



Association of the
British
Pharmaceutical
Industry

Annual Review
2010/11



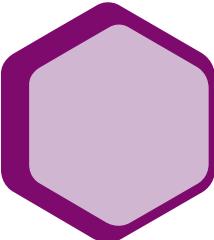


The Association of the British Pharmaceutical Industry (ABPI) represents research-based pharmaceutical companies of all sizes in the UK. The UK pharmaceutical industry is a world leader in the discovery and development of vital new medicines which result in better health for patients here and in other countries, as well as a major contributor to the UK economy.



Our members include the majority of research-based pharmaceutical companies operating in the UK, both large and small. They research, develop, manufacture and supply more than 80 per cent by value of the medicines prescribed through the National Health Service. Our Research Affiliate Members are involved primarily in pharmaceutical research and development, while General Affiliate Members are organisations with an interest in the pharmaceutical industry operating in the UK.

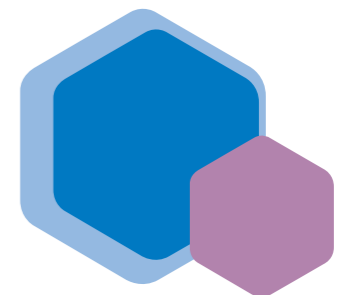
We provide a wide scope of services and support for our members and we represent the views of the pharmaceutical industry in England, Scotland, Wales and Northern Ireland as well as at UK, European and international levels. We maintain close contact with governments, politicians, policy makers, academia and the media and also have extensive links with health managers, patient groups, training and education bodies, research councils and other professional bodies in the healthcare field.



You can find out more about how the pharmaceutical industry benefits patients and delivers growth for the UK economy in [The Value of Industry](#) on our website www.abpi.org.uk

Our mission

We bring together the research-based UK pharmaceutical industry, presenting a compelling single voice founded on a shared understanding with stakeholders, focused on delivering more effective healthcare to benefit patients, the NHS and our members.



This review highlights our achievements and main activities over the last year.

We are delighted that substantial progress has been made against our 2010 objectives. This gives us a very solid foundation for the year ahead, which will be one of significant further change for both industry and the health service.



Simon Jose
President

The last year has seen a very different landscape emerge for all those involved in developing and delivering medicines and healthcare in the UK. Following the election, we have new Ministers and Members in Westminster, the Government has embarked on an ambitious deficit reduction plan and the Health Secretary has begun the most significant reforms to the health service since the 1980s.

The pharmaceutical industry has welcomed the opportunity for regular dialogue with the new Government and we particularly welcome the continuation of the key joint strategic forums: the Ministerial Industry Strategy Group and the Office for Life Sciences. We look forward to continuing to work closely together, especially in negotiating a new, evolved pricing agreement from 2014.

The ABPI has been on its own journey of change. We have made excellent progress in building our organisation to face the challenges ahead in today's dynamic climate. Our work on the environment for innovation, improving the use of innovative medicines and hence the quality of outcomes for patients, and the pricing of medicines has made a significant impact on policy development, not least on the 2011 Budget. Within ABPI we have focused on strengthening our capacity to

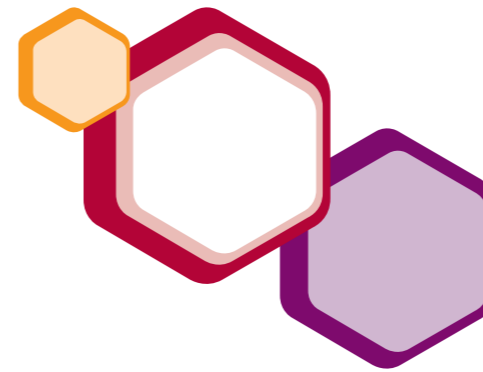
engage with our key partners and our wide membership with a new website, more strategic corporate communications, new member services, a strengthened commercial team and a move into modern new premises.

Over 2010 we made excellent progress towards transforming our relationship with the medical profession by working closely with the Royal Colleges and other medical organisations to increase the transparency of our relationships.

We do not believe that any doctor ever prescribed a medicine because of a branded pen, but both industry and the medical profession agree that practices such as giving branded materials to medical professionals are inconsistent with the level of trust, confidence and professionalism we expect of ourselves. We are looking forward to continuing this important work in the coming year.

I want to thank Dr Richard Barker, who steps down as Director General this year after six years. Richard's commitment and personal contribution to our collective achievements has been outstanding and he leaves us knowing that we will build on his legacy.

I am delighted that the new Chief Executive, Stephen Whitehead joins us on 1 June.



Dr Richard Barker
Director General

This will be my last review as ABPI's Director General and I can safely say that the last year has been one of the most eventful. I am extremely proud of what we have accomplished for our members and critically, what the pharmaceutical industry is achieving every day for patients across England, Northern Ireland, Scotland and Wales.

We have captured industry's value to patients, healthcare and the UK economy in a special report on our new website, 'The Value of Industry' and I hope that you find it useful. In the recent growth review, we have seen the fruition of several initiatives under the Office for Life Sciences, which now plays such a key role, and Life Sciences UK, ensuring that the different industry groups speak as one voice on key issues.

Of particular concern this year has been the supply shortage of some prescription medicines as low prices in the UK encourage the practice of selling abroad by others in the supply chain. Industry has done all it can to ensure that patients can obtain the medicines that have been prescribed for them and is supplying the UK with more than sufficient stocks. We welcomed the new practice guidelines as a positive step forward and look forward to firm action from Government.

Our industry works hard to shape the development of conditions for economic growth and constantly strives to find new



ways to innovate and develop new drugs. We are experiencing a fundamental shift towards greater partnership working between major pharmaceutical companies, SMEs, academia and the NHS and into something that resembles an innovation ecosystem. As the NHS changes, we will have to work closely with its new structures to ensure that one of the key drivers is improving the uptake of new and improved medicines and ensuring that patients get the treatment they need.

On a personal note, it's been a great privilege and (most days) a real pleasure to lead the ABPI through the fast-changing health and industry environment over the last six years. Our members are engaged in one of the world's toughest, noblest and most important challenges – bringing new medicines to change the lives of patients. Our efforts have started to reposition the industry as a partner with Governments and the NHS, so that the ABPI is seen not only as a robust voice for the industry but also as a co-developer of the health system of the future.

Internally, we have a new executive team, new ways of working with members, a new financial robustness, a new website, a new London office and I believe a very sound basis on which the team and the new CEO can build. Since change will no doubt continue apace, I wish them well as they do so.

Delivering for our members

We represent the pharmaceutical industry in the UK in a way that seeks to improve patients' access to the best available medicines and creates a favourable political and economic environment for growth in life sciences. We work to encourage innovative research and development in a system which affords fair commercial returns.

In partnership with our members we work collaboratively with the policy makers in health and business departments to ensure the right research and commercial environment exists to enable the pharmaceutical industry to continue to bring new medicines to patients.

Our members welcomed the 2011 Budget and Growth Review announcements on facilitating and streamlining the processes for clinical trials, the Patent Box, corporation tax changes, developing our future workforce and reviewing the diffusion of innovation in the NHS. Our strength in representing industry on these issues comes directly from our members who make an invaluable contribution through working groups, expert opinions, consultation responses and surveys. We thank them for their time, expertise and perspectives.

Working in partnership with our members, we submitted formal responses to several Government consultations including the NHS White Paper, the Health Bill, Migration, the Growth Review, Cancer Drugs Fund, Value Based Pricing and the Bribery Act. We provided substantive input to the Academy of Medical Sciences Review of Clinical Trial Regulation. We also provided information and research to support members' own submissions.

Representing the views of industry

Over the year, we represented members' views to Government in scores of ways, including these channels:

- Office for Life Sciences
- Ministerial Industry Strategy Group
- Medicines Access Group
- The Better Regulations of Medicines Initiative
- Implementation of the 2009 Pharmaceutical Price Regulation Scheme
- The horizon scanning database, PharmaScan
- Publication of national and international metrics of patient access to innovative medicines
- The Research Capability Programme
- The Office for Strategic Co-ordination of Health Research Strategic Co-ordination Group
- All Wales Medicines Strategy Group
- All Wales Prescribing Advisory Group
- BCUHB D&T Committee, National Institute for Social Care and Health Research Steering Group
- Health and Social Care Board (Northern Ireland) Medicines Management Forum
- Scottish Medicines Consortium
- Patient Access Scheme Advisory Group
- Life Sciences Advisory Board
- Department of Health/Life Science Innovation Delivery Board
- Patient Access Scheme Liaison Unit
- Supply Shortages Forum
- NHS Homecare Review
- QIPP Partnership Group



We work with a wide range of stakeholders in the UK and globally including trade associations and the new joint body Life Sciences UK, professional societies, charities, research councils and regulators, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers Association (IFPMA).

Looking after members across the UK

In Scotland, Wales and Northern Ireland we continue to provide our members with a full update and comprehensive interpretation service on the evolving health service.

Our Smaller Companies Forum members benefitted from a monitoring service on Government Affairs and a workshop on counterfeit medicines amongst other initiatives.

A programme to support smaller companies has been initiated by our new senior staff member with responsibility for members.



Aware of the importance of joint working with the NHS for our members and the industry, we have provided project management, legal advice and contractual scrutiny for critical collaborative projects such as PharmaScan and the PPRS Dispute Panel. All the members of the PPRS scheme were invited to a workshop on critical issues in the NHS such as value based pricing.

All our members had access to information and research through our member Extranet. We also instigated monthly environment reports and the weekly *News Flash* update.

We continued our annual survey with members to see what is working well and where we can improve our services. The results show we continue to improve on what our members already think is excellent; and we will strive to improve our scores still further, especially in communications and understanding our members' business needs.

Developing our members' workforce

We maintained the ABPI examination for representatives so that our members' sales forces can uphold high professional standards including knowledge of the Code of Practice.

We promoted careers with industry and offered our members the opportunity to have direct links to where they advertise vacancies on our careers website. Our schools website continued to provide teachers and students with vital, balanced information of what the industry is and does.

Practical support for members

On behalf of members, we managed campaign teams and standing groups, facilitated play-to-play groups, and task and finish groups.

As a city centre organisation we were able to provide meeting space for our members in London, Edinburgh and Cardiff.



Our objectives

We set ourselves a number of demanding organisational and strategic objectives for the last year and can report that we have made very good progress.

Top level organisational objectives for 2010

- [Secure commitment to Health Technology Assessment \(HTA\) reform and agree principles for future PPRS](#)

As part of constructive dialogue with DH on value based pricing, the Government has set out its key principles. These include an expansion of how the value of a healthcare technology is assessed, which was an issue very high on industry's agenda. We were pleased to see confirmation from Earl Howe that the Government holds to the current PPRS and also to co-creating the shape of the future system.

- [Maintain momentum for Office for Life Sciences](#)

We maintained momentum for the Office for Life Sciences during the transition from Lord Drayson's stewardship to that of the new Government, with David Willetts as Science Minister and Earl Howe as Health Minister. This paved the way to many valuable advances including the Patent Box and the contents of the 2011 Growth Review.

- [Improve smaller member company engagement](#)

We exist to support and represent research-based companies of all sizes and stages of development.

The Smaller Companies Forum has been engaging its membership in new ways. We undertook a comprehensive review of what smaller companies want and need from their membership of ABPI. This included discussion of several specific new initiatives, such as training days on the PPRS, introduction of succinct briefing notes on key issues, and consideration of developing model SOPs on important processes. We also introduced a new series of internal and external speakers at meetings of the Smaller Companies Forum. The recruitment of a senior staff member to support the wide range of our members has already resulted in increased membership numbers.

- [Resolve pension deficit, agree forward ABPI financing](#)

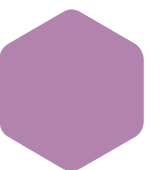
An agreement on resolving our pension deficit has enabled us to move forward on a firmer financial standing. We are grateful for all the support our members have provided to secure resolution of pension fund commitments and challenges.

- [Modernise ABPI systems and facilities](#)

We have modernised our systems and facilities, launched a new website and are shortly moving to new offices.

- [Bring Life Science trade associations together](#)

Life Sciences UK, launched with the BIA, ABHI and BIVDA is helping to provide a united voice for the life sciences industry, particularly in dialogue with the Government, and has been warmly welcomed by Ministers of both past and current Governments.



Value

We said we would:

- **Strengthen** input to HTA debate
- **Secure** commitment to HTA reform such that the UK is an environment that champions innovation
- **Retain** the PPRS and agree principles for future evolution
- **Implement** the Innovation Pass
- **Launch** the Value of Industry campaign
- **Engage** with the NHS QIPP programme (Quality, Innovation, Productivity and Prevention) to improve the quality of prescribing
- **Engage** stakeholders and generate third party support for industry's agenda



We achieved:

- ✓ The new Government confirmed its **commitment to honour the 2009 PPRS agreement** for its full intended term to end 2013. This provides much-needed certainty and stability while discussions continue to take place on the principles of a new pricing and reimbursement agreement that will incorporate greater elements of value based pricing. ABPI is the industry body recognised by the Secretary of State to negotiate with DH, under the terms of the National Health Service Act 2006
- ✓ Commitment to the **reform of NICE** was secured, including recognition that access to medicines is a major issue for the UK
- ✓ The Value Based Pricing consultation stated that **improved access** is one of its objectives. We responded to the Government's consultation on the successor to the Innovation Pass – the Cancer Drugs Fund – to support its successful implementation
- ✓ The Value of Industry campaign was launched, aimed at politicians, policy makers and the media with two reports highlighting the pharmaceutical industry's **contribution to the health and growth of the economy** in the UK
- ✓ An updated 'Did you know?' booklet summarised key facts about the **value of the industry** to the UK and was widely circulated
- ✓ We **met the challenge of QIPP** and gained agreement to the need for the NHS to implement prescribing indicators, such as 'Better Care Better Value', in a more balanced way and not to drive prescribing practices beyond NICE guidelines
- ✓ The opportunity of QIPP was further utilised by **increasing awareness of joint working case studies** that demonstrate the value of medicines in driving better outcomes and quality care, often with efficiency gains
- ✓ We built on relationships with key stakeholders including NICE, patient organisations and NHS leadership to generate **support for patient access to valued medicines**. Through the OLS, we gained agreement to the Life Science Innovation Delivery Board and played a key role in shaping the plan for the Board, one of the aims of which is to drive innovation uptake in the NHS



Innovation

We said we would:

- **Launch** the UK Life Sciences Superclusters, with the first two therapeutic capability clusters in immunology and inflammation
- **Implement** recommendations of Skills Needs for Biomedical Research report
- **Ensure** that the Industry and Higher Education Forum and the Bioscience Skills Board deliver industry's skills and put courses in place addressing critical areas identified by industry
- **Create** a positive environment for experimental medicine and early clinical research
- **Support** the Technology Strategy Board in launching an Innovation Platform in personalised medicine



We achieved:

- ✓ The Life Sciences Super Cluster has begun to take shape, with **therapeutic capability clusters** launched for both joint and lung inflammatory disease – these will now transform into Translational Medicine Networks under NIHR
- ✓ We are moving into a new world of **academic-industry collaboration** through the formation of £11m Medical Research Council–ABPI research consortia in chronic obstructive pulmonary disease and rheumatoid arthritis
- ✓ Key recommendations of ABPI's 2008 Skills Needs for Biomedical Research report have been implemented, including the **development of an accreditation framework** for undergraduate bioscience courses
- ✓ The Technology Strategy Board launched the £50m **Stratified Medicines Innovation Platform** and opened its first competitions worth around £11m in January 2011 and in addition Phase 2 funding has been agreed for the **public-private partnership** Stem Cells for Safer Medicines
- ✓ We worked closely with the Academy of Medical Sciences and responded to its Review of the Regulation and Governance of Health Research, to **improve the environment for clinical research** in the UK, with our position positively reflected in the final AMS Report recommendations published in January 2011
- ✓ We produced guidance for our members on demonstrating value with **Real World Data** to provide clarity around the definitions, use and practical issues which arise when undertaking Real World Data projects; and a Blue Print document to describe why the UK can be a global centre of excellence in demonstrating the value of new medicines
- ✓ We responded to the Government consultation on the Patent Box and R&D tax credit system and to the Advanced Manufacturing Growth Review making recommendations for actions to **encourage future investment in R&D** and manufacturing in the UK
- ✓ Overall, 30 out of 31 of the recommendations our members made for the Growth Review were **included in the Budget 2011**, including key asks on fiscal incentives, clinical trials, education and uptake of innovative medicines



Trust

We said we would:

- **Place** UK industry in a world-leading position on transparency
- **Deliver** detailed proposals for inclusion in the 2011 Code of Practice revision on greater transparency of industry support for education, training and meetings and relationships with external stakeholders
- **Develop** our understanding of stakeholder views and perceptions through a snapshot reputational survey repeated annually to act as a metric for the Trust Imperative
- **Establish** a workstream on 'Transparency in research' to deliver a UK industry position paper to EFPIA by the end of 2010 on best practice in research data sharing
- **Build** on existing progress to support and develop senior level partnering opportunities between industry and develop a platform for increased joint working projects



Changes to the ABPI Code of Practice from 1st January 2011

The industry will no longer provide branded promotional aids, such as pens, pads and mugs, to health professionals.

From 2012, companies will be required to collect and declare, on an annual basis, aggregate total amounts paid to health professionals and others for certain services such as speaker fees and participation in advisory boards. Similarly companies will be required to declare sponsorship for attendance at meetings organised by third parties. The first declaration of payments will be in 2013 for payments made in 2012. The Code does not require individual health professionals to be named but does require the total number of health professionals involved to be declared and the total number of meeting attendances sponsored.

We achieved:

- ✓ After **detailed member consultation**, members supported recommendations from the Trust Imperative on transparency in external relationships and ceasing the provision of branded promotional aids for health professionals
- ✓ We **amended the ABPI Code of Practice** to incorporate the new ways of working
- ✓ External partnerships with organisations like the Royal College of Physicians were created based on **shared responsibility and partnership** in evolving the relationship between industry and its stakeholders
- ✓ Together with the medical Royal Colleges and other health organisations, we issued a **joint statement supporting the changes to the Code of Practice**, which was widely circulated to health professionals and members
- ✓ We developed the UK industry reputation tracking model in partnership with the Reputation Institute which acts as a metric for the ongoing trust work and **provides a deep understanding of the drivers of reputation** across industry stakeholders
- ✓ We made a **significant contribution to the European industry advocacy** on the development of the Falsified Medicines Directive
- ✓ At both UK and European levels, we worked to present industry positions on a number of issues relating to **environmental legislation** affecting the development and manufacture of medicinal products



Access

We said we would:

- **Establish** international uptake metrics and improve national uptake metrics
- **Elevate** joint partnership working to a national scale, utilising the QIPP opportunity
- **Implement** outstanding PPRS commitments
- **Complete** ongoing joint working projects and drive new opportunities
- **Deliver** a live horizon scanning database. Ensure companies have entered their pipeline information

We achieved:

- ✓ We **expanded joint working** with the NHS significantly in pursuit of our aim to make this a national-scale initiative and developed an improved toolkit in conjunction with the Department of Health
- ✓ The **implementation of outstanding PPRS** commitments was achieved, including working with the NHS to improve national uptake metrics through the publication of benchmarks, and establishing international uptake metrics
- ✓ UK PharmaScan, the **horizon scanning database** of the industry's pipeline, was made available to NHS users and will help the NHS to plan ahead for the provision of new medicines to patients



The Office of Health Economics

The Office of Health Economics (OHE) has supported the ABPI with advice, both proactive and reactive, on the major economics-related policy issues in healthcare and the pharmaceutical industry throughout the past year. OHE's research is designed to shape and inform debate about policy relevant to healthcare and the life sciences industry. OHE's research activities are expanding, with increased numbers of peer-reviewed research publications including journal articles, and increased numbers of conferences, seminars and workshops organised and/or presented at to disseminate its research and advance the policy discussions.

The OHE has provided detailed analyses, briefing and advice to the ABPI on evidence about the possible impact of the NHS reforms proposed in the July 2010 Department of Health White Paper – Equity and Excellence: Liberating the NHS.

OHE worked hard over the last year on improved ways of prioritising spending on medicines and other healthcare technologies, known as multi-criteria decision analysis (MCDA). This anticipated the relevance of MCDA to key policy developments, most notably the design of value based pricing for branded medicines proposed by the Government to replace PPRS in 2014, and also to the new NHS Advisory Group for National Specialised Services (AGNSS). This stream of work is continuing, but the summation of it so far was published as an OHE monograph in March 2011.

New approaches to health state valuation developed in research undertaken at OHE in 2010 by Nancy Devlin and Koonal Shah, funded by a Department of Health Policy Research Programme grant, are now being used in eight countries. This is a key element to how the outcomes for patients of healthcare are measured. OHE has continued through 2010/11 to support the Department of Health in ensuring that its landmark patient-reported outcomes measures (PROMs) programme is a success via OHE's ongoing research and advisory roles. This included, in 2010, input to innovative research on the use of PROMs data in measuring hospital productivity, and to the development of case mix adjustment.

A grant from a consortium of 13 British pharmaceutical companies enabled the OHE to research the role of cost effectiveness and other factors on NICE decisions using logistic regression models. This has been completed and submitted for publication in a peer-reviewed journal. It demonstrates empirically the dominant role of incremental cost per QALY in influencing NICE's recommendations about which medicines and other health technologies to recommend for use in the NHS.

The OHE organised several seminars and workshops. Professor Iain Cockburn of the US National Bureau of Economic Research led an OHE seminar with new evidence on the changing geographical allocation internationally of clinical trials. A workshop was held with major public sector, policy, industry and venture capital stakeholders on the way that publicly funded medical research stimulate private sector R&D and vice versa.



ABPI Board of Management 2010/2011

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Lundbeck Ltd

The Senior Leadership Team of the ABPI

Dr Richard Barker

Director General

Amanda Callaghan (from 2011)

Director of Corporate Communications

Alison Clough

Director of Commercial (and
Communications 2010)

Paul Evans

Director of Finance

Dr Rick Greville

Director of ABPI Cymru Wales and
Northern Ireland

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Professor Adrian Towse

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Simmons & Simmons Limited
Star Medical Ltd
Taylor Wessing LLP
TFI Group Ltd
Trinity Conferences Limited
Virgo Health PR Ltd
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Zibrant

The ABPI, supporting you

The ABPI Innovation Board's Real World Data Campaign has been tasked with appraising the UK's strengths in demonstrating the value of medicines using Real World data. Real World data is obtained by any non-interventional methodology that describes what is happening in normal clinical practice. The campaign recognises that data about patients' use of medicines in normal clinical practice, or in settings which reflect the reality of healthcare delivery, is becoming increasingly important in decisions affecting patients' access to medicines in the UK.

We are supporting industry with more detailed guidance on definitions, use and practical issues surrounding the conduct of Real World data studies and have covered these topics in this new guidance. It draws on the expertise of companies and individuals to produce a practical guide for research and development, marketing, commercial and health outcomes colleagues, and can also be used as a reference guide for other allied colleagues within industry.

Demonstrating value with Real World data: A practical guide is available to download from our website www.abpi.org.uk

New
publication



We will be running training and discussion events which will be advertised on our website.

For more information about the ABPI and its related organisations, visit our websites:

ABPI

www.abpi.org.uk

Office of Health Economics

www.ohe.org

Prescription Medicines Code of Practice Authority

www.pmcpcpa.org.uk

Information about careers in the pharmaceutical industry

www.abpicareers.org.uk

Information for teachers and students

www.abpischools.org.uk

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