
2020 HIGHLIGHTS REPORT

ABHI

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PHILIP KENNEDY | CHAIR, ABHI

For all of us, 2020 will go down as the year when everything changed.

For our industry, never before have we been faced with such unprecedented challenges and yet never before have I been more proud of how we faced those challenges and continue to come together, as members of ABHI, as individual companies and as individual citizens, to cope with the impact of the pandemic on all our lives.

Your Association has never had a period of such sustained and intense engagement with its members. Guidance from the team has been practical and timely, with over 100 dedicated COVID updates issued throughout 2020, each demonstrating a well-managed, joined-up response. From providing regulatory expertise for the Ventilator Challenge, through to securing structured engagement with the Department for Health and Social Care, NHS England and NHS Supply Chain, ABHI has led a proactive campaign on behalf of industry, all based on knowledge and relationships.

In my role as Chair, I have had the privilege of being particularly close to this response, and as a Board, it has been our collective duty to guide the organisation through such choppy waters. Whether you are a privately owned UK SME, or an international business operating in all corners of the globe, no company has escaped the COVID impact. This is why it has been so important that ABHI has listened to all concerns and moved quickly to respond. The true value of ABHI's relationships with those in government, the NHS and the devolved nations has been matched, I am pleased to say, by the response

reciprocated from long-term industry partners, senior health leaders and Ministers alike.

In fact, it was one of these Ministers, Lord Bethell who remarked at ABHI's 2020 regulatory conference that it was the HealthTech sector that "stood up first at the onset of COVID, and it is the HealthTech sector that the NHS will depend upon as it looks to restore its services to pre-pandemic levels."

Given that PPE, ventilators and testing equipment were a mainstay of the news cycle last year, one could be forgiven for thinking that the HealthTech industry has avoided much of the difficulties experienced by colleagues in other sectors, such as retail, travel and hospitality. Indeed, demand did surge for critical care products, and the HealthTech sector delivered admirably. But for every company making masks and gowns, there are many more operating in highly specialised areas for example, from orthopaedics to ophthalmology, wound care to surgical instruments. I speak from my own experience in the dentistry sector, where services were switched off virtually overnight, thankfully now recovering. For an industry like ours, dominated by SMEs, the



impact has been particularly acute. ABHI evidenced this in October, with an industry survey revealing that over two thirds of HealthTech businesses had been negatively hit.

It will take time for our sector to recover, but recover we will and, I have no doubt, emerge stronger. In fact, COVID has necessitated the acceleration of many fundamental changes to healthcare provision that

we at ABHI have long called for. To paraphrase the Minister's words, HealthTech is what got us through the pandemic, HealthTech will drive the recovery and HealthTech, I believe, will continue to shape the future.

As ever, I thank you for your support and wish you well for the rest of the year.



The ABHI has been great answering any and every question we have had on all things COVID-19 related. Their thinking ahead to whatever the new normal is, and putting across the industry viewpoint to the government, has been terrific, and long may it continue.

James Urie,
Sales & Marketing Director, Mediplus



PETER ELLINGWORTH | CHIEF EXECUTIVE, ABHI

As Phil rightly says, the challenges we faced in 2020 were unlike anything experienced before. I am, therefore, incredibly proud of the way in which the HealthTech sector stepped up in response to the pandemic.

I was also encouraged by the feedback received from members as to our own COVID response work, with many commending our timely, no nonsense approach to communications and support. We were able to quickly establish and maintain a regular formal dialogue with government to ensure your challenges were conveyed, and solution sought. This highlights how highly regarded medical devices, diagnostics and the digital health sector is regarded. It is also a mark of the relationships that we work hard to maintain across many government departments and our engagement at the formal structures for health, including the Life Sciences Council and the Health Technology Partnership.

While redeploying significant resources to the COVID response, we have continued to make progress on other critical areas for our members this year. Demonstrating our continued commitment to regulation, we worked with colleagues across Europe to secure a 12-month deferment for the implementation of the Medical Device Regulation, and at home, we worked hard to ensure the UK recognised CE marking at the end of the Transition Period. In support of the IVD companies within ABHI, we boosted our regulatory team with the appointment of Stephen Lee, who brings over 20 years of government experience from the MHRA.

Longer-term, we have consistently advocated that the UK's future regulation must ensure patient safety, whilst contributing to the attractiveness of the market as a place to develop and distribute health technologies. I was therefore pleased to hear that the new UKCA Mark has these ambitions

at its core, and our regulatory team is heavily engaged with the MHRA on the impact of these changes to industry. A sovereign system not only presents a great opportunity to cultivate promising innovation, but will be increasingly important for the burgeoning digital health space where we continue to provide strategic leadership on behalf of our long-standing and newly joined digital health members.

In addition to Stephen's recruitment, we have used the platforms we have with government to further raise the profile of the diagnostics sector, with the Secretary of State led Life Sciences Council handing the responsibility of considering a resilient and scalable diagnostics capability for our country, to the Health Technology Partnership, the body led jointly by Ministers and our Chair, Phil Kennedy.

Health Minister, Lord Bethell, is also an advocate of the need to do more to address innovation adoption,



and it is through the Health Technology Partnership where we have proposed a new scheme to support early access to HealthTech that is identified as promising, but where the evidence is not yet sufficient to gain full positive NICE guidance. Importantly, and much like our interactions with the MHRA, we have never experienced such a regular and constructive line of dialogue with NICE as we do now, with a very real commitment from the Institute to address the imbalance between the work they do for pharma versus HealthTech. An Accelerated Access Collaborative that is committed to the idea of driving system change, rather than simply "picking winners", is also taking shape, with Lord Darzi's leadership as Chair instrumental in this revitalised approach.

Cognisant of travel restrictions, we quickly adapted the US Accelerator to a temporary virtual model, and in doing so, helped connect 30 UK SMEs to opportunities in the US. To further develop our offer to British businesses, the creation of the UK Healthcare Pavilion is an exciting initiative developed by our international team, and is brokering a multitude of new partnerships.

We also strengthened ties with AdvaMed, in Washington D.C., to enhance our level of

collaboration and to ensure the alignment of activities on key areas. The US is the largest HealthTech market in the world, and as part of the ongoing FTA negotiations, we continue to engage with senior officials to ensure the industry's position is clearly understood. Our work on trade was extensive in 2020, and we strengthened our relationship with the Department of International Trade to make HealthTech a key consideration as we negotiate new and continuity trading agreements. Internationalisation, both in terms of inward investment and export support, will be critical over the coming years and we have built this key workstream into the remit of our Scotland Working Group, which was relaunched this year.

It is very rarely straightforward in our industry, but this past year was unmatched in its challenges. That HealthTech was called upon to step up in this time of crisis is something that we should all be very proud of, and your technologies and services will be critical to the recovery. All of us at ABHI remain optimistic about the opportunities that lie ahead, and our organisation has never been better equipped to support you through this next period. Our secretariat, the largest and most senior within the HealthTech sector, stands ready to support you.

2020 HIGHLIGHTS



ABHI's Chief Innovation Officer campaign was launched at the annual Parliamentary Reception, with Health Secretary Matt Hancock stating **"innovation can longer be someone else's job."**



ABHI's Surgical Instrument Group published a report into the **critical role of surgical instruments** and how they bring value to the NHS

The UKCA Mark Handbook was launched for members, providing a breakdown of the UK's new regulatory requirements

The ABHI Scotland Group was re-established

The **ABHI annual Group Review** was launched to document external impact



The ABHI Vascular Group supported the development of the National Vascular Registry



ABHI launched **Growth Opportunities** for HealthTech, capturing **five key areas** of importance for the future of our industry



ABHI partnered with NICE to deliver a masterclass session for members



ABHI entered into a **partnership with the CPI** to stimulate innovation development and fuel growth of the UK's SME HealthTech sector

Peter Ellingworth joined the **Trade Secretary's Life Sciences Trade Advisory Group**



ABHI entered into a MOU with AdvaMed and also issued a joint position paper on a potential UK/US free trade agreement



ABHI published **Future Requirements for a World-Class UK Regulator**, an industry perspective on the future regulatory landscape

The Digital Health **APPG launched**, with ABHI providing secretariat support

The role of HealthTech in cancer care was detailed via a series of case studies by the **ABHI Cancer Group**

In a further boost to ABHI's leadership, **Steve Lee** joined the Association, providing diagnostics regulatory expertise



Peter Ellingworth provided evidence to the APPG on **Access to Medicines & Medical Devices**, discussing the challenges and opportunities associated with Brexit and access to HealthTech

Under ABHI's leadership, the Health Technology Partnership produced a diagnostics roadmap; a strategy to invest in **"resilient, scalable and holistic"** diagnostics capability for the UK



1,000

ABHI's virtual events welcomed over **1,000 delegates**

50+ dedicated Brexit-related communications were issued to members



70

ABHI's Groups went virtual, with **over 70 meetings** held throughout 2020

ABHI'S COVID SUPPORT: A Timeline

MARCH

ABHI issues statement on the Ventilator Challenge, calling out the key role of HealthTech in its delivery

ABHI launches dedicated COVID Hub

ABHI calls on Government to recognise HealthTech staff as key workers

ABHI's Phil Brown joins the Ventilator Challenge regulatory team

HealthTech staff recognised as key workers

ABHI partners with ABPI to coordinate Member volunteers to Help the NHS

APRIL

Joint statement of intent issued by the UK's life sciences industry, outlining the sector's commitment to fighting COVID

Request for stronger national coordination on critical products supply acted upon, leading to structured engagements with Department of Health and Social Care, NHS England and NHS Supply Chain

Gained support from UK authorities for proposal to defer MDR

National Testing Programme Expands to include HealthTech workers

Speaking to the International Trade Committee, Peter Ellingworth highlights the huge efforts of industry to maintain the supply of products into the NHS

MAY

ABHI delivers expert input into government's 5 pillar testing strategy

Published guidance for critical HealthTech staff access to healthcare settings

ABHI 'Trust Tracker' launched to capture national restart activity

JUNE

ABHI and trade association colleagues publish Life Sciences Recovery Roadmap, designed to boost NHS, government and industry collaboration

ABHI publishes 'NHS Restart' briefing document, highlighting the impact of the pandemic on patient services

JULY

ABHI shares examples of safe restart activities from other markets in meeting with senior NHS leadership

AUGUST

ABHI's COVID impact survey captures the effect of the pandemic on HealthTech, with the results fed into government policy

SEPTEMBER

Government's PPE strategy launches, to which ABHI provided key industry insights

DECEMBER

ABHI calls for front-line HealthTech industry staff to be prioritised in vaccination roll-out

**OVER 100 DEDICATED
COVID UPDATES WERE
SENT TO MEMBERS**

“We have to commend the pivotal role of ABHI in representing the interests of health technology manufacturers with UK Government stakeholders. As we look to the challenges ahead, the UK HealthTech industry is in safe hands.”

Antoine Valterio, Country Manager UK/Ireland, ResMed

2021 PRIORITIES

Appropriate Regulation



- > New UK sovereign regulation
- > Digital regulation
- > Global alignment
- > Standards
- > Sustainability

Working with an Evolving NHS



- > Development of Integrated Care Systems in England
- > Early Diagnosis
- > Digitalisation of Health Services
- > Technology Adoption
 - >> Value Based Procurement
 - >> Evidence
 - >> Payment Systems

Building UK HealthTech



- > COVID-19 response
 - >> Restart of NHS activity
 - >> Test & Trace
 - >> Vaccination
 - >> Business support
- > Global supply chain resilience
- > SME development/growth
- > Health Technology Partnership
 - >> Diagnosis strategy
 - >> Innovation manifesto

Maximising Global Trade



- > UK - EU Trade and cooperation agreement
- > Rest of World trade agreements
- > Exhibitions and Missions
- > US Accelerator
- > Virtual Pavilion

ENABLED BY DEEP RELATIONSHIPS WITH KEY STAKEHOLDERS

Accelerated Access Collaborative, Academic Health Science Networks, COVID Taskforces, Government Departments, Devolved Administrations, MHRA, NHS Digital, NHSE/I, NHSX, NICE

WITH SUPPORT THROUGH STRUCTURED GOVERNMENT ENGAGEMENT

Life Sciences Council, Health Technology Partnerships, Innovation Data & Research Group, EU Relationship Group, Life Sciences Industrial Strategy Delivery Board

DELIVERED THROUGH ABHI GROUPS WITH STRATEGIC OVERSIGHT BY ABHI BOARD

WHAT THEY SAY

Thank you for doing such a fabulous job, not just in normal times, but now, when things are exceptionally tough.

Giovanna Forte,
CEO, Forte Medical

The advice and information coming out of ABHI in relation to Covid-19 is really stellar. Concise, timely, pragmatic and very useful – thank you.

Adam Mumford, Director of Pharmaceutical Services, Owen Mumford



"ABHI plays a critical role in promoting the best of British innovation internationally, by delivering expert support to our HealthTech ecosystems, through its prominent presence at major world trade fairs and conferences, its HealthTech accelerator programme in the US and its work alongside Healthcare UK, Department of Trade and our overseas trade experts. ABHI is pivotal to the success of British business abroad."

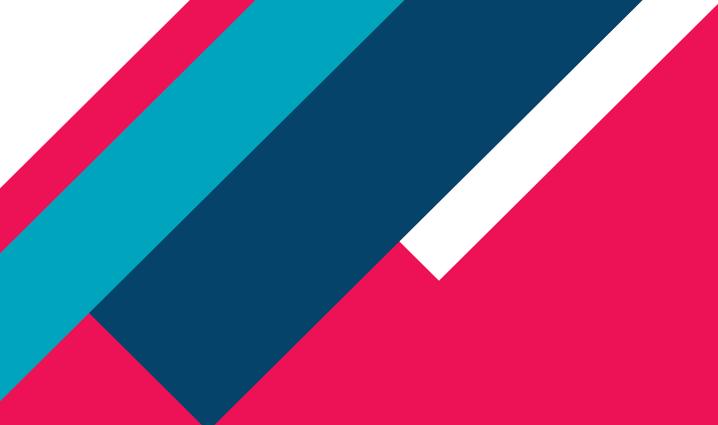
Noel Gordon, Chairman of Healthcare UK's Advisory Board

"Running a smaller business can sometimes be a lonely place and I have relied on ABHI to help bridge the gap between a corporate mothership and an independent SME. The support offered has been invaluable and I strongly recommend membership."

Simon Talbot,
Managing Director, P3 Medical Ltd

"Thank you very much for the superb work and advocacy that you and the ABHI team have done for our health technology industry, our customers and patients."

Mark Leaning,
Founder & CEO, Directed Systems Ltd



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