning of the MDCG, a number of key decisions were taken, notably the approval of a new manufacturer incident report form that the MHRA has been central to drafting and will go a long way to standardising vigilance reporting across the EU.

Conclusion and next steps

15. As we progress with our implementation work, we will continue to engage industry and work closely with other Member States in order to ensure that the MHRA and our stakeholders are prepared for the new Regulations.