Written evidence submitted by the Institute of Physics and Engineering in Medicine (IPEM) to the House of Commons Public Bill Committee which is considering the Medicines and Medical Devices Bill – March 2020

About IPEM

- IPEM is a professional association and Learned Society with around 5,000 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.
- The following response was collated from members of IPEM's Engineering Policy and Standards Panel, and the clinical engineering community.

Executive summary

- IPEM recognises the need to introduce the new Medicines and Medical Devices Bill 90 2019-21 (The Bill) following on from the European Union (Withdrawal Agreement) Act.
- IPEM has identified there are potential key amendments to be considered relating to health institutions.
- IPEM was instrumental in proposing changes to the EU draft regulations, working closely with the Medicines and Healthcare products Regulatory Agency (MHRA). This led to the introduction of the Health Institution Exemption (HIE) within the 2017 Medical Device Regulations (MDR). This exemption is still required within health institutions to manage quality and ensure in-house manufacture meets safety and performance requirements under the regulations. These requirements continue in the new Bill, but there is no explicit reference of their applicability to health institutions.
- The 2017 MDR also introduced the requirement for manufacturers of medical devices to have a 'Person Responsible for Regulatory Compliance' (PRRC) to ensure supervision and control of the manufacture of devices, but this was not included as a requirement under Article 5.5. It is IPEM's opinion that it should be a requirement for health institutions, as best practice, to manage regulatory compliance of medical devices that health institutions are deemed to have manufactured.
- IPEM recommends three amendments to be considered relating to health institutions
- IPEM recognises that health institutions will need to adapt to these proposed changes, especially to identify specialists for the PRRC role. However, IPEM members are currently supporting this type of activity, many of whom are statutory registered Clinical Scientists employed within health institutions and provide advice on the adoption of MDR regulations and medical device safety requirements under the clinical engineering speciality.
- IPEM also recognises that many other specialist health institution staff exist that provide such advice but need to be developed. To this end, IPEM are developing a programme for Clinical Engineering Experts in Regulatory Compliance with curriculum under the National School of Healthcare Science accredited scientific practice programmes.

IPEM's response

1. The Institute of Physics and Engineering in Medicine (IPEM) recognises the need to introduce the new Medicines and Medical Devices Bill 90 2019-21 (The Bill) following on from the European Union (Withdrawal Agreement) Act.

2. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/791) have brought in, as Section 71(5), provisions equivalent to Article 5.5 of the EU Medical Device Regulations 2017/745 and 746. This enables health institutions to continue with the in-house manufacture, deployment and in-house use of medical devices. These provisions are referred to by Medicines and Healthcare products Regulatory Agency (MHRA) as the Health Institution Exemption (HIE). An amendment to give effect to the provision proposed above in the Bill is required.

3. IPEM was instrumental in proposing changes to the EU draft regulations, working closely with the MHRA. This led to the introduction of the HIE within the 2017 Medical Device Regulations (MDR). This exemption is still required within health institutions to manage quality and ensure in-house manufacture meets safety and performance requirements under the regulations. These requirements continue in the new Bill, but there is no explicit reference of their applicability to health institutions.

4. The 2017 MDR also introduced the requirement for manufacturers of medical devices to have a 'Person Responsible for Regulatory Compliance' (PRRC) to ensure supervision and control of the manufacture of devices, but this was not included as a requirement under Article 5.5. It is IPEM's opinion that it should be a requirement for health institutions, as best practice, to manage regulatory compliance of medical devices that health institutions are deemed to have manufactured. This will ensure that appropriate safety assessment and quality management, prior to putting these devices into service, are adopted as part of the requirements under the new Bill. Introduction of this will also support the Bill's requirement to identify persons to carry out such assessments.

5. IPEM has identified that there are potential key amendments to be considered relating to health institutions, one within the Bill itself and two relating to the UK medical devices regulations based on the EU Regulation:
    - Health institutions fall within the remit of the Bill as the manufacturers of medical devices that are "put in to service", and there is a need to explicitly reference the applicability of the requirements to Health Institutions within the Bill so that amendments to give effect to the provision of particular exemption can be adopted.
    - The need within the UK Regulations for the Secretary of State (via the MHRA) to have a full picture of what in-house manufacture is occurring. This links directly with Section 71(6) "*The Secretary of State may require a health institution which has complied with paragraph (5) to provide the Secretary of State with any further information about the devices which it has manufactured or used*."
    - The need within the UK Regulations to identify a PRRC within health institutions to assess that mandatory requirements for medical devices have been fulfilled prior to devices being put into service.

6. To achieve the above IPEM recommends the following three amendments:

Bill amendment:

6.1. Clause 13 subsection 1(c)(i) of the Bill to include the reference to health institutions as follows:

> (c) who may carry out such assessments, including provision about the appointment of one or more persons (whether or not established in the United Kingdom) who meet criteria set out in the regulations —
>
> (i) to assess whether relevant requirements are met, including when devices are manufactured and used exclusively within the same health institution, and ….

This ensures health institutions are covered within the remit of the Bill as manufacturers of medical devices that are "put in to service" within their own organisation.

UK Regulations amendments (based on S.I. 2019/791):

6.2. Regulation 71(5)(e) to include reference to Secretary of State as follows:

> 71(5)(e) the health institution draws up and makes publicly available a statement, which is copied to the Secretary of State, setting out –

IPEM recommends that a register of health Institutions involved in in-house manufacturing is facilitated to best understand and manage the UK scope of these activities.

6.3. Regulation 71(5)(f) to include the PRRC reference as follows:

> 71(5)(f) the health institution appoints a person responsible for regulatory requirements who has relevant qualification, knowledge and experience to draw up a document …..

IPEM recommends this additional requirement which also supports the Secretary of State's need to identify one or more persons to carry out such assessments as per the Bill Clause 13 subsection 1(c) above.

7. IPEM recognises that health institutions will need to adapt to these proposed changes, especially to identify specialists for the PRRC role. However, IPEM members are currently supporting this type of activity, many of whom are statutory registered Clinical Scientists employed within health institutions and provide advice on the adoption of MDR regulations and medical device safety requirements under the clinical engineering speciality.

8. IPEM also recognises that many other specialist health institution staff exist that provide such advice but need to be developed. To this end, IPEM are developing a programme for Clinical Engineering Experts in Regulatory Compliance with curriculum under the National School of Healthcare Science accredited scientific practice programmes. This development of our healthcare science workforce will enable and provide a sustainable workforce of specialist staff advising on regulatory compliance as part of their job description.

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