abpi

Bringing medicines to *life*

Annual Review *2012*

The Association of the British Pharmaceutical Industry

What the ABPI does for its members

The ABPI represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK.

- The ABPI brings companies together to provide a strong voice on your behalf, ensuring you are heard in the corridors of power and on the airwaves.
- The ABPI ensures that the pharmaceutical industry is recognised as a key sector for the UK economy, improving companies' access to decision-makers and placing our issues high on the agenda.
- The ABPI is a strong advocate at the heart of policy development and decision-making to improve the commercial, operational and investment environment for our members.
- The ABPI is the sole body recognised under statute to negotiate pricing with government on behalf of members and non-members. As part of this, we work hard to unite the industry, giving the best chance of a satisfactory outcome.
- The ABPI builds the industry's reputation by promoting the value of medicines and taking targeted action on issues that affect society's and healthcare professionals' perceptions of our industry.
- The ABPI provides high-level networking opportunities within the industry and across government, the NHS and regulators.
- The ABPI keeps members informed and up-to-date with policy briefings and updates, supporting your engagement at the highest levels on all the key issues.

We represent research-based companies on a wide range of issues, advocating on your behalf with key stakeholders and securing policy changes:

- Patient access to innovative medicines
- The operation of Health Technology Assessment (HTA) throughout the UK including NICE in England, Scottish Medicines Consortium (SMC) in Scotland and All Wales Medicines Strategy Group (AWMSG) in Wales
- The value and pricing of innovative medicines
- Purchasing behaviour within the NHS
- Market freedoms including the supply of medicines
- Regulatory affairs
- Pharmacovigilance
- Prescribing guidance to healthcare professionals
- Joint working between companies and the NHS
- NHS commissioning
- Medical affairs and patient outcomes
- Taxation
- Open innovation
- Clinical research including real world data, ehealth and clinical trials
- The operation of Pharmaceutical Price Regulation Scheme (PPRS) 2009
- Education & skills
- Manufacturing and product quality
- Animal research.

Strategic priorities and highlights for 2012

Improving patient access and uptake of medicines

- Significant wins on formularies, NICE Implementation Collaborative (NIC) and the Innovation Scorecard through *Innovation health* and *wealth* (IHW) implementation, support uptake agenda
- Launch of the ABPI Regional Partnerships Team to address local barriers to uptake
- General Medical Council (GMC) agreement to retain unchanged its prescribing guidance for unlicensed medicines

Building reputation and strengthening relationships

- Represented industry in the clinical trial transparency debate
- Progressed disclosure of payments to healthcare professionals
- Shifted debate on medicine supply shortages, protecting industry reputation
- Established new patient group forum, facilitating improved dialogue

Securing a broader definition of value and preparing for negotiation

- United the industry on common priorities in preparation for pricing negotiations
- Secured agreement with NICE and the Department of Health for discussions on industry issues with appraisals

Improving the environment for research and development

- The Translational Research Partnerships, proposed by the ABPI, signed first three projects to advance collaborative research in respiratory and inflammatory joint disease
- Seventy-day set up target to recruit first patient in clinical trials, supported by the ABPI, is enshrined in National Institute for Health Research (NIHR) Clinical Research Network (CRN) contracts to drive NHS performance in clinical research
- Launch of Clinical Practice Research Datalink (CPRD) reflects industry requirements set out by the ABPI
- Led dialogue with operators on the transportation of animals and co-created *Concordat for openness in animal research* across bioscience stakeholders

Providing value for members

- Recruited 17 new members
- Created new CEO and Finance Director Forums
- Revised fee structure to support the growth of companies with sales under £10 million

1891 The ABPI's heritage stretches back to 1891 when it was first established as the Drug Club in London, founded for wholesale druggists

Foreword from ABPI CEO Stephen Whitehead

As we entered 2012, the biopharmaceutical industry faced huge pressures with an environment characterised by austerity, the patent cliff biting ever harder and further job losses. In March, the Health and Social Care Act 2012 was passed, marking the beginning of the most dramatic changes to the NHS in England in its 65-year history.

In this challenging environment we recognised the need for a step-change in the ABPI's capability – across membership, advocacy and policy – to meet our members' changing needs. Our overarching focus is in the key areas of value and partnership. The value of our medicines to patients and the healthcare system, and the value of the research and development (R&D) invested in future healthcare, are realised through the adoption and diffusion of these innovative medicines in the NHS. To deliver this value, we need to work in partnership with all stakeholders across government, the NHS and patients in England, Scotland, Wales and Northern Ireland.

The ABPI was significantly strengthened in 2012. I am delighted to report we recruited an unprecedented 17 new members last year, and feedback from the 2012 member survey showed the ABPI going from strength to strength, with higher than ever levels of member satisfaction.

A decisive moment in 2012 was the start of the pricing negotiations with the Department of Health, encompassing both the next PPRS and the proposed value based pricing scheme. The backdrop of continued austerity together with the proposed inclusion of value based pricing makes these negotiations the most complex and challenging we have ever faced as an industry. In recognition of this we made a significant investment last year to unite the industry around common priorities to put us in the best possible negotiating position.

I am proud of the way the ABPI team rose to the challenges in 2012 on behalf of our members, and there were many achievements during the year which are highlighted in this review. I would however like to mention a few examples including our work with the supply chain, establishment of Translational Research Partnerships and the launch of the Clinical Practice Research Datalink.

I have always believed that effective partnership is critical in progressing our agenda and nowhere was this more evident, in 2012, than in our collaboration with the Department of Health and NHS in shaping the implementation of IHW. In April last year we announced our new Regional Partnerships Team to drive uptake of innovative medicines locally and I am pleased with the excellent progress the team has made in building the foundations for innovative joint working initiatives. Partnership is also at the heart of our work to protect and build the industry's reputation. This includes our work through the Ethical Standards in Health and Life Sciences Group (ESHLSG) to progress disclosure of payments to healthcare professionals, as well as our extensive engagement with stakeholders to address issues around clinical trial transparency.

While good progress was made in 2012, I am in no doubt that there are many challenges ahead and we cannot afford to be complacent. We must continue to demonstrate industry's commitment to transparency. We need to translate our partnership work with the NHS into tangible benefits for patients. Vitally, through both the pricing negotiations and dialogue with NICE, we need to ensure that the value of innovative medicines is recognised and rewarded, and the adoption of new medicines is accelerated to meet patient need.

The bio-pharmaceutical industry in the UK is at a crucial moment, and I am committed to ensuring that the ABPI is at the heart of shaping the future to the benefit of our patients and our industry.

Stephen Whitehead
Chief Executive Officer

Foreword from ABPI President Deepak Khanna

2012 was a year of substantial change in our environment and significant challenges that will shape our industry for years to come. Most importantly, in 2012 we saw the beginning of crucial pricing negotiations which will have an enormous bearing on the UK environment for our members and have been a key focus for the ABPI.

Sweeping NHS reforms, continued austerity and a changing cast of NHS and Department of Health leadership have formed a complex backdrop for members.

In this challenging environment, the ABPI set out to drive value for members, engage with the new NHS and shape policies affecting our members. I am particularly proud of our innovative partnership with the NHS and the Department of Health in implementing IHW, work which we need to see continue under the stewardship of NHS England (formerly the NHS Commissioning Board).

Key to our work in 2012 was preparing for and entering into pricing negotiations with the Government. It was particularly important to align the industry and, through our consultation, I was pleased to see that companies of all sizes and types shared common ground on the key issues.

Industry reputation has also been under scrutiny like never before. In May last year, the ESHLSG, which I co-chair with Sir Richard Thompson of the Royal College of Physicians, launched *Clinical Trials Principles and Facts* to help drive best practice in clinical research reporting. The debate on clinical trials transparency gathered pace at the end of last year and the ABPI worked hard to represent the industry in the media, in Parliament and in stakeholder forums.

The coming year brings with it a number of catalysts for yet further significant change in our environment. The pricing negotiations will be crucial, NICE's role is evolving and there are many more key recommendations of IHW yet to be implemented.

We remain committed to continually improve our service to members and to speak with a strong and unified voice on behalf of the research-based pharmaceutical industry.

Deepak Khanna
President

2012 Review of the year

January

First meeting of Innovation Health and Wealth Implementation Board

ABPI at the table to represent industry and gained agreement for industry representation on all priority Task and Finish groups to shape the future delivery of key recommendations.

February

11th Pharmaceutical Price Regulation Scheme Report

ABPI drives UK low prices messaging, framing the public debate on medicines prices.

March

2012 Budget

Introduction of the patent box and an above-the-line R&D tax credit confirmed by the Chancellor, Rt Hon George Osborne MP, following industry advocacy.

New executives appointed to the NHS Commissioning Board

ABPI engages early to build relationships and secure on-going commitment to the delivery of IHW.

Health and Social Care Act 2012 is passed

ABPI establishes its Regional Partnerships Team as a strategic response to the structural changes in the NHS.

European Commission proposes revised Transparency Directive, laying down requirements to ensure the transparency of pricing and reimbursement measures adopted by Member States

ABPI engages with European partners to ensure patients' needs continue to be met against a backdrop of austerity.

April

Launch of the Clinical Practice Research Datalink (CPRD)

ABPI engaged before and after the launch to convey industry requirements of this new resource.

June

Then Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon MSP launches *Health and Wealth In Scotland: A Statement of Intent for Innovation in Health*

Launch welcomed by ABPI Scotland.

Department of Health reveals process for establishing Academic Health and Science Networks (AHSNs)

Dialogue with Department of Health ensures clear role of AHSNs in innovation and wealth creation and an ABPI role on interview panel for AHSN applications.

July

NICE positioned to take over the work of the Advisory Group for National Specialised Services on assessing high cost, low volume medicines

ABPI drives parliamentary outreach ahead of a debate in the House of Commons.

The Medicines and Healthcare products Regulatory Agency (MHRA) launches consultation on proposals for an Early Access to Medicines Scheme

ABPI champions industry concept of early access to medicines with the MHRA and coordinates industry response to consultation.

The European Commission publishes draft legislation on Clinical Trials

ABPI works with academic and charitable stakeholders in the UK to agree a joint healthcare professional and industry view on the issue and with European Federation of Pharmaceutical Industries and Association (EFPIA) to ensure strong representation in Europe.

July

The European Council agreed a single unitary patent valid in up to 25 European countries

ABPI represents industry concerns to the UK Government in advance of key European negotiating meetings.

August

Progress report on Strategy for UK Life Sciences Strategy published by Government

ABPI calls for greater urgency in delivering actions at a local level across the NHS.

September

Rt Hon Jeremy Hunt MP becomes Secretary of State for Health

ABPI acts swiftly to engage with the new Secretary of State, raising awareness of critical industry issues.

Scottish Parliament's Health & Sport Committee holds inquiry on availability of new medicines in NHS Scotland and the Individual Patient Treatment Request process

ABPI provides evidence advocating improved patient access and Scottish Government announces a review of systems for making new medicines available.

Bad Pharma published

ABPI represents the industry, in a highly charged debate, driving messages about commitment to transparency and the continuing work with all stakeholders to address the complex issue of clinical trial disclosure.

October

Formal meetings begin with the Department of Health to negotiate the pricing environment in the UK post-2014

ABPI enters negotiations having united the industry on common priorities.

Introduction of Wales Patient Access Schemes

Culmination of ABPI engagement with Welsh Government and All Wales Medicines Strategy Group.

November

Department of Health publishes the Mandate for the NHS Commissioning Board

ABPI engages with the Department of Health to ensure commitments supporting research, innovation and economic growth are prominent in the Mandate.

Health Committee inquiry on NICE

ABPI CEO Stephen Whitehead gives oral evidence reinforcing the industry's position on HTA processes and NICE's future role in addressing patient access and value of medicines.

Consultation begins on the NHS Constitution

ABPI calls for patient care plans to include specific reference to medicines and for all patients to have access to new medicines within 90 days of their approval by NICE.

THE NHS CONSTITUTION
the NHS belongs to us all

IMS commentary on NHS Information Centre national metrics report *Use of NICE appraised medicines in the NHS in England* published, showing that patients are still struggling to access NICE recommended medicines

ABPI continues to drive hard hitting patient access messages.

December

Government publishes Strategy for UK Life Sciences One Year On update

ABPI engages with the Prime Minister, Chancellor and other ministers, reinforcing the need to ensure momentum is maintained.

Office for Life Sciences

Improving patient access to, and uptake of, innovative medicines

With the UK among the worst performers in Europe in the uptake of new medicines, ensuring real progress in getting the right medicines to the right patients at the right time remains a key priority.

Implementation of IHW

Following the publication of IHW[1] at the end of 2011 which was co-created with industry, ABPI CEO Stephen Whitehead was appointed to the IHW Implementation Board alongside senior NHS representatives.

The ABPI also facilitated a number of industry secondees into the Department of Health as part of an integrated team supporting the implementation of IHW.

Crucially, we secured industry representation on IHW Task & Finish Groups established to deliver the key recommendations of the report. Supported by the ABPI, industry representatives have been able to help shape the development of critical initiatives launched under IHW.

Industry participation in IHW Task & Finish Groups

- NICE Implementation Collaborative
- Formularies
- Innovation scorecard
- Academic Health Science Networks (AHSNs)
- Aligning incentives
- Never events' regime and disinvestment
- Specialised Services Commissioning Innovation Fund
- NHS Intellectual Property Strategy
- Educational and training
- Joint industry and NHS training
- NHS Innovation Fellowship Scheme
- Leadership and accountability

While we are clear that momentum needs to continue to ensure real change on the ground, a number of important outcomes were achieved in 2012 including:

- A clear message from the NHS Chief Executive and the Chief Pharmaceutical Officer on the requirement to automatically include NICE recommended medicines on formularies, which must be published.
- Ensuring that the first Innovation Scorecard included a good range of medicines, with agreement to further develop a second version of the scorecard.
- Progressing the medicine-focussed NICE Implementation Collaborative (NIC) pilots, which are now the most advanced of all the NIC pilots.
- Securing a seat on the interview panel for AHSNs, enabling us to help shape how they will drive innovation in the NHS.

The NHS Innovation Scorecard highlights areas of England where patients are unable to access medicines, enabling industry to work with the NHS to address barriers to patient access in those areas.

During the first year of IHW, the ABPI also supported the communication of IHW, raising awareness of the key recommendations that local NHS organisations would be expected to implement.

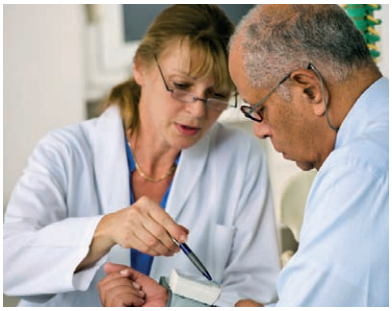
This included a NICE formulary good practice guide for the NHS as well as a series of workshops on the implementation of local formularies guidance.

Looking ahead, we will continue to drive progress on the implementation of IHW recommendations and lead the industry's engagement with NHS England (formerly the NHS Commissioning Board).

ABPI Regional Partnerships Team

As a strategic response to the NHS reforms in England – and the increasing importance of local structures – in 2012 the ABPI began investing in building a new partnerships team to work with members and the NHS, to help identify joint working opportunities and remove barriers to patient access to innovative medicines. With the resource now fully established, we look forward to reporting on the impact of this strategic initiative in 2013.

[1] Department of Health, *Innovation Health and Wealth: Accelerating adoption and diffusion in the NHS*, 5 December 2011



Innovation, health and wealth made clear that the spread and adoption of innovative practice at pace and scale in the NHS is vital if we want to deliver a better service and better outcomes for patients. The journey from co-creation to implementation of IHW has been an excellent example of joint working between the NHS, Government and the life sciences industries. We have built a partnership that has transformed the way we work together. I want to thank the ABPI and the pharmaceutical industry for the essential contribution they have made. Its leadership, technical knowledge and the commitment of experts to this work has been exceptional

Sir Ian Carruthers

Joint working

During 2012, we also created the new *ABPI Quick Start Guide* as a tool to support joint working in the development of local pathways. We were pleased to see an increasing number of successful joint working projects with improved patient outcomes.

Guidance on prescription of unlicensed medicines

When the General Medical Council (GMC) announced its consultation on revised prescribing guidance to doctors – including a proposal to allow the prescription of unlicensed medicines on the grounds of cost – the ABPI HTA Taskforce acted quickly to raise awareness of the implications for patients and the medicines licencing system.

Following a dedicated campaign during 2012, when the GMC's prescribing guidance was released in early 2013 it retained a broad definition of benefit to the patient rather than allowing the prescription of unlicensed medicines on the grounds of cost. As a result, patient choice and patient safety were preserved, and the medicines innovation and life cycle process was protected.

Driving public awareness of poor patient access

Driving hard hitting access and uptake messages in the media remains an important part of our overall approach. The national media coverage we secured for both the national metrics report[2] and the subsequent IMS commentary, is an example of our planned, proactive engagement with the media on this critical topic.

Helping the NHS plan for new medicines

Helping the NHS to prepare for the challenge of introducing new medicines quickly and efficiently is an important contributor to improving uptake.

Throughout 2012 we supported companies in using UK Pharmascan, a database covering all new medicines and indications to be launched in the UK over the next three years.

The ABPI has supported the registration of more than 100 companies and more than 500 medicines onto the database. Pharmascan is now the primary source of information for the NHS to plan and budget for new medicines, enabling faster patient access.

Early access scheme

Following ABPI advocacy on the early access scheme – conceived by the ABPI and other stakeholders at a MISG forum – the MHRA launched a public consultation in 2012 on the design of a scheme[3].

The ABPI actively worked with the MHRA to maintain momentum to ensure the consultation progressed in a timely manner. We continue to engage with the MHRA and other important stakeholders to ensure the design and implementation of the early access scheme delivers improved patient access.

While progress has been made there are still considerable challenges ahead on the access and uptake agenda. Ensuring better patient access to modern medicines will remain a core priority for the ABPI, working with Government, the NHS and NICE.

[2] Health and Social Care Information Centre *Use of NICE appraised medicines in the NHS in England 2012*

[3] MHRA, *Public consultation (MLX 376), Proposal to introduce an early access to medicines scheme in the UK*, July 2012

1929 At a general meeting of the 'Wholesale Drug Trade and Industry', it was agreed that steps should be taken to form a Wholesale Drug Trade Association (WDTA)

Building reputation and strengthening relationships

The strategic importance of protecting the industry's reputation, building reputation capital and maintaining strong, trusted relationships with multiple stakeholders is paramount.

The industry has long recognised the link between transparency and trust in line with increasing societal expectations, and much has been achieved, over the years, as we have advanced on this journey. This agenda gained further pace in 2012 with significant developments and strategic initiatives driven by the ABPI on behalf of members.

Reputation

Disclosure of payments to healthcare professionals

Our industry is leading the way on the transparency of relationships with health professionals. During 2012, the ABPI worked with members to support their aggregate disclosure of payments to health professionals, which begins in 2013 for payments made in 2012.

Aggregate disclosure represents part of the journey towards transparency of payments at an individual healthcare professional level. In June 2012, EFPIA announced a pan-European commitment to make individual disclosure of payments to healthcare professionals a reality by 2016.

The ABPI played a critical role in the development of the EFPIA proposals, ensuring the views of ABPI members were represented, and – importantly – that there was sufficient flexibility over implementation to account for the UK environment and allow for a partnership approach with the health professional community.

This partnership approach was reflected in the UK consultation on the public disclosure of individual payments launched by the Ethical Standards in Health and Life Sciences Group (ESHLSG), a partnership between industry, royal colleges and professional organisations, formed in 2011 and co-chaired by Deepak Khanna, ABPI President.

Developed in 2012 and launched in January 2013, the consultation will inform an agreed approach to the disclosure of individual payments to healthcare professionals to meet the EFPIA commitments.

Medical education

Industry support for medical education has long been a focus of media scrutiny. In the latter part of 2012, the ABPI worked with the ESHLSG to survey health professionals and the industry on what they currently value and what needs to be developed or changed. With over 1,500 responses we have a solid platform on which to work with members and the ESHLSG to develop recommendations for evolving our approach in 2013.

Clinical trial transparency

The ABPI has long advocated its commitment to greater transparency in the reporting of clinical trials and many steps have already been taken towards this goal. This is a complex and global issue and the ABPI continued to work collaboratively through the year with multiple stakeholders and international colleagues.

To help ensure clarity on the existing voluntary and regulatory commitments on trial registry and publication of trial information, in June 2012 we worked with the ESHLSG to publish *Clinical Trial Transparency Principles and Facts*[4]. This was launched to a broad audience at a joint British Medical Journal and ABPI conference examining issues of clinical trial design, implementation and disclosure as part of our ongoing commitment to address these issues collaboratively.

In September 2012 the *ABPI Code of Practice* was amended to require companies to disclose details of the results of all clinical trials in accordance with the International Federation of Pharmaceutical Manufacturers and Association's (IFPMA) *Joint Position on Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases*.

1930 The Drug Club is wound up and the WDTA holds its first meeting

Throughout our close working relationship with the ABPI during 2012, I witnessed at first-hand how, working as a team, the NHS and the pharmaceutical industry can deliver significant patient benefits above and beyond what can be delivered by any one party on its own. That is why I am firmly behind greater partnership working between the NHS and industry and I will be encouraging all of my colleagues across the NHS to continue to engage with this important collaboration.

Mike Farrar,
Chief Executive, NHS Confederation

The extensive publicity around the publication of Dr Goldacre's book *Bad Pharma*[5] in September 2012 resulted in the need to rapidly respond on behalf of the industry. Through dedicated media activity – including high profile interviews with ABPI CEO Stephen Whitehead on Radio 4's *Today Programme* – we sought to highlight the industry's commitment to greater clinical trial transparency, the complexity and global nature of the issue and the need to continue working in partnership with all stakeholders.

In supporting our case, we undertook research to ascertain the extent to which companies publish the results of clinical trials and our analysis showed that the publicly available evidence base for new medicines has improved in recent years.

In December 2012 the Science and Technology Committee announced its inquiry into clinical trials and we took immediate action to develop a robust response for submission in 2013. This includes our intent to introduce new measures to monitor adherence with the clinical trial transparency provisions contained in the *ABPI Code of Practice*.

Supply shortages

Late 2011 and early 2012 saw the emergence of an increasing level of media commentary on shortages in medicines supplies, criticising pharmaceutical companies' supply chain processes as the cause of potential patient harm.

The ABPI responded quickly to protect the industry's reputation, building a strong evidence-based argument on the impact on the supply chain of excessive and unpredictable orders linked to parallel trading.

Through proactive media activity and extensive parliamentary outreach – including evidence to the All Party Pharmacy Group inquiry – we were successful in shifting the debate to focus on excessive ordering as opposed to a problem with pharmaceutical companies' supply chain processes.

Strengthening relationships

We have long recognised that maintaining strong relationships across all our stakeholders is critical to progressing our strategic priorities.

With partnerships at the heart of our work – including initiatives such as the ABPI Regional Partnerships Team, collaborations with ESHLSG and IHW and the Translational Research Partnerships – we have continued to strengthen our relationships in 2012 including our engagement with patient groups.

Developing and strengthening our relationships with patient groups was a key driver for 2012, with a new forum designed to improve engagement and shared understanding on key topics of mutual concern. During the year we sought to build on this re-energised approach through new ways of partnership working including establishing a joint steering group responsible for setting the agenda for discussion.

Another important initiative in 2012 was the extension of our strategic partnership with the NHS Confederation, established to encourage adoption and diffusion of innovation within the NHS by showcasing best practice.

We are proud of the strong and sustainable relationships that we built during 2012 across the NHS, charities, patient groups and research bodies. By continuing to work in partnership, we will improve patient access to innovative medicines and build support for the industry.

[4] Ethical Standards in Health and Life Sciences Group, *Clinical Trial Transparency and Facts*, May 2012
[5] Ben Goldacre, *Bad Pharma*, September 2012

Securing a broader definition of value and preparing for negotiations

We entered 2012 in dialogue with Ministers about the Government's intention to introduce a new value based pricing scheme. This, together with continued austerity, makes these negotiations the most complex and challenging we have ever seen. Alongside, NICE continued to present a challenge in terms of securing patient access to innovative medicines, further contributing to a challenging environment for our members.

Pricing negotiations

A core priority in preparation for the negotiations was to unite the industry. Through a wide and detailed consultation, we achieved consensus across all companies – including both large and small companies – on the key priorities for industry in the negotiations. This reflected broad agreement that the current pricing scheme works well.

This consensus enabled the ABPI – as the negotiator for all industry – to enter the negotiations with the Department of Health in the strongest position.

In addition to detailed preparation supporting the ABPI negotiating team, we established processes to align with other trade associations and the geographical groups.

In advance of the negotiations, the ABPI team collected evidence and key metrics on the UK commercial environment to help build a powerful evidence base to leverage as part of the negotiations.

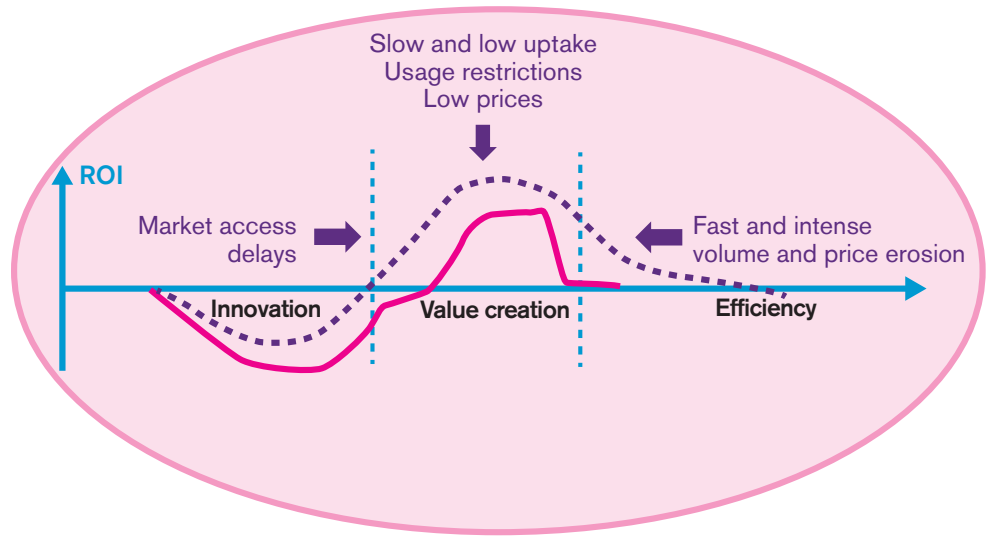
As a direct result of our targeted advocacy, our key messages are being heard at the highest levels in government.

Reform of NICE and HTA processes

During 2012, we were actively involved in discussions about how NICE assesses the value of medicines. This included engagement with NICE and the Department of Health both bilaterally and through the Medicines Access Group.

Underpinned by a programme of work to define a set of agreed industry policy positions, we secured agreement with NICE and the Department of Health to review a number of critical value assessment and process issues directly with NICE.

The life-cycle for innovation in the UK is squeezed on all sides



Old lifecycle curve
Current lifecycle curve

1941 New offices secured in BMA House, Tavistock Square

Ensuring that patients are able to access the most appropriate, clinically and cost-effective medicines relies on a constructive and transparent dialogue between industry and NICE. Our work together helps us maintain this dialogue and we look forward to continuing this productive relationship with our industry partners in 2013

Sir Andrew Dillon,
Chief Executive, NICE

Our policy positions also underpinned our written and oral evidence to the House of Commons Health Select Committee on NICE. We were pleased to see that our concerns about the need to place greater emphasis on the clinical value of medicines and to take into account more fully the perspective of clinicians and patients[6], were reflected in the Committee's report.

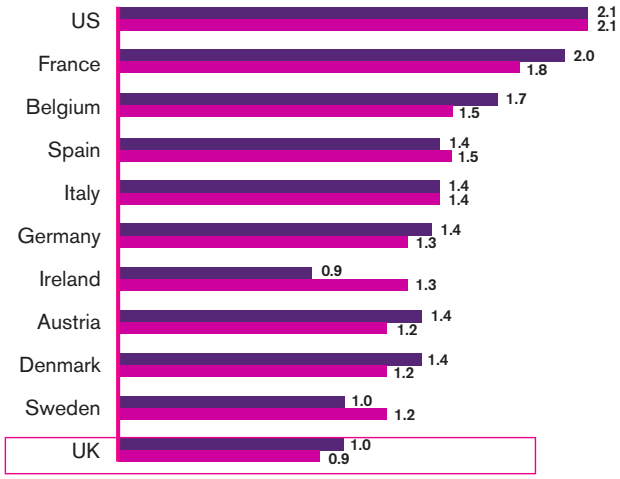
This work undertaken in 2012 laid the foundations for the engagement with NICE in 2013, which is underway, with a core objective of ensuring the broader value of medicines to patients and wider society is recognised and rewarded.

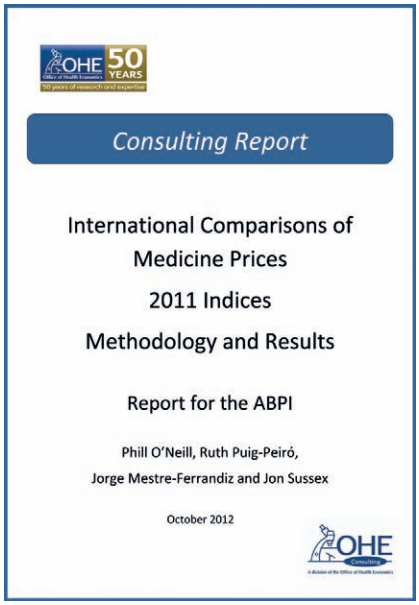
Driving awareness of the cost of medicines

The need to accurately frame the debate on medicines prices was a key driver in 2012. We used the 11th PPRS Report and research conducted by the Office of Health Economics (OHE) on the medicines bill to drive messages about low UK prices and the NHS medicines bill being under control through multiple channels. Through extensive media coverage – including Radio 4's *Today Programme* and the *Times* – and stakeholder outreach, we raised awareness of these key messages.

Our policy work and preparation for negotiations during 2012 have put us in a strong position. With austerity in public spending expected to continue for several years, improving recognition of the value of innovative medicines will remain a key focus for the ABPI.

Spending on medicines as a percentage of GDP, in various countries in 2011





[6] Written evidence from the Association of the British Pharmaceutical Industry (NICE 29) Health Select Committee, October 2012

1948 The Association of the British Pharmaceutical Industry (ABPI) is formed by name change to more accurately reflect the nature of the group

Improving the enivironment for research and development

The UK is in a global race to attract R&D investment. The ABPI has risen to this challenge and delivered significant achievements in 2012 following the launch of the *Strategy for UK Life Sciences*.

Through a focused programme of activity the ABPI helped to ensure government commitments in the *Strategy for UK Life Sciences* translated into real action.

Clinical trial performance

Following the Government's acknowledgment of the need for transparent benchmarks to drive improved performance of clinical research by the NHS, we undertook a programme of work to influence and support the implementation of metrics for performance management within the National Institute for Health Research (NIHR) Clinical Research Network (CRN).

These measures include an initial benchmark in NIHR CRN contracts stipulating that NHS providers must recruit the first patient for a study within 70 days or less from the time it receives a valid research application.

Crucially, the ABPI also supported a commitment for NIHR CRN funding to be conditional on providers meeting the 70 day target from 2013.

We are pleased to see that the NIHR CRN has committed to publishing clinical trial performance metrics against agreed benchmarks in 2013, allowing industry sponsors to see how many trials are in progress and how many patients have access to those trials.

Leveraging health data

Launched in April 2012, the Clinical Practice Research Datalink (CPRD) joins together IT systems across the NHS and provides researchers – academia and industry – with analyses of health records for a range of purposes, including to improve trial recruitment and feasibility, to further R&D(for example into stratified medicines), for outcomes research and to monitor safety.

Importantly, we engaged early with the CPRD and the new Health and Social Care Information Centre (HSCIC) to highlight industry's' requirements for the resource.

Once launched, we hosted a workshop with the HSCIC and the Medical Research Council to update members on the available resources for data linkages and capacity building in key informatics skills.

For researchers: you will be able to access the best facilities and world-leading institutions, real life data and an integrated system for bio-medicine.

For clinicians: you will have an active role in innovation and research into pioneering new treatments and truly add value to the ecosystem, whilst improving patient outcomes.

For patients: you will be empowered to have more choice with better and quicker access to new treatments, for better results.

Strategy for UK Life Sciences

The UK is in a global race and the Government is committed to keeping our life sciences industry at the forefront of research and development. Creating the right environment for growth and inward investment is at the very heart of this ambition.

We are encouraging collaboration between the research base, industry and the NHS. We are supporting innovation through translational funding and we are boosting skills. We are determined that the pharmaceutical sector continues to be a British success story.

Rt Hon David Willetts MP,
Minister for Universities and Science

1957 First Voluntary Price Regulation Scheme is introduced

The ABPI R&D Conference and the Science in Parliament launch

Translational research

During 2012, we proposed Translational Research Partnerships (TRPs) and co-designed the consortium contractual template for the UK. In 2012, the TRPs gained their first three partnership projects between industry and the academic centres of excellence in respiratory and inflammatory joint disease, with many more under consideration.

We also extended collaboration across industry, academia and the NHS in 2012 through leading the establishment of a new MRC-ABPI consortium for Diabetes Stratification.

Animal research

We led initiatives throughout 2012 – in partnership with other stakeholders – to seek a sustainable solution to the cessation of commercial surface routes available to transport animals bred for bio-medical research. Imported animals are small in number but are both research and business critical, and this obstruction also impacts on important international collaboration in R&D.

The ABPI helped form, and acted as the secretariat for, the Life Sciences Transport Group with government, medical research charities and other key stakeholders. This group sought and obtained dialogue with transport operators, increasing shared understanding of the issues and focusing our on-going discussions with them.

Following a poll of public attitudes towards animal research, conducted by the Department for Business, Innovation & Skills (BIS), the ABPI worked with other stakeholders to gain agreement to a *Concordat for openness on animal research*, encouraging the research sector as a whole to improve transparency and communications to the public on animal research. This work is an historic opportunity to advance public confidence in this important area.

ABPI Guidelines for Phase 1 Clinical Trials

In a major landmark to support the critical role of Phase 1 clinical trials in medicines development, we produced an updated edition of the *ABPI Guidelines for Phase 1 Clinical Trials*. These are widely used by industry, academia, health professionals, regulators and ethics committees, not only in the UK but around the world.

The 2012 edition reflected the changing regulatory environment, and feedback from the extensive consultation that the ABPI undertook with members and multiple stakeholders, resulting in a thorough and clear compilation of updated information and guidance on best practice, endorsed by the Chair of the Commission for Human Medicines.

Raising awareness of incremental innovation

Publishing our report *The many faces of innovation*[7] brought public recognition of the value of medicines and of incremental innovation by the pharmaceutical industry. The extensive press coverage highlighted the value that industry brings to patients and reflected our sound arguments to government about the need to protect and enhance the UK environment for innovation.

Antimicrobial Resistance Strategy

With the treatment of diseases like tuberculosis and pneumonia currently under threat because of resistance to antimicrobial medicines, the ABPI coordinated a compelling industry response to the Department of Health consultation on the *Antimicrobial Resistance Strategy*.

While we are pleased with the progress in improving the R&D environment during 2012, more must be done to maintain the UK's position as an attractive location for R&D investment. The ABPI continues to focus on addressing the challenges.

[7] ***The many faces of innovation**, a report for the ABPI by the Office of Health Economics*, **March 2012**

Providing value for members

Against the backdrop of an increasingly challenging environment for the industry, the ABPI upgraded its capability in membership, advocacy and policy, in 2012, to drive increased value for members across critical issues and agendas.

2012 was a year of significant expansion for the ABPI – welcoming 17 new members – and the results from our membership survey showed continuous improvement in the engagement and support we provide to members.

> *More leadership and greater industry consensus on key issues. Much greater "value" of membership*
>
> *ABPI member survey 2012*

During the year we continued to evolve our member communications and resources, building on our positive survey scores.

Our membership survey clearly demonstrated the value of the networking opportunities provided by the ABPI. In response we stepped-up our face-to-face events – including a Business Planning Workshop and a wide range of Master Classes – and introduced new senior level forums for Chief Executives and Finance Directors.

> *Greater visibility, more vocal and more innovative*
>
> *ABPI member survey 2012*

Following members' feedback we also focused more attention on our smaller company members by delivering regular forum meetings, providing a more comprehensive monitoring package and adjusting the membership fee structure for companies with sales under £10 million.

Over the year we built a stronger rapid response process, with an improved ability to respond to complex media issues, across all channels, on behalf of members.

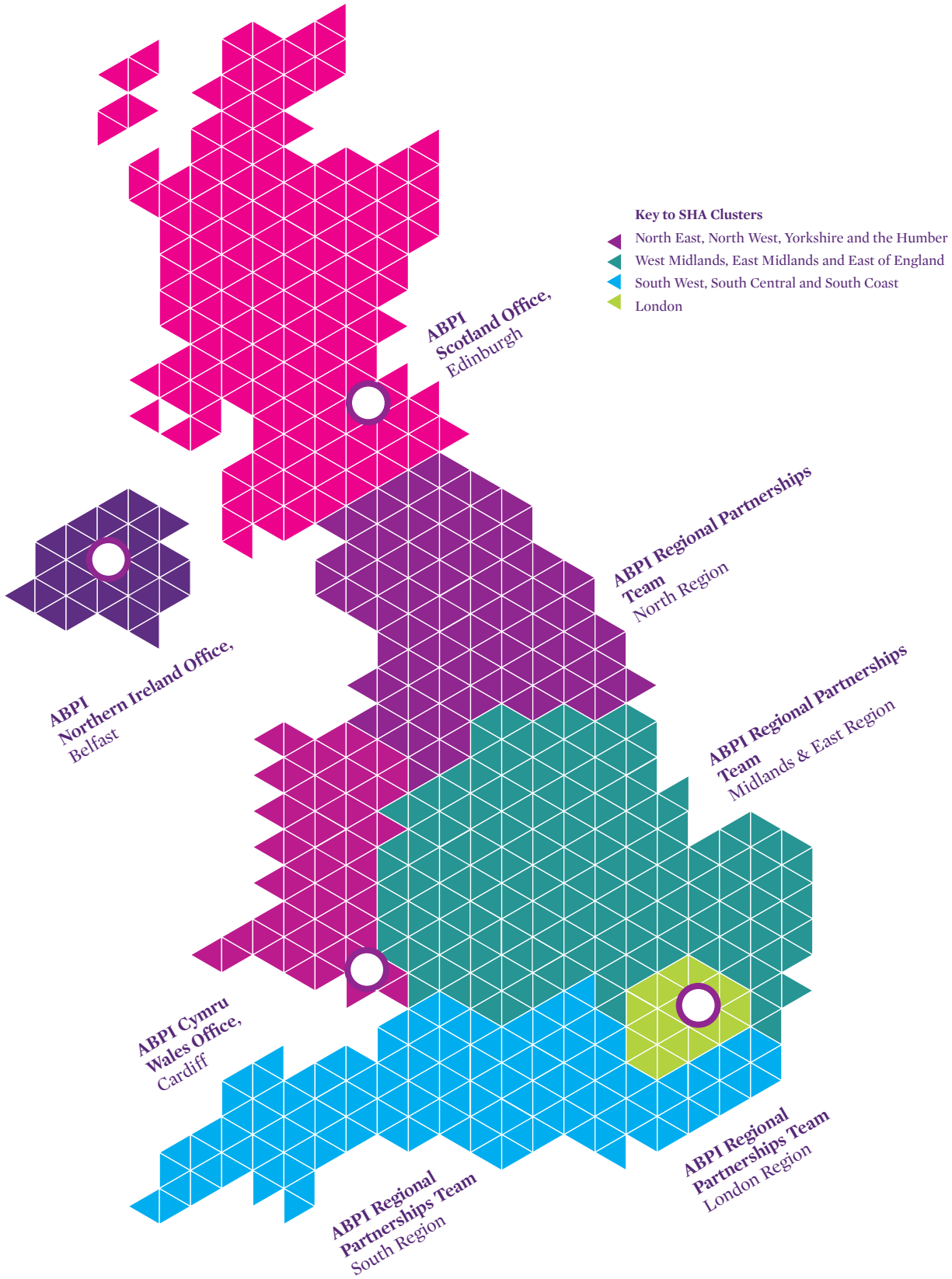
We also strengthened our policy and advocacy capability, with significant policy wins including: the GMC's decision to retain its prescribing guidance for unlicensed medicines, averting more stringent supply chain regulation and securing the requirement to automatically include NICE recommended medicines on formularies, which must be published.

> *More externally focused Leadership Team, with a willingness to more actively engage with critics*
>
> *ABPI member survey 2012*

In 2012 we extended our geographical reach with a dedicated office in Northern Ireland, meaning we now have the capability to work in partnership with stakeholders across government, the NHS and patients in England, Scotland, Wales and Northern Ireland.

While we are pleased that our member survey shows strong levels of satisfaction we remain committed to continuously strengthening the value of our offer and look forward to updating members on new initiatives during 2013.

1958 ABPI Code of Practice introduced



1962 ABPI founds the Office of Health Economics (OHE) to commission and undertake research on the economics of health and health care

The ABPI in the devolved nations

The ABPI is working to improve the environment for the pharmaceutical industry right across the UK. In 2012 we achieved firm commitments to joint working from key stakeholders in both Wales and Scotland and look forward to further success in Northern Ireland following the opening of our new, dedicated office.

Wales

In 2012, through our continued work with the Welsh Government we improved access to medicines through an agreed process and set of principles for implementing Patient Access Schemes in Wales. Through this, companies now have the opportunity to utilise a process, similar to the one operating in England, enabling patients to have access to medicines that may not initially be considered cost-effective by the All Wales Medicines Strategy Group (AWMSG).

ABPI Cymru Wales also strengthened its relationships with AWMSG during the year, assisting in the development of its first ever patient summit, hosted by the Royal National Institute for Blind People. With a focus on the patients' perspective of the value of medicines, the summit provided a platform for sharing messages more widely with policy and clinical decision makers as part of our wide-reaching advocacy programme.

Ongoing engagement with government, academia and NHS Wales on the innovation agenda ensured that the value of the pharmaceutical industry and its products were recognised and reflected in The National Institute of Social Care and Health Research *Industry Engagement in Wales* report[8]. This report confirmed the Welsh Government's commitment to health sciences research, particularly in three key disease areas: cardiovascular disease, cancer and dementia, whilst also recognising the mandatory funding directive in Wales for all medicines recommended by AWMSG and NICE.

Dr Rick Greville, Director of ABPI Cymru Wales and International Affairs, Deepak Khanna, ABPI President and Professor Chris McGuigan of Cardiff University at the Welsh Annual Lecture in Cardiff

Scotland

The ABPI Scotland team was at the forefront of policy development in 2012. Increasingly relied upon by government as an important partner, the ABPI was part of the core team developing the Scottish Government's *Statement of Intent on Innovation in Healthcare*[9], leading to the inclusion of commitments promoting access to medicines and supporting the Government's aim to double the economic contribution of life sciences to the Scottish economy by 2020 to £6 billion.

At the beginning of 2012, ABPI Scotland secured commitments from the Scottish Government to introduce a 90 day limit on local decision making on SMC accepted medicines and the introduction of greater transparency in local decision making. We have continued to drive the access agenda resulting in ABPI Scotland presenting written and oral evidence to a Scottish Parliament inquiry into access to medicines in Scotland, which resulted in the announcement by Scottish Government of a review of access to medicines in Scotland encompassing SMC decision making, the individual patient treatment request (IPTR) process and the uptake of new medicines. The results of the review will be published for consultation in mid 2013.

ALLIANCE-ABPI workshop series

1980 ABPI moves Head Office to Whitehall

We know that the Scottish Medicines Consortium is globally respected and has the fastest and most efficient medicine review process anywhere in the UK. Some clinicians, charities and patients have, though, raised concerns about access to medicines, so it is only right that we look at ways that we could potentially improve access arrangements. Scotland's NHS is renowned as being at the forefront of new technologies and innovation – I want to make sure that the same is true of access to new medicines.

Alex Neil MSP *Cabinet Secretary for Health and Wellbeing, Scottish Government*
The Scottish Government, New medicines review, press release, 14 November 2012

During the year we also played a critical role in prompting a new version of the Chief Executive for NHS Scotland's guidance for joint working between NHS Scotland and industry, *A Common Understanding 2012*[10]. This built on the previous 2003 guidance and provided an up-to-date template for joint working between NHS Scotland and the pharmaceutical industry.

Finally we strengthened our partnership working by joining forces with the ALLIANCE (formerly Long Term Conditions Alliance Scotland). This included facilitating a three year programme of seminars and training, for their 200 patient groups and charities, linked to Scotland's Healthcare Quality Strategy.

Northern Ireland

In 2012 we made a decisive investment in Northern Ireland by establishing a dedicated office in Belfast. ABPI Northern Ireland had a productive year, continuing to build strong relationships with policy and healthcare stakeholders across the region. We were immensely encouraged by the degree of Ministerial participation in ABPI NI events, demonstrating cross-departmental support for the pharmaceutical industry, and were delighted that the Chief Scientific Advisor and luminaries from academic and clinical research engaged with ABPI members personally to discuss the development of a strategy to enhance Northern Ireland's global R&D potential. We were also invited to sit on the Department of Health & Social Care's Steering Group for the Strategic Review of Community Pharmacy, providing industry input into the evolving role of community pharmacists in addressing local health and social well-being needs.

Our patient-focused work continued to go from strength to strength, with policy stakeholders, patient groups and clinicians praising ABPI NI projects in the areas of oncology, immunology and pain management.

Across the devolved nations of the UK, 2012 saw notable successes in deepening our partnerships with governments, the patient community and clinical groups in order to improve the commercial environment and enhance access.

[8] The National Institute for Social Care and Health Research, *Industry Engagement in Wales*, 2012
[9] Scottish Government, *Health and Wealth in Scotland: A Statement Of Intent For Innovation In Health*, June 2012
[10] Scottish Government, *A Common Understanding 2012 - Working Together For Patients*, November 2012

ABPI strategic priorities for 2013

The ABPI is working to improve the environment for the pharmaceutical industry right across the UK. Our objectives for 2013 reflect the priorities of our members: large, medium and small.

Ensure the **value of the industry** to the health of the UK is recognised

Ensure the **economic contribution of the industry** to the UK is recognised

Achieve a **satisfactory outcome** for the pricing negotiation

Create a **leading R&D environment** in the UK

Ensure the industry is **recognised as a trusted and valued partner** at a national, regional and local level

2000 ABPI Scotland office established in Edinburgh

Maintain effective operation of the current PPRS

Improve and protect market freedoms

Achieve improvement to current HTA processes

Improve the environment for access and uptake of innovative medicines

Build the strength and credibility of the ABPI as the voice of the industry

Ensure EU and international legislative reform is positive for the UK industry

List of ABPI members (as at 31.12.2012)

Full members

- A. Menarini Farmaceutica Internazionale S.r.l.
- Abbott Laboratories Limited
- Actelion Pharmaceuticals UK Limited
- Alexion Pharma UK Limited
- ALK-Abello Limited
- Alliance Pharmaceuticals Limited
- Almirall Limited
- Amgen Limited
- Astellas Pharma Limited
- AstraZeneca Plc
- Bausch & Lomb UK Limited
- Baxter Healthcare Limited
- Bayer Plc
- Biogen Idec Limited
- Boehringer Ingelheim Limited
- Bristol-Myers Squibb Pharmaceuticals Limited
- Celgene Limited
- Cephalon (UK) Limited
- Chiesi Limited
- Chugai Pharma Europe Limited
- Daiichi Sankyo UK Limited
- Dainippon Sumitomo Pharma Europe Limited
- Daval International Limited
- Eisai Limited
- Eli Lilly & Company Limited
- Fresenius Medical Care (UK) Limited
- GlaxoSmithKline Plc
- Grunenthal Limited
- Ipsen Developments Limited
- Janssen
- Leo Pharma
- Lundbeck Limited
- Merck Serono Limited
- Merck Sharp & Dohme Limited
- Merz Pharma UK Limited
- Napp Pharmaceuticals Limited
- Novartis Pharmaceuticals UK Limited
- Novex Pharma Limited t/a Quintiles UK
- Orion Pharma (UK) Limited
- Otsuka Pharmaceutical Europe Limited
- Pfizer Limited
- Pierre Fabre Limited
- Rosemont Pharmaceuticals Limited
- Sanofi Limited
- Servier Laboratories Limited
- Shionogi Limited
- Shire Pharmaceuticals Limited
- Takeda UK Limited
- UCB Pharma Limited
- Vifor Pharma UK Limited
- ViroPharma Limited
- Warner Chilcott Pharmaceuticals UK Limited

2011 ABPI rebrands and moves its Head Office to Victoria

Research affiliates

Axess Limited
Centre for Medicines Research International Limited
Charles River Laboratories
Covance Laboratories Limited
ICON Limited
Life Sciences Research Limited
Mitsubishi Pharma Europe Limited
NDA Regulatory Science Limited
ORION Clinical Services Limited
Parexel International Limited
PharmaNet Limited
PrimeVigilance Limited
Quintiles Limited
Quotient Clinical Limited
Randox Laboratories Limited
Richmond Pharmacology Limited
Sequani Limited
Sucampo Pharma Europe Limited
Takeda Global Research and Development Centre (Europe) Limited
TranScrip Partners LLP

General

1HQ Limited
Accenture Plc
Addleshaw Goddard LLP
American Express Europe Limited
Amygdala Limited
Arnold & Porter (UK) LLP
Ashfield In2Focus Limited
Atlantis Healthcare UK Limited
Baker & McKenzie LLP
Banks Sadler Limited
BCD Meetings and Incentives Limited
Bird & Bird LLP
BMI System Limited
Bristows
BTG Plc (British Technology Group)
Cegedim Relationship Management
CMS Cameron McKenna LLP
Compliance Hub Limited
Compliance in Practice
Covington & Burling LLP
DAC Beachcroft LLP
Deloitte LLP
DHR International Life Sciences Europe
DLA Piper UK LLP
Ernst & Young LLP
Eversheds LLP
Excel Communications (HRD) Limited
Five Hats International Limited
Galbraith Wight Limited
Harlan Laboratories UK Limited
Hayward Medical Communications Limited
Healthcare at Home Limited
Healthcare Media Europe Limited
Hogan Lovells International LLP
ID Business Solutions Limited
IDIS Limited
IMS Health Limited
Jigsaw Conferences Limited
KPMG LLP
Linklaters LLP
M D Events Limited
Medicines Management Solutions Limited
Morgan, Lewis & Bockius LLP
PA Consulting Group Limited
Peach Professionals
PH Associates Limited
Pharma Mix Limited
PM Group Worldwide Limited
Policy Matters LLP
Powell Gilbert LLP
Present Value Limited
PricewaterhouseCoopers LLP
Red Door Communications Group Limited
Rouse Legal LLP
RSA Consulting Limited
Simmons & Simmons LLP
SNR Denton UK LLP
Spectrum Regulatory Solutions Limited
Star Medical Limited
Takeda Pharmaceuticals Europe Limited
Taylor Wessing LLP
Thomas Eggar LLP *(rejoined 8/9/11)*
Trinity Events Solutions Limited
Trio Media Limited
Virgo Health Limited
Wragge & Co LLP

ABPI Board of Management (as at 31.12.2012)

Deepak Khanna,
Merck Sharp & Dohme Limited – President of the ABPI

Lisa Anson,
AstraZeneca Plc

Robin Bhattacherjee,
Actelion Pharmaceuticals UK Limited

Nick Burgin,
Eisai Limited

Martin Dawkins,
Bayer Plc

Amadou Diarra,
Bristol-Myers Squibb Pharmaceuticals Limited

Jonathan Emms,
Pfizer Limited

John Kearney,
Amgen Limited

Steve Oldfield,
Sanofi Limited

Cesar Rodriguez,
Janssen

Ramona Sequeira,
Eli Lilly & Company Limited

Camilla Soenderby,
Abbott Laboratories Limited

Matthew Speers,
UCB Pharma Limited

Erik van Snippenberg,
GlaxoSmithKline Plc

Sue Webb,
Novartis Pharmaceuticals Limited

Co-opted Members

Pete Butterfield,
Alliance Pharmaceuticals Limited

Nicola Massey,
Shire Pharmaceuticals Limited

Kate Tillett,
Merck Sharp & Dohme Limited

Steve Turley,
Lundbeck Limited

ABPI Senior Leadership Team (as at 31.12.2012)

Stephen Whitehead
Chief Executive of the ABPI

Jane Atkin
(picture not shown)
Interim Director of Corporate Affairs

Geoff Bailey
Director of Finance

Carol Blount
Director of NHS Partnership

Paul Catchpole
Director of Value and Access

Alison Clough
Director of Commercial

Colette Goldrick
Director of ABPI Northern Ireland

Dr Richard Greville
Director of ABPI Cymru Wales and International Affairs

Samantha Ogden
Director of Membership Services

Andrew Powrie-Smith
Director of ABPI Scotland

Dr Bina Rawal
Director of Research, Medical and Innovation

Heather Simmonds
Director of the Prescription Medicines Code of Practice Authority

Professor Adrian Towse
Director of the Office of Health Economics

Carol L. Wilson
Secretary and Legal Director

The pharmaceutical industry employs around 68,000 people directly (23,000 of those in research and development)[1]

In Northern Ireland, the pharmaceutical industry employs approximately 1,500 in manufacturing[2]

In Wales, the life sciences sector contributes £1.3 billion to the country's economy[3]

In 2012, the pharmaceutical sector's contribution to the balance of trade was the greatest of 9 major industrial sectors[4]

The trading and manufacturing sector within the pharmaceutical industry is estimated to contribute £121,000 per employee to the gross output of the Scottish economy[5]

Each employee in the pharmaceutical industry contributes, on average, £210,000 to the UK's Gross Domestic Product (GDP)[6]

The pharmaceutical industry generates a trade surplus of £5bn[7], which is greater than any other industrial sector in the UK

The UK's pharmaceutical sector invests approximately £13.3 million every day in R&D[8]

In 2011, the overall spend on medicines represented only 9.6% of total UK-wide NHS expenditure, while branded medicines represented 7.5% of total UK NHS spend[9]

There was more research and development performed in the pharmaceutical sector than any other sector in 2011, representing 28% of all expenditure on R&D in UK businesses[10]

The prices of branded medicines in the UK are among the lowest in Europe[11]

Total medicine costs in the UK represent 0.9% of GDP compared to a 1.7% average for 6 major markets[12]

One sixth of the world's most popular prescription medicines were developed in the UK[13]

[1] OHE calculations based on ONS, *Business Enterprise Research and Development (2008, 2009, 2010, 2011)*, accessed March 2013
[2] Department of Enterprise, Trade and Investment, Census of Employment
[3] The National Institute for Social Care and Health Research, *Industry Engagement in Wales*, 2012
[4] HM Revenue and Customs, *UK Trade Info 2012*, February 2013
[5] EP Associates, *Contribution of Pharma-Related Businesses to the Scottish Economy*, analysis for ABPI Scotland, 2008
[6] ONS, *Annual Business Survey 2011 Provisional*, November 2012 (Section C, Manufacturing)
[7] HM Revenue and Customs, *UK Trade Info 2012*, February 2013
[8] ONS, *Business Enterprise Research and Development 2010*, November 2011
[9] OHE, *UK NHS medicines bill projection 2012 – 2015*, analysis for the ABPI, June 2012
[10] ONS, *Business Enterprise Research and Development, 2011*, November 2012
[11 & 12] Department of Health, *PPRS Report to Parliament*, 6th, 10th and 11th reports, 2002, 2009 and 2012
[13] OHE calculations based on IMS Health World Review Analyst 2011

Association of the British Pharmaceutical Industry
7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: +44 (0)870 890 4333 Email: abpi@abpi.org.uk

ABPI Cymru Wales
Floor 4, 2 Caspian Point, Pierhead Street, Cardiff Bay CF10 4DQ
Tel: +44 (0) 870 890 4333

ABPI Northern Ireland
The Mount, 2 Woodstock Link, Belfast BT6 8DD
Tel: +44 (0) 870 890 4333

ABPI Scotland
3rd Floor Crichton House, 4 Crichton's Close, Edinburgh EH8 8DT
Tel: +44 (0)870 890 4333