ABHI Statement in Response to the European Commission's Notice to Stakeholders *10th January 2018*

ABHI has read with interest the European Commission's notice to stakeholders: *Withdrawal of the United Kingdom and EU Rules in the Field of Industrial Products*, issued on 10th January 2018. The document outlines the potential future of industrial products post-Brexit.

Industrial products are encompassed by the New Legislative Framework (NLF), formally known as The New Approach, that requires those products to be CE-Marked prior to being placed on the European market. The Medical Device Directive (MDD) and newly published Medical Device Regulation (MDR) are part of that framework.

The notice to stakeholders describes the legal and practical consequences of the MDD and MDR, post-March 2019, without considering any transitional arrangement that may be negotiated as part of a possible withdrawal agreement. It details the effects of such a scenario on third-party notified bodies and authorised representatives.

These consequences have been well understood and communicated to ABHI members since March 2017. They have formed the basis of subsequent discussions with stakeholders and in the development of preferred post-Brexit industry positions.

ABHI remains fully committed to its core positions of:

- Maintaining alignment with European regulation for medical devices under the MDR
- Ensuring the continued availability of UK-based notified bodies and authorised representatives as part of the NLF
- Development of appropriate transitional arrangements.

These core positions underpin current and future engagements with external stakeholders and were expressed at a recent high-level roundtable event with Lord O'Shaughnessy, the Parliamentary Under Secretary of State at the Department of Health. We are also a founding member of the Brexit Health Alliance: a collective voice for the health sector during Brexit. A key ask of the Alliance, which we are deeply supportive of, is to ensure the continued supply of medical technologies to UK and EU patients.