House of Commons Health Select Committee inquiry into regulatory arrangements needed to guarantee safe and effective supply of medicines, medical devices and products post-Brexit.

Terms of Reference

The Health Committee would like to receive written submissions on the following questions:

1. **What are the key considerations that arise for companies, healthcare services and regulatory bodies in the UK as a result of the UK's withdrawal from the EU? Focussing on patients and the public, what needs to be done to ensure that any adverse impact is minimised or eliminated, and that opportunities to enhance services are maximised?**
2. **Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced? What are the respective opportunities, risks and trade-offs involved?**
3. **How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?**
4. **How will withdrawal from the European Union affect the UK's ability to influence international standards in life sciences?**
5. **What arrangements are needed to ensure the safe, effective and timely supply of medical radioisotopes over the short, medium and long-term?**
6. **What are the implications for medical research and development, including for the timely patient access to new medicines, technologies and other relevant medical innovations developed within or outside the UK? How can any adverse consequences be avoided or mitigated and any potential opportunities be enhanced?**

Respondents need not provide responses to all questions. Equally, if there are any crucial issues not captured under the questions we pose, please highlight what they are and explain their salience.

About IPEM

- IPEM is a professional association and Learned Society with around 4,500 members working in hospitals, academia and industry, who are physicists, engineers and technologists working with applications of physics and engineering applied to medicine and biology.
- 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 this 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.
- 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.

Executive summary

- Clinical Scientists are state-registered in the UK and the title is protected by law. There are reciprocal arrangements with other EU countries so that Clinical Scientists registered in the EU can register and work in the UK. The UK should continue to recognise European equivalence, irrespective of EU membership.
- UK and EU legislation requires the appointment of Medical Physics Experts (MPEs) to work in the fields of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology/Radiotherapy. The UK Government should seek to encourage harmonised systems of training, education and competence of MPEs throughout Europe. This need not be limited by the EU if all countries are following the same system.
- In future, the UK Government will need to determine whether it should mirror EU legislation in the field of ionising radiation, or whether it should derive its own legislation.
- All medical devices on the European market are regulated by the EU and must be CE-marked by law. The world's other large market is the USA where devices are approved by the Food and Drug Administration. Manufacturers tend to design devices for these two markets. In the globalised economy of which we are now part, there is absolutely no prospect that medical device manufacturers would wish, or be able, to make devices specific to a UK market. It would not be economic as there would be little return on investment.
- The new Medical Devices Regulation and the IVD Regulation came into force on 26 May 2017 and although there is a 3-year and 5-year transition period respectively, as Regulations they became part of UK law from that date. This should be confirmed post-Brexit and the transition periods allowed to run.
  The UK has been very influential in the negotiation of these Regulations, with the Medicines and Healthcare products Regulatory Agency (MHRA) being very welcoming of constructive input from IPEM.
  A significant proportion of CE-marked medical devices are imported, either from other EU countries or from the rest of the world. The UK also exports CE-marked devices into Europe, and some non-EU countries rely in part or in whole on CE marking towards their own medical device regulation.
- In terms of formal international standards generated through ISO and IEC, the UK has national membership of these bodies, so there is no change. We understand that the equivalent European standards bodies CEN and CENELEC, although closely linked to the EU, are not exclusively EU-only bodies. UK membership can therefore continue.
- The UK will lose influence at the level of the Commission, for example, the ability in the new Regulations to establish 'Common Specifications' outside of the formal consensus standards making process. It is difficult to see how the UK will be able to play any part in the Medical Device Coordination Group (see Recital 8 and 82 and Article 103 of Regulation (EU) 2017/745 – the MDR).

- Outside of specific EU bodies, the UK should and must be able to continue to play an influential part but much life science research and development is EU coordinated and funded and UK involvement may be difficult.
- The UK remains a key innovator of medical technologies, and devices (for example, medical ultrasound, X-ray CT and MRI) have all been developed in the UK. The UK remains a major world manufacturer of MRI systems with more than 30% of the superconducting magnets in hospitals worldwide manufactured in the UK. As an example, 95% of the magnets made by Siemens Magnet Technology in Oxford are for export. Siemens is now manufacturing new 7 Tesla magnets in the UK. Siemens will partner with universities and hospitals in the UK to further develop this technology and its applications. This development will result in the creation of hundreds of new healthcare science research jobs.
- The UK should negotiate to remain an active contributor to the governance of medical devices on the European market. The UK should resist being an observer with no influence on future Medical Devices Regulations. The UK successfully negotiated, with the input of IPEM, changes to the draft of these recent regulations to minimise the negative impact on the in-house manufacture of medical devices which aids clinical assessment, therapy and treatment of patients in healthcare establishments.
- The medical devices market is world-wide. Post Brexit, the UK should as the norm, continue to insist on CE marking for medical devices to be placed on the market in the UK. It would be counterproductive to establish a different UK only system which would increase cost, and if a laser system would reduce safety and effectiveness UK manufacturers would have to continue to apply the EU CE marking regulations in order to continue to export.
- In terms of healthcare resilience, the UK needs to ensure a sustainable daily supply of time critical deliveries of radiopharmaceuticals from the EU. We are dependent on the EU for our supply; deliveries cannot be delayed by prolonged Customs checks as the radiopharmaceuticals decay with time and are required to meet strict daily hospital treatment and diagnostic schedules.
- From an NHS healthcare perspective, the UK Government should negotiate ongoing opportunities for joint medical and healthcare research, in UK priority areas, with European medical research partners and device manufacturers. This would include the development of new diagnostic and therapeutic technologies, including: point-of-care testing, precision medicine, image processing and data mining; with an emphasis on managing diseases of an ageing European population (including: cancer, cardiovascular disease, stroke and dementia) in addition to improving the management of childhood diseases and debilitating chronic illnesses.

IPEM's response

Key considerations focussing on patients and the public:

1. In order to protect patients, Clinical Scientists are state-registered in the UK and the title 'Clinical Scientist' is protected by law. There are reciprocal arrangements with other EU countries so that Clinical Scientists registered in the EU can register and work in the UK. The UK should continue to recognise European equivalence, irrespective of EU membership.

2. UK and EU legislation requires the appointment of Medical Physics Experts (MPEs) to work in the fields of Diagnostic and Interventional Radiology, Nuclear Medicine and Radiation Oncology/Radiotherapy. The UK Government should seek to encourage harmonised systems of training, education and competence of MPEs throughout Europe. This need not be limited by the EU if all countries are following the same system.

3. European legislation affects much of the UK legislation in medical physics and clinical engineering. As examples:

- Ionising Radiations Regulations 1999 (IRR 1999) - Implement the majority of the European Basic Safety Standards Directive '96/29/Euratom' under the auspices of the Health and Safety at Work etc Act 1974. These regulations protect staff and members of the public. The European Directive was in turn a reflection of the recommendations of the independent International Commission on Radiological Protection (ICRP).
- The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R 2000) - implement the European Directive 97/43/Euratom (The Medical Exposures Directive) and protect patients. Again, the Regulations implement recommendations made by IRCP.
- The European Council Basic Safety Standards (BSS) Directive 2013/59/Euratom will shortly lay down in UK law basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repeals the above Directives plus Directives 89/618/Euratom, 90/641/Euratom, and 2003/122/Euratom. The new BSS Directive incorporates the latest recommendations from the International Commission on Radiological Protection (ICRP) published in 2007, and harmonises the EU regime with the Basic Safety Standards of the International Atomic Energy Agency (IAEA).

4. In future, the UK Government will need to determine whether it should mirror EU legislation in the field of ionising radiation, or whether it should derive its own legislation. UK law could, for example, be derived directly from ICRP guidelines and the standards of the IAEA.

5. The UK recently introduced the Control of Electromagnetic Fields at Work Regulations 2016. These regulations implement EU Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields). The UK was a positive influential partner in developing this Directive. It was IPEM members who realised the original directive would prevent certain medical use of electromagnetic fields. This resulted in the original directive being revoked and replaced. This is an excellent example of how the UK has been an influential, practical and pragmatic partner in developing EU legislation. Without this change, much MRI based healthcare and innovation in Europe would have had to cease and would likely have been exploited elsewhere in the world. There would be an opportunity here to assess which set of legislation and regulations the UK would wish to follow. The UK could potentially be a European “test bed” for new developments in areas currently restricted in the EU. However, this would entail a commercial risk if the EU regulations were not relaxed.

Medical Devices manufacture and safe regulation:

6. There is a critical issue here. All medical devices on the European market are regulated by the EU and must be CE-marked by law. The world's other large market is the USA where devices are approved by the Food and Drug Administration (FDA). Manufacturers tend to design devices for these two markets. The world is a very different place to January 1973 when the UK originally joined the EEC. Since the 1970s the use of health technology has increased dramatically. In the globalised economy of which we are now part, there is absolutely no prospect that medical device manufacturers would wish, or be able, to make devices specific to a UK market. It would not be economic as there would be little return on investment.

7. One possible benefit post-Brexit is that even if the eventual UK legislation was strongly based on requiring CE marking as described above, it would be possible to allow FDA approved drugs or devices to begin to be used in the UK before they had EU approval. However, most US companies pursue FDA and CE approval in parallel. Any significant relaxation in insistence on CE marking would expose the UK to greater commercial pressure from non-EU suppliers.

8. The UK remains a key innovator of medical technologies, and devices (for example, medical ultrasound, X-ray CT and MRI) have all been developed in the UK. The UK remains a major world manufacturer of MRI systems with more than 30% of the superconducting magnets in hospitals worldwide manufactured in the UK. As an example, 95% of the magnets made by Siemens Magnet Technology in Oxford are for export. Siemens is now manufacturing new 7 Tesla magnets in the UK. Siemens will partner with universities and hospitals in the UK to further develop this technology and its applications. This development will result in the creation of hundreds of new healthcare science research jobs.

9. Future investment in large scale healthcare manufacturing in the UK will presumably be dependent on the UK Government's long term plans for participation in EU research programmes, as well as issues around tariffs and trade. The UK Government should also be made aware that some very high-value medical devices (for example MRI scanners) are manufactured in more than one EU country with some stages undertaken in the UK. This has ongoing implications for medical device regulation as well as import/export tariffs. Any barrier to free trade with the EU would presumably inhibit this manufacturing and development cycle.

10. As well as developing medical technologies, UK healthcare scientists and the UK Department of Health have been influential in the development of their safe regulation. The Medical Devices Directorate (Council Directive 93/42/EEC) harmonised the laws relating to medical devices within the European Union. In order for a manufacturer to legally place a medical device on the European market, the requirements of this Directive have to be met. Products meeting harmonised European standards have a presumption of conformity to relevant safety requirements in the Directive. Products conforming to the Directive must have a CE mark applied. The Directive was most recently reviewed and amended by the 2007/47/EC and a number of changes were made. Compliance with the revised

directive became mandatory on 21 March 2010. The Medical Devices Directive was repealed and replaced by a Medical Device Regulation (MDR), which came into force on 26 May 2017. The UK, through the MHRA, has been very influential in significantly improving the original Commission draft, to the benefit of the UK NHS scenario.

11. The UK should negotiate to remain an active contributor to the governance of medical devices on the European market. The UK should resist being an observer with no influence on future Medical Devices Regulations. The UK successfully negotiated, with the input of IPEM, changes to these recent regulations to minimise the negative impact on the in-house manufacture of medical devices which aids clinical assessment, therapy and treatment of patients in healthcare establishments. A new relationship and legal framework would, however, be required as the UK would no longer have voting rights in the European Council and the European Parliament when it leaves the EU.

Medical radioisotopes:

12. In terms of healthcare resilience, the UK needs to ensure a sustainable daily supply of time critical deliveries of radiopharmaceuticals from the EU. We are dependent on the EU for our supply; deliveries cannot be delayed by prolonged Customs checks as the radiopharmaceuticals decay with time and are required to meet strict daily hospital treatment and diagnostic schedules.

Research and development:

13. NHS healthcare scientists lead on European Commission funded research grants. Research and innovation projects benefit from multicentre collaborations and the expertise of European clinicians, researchers and international commercial partners form a larger pool than exists at national level.

14. From an NHS healthcare perspective, the UK Government should negotiate ongoing opportunities for joint medical and healthcare research, in UK priority areas, with European medical research partners and device manufacturers. This would include the development of new diagnostic and therapeutic technologies, including: point-of-care testing, precision medicine, image processing and data mining; with an emphasis on managing diseases of an ageing European population (including: cancer, cardiovascular disease, stroke and dementia) in addition to improving the management of childhood diseases and debilitating chronic illnesses.

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