

ANNUAL REPORT 2010

Association of British Healthcare Industries



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ABHI's Purpose

ABHI is an industry association for companies operating in the UK medical technology sector.

Our purpose is to promote the benefits, value and adoption of innovative, safe and effective medical technologies to ensure optimum and high-quality patient outcomes in the UK and key international markets.

- **Policy:** Focus on the development of policy which takes into account the continuing need for clinical innovation; ensuring clear pathways to market for suppliers while paying attention to the contribution of small and medium sized enterprises (SMEs).
- **Research and innovation:** Encourage the growth of innovation through initiatives that are aligned to the needs of high-quality healthcare.
- **Regulation:** Ensure that medical device regulation remains appropriate, proportionate and sustainable by influencing the UK regulators and the European Union legislative process.
- **Reputation:** Reinforce industry integrity and high ethical standards through the operation and enforcement of the ABHI Code of Business Practice (CoBP).
- **International:** Assist members to access and grow business in markets around the world, to provide opportunities to actively meet new customers and promote the UK medical device industry in a competitive global environment.
- **Membership:** Proactively engage with members to understand their needs and aspirations. ABHI structures enable effective representation and are able to respond to the changing market environment.
- **Resources:** ABHI employees include industry, regulatory, policy and communications experts with the knowledge and insight to deliver real value for members.



M/L Taper Hip with Kenective – Zimmer

Chairman's Discussion

"The biggest development has been the coalition's strategy for the future of the NHS; as laid down in the Health and Social Care Bill. Its direction is becoming clearer as it progresses through Parliament, but I believe we have a real opportunity to help shape the remaining detail that needs to be worked on."

Peter Ellingworth

"The new coalition dominated much of 2010 and the scale and timing of the Secretary of State's plans for the NHS were a surprise to many. It is not difficult to see the intended benefits of his proposals; however, businesses will need to be vigilant to keep abreast of the impacts of marketplace changes which may ensue."

Geoff Cox

Question 1

What were the major developments of 2010 that were of interest to you?

"ABHI has enjoyed frequent and high-level engagement from the new Government's Ministerial team and Senior Civil Servants. We also continue to engage on the iTAPP challenge and help drive the agenda with the Department of Health."

Gary Stapleton

"The impact for NHS suppliers will be a far more challenging business environment. The targeted savings of £15bn to £20bn will require them to deliver significant efficiency and productivity savings. However, suppliers can deliver value through goods and services that address the challenges within the healthcare system; help shape healthcare provision in future and, ultimately, deliver better patient outcomes."

Peter Ellingworth

"ABHI has repeatedly made the case for appropriate equipment investment to modernise the NHS and reduce running costs. However, the NHS has failed to take the efficiency savings from even the best of its investments and we now face the danger of cutting costs of a health service which has not made the improvements envisaged."

Geoff Cox

"In 2011 the budgetary challenges facing the NHS will be more pressing than ever, requiring industry to demonstrate the value of their technologies in helping achieve efficiency. In a tough commercial environment we are working to ensure that procurement is an enabler and not a cost-driver for industry or the NHS."

Gary Stapleton

Question 2

What impact do you think these developments will have on the industry in 2011?

Question 3

How do you think the changes to ABHI governance will benefit members?

"Following the financial crisis the impact of greater scrutiny is evident in the new Code of Business Practice (CoBP) for our industry, which will be followed by the new Bribery and Corruption Act – hopefully members see this clarity as a positive step. ABHI has a new organisational structure, through a new Board of Directors with eight elected officers taken from three electoral colleges – so that all members are represented."

Peter Ellingworth

"The need for businesses to be scrupulous in their dealings and be seen by employees, customers and Government to be champions of best practice in all commercial dealings is paramount. ABHI CoBP can be established at the heart of organisations to prepare them for what is required."

Geoff Cox

"We have put in place an open, transparent and democratic governance system that represents the breadth and scope of industry. The Board has made a strong commitment to engage with ABHI to ensure that the membership is properly represented at all levels of Government and the NHS."

Gary Stapleton

"ABHI needs an active membership and I encourage all members to engage in the debate. You can attend conferences and events as well as be a member of a Special Interest Section (SIS). I will be tasking the Board and the Secretariat to continue to push our key messages with the relevant Government departments as well as the Department of Health."

Peter Ellingworth

"There has never been a greater need for a strong voice for our industry as we move into some of the stormiest waters of the last 25 years. ABHI will, I'm sure, remain at the centre and provide strong representation for our ever increasing membership."

Geoff Cox

"2011 will provide challenges and opportunities for the medical technology industry, and ABHI must be a strong voice to Government and key decision-makers. As well as continuing to run our working groups and SISs effectively, we will also be holding regional events to maximise member participation."

Gary Stapleton

Question 4

How can the ABHI continue to support members effectively as the pace of change accelerates?

Key Achievements 2010



Fogless Protoscopes – Parburch Medical

Policy

Briefing events in June updated members on the NHS policy and commercial environment following the general election and, in November, on the Government's White Paper: 'Liberating the NHS'.

New Government

There was relationship building with the new Government in both health and business departments, through existing consultation channels and many meetings. It became clear:

- That industry concerns about transparency of the NHS procurement landscape are somewhat shared at senior/ministerial level, and heightened scrutiny of NHS procurement practices is to be expected
- That the Government understands medical technology as providing good quality manufacturing jobs, with official figures showing an increase in sector employment

The Government's consultation on economic growth at the end of the year recognised the life sciences industry for its potential to contribute to growth.

NHS leaders

There was relationship building with NHS leaders through the NHS Life Sciences Innovation Delivery Board, which reports to the NHS management board and now provides a forum to address structural problems with adopting technologies. A joint industry-NHS workshop in September kick-started a programme of activity.

Contribution to Payment by Results

This was the second consecutive year that ABHI has contributed to sense check of the proposed tariff for 2011/12. Many members scrutinised the proposals to provide a comprehensive insight into department changes.

Submission to Government White Paper

Responding to the NHS White Paper through close member engagement in policy groups and regional meetings enabled ABHI to make a clear case for scrutiny of innovation and tariff in the subsequent Health and Social Care Bill. This is combined with the need for clarity about existing commercial contracts, which has been central to subsequent interactions with Parliamentarians in connection with the Bill.

Evaluation of medical device technology

After 2 years of development work following the Darzi report, National Institute for Health and Clinical Excellence (NICE) launched the Medical Technologies Advisory Committee to assess single technologies; with a clear recognition of the different evidence and benefits that medical technology may bring to healthcare. ABHI remained concerned about some aspects of processes and methodology, commenting on these throughout the consultation process which has not yet concluded.

Regulation

ABHI has made significant contributions to developing the position of European industry through work on the Recast of the Medical Devices Directive, whilst at the same time working with the Medicines and Healthcare products Regulatory Agency (MHRA) and UK-notified bodies to ensure that, wherever possible, the UK speaks with a single voice in Brussels. ABHI also played a major role in ensuring that the incorporation of Unique Device Identification (UDI) into EU legislation will be an orderly process. We have continued to encourage the NHS to adopt GS1 Standards.

Working with Eucomed, ABHI has been active on a number of issues; particularly ensuring that the plasticiser DEHP was registered for medical device use under Registration, Evaluation, Authorisation & restriction of Chemicals (REACH), and providing information to a consortium compiling a dossier on Ethylene Oxide as a medical device sterilant under the Biocides Directive.

Reputation

ABHI continued to promote compliance with the CoBP and has worked closely with Eucomed on future developments in ethical compliance. A very successful conference on the Bribery Act was held in December.

International

ABHI organised the UK Pavilion at Medica in Germany, Arab Health in Dubai and China International Medical Equipment Fair (CMEF) in China, involving over 200 companies and providing a range of business-matching and partnering opportunities.

ABHI delivered its International Conference and a series of monthly export focused seminars, looking at the opportunities, challenges and strategies UK businesses can adopt to internationalise and grow business overseas.

Connecting members and intelligence

ABHI organised and participated in several missions to connect members to overseas buyers and distributors in key markets including hosting delegations from the Asian Pacific region, India and the USA. We also continued to signpost and provide knowledge and intelligence to members, answering questions and highlighting opportunities in overseas markets

Membership

ABHI recruited 39 new members, the majority of whom were SME members. We also provided membership briefings on the election result, the new Government and the White Paper, as well as frequent updates. In order to keep members informed and seek their feedback, ABHI held regional briefings across the country.

Events

ABHI organised and delivered over 25 events in 2010, ranging from seminars to large conferences that provided information and updates in key policy areas and collaboration with key stakeholders.



Element Stent – Boston



Furlong Hip System – JRI Medical

In the 2009 Annual Report, then Chairman Geoff Cox highlighted that a priority for 2010 was the review of the governance of the Association in order to ensure it is best suited to representing members and providing strategic leadership.

This review was completed in early-summer 2010, and a number of recommendations were made including that:

- Council be disbanded
- A Board of Directors be created to replace Executive
- An election be held to constitute the Board, with members been divided into three electoral colleges for the purposes of nominating Directors
- An Operating Committee be appointed by the Board
- All Policy Groups, Working Groups, and SIS hold elections for the positions of Chair and Vice Chair

The sum effect of the changes to the prevailing system is to increase transparency, democracy, representation and member involvement in the operations and leadership of ABHI.

To enact these changes a new set of Byelaws was created and presented to members for their consideration. On 22 November 2010, an Extraordinary General Meeting of the Association unanimously adopted the new Byelaws of ABHI.

On this date, the election of candidates to the Board was also held. This was a culmination of a process that proved very popular with members. Fifteen nominations were received for the eight positions on the Board and over 40% of members cast their votes.

The new ABHI Board of Directors

The inaugural meeting of the Board was held on 17 January 2011, when the existing Executive Committee transferred responsibility to the Board. The role of the Board is to act as trustees for all the members, setting and owning the Association's strategic direction and providing overall leadership.

Gary Stapleton, Managing Director of 3M Health Care Ltd was elected to be Chairman.

ABHI Chief Executive, Peter Ellingworth, and Executive Directors, Mike Kreuzer and Andy Taylor, will also sit on the Board.

The Operating Committee

The Board also approved the creation of the Operating Committee which will be responsible for proposing policies and strategies to the Board and, subject to their approval, guide the execution of them. It will comprise of the CEO and senior managers of ABHI, and the Chairs of the ABHI policy groups.

Members of the ABHI Board of Directors



Gary Stapleton,
ABHI Chairman,
Managing Director,
3M Health Care Ltd



David Follows,
General Manager –
Market Access UK,
Johnson & Johnson Medical



Phillip Kennedy,
Managing Director,
Eschmann Holdings Ltd



Shah Fayyaz,
Managing Director,
Timesco of London Ltd



Jackie Fielding,
Regional Vice President,
UK & Ireland
Medtronic



Johnny Lundgren,
Vice President,
North West Europe,
Becton Dickinson



Harry Keenan,
General Manager,
Baxter Healthcare Ltd



James Urie,
Sales & Marketing Director,
Mediplus Ltd

ABHI staff on the Board



Andy Taylor
Director,
Healthcare Policy



Mike Kreuzer OBE
Director,
Technical & Regulatory

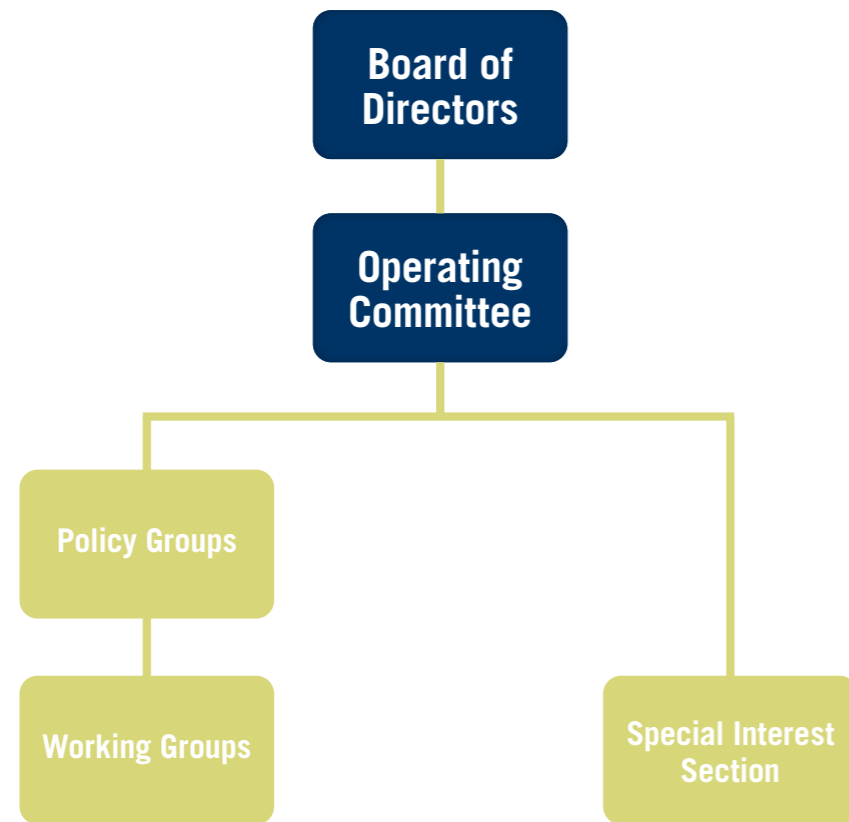


Peter Ellingworth
Chief Executive

Gary Stapleton was elected Chairman of ABHI during the first Board meeting in January.

Summary

With the creation of the Board, the appointment of the Operating Committee and election of Chairs and Vice Chairs of Policy Groups, Working Groups and SISs, the 'total operations' of ABHI will be based on transparency and membership views. These changes ensure that the Association represents the needs of all members, and is best positioned to articulate the benefits and value of medical technologies to our stakeholders.



Policy Groups

- International
- Legal Issues
- Commercial
- Public Affairs
- Research & Innovation
- Technical

Working Groups

- Healthcare Acquired Infections (HCAI)
- Health Technology Assessment
- Payment by Results
- Scotland Medical Technology Industry Group
- Sterilisation & Microbiology
- Supply Chain and eBusiness
- ABHI/ICR/MHRA Clinical Investigations Group
- ABHI/MHRA Postmarket Surveillance Group
- Industry/Notified Bodies Liaison Group
- ISO/TC 210 Mirror Group

Special Interest Sections

- Cardiac Rhythm Management
- Elimination of Sharps Injuries
- Neurosciences
- Ophthalmology
- Orthopaedics
- Primary and Community Health Services
- Spine
- Surgical Instrument
- Theatre Kits
- Vascular

“ Being actively involved in the Payment by Results (PbR) and Health Technology Assessment (HTA) working groups really complements the work we do internally at Cook. These groups provide a high-level forum for discussion of key reimbursement and HTA policy issues with other colleagues from the industry. For a privately owned company such as Cook, it is very positive to work together with both colleagues from SMEs as well as from large corporations. This interaction is possible thanks to the knowledgeable and resourceful ABHI staff, who diligently supports us in the important mission to bring the sector’s innovations to the forefront of the healthcare policy arena and promote the one vision we all share – the best care for the patients. ”

Sandra Lopes, Cook Medical
February 2011

“ ABHI consistently keeps us informed about regulatory changes and in touch with Eucomed, Department of Health (DH), NHS Supply Chain and NICE, which otherwise we might not be able to achieve. Coordinating a potentially very costly proof of decontamination processing through the ABHI saved members considerable amounts of money than if they had had to do it individually. ”

David Peddy, Caterham Surgical
February 2011



Andy Taylor
Director,
Healthcare Policy

What changed in 2010?

As anticipated, 2010 saw two of the biggest upheavals for the UK healthcare environment in recent memory.

One was UK-wide and was the impending pressure on funding for the NHS, following the more general pressure on the public finances after the bailout of the banks. Whilst this pressure did not fully bite in 2010 – that is to come – behaviours in the NHS began to change and many ABHI members saw new patterns of purchasing, reflecting what could be seen as a lack of confidence at working level in parts of the NHS. There was also a resurgence of demands for discounts and extended payment terms, familiar from previous NHS funding squeezes.

The other change was more specific to the NHS in England and followed the General Election in May with the creation of a coalition Government and the publication in the summer of the White Paper, 'Equity and Excellence: Liberating the NHS'.

This triggered major public debate on what will follow the abolition of most of the familiar features of the NHS. There are concerns at almost every level for suppliers, with a change in the balance of decision making between commissioners and providers and changes to reimbursement, as well as simpler but, for business, fundamental matters of continuity of contract management. With the final abolition, after decades of gradual but organic change, of the geographically-based health purchasing body (currently the PCT), the NHS breaks a thread of continuity that has existed since 1948.

Both the above changes are threats, but they are also opportunities. There is for example an urgent need to reduce the intensity of care in order to cut costs by keeping people out of hospital, particularly in the light of an ageing population. This means more care nearer home. Medical device technology already supports such care and members provide products that support this shift.

The report below summarises the main themes of the year and a wide range of activities supported as always by SIS for specific sectors, together with Working Groups on cross-cutting issues including health technology assessment and PbR. Several new groups were formed this year including one to focus on primary and community care in the light of the pressures on the NHS above.

How these changes played out in the commercial environment

The pressure on NHS funding and the White Paper policy both began to have an impact on key features of the environment for members, whether on procurement, evaluation and assessment or reimbursement, with both PbR and Part IX likely to be impacted.

Procurement

The 2009 DH National Innovation Procurement Plan had raised the prospect of a concordat between the industry and the NHS but this faded as the election approached and the main formal change in 2010 was the launch of the National Procurement Council of which Peter Ellingworth is a member, bringing together the NHS with some industry representation, including the Confederation of British Industry (CBI) representing healthcare providers as well as medtech. This provided a forum for more open discussion of procurement with Government than for some years, for example confirmation that there will in future be a stronger emphasis on the NHS benchmarking the prices it pays for products, which is also the expected conclusion of a National Audit Office study due for publication early in 2011.

We learned through this forum that the DH will promote NHS Supply Chain as the channel of choice for NHS Trusts and this was confirmed by the Department at the NHS Supply Chain supplier event in the autumn. Against this however:

- The industry saw the rapid emergence of 'direct from manufacturer' buying on the part of the NHS. This has raised some serious questions about market behaviour on the part of NHS Supply Chain as intermediary, on which ABHI has begun to get legal advice following discussions with Ministers and the DH
- The variety of different procurement behaviours in the NHS continued to proliferate, with different regional hubs approaching their remits quite differently. A range of supplier-charging regimes emerged
- At the year end, the High Court gave leave to the West Midlands Healthcare Purchasing Consortium (HPC) hub to become part of one of the biggest US group purchasing organisations, Healthcare Communications Association (HCA). Such developments tend to add to cost to serve for suppliers at a point when initiatives to reduce costs in the NHS would appear to be the more obvious direction
- Meanwhile, the North West commercial agency merged with NHS Shared Business Services, linking into the latter's provision of back office services to the NHS

Offsetting the above to at least some extent was the emergence of the 'innovation procurement project', which looked for solutions from suppliers to improve the quality and productivity of NHS services through greater adoption of beneficial innovative medical market behaviour on the part of NHS Supply Chain. The initiative is now known as the Innovative Technology Adoption Procurement Programme (iTAPP) and is managed by DH's Procurement, Investment and Commercial Division, with execution being the responsibility of the National Technology Adoption Centre working through Strategic Health Authorities (SHAs).

It is governed within the National Quality, Innovation, Productivity and Prevention (QIPP) workstream on Procurement, with a target to realise efficiency savings of £1,045m on a progressive basis from January 2011 to March 2013. Over 100 solutions were offered by industry to achieve this.

“ The Government is committed to achieving a balanced and dynamic economy in which exports and investment will drive economic growth in the future. As a consistently high-performing and innovative sector, healthcare is a vital part of that economic picture, now and in the future. Government will continue to work with the ABHI, other trade bodies, and companies to ensure the UK business environment stimulates and rewards future growth and job creation. ”

David Willetts, Minister of State for Universities and Science
February 2011



Fess Instruments – Karl Storz

Progress on iTAPP through 2010 was fairly slow, reflecting both the layers of NHS organisation involved and the impact of the General Election. Though it gathered pace over the summer of 2010 momentum was lost over autumn/winter as the upheaval caused by changes in the White Paper resulted in uncertainty as to the status of the NHS Technology Adoption Centre (NTAC). ABHI pressed Earl Howe to guarantee funding for NTAC – a crucial vehicle for delivery – and just prior to the close of the year heard upbeat reports that this was being seriously considered.

ABHI has also worked with the iTAPP Board to recommend alternative routes for implementation given the demise of SHAs by 2012. Options being considered for 2011 include working with pathfinder GP consortia and key provider organisations.

Once again however, the National Audit Office noted, in a report on Management of NHS Hospitals (December 2010), the real-terms reduction in the cost of goods and services inputs to the NHS as in almost all other sectors of the economy over the last decade. The NHS is unusual in the economy in still having no clear strategy to harness the benefits of these technology changes and their associated value improvements.

The new Medical Technologies evaluation pathway was referred to in the report for 2009 and 2010 has seen consultations on methods and process and, before completion of those, some technologies are being looked at by the Medical Technologies Advisory Committee appointed by NICE to lead this work. The ABHI is continuing to engage with NICE to ensure the assessment of medical devices remains relevant and of most use to both the NHS and Industry. Central to these discussions remains the way NICE deals with the majority of new technologies that will benefit patient outcomes, while adding small incremental costs without creating major affordability issues.

ABHI HTA working group outstanding questions on the NICE Medical Technologies evaluation pathway – autumn 2010

- Medical devices play a central role in ensuring the NHS can deliver the outcomes framework
- Although today's financial environment is of critical importance, the value delivered by medical technologies is not just about saving costs but about getting people back to health as quickly as possible
- The effect of NICE focusing on single products has not yet been understood and there remains a lack of clarity about how equivalence in medical devices should be assessed and how competing manufacturers might be included in the assessments
- The investment in assessment will only come to fruition if the outputs of the NICE assessment are integrally linked to the reimbursement and adoption mechanisms of the new NHS commissioning structure

Payment by Results

ABHI's working group finalised its first ever position paper on PbR which informed discussions with Government and the NHS during the year and contributed to the checking of the tariff for the next financial year, as it did for the first time in 2009.

The Association's comments were once again seen to be of value. One of the working group's main concerns during the year was the proposed changes in the tariff regime under the White Paper and this formed a main plank of our response to the White Paper consultation, on the basis that splitting the management of tariff from the pricing was proposed but without any arguments being made to support this. ABHI continues to be concerned about proposals that the tariff will effectively be abandoned to allow new healthcare providers to enter the market. Commentators described this as encouraging a 'race to the bottom' and going against the international evidence on promotion of quality in healthcare. This is likely to be a key briefing point for ABHI in the forthcoming legislation on the NHS.

Machinery

Underlying the above thematic activity was a range of relationships through which ABHI took forward all aspects of those same themes above. Key developments during the year on this front were:

- The continued development of the NHS Life Sciences Innovation Delivery Board under the chair of Mike Farrar, NHS Northwest. A workshop event involving NHS and industry leaders in September produced ideas for joint projects which are now being taken forward
- The Office for Life Sciences (OLS) started under the previous Government was taken up by the coalition Government and a review of prospects for promoting growth across key manufacturing sectors was launched at the year end, with input from industry associations
- The continuation of the Ministerial Medical Technology Strategy Group (MMTSG) under the new Government. The group's co-chairs are Earl Howe as Minister with responsibility not only for industry relations but also innovation in the NHS; and Colin Morgan, Regional Vice President for Johnson & Johnson MDD EMEA. The group highlighted the need for Government policy to reconcile not only the NHS's needs to reduce costs but also those of the wider economy for a vibrant industry sector, together with those of industry for consistent behaviours from the NHS

“ It is a critical time for our industry with all the Government changes in progress. ABHI's input into the Government's thinking is crucial. You never know business logic might win in the end! ”

Bob Urie, Mediplus Ltd
February 2011

Research and Innovation

Paving the Way for Innovation

2010 has been a time of follow-up and change, with many pieces of a complicated jigsaw falling into place recently. The context was a search for savings in the NHS, counterposed with the election, the new Government and a tough comprehensive spending review (CSR). We followed up the OLS initiative, and have reviewed our own strategy and activities to achieve better results for the UK Life Sciences sector.

Collaboration

We continued to work with colleagues supporting the UK research infrastructure, meeting with the National Institute of Health Research (NIHR), Engineering and Physical Science Research Council (EPSRC), Medical Research Council (MRC), Economic and Social Research Council (ESRC), and the Office for Strategic Co-ordination of Health Research (OSCHR).

NIHR has established the NIHR Office for Clinical Research Infrastructure (NOCRI), and we continue to work with this and the UK Clinical Research Network (UKCRN) to identify and overcome barriers to doing good medical device research in UK to ensure that companies can get the best research by working with clinical collaborators in the NHS.

We also work with the Royal Academy of Engineering UK Focus on Biomedical Engineering to raise the profile and capability of the UK's medical engineering community.

Funding

Funding for medical research projects appeared to be under threat in the run up to the CSR. But the development of innovative health technologies and its related high economic growth potential meant that research funding was largely maintained.

The NIHR's Invention for Innovation (i4i) programme and the Technology Strategy Board (TSB) – the Government's main route for funding development projects – continued with active funding programmes for both collaborative projects and innovation platforms.

ABHI involvements

ABHI was involved in TSB's launch-pad competition, which attracted over 150 health technology entries. We also supported the EPSRC Healthcare Partnerships programme, which stimulated a number of research projects involving collaboration with SMEs.

We have continued our support of the i4i research funding programme and the Health Technology Cooperatives (HTCs) which were established as a result of the HITF process.



Oliver Wells
Consultant,
Research &
Innovation

The Wellcome Trust, MRC and EPSRC have all been extremely active in focusing their programmes on delivering impact through translation of research into real technologies for the benefit of patients and the economy. ABHI has continued its engagement with these groups through a number of their research centres, notably the Wellcome/EPSRC Medical Engineering Initiative and the EPSRC Centre for Innovative Manufacturing in Regenerative Medicine at Loughborough University. We have also been working with other stakeholders; in particular supporting the UK Age Research Forum to engage with industry and with presentations on the role industry can play in collaborative research projects.

Health technology

During 2010, the Small Business Research Initiative (SBRI) continued, with a focus on stimulating innovative health technologies in response to challenges from the healthcare community, notably the SHAs: we will continue to support these initiatives and seek ways to continue them once the SHAs cease to exist in 2012.

HTA remains an essential element in enabling industry to accelerate the adoption of good new products. During 2010, ABHI worked actively with NICE to establish the Single Evaluation Pathway for medical technology, with the first technologies emerging from this process by the end of the year. This highlighted the need for better assessment methodologies, and we continue to work with the MATCH group to deliver these and find ways to help align industry and NICE expectations and practices.

SME competitiveness

The research and innovation group has been focusing on the difficulties faced by SMEs in bringing new technologies to market, and have continued to contribute strongly to the work of the SME Competitiveness Working Group which is supported by both the Department for Business Innovation and Skills (BIS) and the DH. BIS produced its first health technology sector database, 'Strength and Opportunity', at the end of 2009, and its second report was delivered at the end of 2010.

We are examining ways to use the data to understand the companies providing support to the industry, and the form and importance of clusters in supporting small companies to grow and be internationally competitive. ABHI continues to work with both the Health Technologies and Medicines Knowledge Transfer Network (HTM KTN) and the Medilink UK network to deliver support and define a better forum to bring together all organisations with a mutual stake in the success of the innovation. We also maintain links with the network of NHS Innovation Hubs, who link inventions from the NHS to industry.



Incise – Renishaw

“ The medical device industry is a key partner in providing the innovation that will help the NHS achieve the aims of QIPP. Through its work with the Life Sciences Innovation Delivery Board, ABHI plays a critical role in promoting the benefits that better uptake of medical devices can deliver. ”

Mike Farrar,
Chief Executive, NHS North West
Chairman, Life Sciences
Innovation Delivery Board
March 2011

Technical and Regulatory

Ensuring Regulation Remains Appropriate

The ABHI Regulatory Affairs team continues to address regulatory, standards and compliance issues, through advocacy with a variety of UK organisations and involvement in the work of Eucomed. The activities are coordinated through the Technical and Regulatory Policy Group (TPG).

The legislative framework for medical devices

A revision was originally proposed in May 2008 but temporarily shelved after opposition, not least from industry. Last year we expressed concern that the move of the medical device unit to DG SANCO might affect the future direction. However, policy makers in DG SANCO accepted the need for close dialogue with industry and recognised the benefits of a safe and efficient system for patients, regulators and industry. Furthermore, it is increasingly acknowledged that the EU system offers significant advantage over that in the USA or Japan in allowing devices to be available to patients up to 2 years earlier. Member State authorities, the Commission and industry largely agree that, whilst some significant improvements should be made, particularly in the oversight of Notified Bodies, the system works well.

One improvement will be increased centralisation to ensure that implementation and interpretation are consistent across the EU. The recent creation of a Central Management Committee (CMC) will move things in this direction in advance of the re-cast being effective.

The Recast is important to all of us. A more bureaucratic system will delay making new technology available to patients, increase operating costs and decrease competitiveness. We must turn this into an opportunity and build on the current strengths of the system.

The Medicines Healthcare products Regulatory Agency

ABHI's relationship with the MHRA continues to be positive and productive. We await the impending announcement on the appointment of a head of the devices section and believe devices should have a higher profile in the agency's work.

Unique Device Identification

ABHI is directly involved in representing EU industry on this topic. The Global Harmonisation Task Force working group has posted its report for consultation. It is recommended that members read it, as it is likely to form the basis of future legislation.



Mike Kreuzer OBE
Director,
Technical &
Regulatory



Clive Powell
Manager,
Technical &
Regulatory

Decontamination

Regrettably, we cannot report industry involvement in ACDST because the new committee is a casualty of Government cut-backs. We continue to explore ways of re-establishing a constructive dialogue with Government on this area.

Environment

The recast of the Restriction of Hazardous Substances (RoHS) in Electrical and Electronic Equipment Directive was agreed during trialogue meetings in late 2010. The vote in the European Parliament plenary session was in favour of the Directive, which will come into force around May 2011.

Medical devices will fall within the scope of the RoHS Directive from around Q2 2014, with In Vitro Diagnostics (IVDs) following 2 years later. Meeting the RoHS Directive may involve some redesign, so manufacturers should plan ahead. DEHP, a plasticiser used in PVC, has been proposed as a 'substance of very high concern' under REACH regulation, so was one of the first chemicals to be registered with the European Chemicals Agency (ECHA).

Eucomed worked closely with DEHP producers to ensure its use in medical devices was properly covered and the registration dossier was submitted. DEHP will not require authorisation for use in medical devices due to the exemption granted by Article 60.2 in the REACH regulation. Also the recast of the Waste Electrical and Electronic Equipment (WEEE) Directive is still in progress, with issues relating to the exemption of infectious diseases and shipment of non-working devices outside the EU. ABHI and Eucomed are working to resolve these.

Standards

ISO 80369-1, or Small Bore Connectors for Liquids and Gases in Healthcare Applications, has been approved at FDIS, and formal publication can be expected at the beginning of 2011. The supporting parts should be published over the next couple of years.

On 15 November 2010, the EU Commission published document 53/2010, giving a formal objection to harmonisation of 11 standards, including the risk management standard EN ISO 14971. This has possible global implications. ABHI and Eucomed are working very hard with other EU trade associations as well as the European standards organisations, CEN and CENELEC to resolve this issue as expeditiously as possible.

“ As the exercise to revise the main medical device Directives comes ever closer it is even more important than usual that the excellent and open relations between the MHRA and the ABHI are maintained in order to ensure that future regulatory developments are relevant, appropriate and proportionate. ”

Steve Owen, MHRA
February 2011

“ The Recast is important to all of us. A more bureaucratic system will delay making new technology available to patients, increase operating costs and decrease competitiveness. We must turn this into an opportunity and build on the current strengths of the system. ”

Zeger Vercoouteren, Johnson & Johnson
February 2011

During 2010, work continued on developing ABHI CoBP to ensure that it reflects the current compliance climate and also that it meets members' needs. This work took place in a number of different forums, including the ABHI CoBP Compliance Working Group (now incorporated into the Legal Issues & Compliance Committee), the Eucomed Compliance Network and ABHI CoBP Complaints Adjudication Panel.

A number of changes to the Code were introduced in November 2009 and came fully into force in February 2010. These were amendments to the Q&A section and mainly focused on companies' dealings with healthcare professionals (HCPs) and their employers in relation to sponsorship to attend conferences or their engagement as consultants. Proforma letters for communication with the HCPs and their employers were provided to assist companies in this area.

Discussions at Eucomed level continued, and these focused on a number of areas including further amendments to the Code itself to reflect issues that had arisen during the year. These changes were scheduled for introduction into the ABHI document in the first quarter of 2011. In addition, a tool was developed to assist members in assessing the suitability of events such as conferences for their support. This was planned to be available in 2011.

A principal area of work of the ABHI group during the year was the development of a new annex to the Code, to cover advertising and promotional activities. At year-end this document was approaching final draft stage, with its introduction due in the first quarter of 2011. It was hoped that this would provide more certainty to companies as to what was expected in relation to these activities.

A further, ongoing work area for the secretariat was answering members' questions on the Code. A small consultative group was established to assist in this process and this system worked well in providing prompt and informative answers to a number of queries where the secretariat staff needed to draw on outside expertise.

Finally, although there had been no complaints under the ABHI Code, we took the opportunity to convene another meeting of the Complaints Adjudication Panel in order to update its members on compliance issues generally and the Code in particular. This was a successful meeting, attended not only by panel members and ABHI staff but also representatives from the equivalent Eucomed group, the Prescription Medicines Code of Practice Authority and another European national trade association that was looking to introduce a complaints panel into its system.

Bribery act

In a related area, there was a great deal of publicity and discussion about the UK Bribery Act 2010 coming into force in April 2011. The legislation has some far-reaching effects, in that it covers not only activity within the UK but worldwide. In addition, potential sentences are severe, including unlimited fines for companies and up to 10 years in jail for individuals.

Clearly all of this is a concern for business generally, but medical technology companies will be interested in how their sector is affected.

ABHI met with representatives of the Serious Fraud Office and has been working to see how the law will operate in practice. A keynote conference on the Bribery Act was held in December 2010 to consider how the industry would be affected, and the steps that companies should take to protect themselves from the possibility of prosecution. This will continue to be a key area of activity in 2011.



Exeter Hip Joint – Stryker

“ The quality of our health services is immeasurably strengthened by the contribution of the UK's vibrant life sciences sector, of which ABHI and its members form an important part. The demographic and financial challenges we face today mean that, more than ever, the future depends on the ability and willingness of the industry to work in partnership with the NHS and with Government. The experience of the last 9 months leaves me in no doubt that the ABHI and its members will continue to do just that. ”

Earl Howe
Parliamentary Under-Secretary of State for Quality
Department of Health
March 2011

International

Helping Members to Grow Business Internationally



Paul Benton
Director,
Commercial &
International

2010 has seen UK industry increasingly target opportunities in overseas markets. ABHI members and wider industry clearly understand the potential that internationalising their business can yield, and have had a busy year building and identifying new opportunities for growth.

The challenges facing companies developing trade overseas are not inconsiderable, and ABHI has worked to support members as they plan and develop strategies to increase their activity in key markets.

2010 has seen ABHI continue to focus on the main areas of international policy, trade promotion and market intelligence and has helped facilitate introductions and develop relationships with a range of customers and policy makers around the world.

Building on the UK's reputation for quality and innovation, ABHI has focused on ensuring that our industry is made more visible and properly promoted overseas as well as being represented appropriately with stakeholders. We have continued to work closely with Government organisations to ensure that key messages reach international customers and that the views and issues facing members continue to be communicated.

It is clear that as we move through 2011 the environment that we operate in will reinforce the need and importance of identifying and capitalising on opportunities in key overseas territories. ABHI will work to provide both the support and platforms for members to reach customers, and to ensure that our industry is well-represented in a competitive global environment.

“Attending numerous Export Clubs has given G+N Medical guidance that has put us on the right road in order to gain market share in these new markets. The knowledge gained has saved considerable time which might otherwise have been wasted. In addition, we have met people at these events and have shared interesting experiences. ABHI has supported us in our exhibitions at both MEDICA and Arab Health. Both events have proven a success and we have no doubt being associated with ABHI gives us good standing internationally.”

Giles Griffiths, Managing Director, G+N Medical
February 2011

Opening up foreign markets

2010 saw ABHI involved in a broad range of international initiatives for members including: missions, business matching events, conferences and seminars organised both overseas and in the UK.

ABHI was again responsible for organising UK Pavilions at trade shows in Europe, the Middle East and China and saw the continued success of our monthly export events.

ABHI's activities aim to provide members with valuable information, business intelligence and introductions to policy makers, buyers and distributors from countries all over the world. Working collaboratively with Government and stakeholders through international working groups and policy groups, ABHI helped shape activity and engagement with overseas organisations and delivered a number of high-profile receptions and partnering opportunities throughout the year.

ABHI continued to develop the UK Pavilion at international trade shows, improving the quality and impact of the UK group and providing a range of new services to industry. Assisting industry, particularly SMEs, has been a priority for the Association and 2010 saw the introduction of a number of new initiatives for providing cost-effective solutions for smaller companies to meet customers. Delegate meeting visitor packages, product and literature showcases and the introduction of micro exhibition stands at tradeshows allowed small companies to have a more flexible, cost-effective presence at key overseas events.

ABHI has had a busy year helping to support members develop their business internationally, and 2011 will be no different. Central to ABHI's strategy is providing members with the support needed to grow, and this will see further refinement and development of support services. International business development will become ever more important as we move through 2011 and beyond.

ABHI will be working hard to ensure that members can gain from the increasing opportunity found around the world.



Careline Monitor – Medtronic

ABHI Membership

Communicating the Value



Dan Jones
Manager,
Communications
and External
Affairs



Angela Jeffery
PA and
Membership
Development
Manager

Throughout the year, as well as communicating with the wider industry, ABHI informs members about changes affecting the medical device industry, and to our political stakeholders and the press we communicate the value of medical technologies to patients, the NHS and the economy.

Political communications

2010 saw a number of changes to the health and political landscape. The new Health White Paper outlined some of the most significant changes in the NHS's history. ABHI has worked to keep up with these changes in the political environment.

General election

Prior to the general election we held meetings with a number of parliamentary candidates to help them understand medical devices; enabling us to build parliamentary links and take part in establishing two All Party Parliamentary Groups: Life Sciences and Medical Technology, allowing communication with parliamentarians.

Party conferences

ABHI once again participated in Health Hotel, an umbrella organisation of over 30 charities and lobby groups that hold events at party conferences, and held events with the Anthony Nolan Trust and Alzheimer's Research Trust. They were attended by frontbench politicians including Baroness Thornton and Earl Howe.

We also held events with the Bio Industry Association and ABPI to highlight the value of the life science industry in the UK. These were attended by the Minister for Universities and Innovation, David Willetts, and Chair of the Science and Technology Committee, Andrew Miller.

“The field of play changes so quickly in medical devices, but ABHI provides a vitally important job in tracking and making senses of the changes and assessing their relevance to the UK industry.”

Ashley Yeo, Principal Analyst – Clinica-Informa
February 2011

LifeSciencesUK

As part of our work to improve the life science environment for our members, ABHI have been working closely with other life science associations: ABPI, British In Vitro Diagnostics Association (BIVDA) and Bio Industry Association (BIA), holding joint media briefings, party conference events and writing joint press releases. The four associations launched 'LifeSciencesUK' to help facilitate further work between them.

White Paper response

The White Paper in July 2010 set out a series of changes for the NHS. ABHI held a number of consultation events in order to respond fully on behalf of industry, and were then able to draft full responses to the consultations that took place. Following their submission, ABHI has been contacting MPs to brief them on areas of the Bill that might affect industry, and will be working on the Bill as it progresses through parliament.

Medical Technology Group

The Medical Technology Group continued to campaign on behalf of industry and patients. The coalition of patient groups, research organisations and industry worked hard to ensure that the new wave of MPs were up-to-date on the importance of medical devices.

Communication with our members throughout 2010

News Review – ABHI delivers a summary of the week's news stories that are of relevance to the sector.

Primed – a fortnightly newsletter with a summary of key points affecting the sector.

Update for Chief Executives – a monthly email with commentary on key events.

Medtech newsletters – a response to key events in more detail.

Regional meetings – to communicate with members who are unable to attend regular SIS or Working Groups.

Working Groups and Special Interest Sections – covering a wide range of issues and topics within the medical device industry.

“ **ABHI's conference and seminar programmes provide informative and comprehensive insight into key issues facing the medical device industry. ABHI events are a must for any business working on long-term planning and are great value for money.** ”

Richard Phillips,
Public Affairs and
Reimbursement
Manager, Medtronic.
February 2011

Over 20 events ranging from large conferences to small workshops gave the industry opportunities to learn about developments in ABHI's main policy areas as well as communicating with members and stakeholders about the ever-changing healthcare landscape.

Key events 2010

The key events of 2010 attracted audiences of over 300 people. The Legal and Regulatory Conference had an international panel of speakers from industry, the Commission and MHRA to give a unique insight into the Medical Device Directives recast, Unique Device Identification/Auto Identification and Data Capture, and the future regulatory landscape.

The increasing interest from industry on exporting and international trade has remained central to our work, so the launch of our Inaugural International Conference in May provided valuable information on export opportunities, challenges and gave practical advice on developing business strategy in key markets, including: China, India, USA, Middle East and Western Europe.

An annual conference was also launched to complement the ABHI annual dinner, at which we updated members on the new Government's policies and what they mean for the NHS. Sir Michael Rawlins, Chairman of NICE, gave a speech to key industry figures and policy-makers.

The flagship event was the UK Market Conference, covering major changes affecting the NHS following the spending review and attracting key chief executives from the NHS Trusts, Royal College of Nursing, NHS Confederation and Minister Earl Howe. It provided members with information on the current landscape, and provided the opportunity to network with key decision makers. ABHI also worked with stakeholders through the DH's Healthcare-Associated Infections Conference attended by over 200 people.

The year ended successfully, with over 150 people attending the UK Bribery Act Conference, with speakers who were lawyers and experts in corruption control and ethical compliance in the medtech sector. The Act is one of the most significant pieces of legislation to affect UK businesses in several years.

The calendar for 2011 already has many significant events planned.

Staff Plus Our People

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Chairman, ABHI
Business Director, Health Care Markets UK and Ireland, 3M Health Care Ltd

Peter Ellingworth

Chief Executive

Mike Kreuzer, OBE

Executive Director, Technical and Regulatory

Andy Taylor

Executive Director, Healthcare Policy

Paul Benton

Director, Commercial and International

Clive Powell

Technical and Regulatory Manager

Nishan Sunthares

Commercial and Market Access Manager

Judith Mellis

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Daniel Jones

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Angela Jeffery

PA to Chief Executive and Membership Development Manager

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Accounts Administrator

Ian Cranston

Accountant and Company Secretary

Andy Vaughan

Consultant, Standards

Oliver Wells

Consultant, Research and Innovation

Steve Cook

Consultant, Research and Innovation

Members

3M Health Care

A A Algeo Ltd
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Anetic Aid Ltd
AngioDynamics UK Ltd
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Arjo Huntleigh, Akron Products Division
Arjo Huntleigh, Diagnostic Products Division
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Compliance Hub/Wellards Partnership 2011
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Corin Ltd
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t/a G&N Medical
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O'Mara Medical Supplies
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Ortho Solutions Ltd
Orthovita UK Ltd
Owen Mumford Ltd

P P3 Medical Ltd
Pall Medical
Pan Globus Ltd
Parburch Medical Developments Ltd
PDI Europe
Pennine Healthcare

Pfizer Consumer Healthcare Ltd
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Proplink Medical (Europe) Ltd
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Q Quanta Fluid Solutions Ltd
Quintiles Consulting
Quotec Ltd

R Rayner Intraocular Lenses Ltd
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Renishaw Plc
Richard Wolf UK Ltd
Roberts Surgical Healthcare Ltd
RSA Group
Ruston Poole International Plc

S S Murray & Co Ltd
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SDMA
SGS United Kingdom Ltd
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Sorin Group (UK) Ltd
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Symmetry Medical
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Systagenix Wound Management International Ltd

T Tangram Medical Technology Consulting Ltd
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Terumo UK Ltd
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Tornier UK Ltd
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V Verathon Medical
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X Xiros Ltd
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