Written evidence submitted by the Institute of Physics and Engineering in Medicine (IPEM) to the House of Commons Health Committee inquiry on Brexit: Health and Social Care – October 2016

The Health Committee invites written submissions on the priorities for health and social care in the negotiations on the UK's withdrawal from the European Union. The Health Committee is responsible for scrutinising the work of the Department of Health and its associated public bodies. Submissions should therefore address matters for which the Secretary of State for Health is responsible. However, comments are welcome on matters (such as, for example, the free movement of labour, or the single market) where the Secretary of State for Health may not have lead responsibility, but where the withdrawal negotiations led by other Ministers have important implications for health and/or social care in England.

The Committee will not be attempting to examine in detail the whole range of issues affected by UK withdrawal from the EU in the health and social care policy area. Rather, it will be attempting to identify the priority issues which the Government will need to address in the negotiations, and to hold the Government to account for what it achieves.

The Committee may choose to proceed by examining the issues through a "case study" approach, looking in detail during oral evidence sessions at a particular area—for example, a particular EU directive, such as the Clinical Trials Directive, an institution, such as the European Medicines Agency, or a policy area, such as the implications of the loss or restriction of free movement of people on health service staffing and/or access to healthcare—to consider the implications of that particular issue for health and social care. The Committee would welcome suggestions for the area or areas it might look at if it decides to take that approach.

About IPEM

- IPEM is a professional association and Learned Society with 4,300 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

- EU professionals, including healthcare scientists, employed in the NHS need special protection. Arrangements need to be put in place to continue to attract healthcare workers from the EU to UK shortage professions.
- If the UK is to become less dependent on employing staff from Europe, the NHS needs an urgent national strategy for training more clinical technologists and clinical scientists.

- The UK should negotiate to remain an active contributor to the governance of medical devices on the European market. The UK successfully negotiated, with the input of IPEM, changes to these recent regulations.
- 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 radiopharmaceuticals decay with time and are required to meet strict daily hospital treatment and diagnostic schedules.

IPEM's response

1. EU professionals, including healthcare scientists, employed in the NHS need special protection. They are already important contributors to our health service, often in shortage disciplines. Arrangements also need to be put in place to continue to attract healthcare workers from the EU to UK shortage professions. The simplest mechanism would be that EU workers who were already ordinarily resident [as confirmed by council tax or voting register, or had a National Insurance number] on 24 June 2016 can convert to indefinite leave to remain. Those who enter the UK after this date, do so knowing the Brexit situation and therefore cannot assume automatic leave to remain. A scheme similar to that of the EU Blue Card or five tier points-based system (currently used for non-European members) should be introduced for EU citizens. This system would need to respond in a timely manner.

2. The UK NHS workforce is ageing. If the UK is to become less dependent on employing staff from Europe, then the NHS needs an urgent national strategy to invest in funding the training of more Clinical Technologists and Clinical Scientists. To date, this long term vision and funding has been lacking from the national agenda.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. The UK Government should also prioritise research into mental health and brain disorders which represent the greatest health burden to Europe from a societal and economic perspective as highlighted in a recent publication (Mental health research priorities for Europe).

9. 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).

10. 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.

11. The UK has 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 that realised that 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.

12. With regards to transposition of EU Directives into UK law, the UK Department of Health is currently finalising the following (Hansard, 4 July 2016):

    - European Qualifications (Health and Social Care Professions) Regulations 2016, which will transpose the relevant sections of the revised Mutual Recognition of Professional Qualifications Directive into the healthcare regulators' governing legislation;
    - Commission Implementing Decision (EU) 2016/787 and certain aspects of the Tobacco Products Directive 2014/40/EU;
    - Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells;
    - Commission Directive (EU) 2015/566 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells; and
    - Elements of the Falsified Medicines Directive 2011/62/EU (safety feature elements).

13. With regards to negotiations, the UK Department of Health is currently leading on:

    - Regulations on Medical Devices and In Vitro Diagnostics; and
    - Amendments to Regulation No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

14. 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 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.

15. The UK remains a key innovator of medical technologies, and devices (e.g. 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.

16. 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 (e.g. 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.

17. 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 with 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 is being repealed and replaced by a Medical Device Regulation (MDR). The UK, through the Medicines and Healthcare products Regulatory Agency (MHRA), has been very influential in significantly improving the original Commission draft, to the benefit of the UK NHS scenario. This new Regulation will likely come into force in the autumn, so will be enacted in UK law.

18. 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.

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