Written evidence submitted by the Institute of Physics and Engineering in Medicine to the Commons Select Committee Call for Evidence regarding EU regulation of the Life Sciences – March 2016

Summary

- IPEM is a professional association for physicists and engineers working with applications of physics and engineering in medicine. Its senior and specialist physicists and engineers have compiled this response.
- The EU directives in place around medical device research and the medical exposure to ionising radiation of research participants are essential for patient safety,
- The UK, working through the MHRA and NHS Confederation for medical devices, and the Department of Health for medical exposures, has been able to influence EU directives successfully, including making IPEM-recommended changes to reduce the impact of new directives / regulation on innovation in the NHS.

About IPEM

1. IPEM is a professional association and Learned Society with 4,300 members who are physicists, engineers and technologists working with applications of physics and engineering applied to medicine and biology. Our members work in hospitals, academia and industry, and IPEM has a unique role in linking the three areas.

2. As a charity, IPEM's aim is to advance the application of physics and engineering to medicine for the public benefit; and to advance public education in the field. We do so by supporting and publishing research, and supporting the dissemination of knowledge and innovation through project funding and scientific meetings; and by setting standards for education, training and continuing professional development for healthcare scientists and clinical engineers.

3. We also produce information for the public about the role of physicists and engineers in their healthcare services, and hold a series of public lectures each year. Our members are also involved in outreach events for young people and University students, to promote healthcare science careers.

4. In preparing this response, we have consulted with our Vice President – Engineering who chairs our Engineering Advisory Group, and our Director of the Science, Research and Innovation Council who are both Trustees of IPEM; a senior and experienced engineer member who has led on work with the Medicines and Healthcare products Regulatory Agency as our representative for some years; and our Clinical Engineering Special Interest Group. We have set out our response in line with the specific questions posed in the call for evidence.

What are the key EU regulations and frameworks that govern/influence the conduct of research and innovation in the UK life sciences?

5. The main EU directives and UK regulations that govern/influence the conduct of medical device research and innovation in the UK Life sciences are:
    a. The Medical Devices Regulations (MDRs) 2002 (UK regulations)

- Directive 90/385/EEC regarding active implantable medical devices (AIMD)
- Directive 93/42/EEC regarding medical devices (MDD)
- Directive 98/79/EC regarding in vitro diagnostic medical devices (IVDD)

b. Guidance on the requirements of conducting medical device research in the UK is given in Medicines and Healthcare products Regulatory Agency (MHRA) document 'Clinical Investigations of Medical Devices - Guidance for Manufacturers'.

6. In addition, the principles of clinical investigations of medical devices are set out in the standard BS EN ISO 14155:2011 Clinical investigation of medical devices for human subjects. There are other regulations / directives / standards that apply to ensure that hazards have been assessed and risks reduced to demonstrate device safety. These are dependent on the type of device, and include software as a medical device.

7. The main EU directives and UK regulations that govern/influence the use of ionising radiation in medical research in the UK are:
   a. The Ionising Radiation (Medical Exposure) Regulations 2000 (UK regulations)
   b. Directive 97/43/Euratom

8. These directives / regulations arise from evidence-based recommendations on the safe use of ionising radiation which are issued from time to time by the International Commission for Radiological Protection.

In what ways do these EU regulations affect the UK life sciences? What are their benefits and drawbacks?

9. The requirements provide a governance structure to ensure that medical device research is conducted in a safe and effective manner, and that ionising radiation is used appropriately in medical research studies. In both instances the aim is to reduce patient risks to as low as practicable, and to ensure all potential benefits outweigh risks. Clearly the benefits of these EU directives are therefore patient safety and control.

10. For medical devices, the drawback for the researcher is the quantity of work required to compile technical files to enable assessment of safety. There is often a great variation in the amount of documentation created and submitted by the researchers, and also local requirements/expectations for proof on concept studies that may not need assessment by the UK competent authority. This variation is often attributable to the knowledge of requirements/regulations and resources available within NHS based clinical engineering departments.

11. For medical exposures, administrative overheads exist for both the researcher and for the departments where the medical exposures.

How transparent, consultative and evidence-based are EU policy-making processes?

12. Changes to policy are communicated and put out to public consultation via the MHRA for medical devices and the Department of Health for medical exposures.

IPEM quite often takes advantage of this approach and encourages members to provide expert opinions. IPEM has also allocated an experienced member to be involved in the development of the MDRs through close collaboration with the MHRA and Members of the European Parliament. IPEM also participates in stakeholder meetings with the Department of Health in advance of public consultations.

To what extent is the UK able to shape regulatory processes at the EU level that affects the life sciences?

13. The UK is able to shape EU directives as described above. IPEM has been able to advise on recent changes to reduce the impact of the revision of the Medical Devices Directive on innovation within the NHS and academia. IPEM considers that the MHRA and other government bodies are very influential in the Council negotiations, and have succeeded in having agreed UK changes accepted onto draft revised directives. These contacts have been greatly facilitated by the excellent input and help from the European Office of the NHS Confederation. This approach has worked and the Commission has listened.

Is the UK able to depart from the application, standards or timings of such EU regulation?

14. This would be problematic and advice is best sought from the Competent Authorities in the UK for implementing the EC Directives, such as the MHRA.

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