

Medicines and Healthcare products Regulatory Agency: The revision of European legislation on medical devices

Response by the Wellcome Trust

January 2013

Key Points

- The Wellcome Trust broadly supports the proposals put forward by the European Commission to revise legislation on medical devices. We consider the proposals to be largely balanced and proportionate, providing a greater level of scrutiny of devices regulation that will protect patients while providing a clear legal framework for researchers and companies working in this area.
- We support the proposed changes in scope of the regulations, but suggest greater clarity be sought with regard to the definition of near-patient testing in the *in vitro* diagnostics (IVD) regulation. We also suggest greater clarity be sought with regard to the circumstances under which the exemption for devices developed 'in-house' would apply.
- We support, in principle, the MHRA's position on the requirements for clinical evaluation and for a 'qualified person responsible for compliance, but are concerned about the potential for a disproportionate administrative and cost impact on small and medium sized companies.
- We support the introduction of a unique device identifier (UDI) system, but suggest greater clarity be sought as to how this will work in practice. We also support the MHRA's positions with regard to additional pre-market scrutiny for higher-risk devices and transparency and confidentiality.

INTRODUCTION

1. The Wellcome Trust is pleased to have the opportunity to respond to this consultation on the revision of European legislation on medical devices. A significant part of the Trust's translational funding portfolio supports researchers and companies in the development and commercialisation of medical devices and technologies, and so it is important that regulation of this area takes a balanced and proportionate approach, supporting innovation while protecting the safety and interests of patients.
2. We broadly support the European Commission's proposals to revise the legislation on medical device regulation, particularly in light of recent concerns about safety and standards arising from the PIP breast implants case, and concerns around metal-on-metal hip implants. On initial review, we consider that the proposals are largely balanced and will help to provide a necessary greater level of oversight, as well as legal clarity and protection for researchers and companies involved in the design and manufacture of devices. However, we have identified several areas of potential concern and points for

greater clarification, as set out below. We look forward to continuing dialogue with the MHRA in these areas as negotiations on the regulations proceed.

SCOPE OF THE PROPOSALS

Question 1: Do you agree with our proposed position [on the proposed scope of the medical devices regulation]? If not, please explain why.

3. We largely support the scope of the proposed regulations, and agree that the proposed changes are helpful and provide considerably greater clarity. We support the MHRA's recommendation that products composed of substances or combinations of substances intended to be ingested, inhaled or administered vaginally or rectally and that are absorbed by or dispersed in the body should be excluded from the scope of this regulation. We consider that these substances should be regulated as medicinal products rather than devices.

Question 7 – Do you agree with our proposed position [on the inclusion of software, genetic tests and companion diagnostics within the scope of the IVD regulation]? If not, please explain why.

Question 8 – Are the definitions of companion diagnostics and near patient testing useful? If not, how could they be improved?

4. We support the MHRA's position on the inclusion of software, genetic tests and companion diagnostics within the scope of the IVD regulation. However, we would question the definition of a device for near-patient testing as “*any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient.*” We suggest that such testing would not necessarily occur outside of a laboratory environment if, for example, such testing was taking place in an acute environment with its own on-site laboratory facilities, as opposed to outside of a clinical setting such as the patient's home when a nurse or doctor is attending. We would therefore suggest that this definition be worded more precisely in order to capture the difference between testing in an acute care or hospital setting and testing elsewhere.

Question 9 – Do you agree with our proposed position [on the mechanism for the Commission to make a binding decision on the regulatory status of products the proposal to set up an expert group to support the Commission's decisions]?

5. We support the MHRA's position on the proposed mechanism, and agree that it is potentially a helpful way to provide greater clarity and consistency of decision making across the EU.

PLACING ON THE MARKET AND PUTTING INTO SERVICE

Question 10 – Do you agree with our proposed position [on the requirement on manufacturers to provide a clinical evaluation and the provision on ‘in-house’ devices]? If not, please explain why.

Question 11 – Do you agree with our proposed position [on the requirement on manufacturers to provide a clinical evaluation of new in vitro diagnostic devices]?

6. We support, in principle, the MHRA’s proposed position with regard to the requirement on manufacturers to provide a clinical evaluation when demonstrating the conformity of their devices. However, we have some concerns that this requirement could potentially have a disproportionate impact on small and medium-sized manufacturers in terms of administrative time and costs, particularly for products which may be derived from an existing device and for which there is existing clinical data available.
7. We support the MHRA’s position on the proposed change to the current ‘in-house’ exemption requiring that devices manufactured and used ‘in-house’ must comply with some of the obligations in the medical devices regulation. We suggest, however, that greater clarity be sought on the circumstances under which the in-house exemption may apply, for example in cases where a device may be manufactured and used within different arms (e.g. academic and clinical) of the same legal entity. Our understanding is that the exemption would continue to apply in such cases, but it would be helpful for the regulations to define this so as to avoid ambiguity.

GENERAL REQUIREMENTS OF ECONOMIC OPERATORS

Question 16 – Do you agree with our proposed position [on the requirement for a ‘qualified person’ responsible for regulatory compliance]?

8. We share the MHRA’s concerns that the requirements for a ‘qualified person’ as defined in Article 13 of the regulations has the potential to place a disproportionate burden on small and medium-sized manufacturers who may collectively have such qualifications and expertise, but may not have individual members of staff available who fit with the requirements. We agree that changes should be considered to allow greater flexibility within the requirements, perhaps by taking stock of the totality of expertise and experience across the company by allowing responsibility to be shared across two or more named individuals rather than requiring a single individual to act as a ‘qualified person’.

IDENTIFICATION AND TRACEABILITY

Question 27 – Do you agree with our proposed position [on the introduction of a unique device identification (UDI) system]? If not, please explain why.

9. We support the MHRA's position on the introduction of a UDI system. This change is positive in principle, but there will need to be further examination and discussion of how this will work in practice, particularly with regard to harmonisation within Europe and international compatibility existing systems and databases, such as those employed by the Food and Drug Administration. It will be important to ensure that any new Europe-wide system is internationally compatible in order to facilitate the export and sale of devices and products worldwide.

Question 29 – Do you agree with our proposed position [on the establishment of a new central database]?

10. We support the MHRA's position on the establishment of a new central database, and the requirement to produce a summary of safety and performance. We agree that this proposal will increase transparency and aid informed decision making, but suggest that more detail be sought on how the proposal will work in practice, particularly what kind of information will be contained within these summaries and what level of detail will be required.

CLASSIFICATION AND CONFORMITY ASSESSMENT

Question 39 – Do you agree with our proposed position [on the changes to classification and the role of competent authorities]?

11. We support the MHRA's position on these changes, and agree that they will provide greater clarity and consistency for manufacturers.

Question 40 – Do you agree with our proposed position [on the proposed changes to classification as set out in the medical devices regulation]?

12. We support the MHRA's position here, in line with our response to Question 1.

Question 48 – Do you agree with our proposed position [on additional pre-market scrutiny for higher risk devices]?

13. We support the MHRA's position on this issue, and agree that an alternative approach should be explored in order to prevent unnecessarily delaying patients' access to new technologies.

CONFIDENTIALITY AND DATA PROTECTION

Question 65 – Do you agree with our proposed position [on the requirements relating to transparency and confidentiality]?

14. We support the MHRA's position on this issue, and agree that the default mode in the regulations should be towards transparency, while seeking an appropriate balance with the need to protect personal data.

The Wellcome Trust is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

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