
ANNUAL REPORT

2018

ABHI

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CONTENTS

FOREWORD PHILIP KENNEDY	4
FOREWORD PETER ELLINGWORTH	5
ABHI'S SUPPORT FOR SMES IN 2018	6
2018 HIGHLIGHTS	7
ABOUT ABHI	8
MIKE FARRAR: WHY ABHI IS RESPECTED WIDELY AT THE HIGHEST LEVELS OF THE NHS AND WHITEHALL	9
COMMERCIAL UPDATE	10
ENGAGEMENT WITH THE OPERATING MODEL	11
HEALTHCARE POLICY UPDATE	12
THE HEALTH TECHNOLOGY PARTNERSHIP	13
INTERNATIONAL UPDATE	14
ABHI'S US ACCELERATOR	15
REGULATORY UPDATE	16
THE ANNUAL REGULATORY CONFERENCE	17
MARKET ACCESS UPDATE	18
HEALTHTECH CONNECT	19
ABHI AT 30	20 – 21
BOARD OF DIRECTORS	22
STAFF	23



FOREWORD

PHILIP KENNEDY

ABHI CHAIR



Welcome to our annual report for 2018. I start, as ever, by thanking you for your commitment over the past 12 months. For ABHI to provide an effective, coordinated voice, your input is vital, and I am delighted that so many of you have engaged with us this year.

For obvious reasons, Brexit has been at the forefront of our activity. I was, therefore, pleased to represent ABHI at the Brexit Health Alliance. The group has been an important and necessary vehicle for articulating the needs of the health sector throughout the Brexit negotiations, with firm attention given to ensuring the continued supply of technologies to patients. Throughout the year, we also advised the Department of Health and Social Care on contingency plans in the event of a no deal Brexit: work which shaped the Department's own advice to NHS Trusts and suppliers alike.

The NHS' 70th birthday afforded us the opportunity to reflect on the system's substantial achievements, and along with it came a "birthday gift" of £20bn from the Prime Minister. Although welcome, the boost was below what many analysts recommended was needed to tackle the systemic issues it faces, and with a drive to centralise how the NHS buys products, SMEs are being disproportionately hit. This "price-only" approach to procurement is hurting companies. With confidence falling in the NHS as a place to launch innovations, the UK risks becoming a deprioritised market for investment.

Yet industry remains committed to tackling these challenges head-on. A series of partnership agreements with key strategic regions brokered closer collaboration with the UK's HealthTech hubs this year, and through the creation of two new Ministerial engagement platforms, I am pleased to say that ABHI has never been in a stronger position to advocate on your behalf.

Whilst tackling the issues of today, the association remains future-focussed. The rebranding of ABHI, informed by our members, acknowledges the blurring nature of much of your technologies. To best represent you, and broader industry, we must present ourselves in the relevant way.

From its regulatory based inception, ABHI has grown, not just in size, but in its activity and crucially, impact. With 2018 marking 30 years of ABHI, and a leadership team expertly positioned to represent their 300 members, I am proud that ABHI's voice has never been better, louder or stronger.

"Healthcare is a hugely innovative industry. The advances in my lifetime for example, joint replacements or interventional radiology, have been extraordinary. Looking ahead, genomic medicine and robotic surgery show that healthcare is still pushing at the frontiers of technology and science. The work of ABHI is critical to this and by working closely with the NHS together we can ensure that clinical care and outcomes in England remain amongst the best in the World."

Lord David Prior
Chair, NHS England

FOREWORD

PETER ELLINGWORTH

ABHI CHIEF EXECUTIVE



Particularly gratifying for me in 2018, has been the way in which our investment in staff, over several years, continues to bear fruit. We have talent at all levels throughout the organisation, and the energy, commitment and ambition of our team, ensures that we can deliver on the priorities set for us by you, our members.

We allow ourselves the occasional wry smile when external stakeholders, established as well as new ones, express surprise at just how small our team actually is. We continue to be the go-to trade body in our space for government, evidenced by our membership of, amongst other things, the Life Sciences Council, Industrial Strategy Implementation Board and the Brexit-facing EU Relationship Group. No other HealthTech industry association can boast this level of involvement, or the capability and capacity to deliver on the opportunities presented. ABHI punches very considerably above its weight.

Our engagement allows us significant reach across government, into the NHS, and, increasingly, around the world. Advancing the public policy agenda for the benefit of our sector is very much a long-term activity, but we have made significant progress in the last 12 months. The focus on HealthTech in the recently published NHS Long Term Plan, including references to many issues we have long advocated for, is testament to our success. On the international front, our leadership, notably with the Dell Medical School in Austin, Texas, has highlighted exactly what our sector can achieve given some focus and support.

We also take our role as ambassadors for the wider HealthTech sector, often beyond our traditional membership base, very seriously. This has involved a significant focus on collaborations to create the right environment for new, data-enabled technology. Our work in regional footprints, bolstered by a series of MoUs, gives us a strong platform to better help the many hundreds of SMEs not yet part of our community.

I am pleased that we continue to lead efforts to protect and enhance the reputation of our industry. We have seen an internationally coordinated media campaign question some of the things that are most important to us, such as our relationship with healthcare professionals and our bespoke regulatory system. We have worked alongside the

Royal Colleges and the MHRA to address some of these concerns. This activity, along with the uncertainty created by Brexit and the move to the new MDR, makes regulation one of our key priorities in 2019.

We will also advance our work in the area of human rights and modern slavery. We believe that our industry must take a strong ethical stance in these issues, not least because the focus on price over value in some procurement activity, has led to concerns about the integrity of international supply chains. Procurement remains another key priority for us in the year ahead.

Much of our success has been enhanced by our strong relationships with supportive, well informed Ministers. Many of you will have had the chance to meet Lord O'Shaughnessy, who has been our sponsor in the Department of Health and Social Care for the past two years. He was an outstanding advocate, with whom we made much progress, including the establishment of a formal government / industry forum, the Health Technology Partnership (HTP). Whilst we were saddened that he has now resigned from frontline politics, his successor, Nicola Blackwood, who we knew in her previous Ministerial role, is already engaged and looking forward to leading the HTP this year.

Two other former HealthTech Ministers, both great, longstanding supporters of ABHI, were appointed to pivotal roles in 2018. Lord Prior, who held the brief in both Health and Business, is now Chair of NHS England, whilst Lord Darzi will lead the new Accelerated Access Collaborative. Lack of reach into the operational NHS has been a major barrier to the implementation of previous national innovation pull initiatives. These two appointments offer great cause for optimism as we seek to play a full and active role in the delivery of the Long Term Plan.

We will continue to be guided by you, your concerns and the potential our industry has to positively impact the patients we serve.

“It was great to be part of the ABHI family at the Arab Health exhibition in Dubai. Possibly the best reaction I have ever got at any trade show to a new product introduction. I really appreciate all the support and introductions – it has had a huge impact for a UK SME beginning its export journey.”

Kevin Auton
Managing Director, Aseptika Ltd

ABHI'S SUPPORT FOR SMES IN 2018

“As a small business, you can't really ask more from your trade association than being put in a room with the Director of Procurement from the Department of Health.”

Daniel Coole
Managing Director, Surgical Holdings

“The UK HealthTech sector is vibrant and growing, with an international reputation for quality. The export journey is critical to both SMEs and larger companies to scale and sustain their business and access new markets. ABHI plays an important role in supporting such companies to develop their business overseas. The Department for International Trade is delighted to continue our work with ABHI, through our life sciences team and Healthcare UK, to export our successes and help the world access the best of British HealthTech – to build, equip and operate the hospitals and health systems of the future.”

Noel Gordon
Chairman, Healthcare UK Advisory Board & Chairman, NHS Digital



REGULATION

The strength and depth of our relationship with the MHRA was apparent in their involvement in a comprehensive series of events and resources aimed at supporting transition to MDR.



BREXIT

ABHI worked extensively to ensure that members understood the implications of Brexit on their business, with a series of seminars, briefings and weekly updates providing up-to-date insights.



PROCUREMENT

ABHI worked tirelessly on the procurement agenda, championing the critical message of value over price, and led several SME delegations to meet with the NHS' commercial divisions.



INVESTMENT

ABHI signed an MoU with the British Private Equity & Venture Capital Association, designed to connect HealthTech's vibrant SME community to investors.



INTERNATIONAL

ABHI supported hundreds of UK SMEs at exhibitions across the globe, and new opportunities were opened up in the US, including the scaling-up of the ABHI Innovation Hub.

2018 HIGHLIGHTS



ABHI was instrumental in establishing the **Health Technology Partnership** and the **Life Sciences Council**



Published the **ABHI Women in Leadership** industry best practice document, which details how companies are engaging with the gender diversity agenda



Teamed up with the **Nuffield Trust** to produce an important report on why the NHS is struggling to make the most of new innovations



Hosted a series of **webinars** and **seminars**, covering a range of topics, from the transition to the new regulations, Brexit preparedness and the NHS at 70



Demand dictated that the **ABHI Innovation Hub** at the **Dell Medical School** double in size



Gained **650** Twitter followers



ABHI underwent a comprehensive rebrand, in turn becoming: the **Association of British HealthTech Industries**



ABHI hosted its first Annual Parliamentary Reception, attracting over 170 members, parliamentarians and stakeholders

ABOUT ABHI

ABHI is the UK's leading industry association for health technology (HealthTech). ABHI supports the HealthTech community to save and enhance lives.

Members, including both multinationals and small and medium enterprises (SMEs), supply products from syringes and wound dressings to surgical robots and digitally enhanced technologies. We represent the industry to stakeholders, such as the government, NHS and regulators. HealthTech plays a key role in supporting delivery of healthcare and is a significant contributor to the UK's economic growth. HealthTech is now the largest employer in the broader Life Sciences sector, employing 121,000 people in 3,500 companies, with a combined turnover of £22.2bn. The industry has enjoyed growth of around 5% in recent years. ABHI's 300 members account for approximately 80% of the sector by value.

WHAT WE DO



Shaping the future

Utilising data and technology to transform healthcare and the lives of patients.



Leading access to HealthTech

Working with the industry and the healthcare system to show the value of health technology.



Supporting regulation

Engaging with regulators and companies to ensure patients can access HealthTech safely and quickly.



Encouraging growth

Creating a positive business environment that encourages growth.



Building trust

Driven by our Code of Ethical Business Practice, we insist on the highest standards and ethical

"The industry needs a strong, clear and co-ordinated voice. ABHI is without doubt well placed to be this voice and I am hopeful for the UK HealthTech industry as a result."

Professor Sir John Bell
Regius Professor of Medicine, University of Oxford

WHY ABHI IS RESPECTED WIDELY AT THE HIGHEST LEVELS OF THE NHS AND WHITEHALL

"Leading an organisation is difficult, but leading an industry is many times harder". Not something you would hear a large number of global corporate boards saying loudly, but something that every national sector representative body would shout from the rooftops.



It's not the logistics that makes it hard - it's the balancing of competing views, the need to support all members despite them having different opinions, the translation of

policy into practice and the coal face reality into government ivory towers, and the constant nuance of how to be constructively critical of those in authority whilst retaining a seat at the table and maximising the sector's influence.

So, step forward ABHI if you want to see one that does this brilliantly. I have been a huge admirer of the organisation since my days leading Strategic Health Authorities, long before I ever tried to do a similar but parallel job as the CEO of the NHS Confederation.

ABHI has developed a way of working that enables it to speak truth to power, whilst being pragmatic and realistic about its aims and needs. It reflects its diverse membership in its advocacy, always remembering it has a range of the largest companies in the world alongside many important, yet still

embryonic SMEs. This is fully reflected in its governance, its events and its policy - and the process by which it engages them all. Interestingly, this range and reach is played effectively into the national conversations aimed at influencing policy as a virtue of the sector, and a reminder to government of how a country needs every one of its large stalwarts, innovators and local core suppliers. It must value all their interests.

But the real talent of ABHI lies in its people. Selling the aims of the sector to policy makers is always going to be met with the rebuttal "Yes, but you would say that wouldn't you". So, it's a testament to the tone, style and values of the ABHI team, that their views are presented with the right balance of challenge, insight, and critically, with clear and positive solutions to problems. This has avoided it being seen as whingeing and negative. It is this style and these people that ensure the industry is listened to and influential.

As someone who has worked with and alongside ABHI at national level, I may have a closer understanding of this than some of its members, so I should provide some evidence to back up my

views. Well, ABHI is 'always invited into the room', and ABHI has senior executive and non-executive members in positions of influence in the NHS itself (AHSNs and the NHS Boards) reflecting its insights that in today's world it is insufficient simply to have Whitehall relationships. ABHI produces influential policy that has, over time, served to shape areas such as supply chain, procurement, innovation and finance flows. I could list many other ways that they have demonstrably served their members interests and delivered high-value returns for fees.

So, in this year's annual report, I would like to end my independent appraisal of the organisation's approach and achievements, by stating, that in this the time of Brexit (or not), hard, soft or all points in between, the HealthTech sector and the country has never needed you more to be brilliant. Looking ahead, if history is a predictor of the future, you will be.

Mike Farrar CBE, FRCP, FRCGP
Managing Director, Mike Farrar Consulting Ltd. Former CEO of NHS Northwest SHA and the NHS Confederation.

COMMERCIAL UPDATE

At the beginning of the year, our annual business survey of members highlighted NHS procurement as the single greatest barrier to achieving growth. A stark reminder that, even with testing external factors, most notably Brexit, doing business with the NHS remains a perpetual challenge for industry. As such, addressing the issues behind this sentiment were my priority through 2018.

A short-term, transactional approach to purchasing was referenced as a key negative behaviour. As members will testify, HealthTech has the ability to help deliver healthcare efficiently, safely and to high quality outcomes. But only when procurement is partnership driven and conducted through value-based methods.

The Commercial Policy Group responded accordingly. Its two-track approach helping members make a smooth transition to the new Category Tower purchasing system, whilst working to move procurement practices towards best overall value.

As detailed by government at March's Procurement Conference, the Operating Model's Category Tower Service Providers are incentivised to deliver system value. A positive move. But transition has not been easy, and we regularly fed back to the new procurement management function, Supply Chain Coordination Limited (SCCL), on the issues curtailing progress.

When unconstructive comments on pricing were made by those responsible for managing procurement policy, we responded strongly, ensuring that dialogue remained constructive in our ongoing programme of engagement with SCCL.

Work was complemented by activities carried out between ABHI's special interest section groups and the Category Towers. There were specific

engagements from our orthopedics, spine and ophthalmology communities who met to learn about the sourcing strategy for their respective categories.

To realise value through purchasing arrangements, we reframed the narrative, showcasing industry as a critical partner to solving challenges, and in turn, started to build a credible stakeholder network of value-based procurement champions. We sought to highlight what exactly is meant by value and how it can be measured, yet work remains on gaining consensus on these two aspects. The creation of a joint group, industry and SCCL, to develop value-based buying approaches was therefore an important step in identifying methodologies.

The publication of the NHS Long Term Plan, which will frame much of 2019's engagements, has set out a number of positive commitments and recognises the importance of the NHS working with its external partners. Using these principles of co-design and collaboration, we will continue to engage with system leaders to ensure future decisions recognise the holistic value of HealthTech to the health service and patients alike.

Nishan Sunthares
Chief Operating Officer

ENGAGEMENT WITH THE OPERATING MODEL

The NHS is in a time of unprecedented financial pressure. With this pressure comes change and the core change in the procurement landscape for NHS England was the development of the new NHS Supply Chain Operating Model, formerly known as the Future Operating Model, which is tasked to procure and deliver health technologies (HealthTech) for the NHS in England.

The objectives of the new NHS Supply Chain Operating Model are to reduce unwarranted price variation and to increase product range optimisation across the NHS, delivering value for money and providing more consistency in both clinical and patient experience. Working as part of the NHS, the new NHS Supply Chain will deliver clinically safe products for the best possible value, and aims to realise £2.4bn of savings in its first five years of operation. This will be achieved by:

1. Increasing uptake/volume of products purchased via the national route
2. Increasing use by the NHS of a standard range of clinically appropriate products to reduce unwarranted variation in the system
3. Using increased buying power to affect purchasing behaviours.

ABHI's Commercial Policy Group (CPG) is a forum of ABHI suppliers whose goal is to ensure that NHS patients are protected with UK hospitals being supplied with the correct quality and supply of HealthTech. The ultimate goal of the CPG is to partner with the NHS to move from a short-term, price-based procurement focus, to a value and patient outcome purchasing model.

In order to achieve this, we are undertaking a number of core workstreams:

1. Host quarterly SCCL review sessions with the purpose of reviewing and discussing members' concerns around the transition to the Operating Model and sub-optimal procurement practices

2. Develop a network of interested healthcare stakeholders who support the view that some procurement practices damage value for the NHS and patients. We will work with these stakeholders to communicate and highlight to SCCL that there can be an impact of poor procurement practice on the NHS and patients' health
3. Focus on Value Based Procurement to work with the NHS to develop a deep understanding of what is value in healthcare and how we can translate this into practical tools and methodologies. As an outcome, we will agree the core activities and stakeholders so as to align with other healthcare systems by moving towards Value Based Procurement in healthcare.

ABHI are very clear that every penny of NHS funding must be used to its maximum potential. The concerns have always been that a total focus on cost produces sub-optimal quality and continuity of supply. Through the ABHI CPG, we believe that working in partnership with the NHS, the HealthTech sector can become the solution to the current funding challenges and deliver on the objectives of the NHS Long Term Plan.

Graeme Cameron
Division Manager, Hospital Care Division B Braun & Chair, ABHI Commercial Policy Group

HEALTHCARE POLICY UPDATE

Our work in the public policy arena this year has been dominated by preparations for Brexit. We have maintained our membership of what is now known as the EU Relationship Group, involving Ministers from the Departments of Health, Business and Exiting the European Union.

The group was established immediately after the Referendum to ensure that key messages from our sector were heard by policy makers. That medical devices are now part of the government's highest priority category in Brexit preparations, indicates the success we have had. Alongside our members, we have worked closely to ensure that the very detailed plans to protect supply that have been drawn up by both NHS England and the Department of Health and Social Care, are practicable.

We have also joined colleagues from the NHS and voluntary sectors as part of the Brexit Health Alliance. The Alliance has established itself as a trusted resource for government and provided us with another, broad platform from which we can deliver important messages on your behalf. More practically, we delivered, and continue to deliver events and information to ensure companies are prepared for Brexit whenever it happens and under whatever terms.

Another key platform established this year is the Health Technology Partnership. This is a standing group that allows Ministers and senior industry leaders to discuss matters of mutual importance. Its predecessor, The Ministerial Medical Technology Strategy Group, had grown in to something that was neither delivering value for industry, nor making good use of Ministerial time. To have constituted a more valuable vehicle, on very much our own terms, has been a very significant achievement. It was particularly pleasing that the Partnership was, in a matter of weeks, able to make a significant contribution to the Life Sciences Industrial Strategy by way of a Sector Deal for wound care.

The publication of a new Long Term Plan for the NHS provided evidence that many of the messages we have been delivering over a number of years have landed. It is the first time that a document of its type has contained so much that has demonstrated the impact we have had as a sector. As well as a strong focus on HealthTech generally, there are a number of specific items of relevance to ABHI members. There is a new funding mandate for non-pharmacological technologies that the National Institute for Health and Care Excellence (NICE) finds to be cost saving. A single front door for innovators, with effective signposting provided by the Academic Health Science Networks (AHSNs) is proposed, as is the incorporation of the adoption of proven innovations into the performance metrics of NHS organisations. There is also specific acknowledgement of the fall-off in elective work over recent years, and a commitment to increasing activity, with cataracts and joint replacements being used as examples.

Specific interventions are also highlighted which reflect the successful work of many of our members over a long period of time. The focus on the detection and management of atrial fibrillation, public access defibrillation, the provision of flash and continuous glucose monitoring and a focus on the management of sepsis are all themes advocated as part of the public policy debate by our industry over the last decade.

We look forward with some confidence to advancing all these themes in the year ahead.

Richard Phillips
Director, Healthcare Policy

THE HEALTH TECHNOLOGY PARTNERSHIP

In 2007 the Ministerial Medical Technology Strategy Group was established to provide a platform for senior industry leaders to discuss topical issues of mutual importance with relevant Ministers. However, over time the group grew significantly, becoming more conference-like in format, and consequently, less action-focussed. The group was therefore paused in 2015.

Yet, the imperative that comes with ministerial involvement does give us the best opportunity to realise the bold ambitions set out in the Industrial Strategy and elsewhere. Therefore, in 2018, the Health Technology Partnership (HTP) was formed, replacing pre-existing arrangements, and thus becoming HealthTech's formal interface with government. The group now consists of a small number of very senior industry leaders, including ABHI, NHS England, NHS Providers, NHS Confederation and government officials, with decisions taken at meetings enacted with minimal recourse to third party approvals.

The HTP has three key workstreams: maximising trade, NHS collaboration and the Sector Deals (as detailed below). The latter refers to the 2017 publication of the Life Science Industrial Strategy, which saw a wave of Sector Deals released, designed to support the implementation of the Strategy. Whilst welcome, the deals lacked HealthTech focus, and as such, the HTP was challenged to increase our industry's contribution within the second wave.

With this impetus, ABHI, and HTP colleagues, formulated a 'framework' for such deals. It was through this framework and the significant contribution of members, that the Wound Care Sector Deal was formed in December. The deal involves industry, the AHSN network and the NHS working together, with government commitments to improve innovation adoption, to reduce variation and improve patient outcomes in wound care treatment.

The deal acts as an excellent example of the HTP bringing different organisations together to meet an identified joint need. Work is now underway to utilise this framework for other such deals.

Eleanor Charsley
External Affairs Manager

Priority focus:

The Health Technology Partnership set out to focus on three priority areas to deliver significant and measurable improvements to the health technology industry.

1. NHS Collaboration

Issue: Current policy is not obtaining best value for the NHS via procurement initiatives, nor providing route to market and adoption and spread.

Aim for HTP: Engage and support the implementation of the NHS Long Term Plan and the Accelerated Access Review. The partnership should also explore value-based procurement.

2. Maximising Trade

Issue: There is a sense among industry that the UK is not sufficiently articulating its offer, especially to global HealthTech companies. Alongside this, tangible support for companies in their export activities has reduced in recent years, at a time when many are looking to expand their activities beyond the EU.

Aim for HTP: Develop a UK offer to promote the UK as a place for HealthTech companies to invest and ensure clear communication on HMG support for exports.

3. Shaping a Sector Deal

Issue: There was a distinct lack of understanding of what a sector deal is / might look like for the HealthTech sector. The group developed a working framework and has since facilitated the Wound Care Sector Deal.

Aim for HTP: Support the implementation of the Wound Care and Digital Pathology Sector Deals and utilise them to encourage broader industry engagement with government initiatives through the Life Science Industrial Strategy.

INTERNATIONAL UPDATE

January's business survey identified the importance of trade in realising the growth strategies for many of our members. With this insight, and the steer of our Board, the international team were given a clear mandate to provide the necessary opportunities to support members with their international expansion plans.

To enable this aim, cultivating the right environment for trade is critical, and in my role as Chair of the Healthcare and Life Science Advisory Group (a sub-group of the Trade and Investment APPG) I met with Trade Secretary Liam Fox on two separate occasions to discuss the necessary support needed, particularly for SMEs. Through continual engagements with the Department for International Trade (DIT), and broader government, we are now recognised as an important stakeholder on the matter.

By creating a two-way trading bridge with key markets, we connected UK companies with some of the world's leading HealthTech ecosystems. To reciprocate this, our work helped overseas businesses understand the UK's unique health and care system, whilst supporting them to find partnering opportunities.

This bilateral approach was evident in our collaboration with OCTANE, Southern California's leading technology innovation accelerator, and with the Greater Irvine Chamber of Commerce, the economic growth catalyst for the Irvine/Orange County region: partnerships that now provide UK companies with expert support as they develop their growth strategies in California.

The US West Coast was also the destination for our October trade mission. The first half of the week saw delegates attend ASA's ANESTHESIOLOGY conference, before visits to some of the region's leading hospital systems and academic institutions, including

Stanford Medicine: a relationship I am keen to develop in 2019. This mission format was replicated on the East Coast, this time, AdvaMed's MedTech Conference and the hospitals of Pennsylvania offering the surroundings for the UK contingent.

Work in Texas continued apace, with three separate trade mission visits to the state, the expansion of the ABHI Innovation Hub at the Dell Medical School in Austin and the development of a Mentors Network. Our US Accelerator Programme continued to build its comprehensive offer, with further activity planned for 2019 as we enhance existing relationships and seek-out new partners.

We strengthened and improved our exhibition activity throughout the year as well, with India, China and Singapore all proving compelling destinations for companies looking to forge business within some of the world's fastest growing economies. For Europe and the Middle East, where British technologies are held in particularly high standing, MEDICA and Arab Health continued to provide an important platform to develop connections. It was pleasing to see so many new exhibitors at these shows, and as we bolstered our collaboration efforts with DIT, regional governments and the AHSN network, ABHI's UK Pavilions were a focal point for industry on the global stage.

Paul Benton
Managing Director, International

ABHI'S US ACCELERATOR

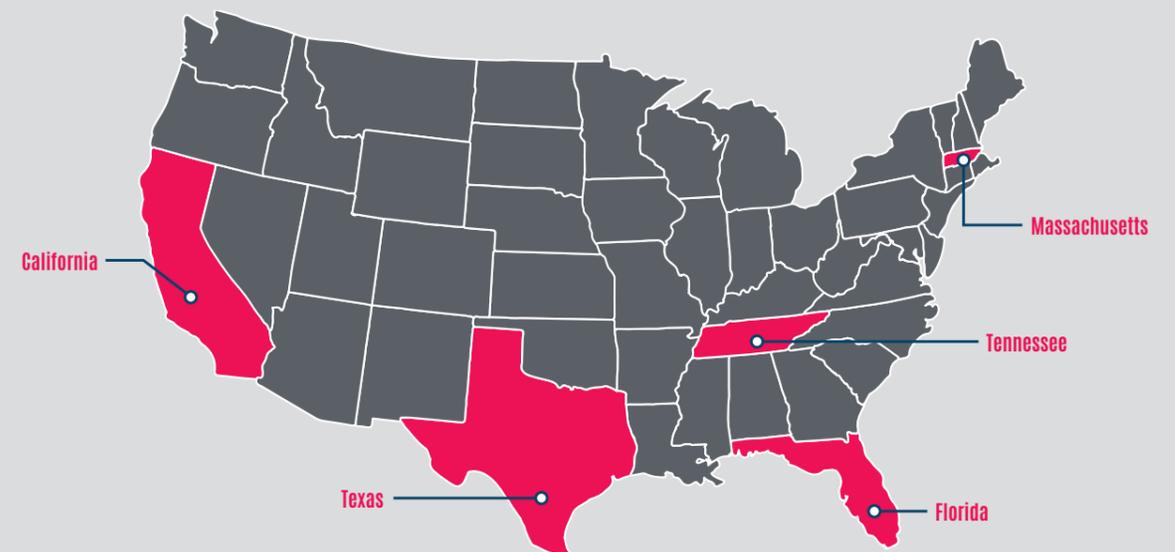
The philosophy of ABHI's international work is all about creating the right opportunities that enable UK companies to grow their businesses overseas. Over the past decade, we have enhanced our activities across key markets, with the USA repeatedly identified as a top priority for UK businesses.

Taking a state-by-state approach, our US Accelerator has gradually expanded across the country, leading to the establishment of the ABHI Innovation Hub in November 2017. Six months later, the Hub doubled in size: its offer proving compelling for companies.

With the size of the country, its technology-driven cities and world-class academia, it is easy to see why many companies view the US as the most prized HealthTech market in the world.

Paul Benton
Managing Director, International

In 2019 ABHI will visit:



"A superbly organised visit, with plenty of very high calibre meetings with the major health related organisations in each city. As a direct result of this trip we have been able to engage with key clinicians in the areas we are targeting and are now moving forward at pace. The trip was an excellent and efficient use of time – we could not have engaged as many people as quickly as this without the relationships that the ABHI have already established."

Andrew Thelwell
Chief Commercial Officer, FirstKind

REGULATORY UPDATE

The role of standards within the European regulatory framework is often overlooked. Whilst the regulations state what the manufacturer must comply with in order to be lawful, standards explain how that is achieved in practice.

During 2018, I was fortunate to be elected as Chair of BSI's standard group CH/210, which oversees the development of several of the more general standards, such as quality management systems, risk management and symbols. This culminated in leading the UK delegation to Seoul, to input into the new iterations of the standards and a new technical report on the conduct and collection of post marketing surveillance data.

Notwithstanding the transition to the Medical Device Regulation (MDR), both quality and risk management standards are also beginning a new review cycle. The quality standard may be particularly challenging, having only just been issued as the 2016 version, with both manufacturers and notified bodies adjusting to new practices. The value of our ABHI standards role, therefore, is to be part of the team that resists such change, which would undoubtedly add further financial and auditing burden on an already strained system.

Brexit has also had a significant impact on regulation during 2018. Clarification as to the framework the UK is to follow beyond March 2019, along with the more practical questions of certification validity and manufacturing operational considerations, has been uppermost in our efforts.

We welcomed the technical notices issued by the UK Government in September, which provided written direction as to the implementation of MDR as the basis for UK market entry. However, the acceptance of conformity assessment certificates issued by UK-based notified bodies has had to be reconsidered, leading to further clarification in January 2019.

But these are clearly UK decisions. It is therefore critical for UK manufacturers that we continue to talk and work with our European trade association colleagues, both nationally and internationally, to ensure that the resulting outcomes are reciprocal across Europe and that UK industry is not unduly disadvantaged.

Brexit will not only affect industry however, as the MHRA will undoubtedly have to change its practices and structures to accommodate the expected changes. ABHI will be liaising closely with the competent authority in the coming months to understand and minimise any impacts on industry, as well as looking for those potential benefits that becoming an independent voice may bring.

To provide real-life examples of where Brexit and standards change are likely to prevent product development and placement on the market, we have actively involved members in these discussions. Of course, all our endeavours are for the patient. If any such changes result in less innovation, or fewer products reaching the UK, it is critical that we highlight this. Our collective job is to ensure patient safety and to enable product access, with the ABHI Technical and Regulatory Group an important and engaged forum working to this objective.

Phil Brown
Director, Technical and Regulatory



THE ANNUAL REGULATORY CONFERENCE

The Annual ABHI Regulatory Conference in October was a highlight for 2018, being held this year in London at the Royal College of General Practitioners. The meeting once again attracted over two hundred delegates, who attended to hear presentations on Medical Device Regulation implementation topics from the MHRA, notified bodies and industry alike.

This year, three main themes were discussed:

- Clinical evidence, including a presentation as to how notified bodies will audit company data, both pre- and post-market
- Strategies for Medical Device Directive to Medical Device Regulation transition planning
- Implementing and Delegated Acts, particularly that related to EUDAMED, UDI and future European databases.

There was of course, the all-important wrap-up on the current thinking regarding Brexit, which added an additional layer of complexity to strategic implementation strategies.

This conference set a high bar for future events, matching a practical industry element alongside the expectations of the regulators, all in an environment that allowed for open debate and shared experiences.

2019's conference will explore how 'risk' impacts on our regulatory compliance work.

Phil Brown
Director, Technical and Regulatory

MARKET ACCESS UPDATE

2018 was a challenging, but ultimately rewarding year in the market access area. We revamped the approach of the Market Access Policy Group, reframing our objectives to drive a more strategic approach on the innovation and adoption landscape. Our overarching objectives were updated to reflect this thinking:

- Establish a value-based regime for the assessment, commissioning and procurement of health technology
- Simplifying the landscape: process linkage, avoid overlap and over reach of organisations.

A gap analysis highlighted key functional areas that needed to be addressed:

- Unified reimbursement mechanism to support rapid introduction of new technologies, services and procedures
- Accelerated Access Collaborative to take responsibility for management of the innovation adoption process
- Creation of a robust signposting function.

Blending an approach that utilised our existing engagements and opportunities, alongside identification of new stakeholders and communication routes, we have consistently championed the needs of industry and the benefits to be gained from the adoption of best-in-class practices and technologies.

Through responses to numerous consultations from NICE, NHS England and the Department of Health and Social Care on funding mechanisms, health technology assessments and new procedures, we made the case that a value-based approach needs to be embedded in all parts of the infrastructure.

Many of our proposals for system improvement are longstanding recommendations that have culminated in positive outcomes in 2018; others are shorter in-year projects. Both have delivered significant advances:

1. Our work with NICE over a long period of time has culminated with the announcement in the NHS Long Term Plan that there will be an increase in available funding for evaluation of medical technologies through NICE, alongside the commitment to a new programme for HealthTech with a funding mandate.
2. We have also worked closely with NICE throughout the year on the development of HealthTech Connect, ensuring strong industry input into the design and are pleased that early 2019 will see its launch. This new system aims to go beyond the important role of systemic horizon scanning, to also support improved signposting for innovators.
3. Many issues of adoption in the NHS arise due to the plethora of organisations and processes involved in assessment, commissioning and procurement of HealthTech. Since the start of the Accelerated Access Review, we have recommended that there are mechanisms to align and streamline this process. Specifically, we have requested that the Accelerated Access Collaborative takes a lead role of curating the innovations adoption landscape. This recommendation was recognised in the publication of the second Industrial Strategy Sector Deal.
4. Recent tariff proposals have also incorporated feedback we have provided about the net addition of new technologies onto the High Cost Device list, as well as expansion of the scope to incorporate delivery accessories.

This represents important progress which will accelerate patient access to valuable technologies in the NHS.

Andrew Davies
Director, Market Access

HEALTHTECH CONNECT

The Accelerated Access Review identified that the NHS should develop an enhanced horizon scanning process and clarify its needs to innovators. This has come to fruition for the health technology sector through the development of HealthTech Connect.

Originally called MedTechScan, the system was renamed to HealthTech Connect to convey the wider role it is intended to play in being a connector within the system.

Developed by NICE, with funding from NHS England, HealthTech Connect has been developed to reduce the duplication and complexity involved in getting a health technology adopted in the UK. It is a clear and simple point of entry for health technology to access support and national evaluation programmes.

The process undertaken was a rigorous user requirement gathering exercise, utilising a wide range of partner organisations across both industry and the health system. As the project progressed, potential company users were engaged to 'test drive' the new system and provide detailed feedback.

HealthTech Connect is an excellent example of co-creation between industry and national bodies, and the realisation of government policy in a practical user-focussed tool. The tool itself is only part of the solution and the work behind

the scenes on joining up processes between organisations will be as, or more, critical than the system itself. The inclusion of NIHR, the AHSNs and the Office for Life Sciences, alongside NHS England as partner organisations, is critical to ensuring that the objective of a simpler and quicker route to market is met.

Throughout the development process NICE and ABHI paid close attention to industry concerns over data security and confidentiality, with strict legal and technical controls put in place to prevent inappropriate disclosure. The basic principle that the company retains control over who accesses their data is paramount.

The systems and processes now in place with HealthTech Connect will help organisations and programmes that support or evaluate health technologies to better identify them and make quicker, better-informed decisions.

For industry, a known entry point with processes and support to aid the progression from inception to adoption will remove complexity and uncertainty.

It's great when a plan comes together!

Andrew Davies
Director, Market Access

"Under the collegiate leadership of ABHI, for 30 years the industry has flourished, saved lives, extended our well-being and played an invisible role in family life."

Roy Lilley
Health Policy Analyst, Writer,
and Commentator

"Working through a Memorandum of Understanding with ABHI has given a greater sharpness, beyond a sense of one-off deals. The leadership of ABHI uses its off-stage diplomatic skills to pull people together, identify areas of convergence with health and science partners, and to keep the channels open for further development."

Malcolm Lowe-Lauri
Executive Director, Cambridge University Health Partners (CUHP)

"Through industry bodies including ABHI, our industry will remain perfectly placed to deliver care that is based on true value for patients and providers."

Michelle Brennan
Company Group Chair, Johnson & Johnson Medical
Devices Companies, Europe, Middle East & Africa
(EMEA) and Chair of the Board of MedTech Europe

"An organisation like ABHI offers access to a forum of 30-years expertise, in which challenges and experiences can be worked through collaboratively, in a non-partisan fashion, to ensure better healthcare for patients and professionals alike."

Neil Mesher
CEO, Philips UK and Ireland

ABHI AT 30

2018 marked 30 years of ABHI. From its regulatory based inception, the association has grown, not just in size, but in its activity and crucially, impact. Here are a just few of the voices that have been a part of that journey.

"I have had the pleasure of working with and alongside the ABHI for the last 16 years, witnessing its tremendous industrial advocacy and leadership for more than half its lifespan."

Tony Davis
Commercial Director, West Midlands Academic Health
Science Network

"ABHI has been a trusted and, when needed, critical friend of NICE, giving valuable insight and expertise to help us develop effective advice and guidance for the NHS."

Sir Andrew Dillon
Chief Executive, National Institute for Health and
Care Excellence

"ABHI was founded in order to be inclusive and reflect the breadth of the medical device industry. They have been effective in ensuring that the industry's views on policy and regulation have been collected and collated in ways that help the MHRA to understand the implications of changes to legislation, policy and implementation. Regulation is at its most effective when the industry has a strong engagement with and understanding of the regulatory context in which they are operating. Initiatives such as the ABHI Code of Ethical Business Practice support the development of such an environment."

John Wilkinson OBE
Director of Devices, The Medicines and Healthcare products Regulatory Agency

"I have been particularly impressed with ABHI's longstanding leadership on ethics, integrity and industry reputation."

Christopher L. White
COO & General Counsel,
AdvaMed

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