ABHI is the leading medical technology industry association in the UK. We are a community of over 250 members, from small UK businesses to large multi-national companies. We champion the use of safe and effective medical devices. The work of our members improves the health of the nation and the efficiency of the NHS.

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Dear Member,

Welcome to our Annual Report for 2016.

I start, as always, by thanking you all for your input and energy over the past twelve months. To get the most from your membership, you have to take action, and I am pleased so many of you have this year. The decision to leave the European Union has prompted the development of a new UK Industrial Strategy. MedTech has repeatedly been identified as a key sector for future economic growth. We welcome this recognition from government. However, there is a gap between ambition and the reality that our members face.

The UK’s differentiating factor is the National Health Service. As the world’s biggest single-payer health and care system, the NHS can be a superb test-bed for members’ innovative technologies. This well-rehearsed case has been the subject of countless interactions in places such as Texas. Others have joined us in high-level discussions to shape the future industrial landscape of our country. We urgently need actions, delivered at pace. Whilst shrouded in uncertainty, 2017 offers a micro-business or a large multinational, MedTech’s opportunities.

At home, we quickly built ministerial connections in the new Department for International Trade, and are in regular contact with officials in the UK Life Sciences Organisation. Our Industrial Strategy document contains a number of recommendations to improve support for companies exporting from the UK. It shows that we now operate at a far higher level than ever before when it comes to developing trade policy.

In the increasingly cash-constrained NHS, our work to show MedTech’s value takes on particular significance. This work is never easy, but we remain resolute. We recognise that this commercial aspect of our activities adds immediate and substantial benefits to our members. We continue to have a robust exchange with the Cartier team, certain that MedTech is fundamental to their efforts to improve the NHS’s operational efficiency. We also briefed MPs from all parties on the unintended consequences of the NHS Medical Supplies (Costs) Bill. The Bill takes a very “bread and butter” approach to dealing with a specific issue in the pricing of generic pharmaceuticals. The new information-gathering requirements are also potentially burdensome for our members.

Finally, our efforts to develop a weighting network of NHS leaders continues apace. We have had detailed local engagements at Chief Executive level in Greater Manchester, Oxford, Devon, Somerset, Birmingham and London amongst others. We have opened a dialogue with the new body, NHS Improvement, and have numerous, regular interactions at senior level with NHS England. Few, if any other organisations, come close to matching the breadth and richness of our stakeholder engagement.

On a personal note, in my role as Chair of the National Associations Council and Vice Chair of the Eucomed Board, I have enjoyed an interesting and stimulating experience being close to the constitution of MedTech Europe. The value of a fully integrated industry voice will doubtless become apparent to all in due course.

Closer to home, ABHI is now well and truly settled at the new office at Gray’s Inn Road. We have strengthened our Executive team with the addition of Phil Brown, who leads our Regulatory function. Our membership continues to grow, as does our strategic representation across the breadth of our industry’s activities. The valuable work this year, of our relatively new Medical Directors and HR Directors forums, has shown the value of our broader sector leadership.

I reflect on a busy 2016, in which ABHI has, once again, had great impact. The challenges ahead are likely to be even more significant. However, with our engaged and energetic Chair and Board of Directors, as well as our excellent team here in London, we are better placed than ever to address them.

PHIL KENNEDY
ABHI Chair and Chief Executive of PAK Medtech Services Ltd.

I am proud that ABHI’s voice has never been better, louder or stronger. We have a level of participation in policy discussions and a network that is unsurpassed by others in MedTech.

Overseas, through our international programmes, some of our members have enjoyed game-changing interactions in environments, and reassurance that the NHS is ready and willing to be a true partner. Get more from your input and energy over the past twelve months. To get the most from your membership, you have to take action, and I am pleased so many of you have this year. The decision to leave the European Union has prompted the development of a new UK Industrial Strategy. MedTech has repeatedly been identified as a key sector for future economic growth. We welcome this recognition from government. However, there is a gap between ambition and the reality that our members face.

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Yet the NHS is increasingly hostile to companies that are critical to our nation’s health and prosperity. Only one in eight survives the challenges of negotiating a complex, fragmented market, and the plans to reduce the number of suppliers make these odds even tougher. Of course, SMEs are disproportionately affected. Almost every week, members tell us that they are leaving the NHS to focus on other markets, frustrated by the barriers and this “price-only” approach to procurement. These are often British companies, supplying British innovation. Their loss to the NHS affects the health and wealth of our country.

We have reached, I believe, a watershed moment. We urgently need actions, delivered at pace. We need certainty in the regulatory and trade environments, and reassurance that the NHS is ready and willing to be a true partner.

The issue of Brexit could easily have settled at the new office at Gray’s Inn Road. We have strengthened our Executive team with the addition of Phil Brown, who leads our Regulatory function. Our membership continues to grow, as does our strategic representation across the breadth of our industry’s activities. The valuable work this year, of our relatively new Medical Directors and HR Directors forums, has shown the value of our broader sector leadership.

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PE TER E L Lingworth
Chief Executive

ABHI's preeminent position in MedTech. We significantly advanced the investment and growth agenda for our members in 2016. Alongside our established missions to Arab Health and Medica, we extended our horizons.

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ABHI HIGHLIGHTS AND ACTIVITIES

Gained 580 Twitter followers
Completed more than 15 consultation submissions
Created a new clinical and medical forum group to engage clinical leaders in our industry
Gained 33 new members
Hosted a total of 48 member group meetings
Over the span of three missions, we have now taken 26 companies to Texas

After years of significant ABHI regulatory work, we have reached the finalisation of the new Medical Device Regulation (MDR).

Peter Ellingworth invited to represent the MedTech industry on the Life Sciences Industrial Strategy Board.
Philip Kennedy presented oral evidence to Parliamentary Bill Committee on Health Service Medical Supplies (Costs) Bill.

Surgical Instrument Special Interest Sector Group published the Surgical Instrument Purchase and Care Guide
This highlighted the quality of surgical instruments in light of criticisms. The document shows the various stages of surgical instrument care and helps healthcare providers achieve the best whole life value in their purchasing decisions. It has proven extremely popular with members and stakeholders alike.

Regulatory Conference
210 delegates from 110 companies and 12 international speakers

Transposed the MedTech Europe Code of Business Practice into the ABHI version, including the additional UK-specific elements.

eProcurement working group met with senior stakeholders, including the Department of Health, NHS Trusts and GS1 UK. We conveyed member concerns around the strategy’s implementation and continue to provide updates and clarity as they progress.
WHO WE ARE AND WHAT WE DO

WHO WE ARE:
We are the voice of the industry communicating the interests and issues of our members. We are recognised as building trust and cooperation between industry and our partners. We are the support that powers industry, providing insight and expertise. Through our strategic vision, we develop policy in areas such as regulation, procurement and technology adoption. We facilitate collaboration and help businesses prosper through member-led groups, as well as running international trade missions and provision of support for UK companies in overseas markets.

WHAT WE DO:
Through engagement and representation ABHI strengthens the relationships between industry, the NHS and government, enabling a collaborative network. Collectively, members have the opportunity to shape the policy environment. Through our insight and intelligence work, members have access to bespoke market analysis, through written briefings, meetings, webinars and conferences. Together, we guide the sector’s principles, ethics and best practice. Members benefit from networking opportunities at home and internationally. Through value promotion Member groups promote the contribution of MedTech to the health and wealth of our country.

ALL OUR WORK IS UNDERPINNED BY A ROBUST CODE OF BUSINESS PRACTICE, ACCEPTED BY EACH MEMBER ORGANISATION. THIS DRIVES A COMMITMENT TO HIGH ETHICAL PRACTICES BY ALL.

OUR STRATEGIC PRIORITIES

INVESTMENT AND GROWTH
Stimulates company growth, through economic initiatives and skills development.

VALUE NOT PRICE
Supports NHS efficiency drive, by encouraging smart use of techniques and technologies through improved systems for payments, incentives and procurement.

HEALTH SYSTEMS
Engages with and influences new local leadership and care models.

REPUTATION
Promotes robust, industry-wide regulatory and compliance systems to improve trust and collaboration between industry, clinicians, government and the public.
2016 began with stories about the condition of NHS finances and the publication of Lord Carter’s final review into hospital efficiency. The NHS (and the Department of Health) stayed within its compulsory ‘control total’ for 2015/16. Stringent financial controls and a series of one-off measures, such as using the capital budget to meet day-to-day running costs, enabled this. However, over 80% of acute hospital trusts could not balance their books and reported deficits.

It meant that the impact of actions to tackle these deficits was, for ABHI and our members, the dominant theme through 2016. We have focused on supporting members to manage the myriad of cost-containment approaches implemented by different governmental and NHS organisations. We have worked to ensure a balance between short-term procurement measures and a strategic approach to fostering and extracting value from industry-NHS partnerships.

When we believe there will be a strong negative impact on industry, our leadership and strong commercial knowledge allows us to adopt an assertive position with key stakeholders.

This has included aspects of Carter Review implementation, especially the launch of product and supplier rationalisation programmes. Responsibility now resides with NHS Improvement and we are building relationships with key individuals within it. It also owns Get it Right First Time (GIRFT), designed to help the NHS reduce cost and performance variations. Our 2015 Election Manifesto emphasised the importance of using data to reduce this kind of variation, so we can build on these synergies.

We worked with NHS England, the NHS Business Services Authority and NHS Supply Chain to engage members on the rollout of a new procurement model – the “zero-cost” model - for buying tariff-excluded devices. These are used to treat patients with complex conditions. NHS England, as the single commissioner for specialised services, will be the only organisation that buys these products, not individual hospitals, and at a national level. We quickly engaged with their commercial team, explaining sector dynamics, our position and recommendations to ensure success. We now have regular and constructive dialogue allowing members to receive updates, as well as raising and resolving issues. The project is still in its early phases and we will make sure members contribute to the scheme’s design.

We also supported the Department of Health to ensure members improved their understanding of the Future Operating Model (FOM) of centralised procurement. That new system will mean a wholesale change to how national NHS procurement is structured and how it operates. This will have significant implications for members and industry at large. As the FOM continues to build, we will contribute to its development.

On credentialing, we have made excellent progress. We brought NHS England together with an alliance of trade associations from across Life Sciences. In 2017 we will launch a national register. This will be the start of a journey to improve standards and create a positive framework for working with the NHS.
THE AGENDA HAS BEEN DRIVEN BY TWO KEY ISSUES IN 2016:

• THE FINALISING OF THE NEW MEDICAL DEVICE REGULATION (MDR)
• INTEGRATING AND PRIORITISING REGULATORY PRINCIPLES INTO THE BREXIT DEBATE, AS A KEY PILLAR OF THE MEDTECH INDUSTRIAL STRATEGY.

THE NEW MEDICAL DEVICE REGULATION

In 2016 the new MDR was finalised by the European Commission, the EU Council and the European Parliament. This is the culmination of eight years of significant work by ABHI and the European Trade Association. We worked to protect the industry’s best interests in a new ‘Gold Standard’ medical devices Regulation.

As far as possible, the outstanding issues were resolved, including the new scrutiny process for high-risk products, clinical evaluations and re-processing of single-use devices.

The Regulation will likely be published in the spring of 2017. We are committed to a smooth transition and implementation phase, through our increased liaison with Notified Bodies and the MHRA, the UK Competent Authority.

IMPLEMENTATION PROGRAMMES

Managing the Regulation’s three-year transition period will be challenging for all stakeholders. The complexity of potential company strategies led us to work closely with the MHRA in 2016, through the Medical Device Industry Liaison Group (MDILG). This led to a mutual understanding of timelines and greater transparency of the processes needed for the Regulation’s successful implementation.

However, the new MDR is not the whole answer. It will be supported by a series of Implementing and Delegated Acts, which will dictate how the Regulation operates. These are being drafted now. We will work throughout 2017 and beyond to make sure they are both appropriate and proportionate.

A ‘BUSINESS PROCESS’

Although it has technical challenges, the Regulation is an opportunity to integrate regulatory compliance into business strategies. Industry will need to find new ways of working, to address the legal requirements for quality and manufacturing initiatives, risk management and post-marketing control. This will mean that regulatory liabilities will have to be married more closely to product life-cycle management and management responsibilities.

While these regulatory factors are complex, the referendum’s implications add new uncertainty. During 2016, discussions on how leaving the EU will change MDR implementation plans has been rewarding and complex. In both industry and MHRA liaison meetings, regular agenda items now include the fate of UK Notified Bodies and Authorised Representatives, transition periods and future European influence.

THE ‘DAY-JOB’

The new Regulation and Brexit discussions are just two of 2016’s achievements. We have also seen a new iteration of the Quality Management standard ISO 13485. This places greater emphasis on management responsibility. We also ran another successful Regulatory Conference, which attracted over 200 European delegates and speakers from across industry, Notified Bodies and the MHRA.

In 2017 we will deepen our intelligence on international regulatory issues and provide education programmes on implementing the Regulation, for ABHI members and with other stakeholders. We will make sure our industry becomes more transparent and acceptable to the wider patient population.

“Within the technical and regulatory environment it is essential to understand all perspectives before developing positions on often complex issues. ABHI have consistently been a key stakeholder for MHRA in this field. They are a leading source of insight for our industry engagement activities.”

John Wilkinson
Director of Devices, MHRA
Our industry’s standing is the foundation of our constructive interactions with government and the NHS, and of society’s positive perception and awareness of what we do.

Central to our reputation is our Code of Conduct. It governs how we interact with healthcare professionals. In 2016, there were two significant initiatives which will impact this relationship. One comes from industry, and one from the NHS.

Spurred by unfavourable press coverage of pharmaceutical companies’ relationships, the NHS decided to launch a major review. The aim was to improve how it manages conflicts of interest, and clamp down on inappropriate behaviour.

The review, led by Sir Malcolm Grant, Chair of NHS England (NHSE), addressed issues both within the service and with key external groups, including industry. Co-ordinated by a select steering group, which included ABHI, the review published wide-ranging recommendations on transparency requirements, and guidance frameworks to support NHS staff in their interactions.

We contributed to the review through our place on the steering group, through the consultation and directly with Sir Malcolm and his team. The new rules are expected to come into force in early 2017. We continue to work with NHSE on implementation and alignment with our Code of Conduct.

The new ABHI Code of Conduct comes into force in 2017. Last year we worked to increase members and clinical groups’ awareness of the changes. We drew particular attention to the changes around sponsorship of HCPS to third party congresses. These changes reflect the core principles of “Transparency” and “Separation”. They will create further rigour in how our industry works with clinicians. The changes ensure continued alignment with MedTech Europe and create a progressive, robust code, which goes beyond legal compliance and requires adherence to higher standards.

Alongside changes to the code, we have introduced a new complaints process. This is designed to improve transparency and make sure we have access to the right skills and expertise to investigate and rule on complaints.

Our code was endorsed by the AHSN Network as an exemplary model, and we have started conversations with NHS England about its formal recognition in procurement processes. We will pursue these further in 2017. We aim to create a single code for the MedTech sector that is recognised by the health system and universally adopted by all companies.

ABHI has provided us with a very helpful platform through which to interact with MedTech companies. The brokering of discussions between the NHS and industry by a third party such as the ABHI is a sensible way to explore mutual beneficial opportunities.

Paul Mears
Chief Executive at Yeovil District Hospital NHS Foundation Trust

Sir Malcolm Grant
NHS England Chairman

Transparency of interactions between industry and the NHS is critical and I welcome the lead ABHI has shown in the MedTech sector by establishing a robust Code of Business Practice that has this at its core.

MAINTAINING OUR INDUSTRY’S REPUTATION

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During 2016 we continued to deepen and build relationships with current, new and emerging system leaders.

We improved our understanding of the commercial environment and created mutually beneficial opportunities with individual organisations through Board-level engagements with Chief Officers in the operational NHS.

We spent time with representatives from the new Sustainability and Transformation plans. These groups are developing proposals to make improvements to health and care at a regional level across England. This gave us an insight into the future delivery of such plans.

As English regional devolution advances, we have enhanced our relationships within Greater Manchester and are looking to formalise our relationships with Health Innovation Manchester. In December, the Greater Birmingham and Solihull Local Enterprise Partnership not only hosted our Board meeting, but also showcased some of the city’s impressive life sciences assets.

Alongside our operational engagement, we worked with strategic influencers. We have regular and constructive conversations with senior officials in NHS England and have made good contacts with the new body, NHS Improvement.

The decision to leave the European Union prompted a flurry of work and a broader-than-usual set of cross-Whitehall engagements. The creation of an EU UK Life Sciences Transition Programme produced a series of meetings. These aimed at describing the risks and opportunities associated with Brexit, work carried out alongside our colleagues in the broader Life Sciences sector.

We continue to work closely with the national network of Academic Health Science Networks (AHSNs). We jointly hosted a Parliamentary dinner, took part in the annual MedTech Week and took part, along with our members, at events during the annual MedTech Week in November.

We were pleased, once again, to support the work of the Medical Technology Group and took part, along with our members, at events during the annual MedTech Week in November.

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The country’s decision to leave the EU provided the context. From the outset, our engagements with ministers and officials highlighted that this strategy should be formed together. To that end we took a number of steps to outline the interests of our membership and the wider industry.

The Life Sciences Industrial Strategy Board was created under the leadership of Professor Sir John Bell to bring together MedTech, BioPharma, the NHS and Government to develop such a strategy.

After carrying out a survey and many in-depth discussions with members and stakeholders we developed our report “Healthy outside the EU” as our official input into this overarching strategy. The series of recommendations aims to outlines how the UK can best forge successful international relationships, increase efficiency of healthcare delivery and improve patient outcomes.

This crucial piece of work gives us a position of real strength. Our robust relationships and recommendations on Brexit issues, such as regulation, trade and manufacturing, give our industry a clear and coherent voice across our diverse range of stakeholders and clear input into the Industrial Strategy.
Our seminar on Managed Services in the NHS at the end of June provided guidance to industry on how to operate these schemes.

The Regulatory Conference in September was our best attended one. This reflected a high level of interest from members and non-members on the new Medical Device Regulation. This initiated a programme of training webinars related to the implementation of the new MDR.

An updated ABHI Code of Business Practice was launched at the Autumn Compliance seminar. This gave members the opportunity to assess new requirements and what they mean for their businesses.

The focus at our Annual UK Market Conference in November was on how Sustainability & Transformation Plans and new models of care would impact health and care delivery.

Early in 2016, the Orthopaedics Special Interest Section (OSIS) set out to positively influence a number of changes in the external environment. We agreed a clear vision statement: “Together, we will shape and improve the future of orthopaedic care” – and launched an outreach campaign to deliver this vision. The campaign covered three areas:

**PR**
We began a work programme to gain understanding of our target audience and what is important to them. This involved identifying who we wanted to connect with to support our work. We also spent time defining the tone and nature of the group’s public statements. This enabled us to meet and engage with stakeholders who share our vision of the benefits of effective orthopaedic care.

**SHAPING THE ENVIRONMENT**
We further developed materials to communicate our vision. These included key messages targeted at each stakeholder. To enable more clarity and support of our objectives, we provided industry factsheets with evidence and information focusing on the patient benefits of orthopaedic treatment. We also developed an industry infographic that clearly sets out the contribution that industry makes to patient care in orthopaedics.

**PROVIDING AN INDUSTRY VOICE**
To strengthen our voice, we commissioned a report to examine commissioning behaviour on patients’ access to orthopaedic treatments. The report was designed to enable us to make a clear and insightful contribution to the public debate around the use of NHS resources. There was strong media interest in the impact of lengthening waiting times and variations in commissioning of orthopaedic services.

In 2017, our work will continue with further engagements aimed at bringing together relevant patient groups, the clinical community and representatives of NHS England to discuss patient access to orthopaedic care.
The outcome of the referendum placed new focus and importance on our country’s export performance and future trading relations.

Understanding and assessing the trade issues members face, not only because of Brexit, but also in key markets outside the EU, is an important responsibility for ABHI’s International Policy Group. The Group has quickly engaged with new Ministers, including in the new Department of International Trade. This was previously UKTI and is now a fully-fledged government department. We have also been active in government trade forums, working groups, raising trade and export support. To help our trade policy work, our International Policy Group (IPG) has created three Geographic Working Groups to focus on North America, Middle East and Asia. They support the IPG by taking a lead on strategy development in these regions and working with the UK government on barriers and opportunities. In 2017, the IPG and regional working groups will represent the industry at the highest levels of government to promote the industry’s growth and prosperity in overseas markets.

In 2016 our USA strategy significantly progressed. Following extensive research and relationship building, we took two trade missions to Texas. Through these, we developed a significant network of relationships with hospital systems, group purchasing organisations, clinical communities and professional services companies. This work will continue in 2017 with a busy schedule of market visits in Texas and other key states. We ran an extensive trade promotion programme of international trade fairs and missions.

- At trade shows in China and Germany we helped members engage with customers and created a global platform for the UK MedTech sector.
- Asia continues to be the fastest growing region for our industry and an important priority. Visits by the IPG to Japan and South Korea and missions and trade shows in Singapore connected members to new partners and dealers.

In 2017 we will focus on developing industry’s trade strategy, creating and provide opportunities for members to build successful international businesses and open up new markets. Now, more than ever, our support is crucial in helping members become truly global.

Forte Medical recently accompanied ABHI’s international trade mission to Texas. Quite simply, the level of access to such a market would not have been achievable without the leadership, support, network of contacts and expertise of ABHI. In fact, it delivered such tangible promise that we are going again to crystallise the relationships from the introductions forged by the ABHI team.

Giovanna Forte
CEO, Forte Medical

Ruben Rathnasingham, Dell Medical School
UK delegation of 15+ health startups @DellMedSchool – many shared goals in value-based health #InnovationisGREAT

Alistair Burt MP
Opening the UK Pavilion at #arabhealth today. Impressive work being done here.

Mediplus Urology
#ArabHealth has been a great meeting. Thanks to the @UK_ABHI for their support #UKArabHealth #UKInnovation

Texas Children’s Hospital
Thanks @UK_ABHI for visiting! We search the globe for the best products for our patients and you help us find them.

ABHI
We are celebrating the record number of UK companies at @Arab_Health this year
#networking #innovation

Department of International Trade in Germany
Learn how to be competitive on the #healthcare & #LifeSciences world stage. Meet our experts @Medica @UK_ABHI #UKatMEDICA