ABHI – ADVAMED

MEMORANDUM OF UNDERSTANDING

REGARDING COOPERATION AND COLLABORATION

June 24, 2024

Purpose

The Association of British HealthTech Industries (ABHI) and the Advanced Medical Technology Association (AdvaMed) will cooperate and coordinate activities on matters of mutual interest.

The objective of this Memorandum of Understanding (MOU) is to outline the roles of each association and to increase the opportunities for cooperation, as a means of improving and enhancing their effectiveness in influencing policies affecting the industries we represent in the United Kingdom and the United States. In this way, we will enhance our abilities to meet and serve our members' needs.

Membership

ABHI's members are companies and organizations that provide products and services in the healthcare and healthcare technology sector in the UK. Some of ABHI's members are also members of AdvaMed. ABHI membership is open to companies, both indigenous and internationally owned, who have registered offices in the UK and sell healthcare technology products in the UK. ABHI supports the HealthTech community to save and enhance lives. Members supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. The Association represents the industry to stakeholders, such as the government, NHS and regulators.

AdvaMed members are companies and organizations doing business in the healthcare and healthcare technology sector in the US and globally with an exclusive focus on patient health. We enhance our members' experience by representing a wide variety of companies in the industry in unique ways, including in separate divisions (IVD, imaging, small companies, and digital), as well organizing sessions on specific areas of interest, such as an innovators forum, cybersecurity and AI. AdvaMed advocates globally for the highest ethical standards and patient access to safe, effective and innovative medical technologies that save, extend, and improve lives. AdvaMed works with members and other associations as determined by its Board.

Collaboration

ABHI and AdvaMed will continue to cooperate and coordinate activities, where possible, and seek to align on matters that will bring benefits to their membership, to the industry more

broadly, to patients and to public health. Both associations aim to maximize benefits for their members in an efficient and collaborative manner.

Areas of collaboration should include, but not be limited to:

- **Board Meetings**. Each organization's CEO (or agreed upon designee) will be extended the opportunity to attend regular in-person Board meetings, for the purpose of ensuring alignment and better opportunities for coordinated action. For AdvaMed, this would enable ABHI's CEO or designee to attend the full Board meetings, and if specifically invited, International Board Committee (IBC) meetings in open session. For ABHI, this would enable AdvaMed's CEO or designee to attend ABHI full Board meetings.

- **Conferences.** ABHI agrees to encourage its members to attend AdvaMed's annual conference. At the request of ABHI, AdvaMed will inform its members of ABHI delegations to the US.

- **Regulatory Convergence**. Harmonized international global regulations and standards are a priority for both organizations. As the UK regulatory system is currently undertaking significant revision at this time, the shared objective is to ensure the finalized UK regulatory system will accept approvals from trusted regulators, including FDA. To better ensure these objectives, we will undertake the following actions --
    - Participation of each association's designee in the other association's working groups that are addressing regulatory convergence issues related to MHRA regulatory processes, international best practices or use of FDA approval processes.
    - Continuing joint participation in high-level meetings between the organizations and/or with MHRA to ensure messaging to MHRA and UK regulators is aligned as well as with U.S. FDA.
    - Collaboration to align regulatory practices in third-party markets, such as China and Latin America, in accordance with international best practices, including IMDRF.
    - Collaboration relating to IMDRF Committee activities to achieve agreed upon regulatory goals.
    - Assistance with possible US FDA and MHRA consideration of training opportunities, where possible, to strength the trans-Atlantic regulatory cooperation, and consideration of training opportunities for AdvaMed and ABHI members.

Member Services and Support.

- AdvaMed and ABHI will work to develop programs and/or materials to assist mutual members on respective domestic regulatory or payment issues.
- AdvaMed will facilitate ABHI engagement in AdvaMed Accel and other AdvaMed groups to benefit members who want to increase their understanding of the US medtech market, including payment and regulatory issues.

- ABHI and AdvaMed will facilitate greater member engagement in industry/patient collaborations, such as the Medical Technology Group (MTG).
- AdvaMed has established a system to facilitate monitoring FDA's regulatory performance commitments. Companies' submissions to this system will create a means of determining FDA's performance. Both associations will encourage their members to submit the relevant data and responses to the FDA Accountability Database. AdvaMed will provide a briefing to ABHI members on the overall FDA performance metrics.Both associations could improve members' understanding of the market in their respective jurisdictions and globally with additional data, especially on specific sectors. In that respect, they agree to explore the interest of their members to implement a data collection survey.

Software and AI Regulation. To better ensure policies that support and harmonize the AI and software aspects of medical technology, and alignment of those policies in both the UK and US, we will undertake the following actions --

- Participation of each association's designee in the other association's working groups that are addressing software and AI regulatory issues of mutual concern and interest.
- Collaboration on the development of software and AI regulatory practices and policies that foster innovation and benefit patients in both markets.
- Support of joint policy recommendations to the governments of the US and the UK on the appropriate regulation of software and AI related to medical technology.
- Collaborate on initiatives under the US/UK AI Partnership on AI Safety to propose outcomes that benefit patients and the medical technology industry.

- **Supply Chain.** ABHI and AdvaMed will undertake the following collaborative actions with regard to supply chain resiliency.
  - Cooperation in resolving international shipping and natural resource disruptions.
  - Participation by each association's designee in the other association's working groups related to supply chain issues.
  - Collaborative efforts to formulate joint recommendations to support appropriate prioritization of resources for medical technology (including raw materials and semiconductor chips) when shortage conditions occur, or in preparation for shortage conditions.

- **Legal Issues**. ABHI and AdvaMed intend to work to address selected, agreed upon legal issues where mutual collaboration can be instructive and/or bring about positive changes for our industry. ABHI and AdvaMed will undertake collaborative actions with regard to legal issues including --
  - Participation by each association's designee in the other association's working groups on legal issues, including enforcement and compliance actions by the US

or UK governments, proposed or implemented restrictions on labor or natural resource inputs, product liability or tort reform.
    - Collaboration to address global compliance or issues related to the restriction of labor or resource inputs, including formulation of joint position papers.
    - Supporting codes of ethical business practices and governance practices to address compliance and related issues, including supply chains labor inputs.

- **Environmental Issues.** AdvaMed and ABHI intend to work to inform policy makers and officials of the impact on the medical technology of measures that are proposed or undertaken to regulate chemicals or environmental standards, and policy options. ABHI and AdvaMed will undertake the following collaborative measures to address these issues;
    - Participation by each association's designee in the other association's working groups on environmental and/or chemical issues.
    - Joint initiatives to provide scientific or relevant information to inform policy makers on impacts of proposed or current rules, and alternatives.
    - Sharing of best practices in particular markets.
    - Consideration of development of fact-based repositories to increase effective responses to regulatory or policy initiatives relating to environmental or chemical issues.
    - Consideration of mutual collaboration with external expert or patient-based groups to address concerns about potential or current restrictions relating to environmental or chemical issues.
    - ABHI will enable AdvaMed engagement in its working group activities to address UK or industry related chemical or environmental policy, such as NHS Net Zero.
    - AdvaMed will enable ABHI engagement in selected (TBD) working groups relating to US chemical or environmental policy, such as PFAS restrictions.
    - AdvaMed and ABHI will consider how best to collaborate on addressing external comprehensive regulation in the environmental or chemical areas, including proposals made by the EU.

- **Diagnostics**. AdvaMed and ABHI intend to work closely on in vitro diagnostics issues to enhance specific policies and support for IVDs and achieve greater regulatory harmonization and mutual benefit to our members.
    - AdvaMedDx will enable an agreed upon ABHI designee to attend Dx Board meetings and relevant Dx working groups (TBD).
    - ABHI will enable an agreed upon AdvaMed/AdvaMedDx desginee to attend ABHI's diagnostics related Board meetings, and relevant ABHI working groups (TBD).

- **US-UK Free Trade Agreement (FTA) and Global Trade.** AdvaMed and ABHI will work where possible to obtain a bilateral FTA and promote policies that will enhance US-UK trade in medical technology and to oppose measures in other countries that restrict

market access, impose barriers to trade or disadvantage medical technology manufacturers or medical technology exports globally or in any major global market.

- Both organizations will work with their respective trade/commerce authorities to encourage trade policies that are beneficial to our industry.
- AdvaMed will enable ABHI to participate in selected policy groups to address market access and industrial policy issues in geographies such as China, India and Latin America, for purposes of enabling ABHI to support, AdvaMed activities in these markets. In agreed upon instances where the industrial policy threatens key segments of the industry, we agree to conduct advocacy and formulate policies to address industrial policy issues. .
- ABHI will enable AdvaMed participation in selected policy groups that address issues in the Middle East for purposes of enabling AdvaMed support, where possible of ABHI activities in this region.
- Both organizations will work together to oppose tariffs and industry restrictive measures impacting our members in the global arena, including major markets and in multilateral forums such as WHO/UN. Both associations recognize that the policies of large countries that provide governmental assistance to their medical technology industries can threaten key segments of the industry and agree to collaborate on ways to counter such threats.

To enhance collaboration and avoid duplication, the associations commit to sharing information and keeping each other updated on efforts and initiatives relevant to the UK, and otherwise on matters deemed by the associations' respective Boards to be of high importance to both associations. The exchange of information between associations shall be accomplished in a manner that is efficient and values staff time. Participation in events held by the other association, where appropriate, will be encouraged.

ABHI and AdvaMed shall be permitted to share with their members documents, studies and position papers that are not considered proprietary or confidential, subject to limitations that may have been agreed between either association and/or a third party.

Review & Revisions

The scope and provisions of this MOU shall be reviewed every two years and may be revised during such review or at such other times as the ABHI and AdvaMed Boards agree. All revisions must be agreed to in writing as an amendment to this MOU and be signed by authorized representatives of both associations.

Contact

The respective Boards of ABHI and AdvaMed will oversee implementation of this MOU through the Chief Executive of the ABHI and the Chief Executive of AdvaMed serving as 'contacts' regarding this MOU. Each association agrees to inform the other about its activities at the request of the 'contact' of the other association.

Scott Whitaker, CEO, AdvaMed — Date: 6-24-24

Peter Ellingworth, Chief Executive, ABHI — Date: 25/06/2024