The Association of British HealthTech Industries (ABHI)– Written evidence (FFT0018)

About ABHI and Reason for Submitting

1. The Association of British HealthTech Industries (ABHI) is the leading health technology industry association in the UK. We are a community of over 280 members, from small UK businesses to large multi-national companies. We champion the use of safe and effective medical devices, diagnostics and digital health technologies. The work of our members improves the health of the nation and the efficiency of the NHS.

2. The health technology (HealthTech) industry makes a vital contribution to economic growth in our country. The industry employs over 127,400 people across 3,860 companies, mostly small and medium sized enterprises (SMEs). Many companies are working closely with universities and research institutions. The industry is generating a turnover of over £24 billion and has achieved employment growth of greater than 5% in recent years. ABHI's members account for approximately 80% of the value of the sector as measured by sales to the NHS. As the most highly regarded universal healthcare system in the world, the NHS in turn is dependent on technology produced by the industry to enhance the efficiency of services and drive continuous improvement in their delivery. The NHS has grown and developed partly on the basis of the UK's historic 'can do' approach to engineering and problem solving.

3. HealthTech is accordingly an engineering-based industry, characterised by rapid, often iterative product design and development, and a large number of SMEs. It is one of two distinct subsectors of the broader Life Sciences. Future growth and success will mean the HealthTech sector being recognised in its own right. The sector has evidence, regulatory and adoption needs that differ significantly from those of the other, biopharmaceuticals.

4. As well as the EU being the largest market for UK HealthTech companies, there has been an interdependence between the UK and the EU in the regulation and supply of HealthTech products. We estimate that 70% of products used by the NHS are ultimately imported from the UK, regardless of where in the world they are manufactured. Furthermore, in around a fifth of procedures where a medical device is the main element of the procedure, for example an implantable defibrillator, the device is delivered on an overnight / just in time basis. This reflects the fact that many companies base their international distribution centres in the Low

Countries. In our submission we attempt to draw out points relevant to the HealthTech sector in line with the questions posed.

5. The HealthTech sector, like many others relies on complex, international supply chains. Many products cross existing UK / EU borders multiple times during their lifecycle for raw material sourcing, manufacture, assembly, sterilisation and onward distribution.

6. We have identified seven key non-tariff barriers that could affect future UK-EU trade in goods and their impact on UK businesses in our sector. We consider each below.

7. **Environmental considerations**: New and revised versions of specific environmental requirements for medical devices have been a consideration for many years. These include the 'Blau Punkt' process in Germany, that levies manufacturers on packaging waste and re-cycling. Her Majesty's Treasury intends to impose a tax on plastics used as primary packaging. This tax does not exclude medical technologies, although makes specific exemptions for pharmaceuticals. We would note here that the technical challenges of developing, validating, verifying and tracing plastics through the supply chain is no different for devices than for pharmaceuticals. Careful consideration should be given to any current or future impositions of unilateral restrictions on chemicals, components, packaging materials, and partially constructed products. It would be essential for the UK to maintain parity with the global community in environmental restrictions and regulations, to ensure that product manufacture is not unduly burdened or curtailed.

8. **Rules of Origin**: The manufacturing of medical technologies is a global endevour, with companies routinely sourcing, importing and exporting materials and components from multiple jurisdictions prior to final assembly and distribution. As such, poorly crafted requirements for 'Rules of Origin' may seriously impede that potential for the UK to act or partake in this global operation.

9. **Safety issues**: In developing future regulations, or guidelines as adjuncts to existing regulations, the Government should ensure that they are primarily for the benefit of patient safety and do not damage the attractiveness the UK as a location to develop and distribute health technology, principles enshrined in the Medicines and Medical Devices Bill currently passing through Parliament. The UK has always been seen to be a leader in innovation, both from a technology and regulatory perspective,

as has been experienced with the advent of effective registers such as the National Joint Registry.

10. **Certificates of Free Sale and recognition of regulatory structures in third party countries**:
    For UK manufacturers of medical technologies to obtain regulatory clearance in a number of third countries, such as those in the Middle and Far East, Africa or South America, they would normally be required to obtain evidence in the form of a 'Certificate of Free Sale', that the product is freely available on the EU market. This certification would be provided by the Department of Health and Social Care, as an EU Institution, and then subsequently ratified by the appropriate Chamber of Commerce or Embassies. Being outside of the EU will make this process more difficult and potentially prohibitive, unless that UK can demonstrate to those third parties that the product has undergone a rigorous and robust regulatory process in the UK.

11. **Movement of people for maintenance of equipment and training activities**: Highly technical products generally require a degree of maintenance or training in order to ensure appropriate and safe use. This is often provided on multi-jurisdiction basis, and nearly always as "All Ireland." Whilst not related specifically to goods, the impact of Brexit on the movement of appropriately qualified individuals and the recognition of their qualifications, may restrict the ongoing use of some products. Furthermore, in order to satisfy aspects of clinical performance, a manufacturer may have to conduct specific clinical investigations. Once again, the restriction of personnel that conduct these investigations, may hamper the ability of the UK to present as a research hub for medical technologies.

12. **Future MHRA Fees for registration, vigilance reporting, and appropriate resourcing for the Medicines and Healthcare Products Regulatory Agency (MHRA)**: As a national requirement and consequence of the UK's EU-exit, the MHRA will be expanding its registration scheme for medical devices. This scheme will require manufacturers of all medical technologies to register their products prior to placing on the UK market. At present, this requirement only covers the lowest risk products i.e. those that do not have a Conformity Assessment Body oversight (Class I products), Procedure Packs, Custom Made products and Clinical Trial materials. The expanded registration scheme will, however, ensure that the MHRA has oversight of all medical technologies being made available to UK patients. Registration onto the scheme will necessitate payment of a fee and will be a mandatory

requirement. This registration process will be the responsibility of the UK Authorised Representative identified by the manufacturer if that manufacturer is located outside of the UK. For manufacturers of products comprising of multiple components, these fees may be prohibitive. It has also been suggested that the MHRA would consider a wider scheme of fees covering any services rendered by the Agency, such as for vigilance activities and clinical trial approvals. ABHI has been consistent in opposing such fees, particularly as fees are already paid to the Conformity Assessment Bodies for regulatory purposes prior and post CE Marking. Additional fees would potentially impinge on the UK's attractiveness as a destination for the HealthTech industry, failing one of the tests enshrined into the Medicines and Medical Devices Bill.

13. **Additional and/or parallel auditing**: Careful consideration should also be given to any additional testing requirements that may accompany the placing of product on the UK market. Whilst unilateral recognition of an EU CE Mark as a prerequisite of UK acceptance is preferential, any further testing or registration may well add time and cost to the already burdensome CE marking process. Rather than ensuring safe and effective product is available to UK patients, such practices may well prohibit manufacturers outside of the UK to view the UK as a 'primary market'. Additional testing can also be extended to the duplication or non-recognition of auditing conducted by EU Conformity Assessment Bodies. Such bodies conduct auditing of Quality Management Systems as well as of the Technical Files which contain the appropriate data to demonstrate regulatory compliance. Such auditing for complex products run into £100,000's, and as such, un-necessary duplication would be seen as prohibitive. It is important, therefore, that any auditing carried out by a EU Conformity Assessment Body is recognised, in order to ensure firstly, continuation of existing product supply, secondly, the attractiveness of the UK market and thirdly the availability of new technologies to UK patients.

14. We have identified six key technical barriers that could affect future UK-EU trade in goods and their impact on UK businesses in our sector. We consider each below.

15. **Regulations**: The Medical Device Directive/Medical Device Regulation and In-vitro Diagnostics Directive/Regulation (MDD/R & IVDD/R) are the primary controls for medical technologies and In-vitro diagnostics respectively. The Medical Device Directive has been extant since 1993 and allows manufacturers to place product onto the European-wide market by affixing a CE-Mark according to 'New Approach' principles. This Directive, however, is currently being superseded by the Medical Device

Regulation, which ends it transition period on 26th May 2021, after which the Directive will no longer be applicable. The new Regulation is also based on 'New Approach' principles thereby requiring CE-marking. The new Regulation is seen as the 'Gold Standard' for medical device regulation, developing the themes of the Directive to ensure greater safety and clinical performance monitoring in light of technological advancement since inception of the Directive in 1993. Whilst the Directive and Regulation represent the primary requirements for placing medical devices on the market, there are a significant number of other European Directives and Regulations that impact on the medical technology industry. A manufacturer must ensure that the product to be placed on the market complies with the relevant elements of these additional requirements. A non-exhaustive list of these documents is appended to this submission. Any divergence from existing EU regulations in the immediate term will present a significant barrier to trade.

16. **Standards**: The application of harmonised standards is seen by Conformity Assessment Bodies as a recognised route to regulatory compliance. If a manufacturer applies a harmonised standard, the Conformity Assessment Body accepts the derived technical data as an appropriate method of compliance, whereas if the standard is not followed, a justification as to why, has to be provided. It is critical, therefore, that in order for a manufacturer to claim compliance with the European system of CE Marking, that the harmonised standards are followed as is practicable. It should be noted that the involvement of UK institutions in the development of these standards would not be affected by a UK withdrawal from Europe, indeed, the UK would still be involved in global standards development through the International Standards Organisation. It would be preferential for the UK to continue, or indeed increase standards involvement, as whilst application of standards is always voluntary, they do dictate how the mechanics of the regulation are performed. In other words, if the UK does not have the ability to develop regulation, it will have a route to influencing how those regulations are practically managed.

17. **Person Responsible for Regulatory Compliance/Authorised Representatives**: The current and future UK regulatory requirements will potentially necessitate manufacturers from outside the UK to identify both a 'UK Authorised Representative' and a 'Person Responsible for Regulatory Compliance'. These individuals are considered by the regulator as the points of contact for product entry and release onto the UK market. Likewise, any UK manufacturer who wishes to market or distribute product in Europe, will need to identify an 'EU Authorised Representative' and an EU 'Person Responsible for Regulatory Compliance'. Firstly, these roles are duplicative as they fulfil the same criteria in both UK and EU

jurisdictions according to the same set of regulations and, secondly, they necessitate additional resource and cost in order to implement. One such area of additional cost would that related to labelling, where the regulations may demand identification of the UK Authorised Representative on packaging. This may also be extended to the Person Responsible for Regulatory Compliance, although this is yet to be decided.

18. **Delegated and implementing acts after the end of the Transition Period**: It is hoped that the MHRA will adopt the medical devices regulation into UK law, even though the end of the transition period for the regulations is beyond December 31st 2020 (6th May 2021.) Indeed, manufacturers of low-risk Class I products can already attest to compliance with the regulation, based on the ability to 'self-declare' those products using the appropriate Conformity Assessment route. The Regulation however, is to be underpinned by a number of 'Implementing and Delegated Acts', which may well be issued after 31st December. It is important, therefore, in order to maintain unilateral recognition of the regulation, to also adopt these 'Acts'. A failure to do so, will create a divergence from that recognition and therefore increase barriers to trade.

19. **Data protection, particularly with regard to digital technologies**: Consideration should be given to the potential impact on digital technologies and allied data flow, as a consequence of Data Protection regulations. Whilst the tangible requirements of product distribution and regulation on medical technologies is evident, the impact on digital data flow is less so. Central to any elements of a Free Trade Agreement will be arrangements to facilitate the transmission of information across borders to maximise patient benefit and facilitate beneficial medical research and clinical trials whilst still protecting personal privacy.

20. **Human and animal tissue / combination products**: There are a number of regulations which will have an impact on those medical technologies which are considered as 'combination products', either those which combine medical technologies with medicines or biological components, blood components, or other human or animal tissue. In these instances, the regulation is generally governed by the primary intent of the product itself. For example, a hip implant with a coating developed to promote bone ingrowth, is still considered as a medical device not a medicinal product delivery device and subject to different regulations. Because of these complications, consideration has to be made of potential changes or lack of recognition of these allied regulations. Failure to do so will promote regulatory divergence rather than allowing for unilateral recognition or access to either the UK or EU market.

21. We have identified three forms of regulatory cooperation relevant to our sector that might be needed between the UK and EU, including with EU agencies. We consider each below.

22. **Counterfeit products and border control cooperation**: An increasing issue with regards to the import of medical technologies into Europe, as well as into the UK, is the increased influx of counterfeit products. This is seen across the medical devices spectrum, from low- to high risk products, Personal Protective Equipment as well as component parts of medical technologies. At present, there is strong cooperation between the MHRA and their European counterparts through programmes such as 'Pangea', which routinely investigates claims and prevents the import of counterfeit products. It is ana rea of cooperation that should continue to protect patient safety in both the UK and EU

23. **Consideration of recognition for "New Approach" elements**: There are a number of elements within the 'new approach', which would allow for Mutual Recognition. These include Conformity Assessment, details related to Risk Management and product classification, clinical investigation, post-marketing data review, vigilance and labelling.

24. **Continued standards development through the European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC)**: The Medical Device Directive and Regulation are considered as 'New Approach' documents, in that they are based on compliance to a set of Essential Principles, use of standards as a route to compliance and the involvement of Conformity Assessment Bodies. Despite the voluntary nature of standards, adherence to them ensures recognition with the Conformity Assessment Bodies at time of auditing. Such standards include Quality Management, Risk Management, Safety, and Clinical Investigations. Importantly, we believe that the MHRA should be encouraged to participate in the development of these standards. Whilst the UK Agency may not be able to influence the content of the regulations post-Brexit, it can influence the operation or mechanisms for compliance to those regulations.

25. Finally, we consider how the UK and EU could minimise the costs and disruption associated with any testing and compliance processes that will be required, including conformity assessments.

26. **Mutual recognition of Quality Management and testing facilities, and the provision for UK based Notified Body activity against MDR/IVDR**: The most appropriate mechanisms to minimise costs and disruption, would be to ensure Mutual Recognition of processes, particularly of Quality Management System auditing and Conformity Assessment Body accreditation. Such recognition would ensure that auditing and regulatory practice conducted in the UK by UK manufacturers would be applicable in Europe and would negate the need to duplicate effort and cost. This recognition will be equally applicable for those manufacturers in the In-Vitro Diagnostics industry, who are currently facing challenges with Conformity Assessment Body capacity within the CE marking system. With the pending transition to the In-Vitro Diagnostics Regulation, approximately 80% of products, as opposed to 20% with the older Directive, will be subject to Conformity Assessment Body interaction. This shift in coverage will no doubt cause greater stress within the review process, which can be mitigated by appropriate mutual recognition.

6 July 2020

Annex: Non-exhaustive list of the 'Secondary legislation' impacting on medical technologies.

Failure to comply with any of these applicable requirements whilst applying the CE Mark according to the Medical Device Directive or Regulation, will represent a 'Technical Barrier to Trade' and an inability to be able to place that product on the market;

- Machinery Directive 2006/42/EC
- Low voltage Directive 2014/35/EEC
- Radio equipment Directive 2014/53/EC
- Electromagnetic Compatibility 2014/30/EC
- Biocidal products 98/8/EEC
- Personal Protective Equipment Regulation 2016/425/EC
- Machinery Directive 2006/42/EC
- Misleading Advertising 2006/114/EC
- Packaging and Packaging Waste Directive EU 2018/852
- Waste Electrical and Electronic Equipment Directive 2012/19/EU
- Restrictions on Hazardous Substances 2011/65/EC)
- Batteries 2006/66/EC
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) EU 2020/507 (as amended)
- Pharmaceutical (Human Medicines) Directive 2001/82/EC (as amended)
- Blood and Blood Products Regulations, Directive 2002/98/EC as amended)
- Human tissue regulations (Directive 2006/17/EC, 2006/86/EC as amended and supplemented)
- Good Clinical Practice (Directive 2001/20/EC)
- Personal Data Protection Regulation EU 2016/679
- Product Liability 85/374/EC
- General Product Safety 2001/95/EC