

Annual Review 2014

The Association of the British Pharmaceutical Industry



99% of members

think ABPI services improved or stayed at the same high level



paid back to Government from industry under PPRS



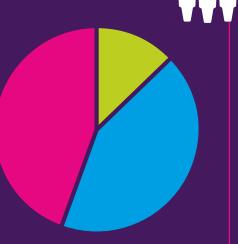


Membership make-up



54 Affiliate

16 Research



90% of branded medicines are from ABPI members











43 meetings held with political stakeholders in England plus

- 10 in Wales
- 8 in Scotland and
- 32 in Northern Ireland

14 roadshows underway in all AHSNs on PPRS/Medicines Optimisation







ABPI delivered 37 events in England for more than 2,000 delegates – 11 member-only events plus 4 in Wales, 8 in Scotland and 2 in Northern Ireland

Contents

Foreword from ABPI President Jonathan Emms	6
Foreword from ABPI CEO Stephen Whitehead	7
Achievements in 2014	8
Tomorrow's medicines today	8
Delivering a transformed commercial environment in the UK	10
Transforming relationships	12
PPRS one year on	14
The ABPI in the devolved nations	15
Northern Ireland	15
Scotland	16
Wales	17
Member survey 2014	18
Events	19
Annual conference: Securing a future for innovative medicines	20
R&D conference: Stratified Medicine – from Discovery to Patient – Mind the Gap	22
Publications	24
Priorities for 2015	25
Board of management as of 31.12.14	26
Senior leadership team as of 31.12.14	27
Membership as of 31.12.14	28
ABPI – a voice for industry	30

Foreword from ABPI President Jonathan Emms

As my term as President comes to an end it is with great pride that I look back over 2014 and review what the ABPI and industry have achieved during one of the most unpredictable periods in our history.

I would like to take this opportunity to thank the staff of the ABPI, particularly Stephen Whitehead and the senior leadership team and my colleagues on the board of management, without whom none of our achievements would have been possible. It is the dedication and hard work from everyone at the ABPI – staff and members – that enable us to continue to focus on putting patients at the heart of everything that we do.

2014 was a year of great change and challenge but we remained steadfastly focused on developing the best commercial and reputational position for the industry and our members – and I am delighted to say we are seeing some significant success.

The first year of the Pharmaceutical Price Regulation Scheme (PPRS) has seen a growth in medicines use but we know this still tends to be in older medicines and specialised commissioning. We have strongly argued for fair funding for all innovative medicines through 2014 and we have positioned ourselves as a valued voice in discussions on reforming NICE and the CDF to help achieve this. We have yet to see the full benefits of the PPRS come to fruition but we continue to work in partnership and campaign where necessary to bring this about in 2015.

The PPRS is the industry's commitment to supporting the NHS in times of austerity. In 2014 we made a total payment of £310 million to underwrite the medicines bill and while the increased use of branded medicines is encouraging, industry would still like to see greater equality of access for patients to all medicines across care sectors. We remain committed to working with all parties to ensure that the barriers to the use of new medicines in all care settings are removed and that NICE appropriately assesses medicines so that ring-fenced funds for selected therapy areas are not needed.

Our commitment to the Ministerial Industry Strategy Group (MISG) saw us participating in the short life working group looking at the barriers to uptake in the system for non-NICE approved medicines, for example in primary care.

And we started to see the additional commitments of the PPRS come to fruition with increased engagement on PPRS and medicines optimisation. Most notably this involved planning and preparation for PPRS/MO roadshows in each of the Academic Health and Science Network (AHSN) regions throughout England.

In 2014 our work has been instrumental in the development of the end-to-end, Innovative Medicines and MedTech Review – now known as the Accelerated Access Review – and the ABPI has made the case for the necessary reforms that are

being examined. We have strengthened our partnership with the NHS through our Memorandum of Understanding and the PPRS/medicines optimisation joint programme, and we will continue to develop these relationships working towards the partnership model described in the Five Year Forward View.

We have also strengthened our position as thought leaders in the R&D arena with our highly regarded work on stratified and personalised medicines looking at how these can be optimised within the system for greater patient benefit.

It has been a pleasure to work with and for you during 2014. Your energy, enthusiasm and commitment to ensuring that medicines make the difference we know they can for the people who need them is what inspires us to strive harder and further every day on behalf of a truly inspirational industry. As I hand over the presidency to John Kearney I do so knowing that we are heading in the right direction and that, with the ABPI leading the way as our voice, the industry will continue to make a significant impact on the health and wellbeing of the nation.

Jonathan Emms President



Foreword from ABPI CEO Stephen Whitehead

2014 provided the ABPI and industry with significant challenges, not least the implementation of the unique Pharmaceutical Price Regulation Scheme (PPRS), negotiated in order to provide UK patients with the opportunity to benefit from the newest, most innovative medicines when they need them most, during a time of financial austerity. The 2014 scheme underwrites the overall growth in spend by the NHS on branded medicines within the scheme.

Following tough negotiation we secured an agreement which maintained freedom of pricing in the market, maintained list prices, fought off the threat of value-based pricing and maintained the NICE threshold, when it was threatened to reduce - all positive outcomes for industry.

The scheme also gave companies a lower than expected payment in year one with the opportunity to plan for future years. More growth has been seen in the market than expected. Unfortunately because this is not across all new medicines in all care settings some companies have faced challenges this year, whilst others have benefitted from the growth. The growth rate notably slowed in quarter four so we will be monitoring this closely in 2015. We will also be reforecasting the market growth to provide greater predictability.

The challenges of 2014 are our opportunities for 2015 and I look forward to the coming year with a significant degree of optimism as we start to see our past achievements evolve into further success.

In particular I am pleased to say that our members believe we continue to provide valuable services and support. The results of the 2014 member survey show that 99% of members who participated in the survey say our services have improved or stayed the same. To hear that members think that "the ABPI raises the profile of the industry and has enabled the

pharmaceutical industry to be seen as a valued partner within the NHS" is positive feedback for the whole organisation and the wider industry. It is evidence that our work is making a difference – this is both personally and professionally very pleasing and provides us with a platform from which to push ahead.

Most importantly we will continue to push for reform that will unlock the full benefits of the PPRS for patients and the NHS. Industry has played its part – putting its money where its mouth is with payments of £310 million made in 2014. Now we expect the NHS, Department of Health and Government to play its part and fulfil its obligations under the PPRS agreement in order to make sure UK patients can access the medicines they need when they need them regardless of therapy area or care setting.

In an election year we will continue to promote our policy positions amongst politicians, parliamentarians and policy makers to ensure that the industry voice is heard frequently and clearly by the incoming Government. Our work will focus on ensuring that the pharmaceutical industry is further seen as integral to a successful economy and a sustainable healthcare system – a partner in the truest sense – and one which has the interests of patients at its heart.

Our position as the authoritative voice of industry was further embedded during 2014 with invitations to participate in high-level negotiations on NICE and the CDF – two of the most significant topics impacting industry this decade. We are not complacent about earning this position however. Throughout 2015 we will continue to strive to represent industry as a driving force in the life sciences sector in the UK.

We maintain our authority and credibility through developing leadership and thinking to improve the UK environment for research, development and manufacturing. Throughout 2015 we will be building on our innovation and its impact on commercial success.

A key priority will be improving the perception of industry – ensuring that the role that life-saving and life-enhancing medicines play in the health and wellbeing of the nation is clearly articulated, and that our drive for greater industry transparency is understood. In particular 2015 will be an important year in preparing for the disclosure of payments to healthcare professionals in 2016 and clinical trial transparency. We will be working with members and nonmembers alike to ensure the industry and our stakeholders are prepared for these game-changing developments.

Stephen Whitehead CEO

Achievements in 2014

Our broad strategic priorities for 2014 focused on tomorrow's medicine today and delivering a transformed commercial environment in the UK underpinned by transforming relationships with our range of key stakeholders, and we have made significant progress on delivering against all of these on behalf of our members.

Tomorrow's medicines today

We said we would

Focus on the opportunities of a changed R&D model, particularly stratified medicine, and the need for regulatory innovation and new approaches for HTA for such targeted medicines

We...

- ✓ Delivered the annual R&D conference focusing on the opportunities and challenges that the science of stratified medicines presents. This included a presentation from Life Sciences Minister George Freeman MP and the launch of our research publication Stratified medicine in the NHS in partnership with the Royal College of Pathologists (see Events section).
- Held a standing-room-only Big Data event in partnership with the All-Party Parliamentary Group on Medical Research and Genomics England.
- Engaged closely with the Farr Institute of Health Informatics Research and the UK Health Informatics Research Network to deliver the second Farr Institute Industry Forum in December to discuss the use of real world evidence.
- Sat on the Department of Health's Regenerative Medicines Expert Group to help develop an NHS regenerative medicine strategy to ensure delivery of these innovative treatments.

We said we would

Demonstrate the importance of the link between the commercial environment and R&D

We...

✓ Worked with the Office of Life Sciences on the development and publication of competitiveness indicators showing how the commercial environment and R&D are connected and the implications for the UK pharmaceutical industry, including ensuring that uptake of medicines is included as a key indicator influencing the commercial environment.

We said we would

Stress the importance of stakeholder relationships and partnership working integrating and linking together basic science, the R&D process and manufacturing

We...

- Established the Medicines Manufacturing Industry Partnership (MMIP) in partnership with the BioIndustry Association (BIA) to create an attractive and innovation-rich environment in medicines manufacturing. Approved by the Ministerial Industry Strategy Group (MISG), the MMIP brings the biopharmaceutical industry together to work towards a common goal of ensuring UK competitiveness in medicines manufacturing. The MMIP includes partners Actavis, AstraZeneca, Eisai, FUJIFILM Diosynth Biotechnologies, GlaxoSmithKline, the Knowledge Transfer Network, Oxford BioMedica and Pfizer.
- Provided evidence to the Business Innovation and Skills (BIS) Committee inquiry on business-university collaboration considering how collaboration can benefit business and universities which develop the UK as a centre of innovation.
- Under our Memorandum of Understanding (MoU) with the BIA, undertook a number of joint initiatives including the 'one-stop-shop' Understanding the early

- access to medicines scheme in April for 130 delegates and Adaptive licensing, EMA explains what it's all about and how to engage in June for 96 delegates.
- Renewed our collaboration (funded by member companies) with the Medical Research Council (MRC) Centre for Drug Safety Science at Liverpool University, and the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) now in its 10th year.
- ✓ Organised a pivotal stakeholder event to discuss delivering excellence in medication safety across the UK through the ABPI's Pharmacovigilance Expert Network (PEN). This was the first occasion where the ABPI provided a platform to discuss real world use of medicines, reporting of Adverse Drug Reactions (ADRs), and share knowledge of best practice. Attendees have contributed to the ongoing development of the Medicines & Healthcare Products Regulatory Agency's (MHRA's) draft strategic Yellow Card road map and Good vigilance practice guidance for NHS.

We said we would

Continue to engage with patient organisations to facilitate collaboration

- Held four meetings of the Patient Organisation Forum (POF), bringing together more than 70 patient groups and charity organisations to examine and identify areas of common interest and ways of working together.
- Refreshed the POF steering group with representatives from eight member companies.
- Partnered with the Association of Medical Research Charities (AMRC) to deliver a series of party political conference breakfast events highlighting the importance
- of industry collaboration in achieving improved health outcomes.
- Held joint seminars with ABPI Scotland and leading Scottish patient group Health and Social Care Alliance.
- Ensured all Members of the Legislative Assembly in Northern Ireland are able to help GPs and pharmacists to signpost carers to the help they need following a partnership project with Carers Northern Ireland.

Delivering a transformed commercial environment in the UK

We said we would

Drive a pro-innovation health technology appraisal (HTA) evaluation process through NICE/SMC/AWMSG reform

We...

- Contributed to the National Institute for Health and Care Excellence (NICE) consultation on value-based assessment of health technologies, the outcome of which is in line with the ABPI's position of a more fundamental review of NICE.
- Established the case for reform of HTA processes by highlighting patient access issues with political and health audiences.
- ✓ Formed the HTA strategy group in order to develop clear, common industry positions through a series of workstreams.
- Gained agreement to NICE review in the terms of reference for the Accelerated Access Review.
- Implemented patient and clinician process with the Scottish Medicines Consortium (SMC) which has resulted in six out of nine ABPI recommendations being reflected in recent decisions.

We said we would

Influence access and uptake for specialised medicines, ensuring appropriate models of value assessment for cancer and orphan medicines

- Signed a compact agreement with NHS England to ensure effective partnership working between ABPI member companies and Specialised Services Clinical Reference Groups (CRGs). The agreement highlights a number of commitments from both parties that will enable them to work collaboratively to drive the delivery of high-quality treatments and services to add value to patients.
- Focused the 2014 annual and R&D conferences on improving access and uptake of innovative medicines in the UK (see Events section).
- Sat on the Department of Health's Cancer Drugs Fund (CDF) working party to shape the future of assessing and accessing cancer medicines in the UK.
- Saw the Scottish Government accept ABPI Scotland's recommendation to extend the Rare Conditions Medicines Fund into a New Medicines Fund, funded by the PPRS payments received by the Government.
- Commissioned the New Medicines and the NHS in Wales report to provide the Welsh Government with a better understanding of how new medicines can be best harnessed to its modernisation agenda.

We said we would

Align therapy groups to strategic priorities and drive best practice

The PPRS/Medicines Optimisation programme (See PPRS one year on section) outlines the ABPI and NHSE commitment to strategically align the work of the ABPI therapy groups with the priorities of the NHSE National Clinical Directors (NCDs) during 2015.

We...

- ✓ Committed to undertake a strategic review of the therapy group activities in order to ensure the therapy groups are 'fit for purpose' to meet the challenge of this agenda. The ABPI Board of Management reviewed the outputs of the strategic review and approved the direction of travel into 2015. As a result, by the end of 2015, all existing therapy groups will:
 - develop clearly defined work plans demonstrating an active contribution to ABPI objectives
 - have an ability to deliver against objectives ensuring that they operate an appropriate size and structure, and have the right skill set within membership and project support

- adhere to a clearly defined set of the therapy group governance requirements
- demonstrate the ABPI values of collaboration, communication, innovation, integrity and ownership.

During 2015, the therapy groups operating within the devolved nations will be incorporated into the review, enabling new groups to form (subject to Board of Management approval) and existing groups to build upon their strengths while transitioning into the new framework.

We said we would

Drive and influence commercial priorities including biosimilars, distribution and supply, homecare and the Falsified Medicines Directive

- Worked to increase awareness and understanding of the recommendations set out in the ABPI position paper on biological medicines, including biosimilar medicines, through the ABPI Biological Medicines Access Group (BMAG). The group has engaged extensively with stakeholders including: national policy makers, pharmacists, procurement groups, HTA groups and clinical and patient organisations to discuss our position and understand and inform stakeholders' consideration of the developing biological medicines market. In particular, biosimilar medicines have been identified as a key priority for NHS England and are being approached in partnership with industry. A joint industry approach has been encouraged and the ABPI has successfully agreed a number of industry positions with the British Generic Manufacturers Association (BGMA). These are set to form the foundation of an educational joint work programme that has been agreed in principle by both the BGMA and NHS England.
- Worked with the British Association of Pharmaceutical Wholesalers (BAPW) to agree revised wholesaler codes to pharmacy when a product is in short supply, and draft a Good Practice Framework for Supply Chain Partners, which will be advocated to the Department of Health's Supply Chain Forum in 2015.
- Strengthened our representation at the National Homecare Medicines Committee encouraging

- direct engagement and collaboration between NHS organisations and members.
- ✓ Jointly hosted with the National Clinical Homecare Association (NCHA) and the Department of Health *The* definitive homecare event: managing homecare in the new NHS – a collaborative approach for 225 delegates from across the NHS and industry, considering the final recommendations from the Hackett review and the work of the implementation board, whilst providing a platform for the launch of the Royal Pharmaceutical Society Homecare Handbook.
- ✓ Drafted, alongside other UK stakeholders BAPW, the British Association of European Pharmaceutical Distributors (BAEPD) and National Pharmacy Association (NPA), the principles for an appropriate UK model as part of the development of the European Stakeholder Model as a solution to the needs of the EU Falsified Medicines Directive. This included an Interim MoU, with the BGMA confirming their future engagement and input in the project.
- Strengthened collaboration with the BGMA, working with the NHS and Commercial Medicines Unit on outsourced outpatient pharmacy arrangements and when the contracted supplier is unable to supply offpatent medicines.

Transforming relationships

We said we would

Tell the positive story of the industry

We...

- W Held 43 meetings with senior political stakeholders of which 16 were at Minister or special adviser level – including regular meetings at No. 10 and our first contacts with Chuka Umunna, Shadow Business Secretary and Ed Balls, Shadow Chancellor.
- Held eight political events and roundtables with 272 stakeholders, including a 'two year on' event for the Life Sciences Strategy, a 'shadow MISG' with Chuka Umunna and Andy Burnham.
- Updated the *Delivering value to the UK* booklet and improved the Knowledge hub on the ABPI website, which outlines the industry's impact on the health and economy of the nation.
- ✓ Launched a new, externally accredited ABPI qualification for medical representatives in January 2014. Accredited by Industry Qualifications, the new qualification the Level 3 Certificate/Diploma in the promotion of prescription medicines attracted over 1700 registrations in 2014. The new qualification covers the Code of Practice, the structure and function of the NHS and human body systems, as well as specialist disease areas.

- Supported promotion of the International Federation of Pharmaceutical Manufacturers & Associations' (IFPMA) Ebola knowledge base on the ABPI website.
- Supported the ABPI's vaccines group running Westminster Flu Day, hosted by Dr Dan Poulter, Parliamentary Under Secretary of State for Health, to promote the importance of vaccination against influenza, particularly for at-risk groups.
- **⊘** Posted 33 blogs on the ABPI website over the year with over 5,500 unique page views in total.
- **⊘** Achieved over 5,000 Twitter followers for @ABPI_UK.
- Produced the ABPI Manifesto for change in preparation for the 2015 election.
- ✓ Increased use of the ABPI schools website a much valued resource in education. In 2014 the total number of users was up 45% from 2013 with around 30,000 users visiting the site each month.
- Saw the ABPI intern project *Quantifying the*pharmaceutical industry's contribution to published 3Rs

 research 2002–2012 published in Toxicology Research,
 showing increased contribution of industry to 3Rs
 (Reduce, Refine and Replace the use of animals in
 research) literature over the last decade.

We said we would

Progress disclosure of individual payments to healthcare professionals

- ✓ Disclosed aggregate payments to healthcare professionals of £38.5m, for payments made during the 2013 calendar year. This covered payments for consultancy, and sponsorship to attend third party medical education events. Our commitment to greater transparency around our financial relationships with healthcare professionals was strengthened in 2012, when we introduced a requirement through the 2012 Second Edition Code of Practice for companies to disclose aggregate totals paid to professionals.
- Continued working with companies to prepare for the next step in transparency, when companies will publish
- details of a wider range of payments on an individual, named basis for healthcare professionals and healthcare organisations. This more detailed information will be published in 2016, on payments made during 2015.
- In November, with publication of the 2015 Code of Practice, the last regulatory requirements were put in place to set out how companies will publish their data, through the new UK industry disclosure database, to be run by the ABPI.
- ✓ A key priority for the ABPI for 2015 will be the development of this new database.

We said we would

Continue our work on clinical trial transparency

We...

- Commissioned a study carried out by Livewire Editorial Communications Ltd, which was published in the peerreviewed journal Current Medical Research and Opinion (CMRO) assessing the levels of disclosure of results of industry-sponsored clinical trials in patients for new medicines approved between 2009 and 2011 by the European Medicine Agency (EMA).
- Commissioned a follow-up study to assess rates of disclosure for trials approved by the EMA in 2012, for completion and publication in 2015.
- ✓ Updated the clinical trial disclosure toolkit (first launched in August 2013) to incorporate changes related to the EU Clinical Trial Regulation (CTR) coming into force in 2016 and the new EMA policy on the publication of clinical trial data published in October 2014.
- Supported members with two training sessions for a compliance audit exercise, which aims to help prepare companies for the transparency requirements under the CTR.

We said we would

Establish a medical school module on drug discovery

We...

✓ Developed a module to enable undergraduate medical students to learn how medicines are discovered and developed and to experience the types of role that pharmaceutical physicians carry out in companies. The five-week module, being piloted in early 2015, will include placements in both contract research organisations and pharmaceutical companies and will provide opportunities to learn about preclinical and clinical research, regulation of medicines and of the industry, pharmacovigilance and medical affairs.

We said we would

Work with patient organisations to produce a joint working guide

We...

✓ Established a working group in partnership with National Voices for developing a Patient Collaboration Guide – a patient group/industry collaboration on how to work together effectively. The guide is due for publication in 2015.

PPRS one year on

The 2014 Pharmaceutical Price Regulation Scheme (PPRS) is unique in many ways. For the first time in the UK we have a deal which supports the Government, NHS and patients, by underwriting growth in the branded medicines bill. In return the scheme sets out a wide range of commitments from the Department of Health and NHS England on NICE, Innovation, Health and Wealth (IHW), innovation, access and uptake of medicines. The scheme will be a success if both sides of the equation balance.

In the first year of the scheme, the payment mechanism worked to plan. Industry made a total payment of £310 million to underwrite the medicines bill. We had higher growth of medicines than had been anticipated when the PPRS was first published, which led to a higher payment percentage for 2015. Increasing uptake of medicines in the right setting is good, and many companies have performed well in the UK. We recognise, though, that the scheme needs to be of benefit across the board and some companies were frustrated at the growing payments, particularly those operating in the primary care setting where access remains challenging, and there are cost constraints on new medicines regardless of the PPRS.

In negotiating the 2014 PPRS, industry was able to gain a range of commitments. The QALY threshold range was maintained, although it remains under constant challenge. Companies are able to request NICE appraisals. A NICE Implementation Collaborative (NIC) is in place to support faster and more consistent access to NICE-recommended medicines, treatments and technologies, and to seek to understand the system-wide barriers that restrict expected levels of implementation and uptake of NICE guidance in the NHS system in England. We were consulted on Value Based Assessment (VBA). The scheme set out commitment from government to IHW through the Mandate. Despite consultation, IHW has not been delivered or maintained by the Department of Health or NHSE, so through a range of activities we have focused on keeping innovation high on the agenda regardless of IHW.

We have strengthened our partnership with the NHS through the PPRS/medicines optimisation joint programme. This aims to maximise the benefits of PPRS through a joint programme of action, to accelerate uptake of innovative medicines, to create pull for patient access, and improve patient outcomes from medicines use. A series of NHS England and Academic Health and Science Network (AHSN) roadshows have taken place across England with high NHS local management attendance at each event. We have continued to work with government, NICE and NHSE on the development of the Innovation Scorecard. Each version of the scorecard has

improved, with more new products and wider estimates. We will continue to drive our message that the scorecard should become a key tool in identifying the uptake of innovation in the system.

The PPRS has given industry a platform to focus on reform, and beyond the text of the scheme we have been successful in achieving other initiatives focused on access and uptake. The most important of these is the end-to-end Accelerated Access Review. The ABPI has influenced the terms of reference towards a greater focus on uptake, we have provided input to initial review research, and agreed in principle to support an industry secondee joining the review. Separately, through the Ministerial Industry Strategy Group (MISG) we have set up a short life working group to review barriers to non-NICE and non-specialised medicines in the system.

In 2015 industry wants to see the benefits of the PPRS come to fruition. In support of this the ABPI will focus on two fronts: the first to help guide members through the scheme, by continuing a programme of company engagement and briefings, and a detailed re-forecasting exercise to help try and predict market and PPRS growth and payments. Secondly we will continue to work with government, the Department of Health, NICE and the NHSE to ensure all the commitments set out in the scheme are progressed at a pace which delivers change in the system. We will push for reform to achieve the full benefit of the PPRS for patients and the NHS regardless of therapy area or care setting.

The ABPI in the devolved nations

Northern Ireland

2014 was an outstanding year for the Northern Ireland (NI) Innovation Group. The connections between inward investment and adoption of innovation were reinforced at numerous stakeholder events and the group participated in developing the forthcoming Health and Social Care R&D strategy, the Department of Enterprise Trade & Investment Innovation Strategy and the Matrix Review, as well as assessing the Department of Health's first ever Small Business Research Initiative competition.



The ABPI's Colette Goldrick pictured (third from left) with Anne Clarke and Coirle Butler (Chair and Deputy Chair of our Partnership & Citizenship Group), along with the NI Healthcare Leadership Forum

As a result of the group's work, 19 of our companies spent two days being immersed in examples of Northern Ireland's outstanding biomedical research capability, resulting in five new clinical trials being placed here and 18 ongoing collaborative discussions.

The Partnership & Citizenship Group also made significant strides in driving home the theme of partnership to our stakeholders in 2014. In June, the year-long partnership with Carers NI came to fruition. As a result, all members of the Legislative Assembly in Northern Ireland are now able to help GPs and pharmacists signpost carers to the help they need in order to fulfil their vital role. The group was also a key driver in delivering our inaugural conference, Joint Working: Bringing the Benefits Home, where six examples of

NI partnership and joint working were showcased alongside a further eight initiatives from GB. With the group having elicited personal commitments to enhancing partnership and joint working from Health and Social Care Minister Jim Wells and HSC CEO Valerie Watts during 2014, industry has never been better placed to move to a new and more mature relationship with our stakeholders in 2015.

The ABPI's NI therapy groups also enjoyed a positive year. Successes included:

- The Immunology Therapy Group successfully engaged stakeholders to reduce waiting times for most biologics patients to zero, in line with NICE guidance. Previously, some patients had been waiting for 18 months after having been assessed as suitable for these medicines.
- The Pain Therapy Group developed strong links with the Patient Client Council and the Pain Alliance of Northern Ireland. The three organisations have together worked to raise the profile of pain as a condition in its own right, requiring healthcare planning and funding.
- The Cardiovascular Therapy Group came into being in February 2014 and just six months later was approached by the Health and Social Care Board's Medicines Management team to work on a partnership initiative to improve patient safety issues arising from healthcare professionals' lack of familiarity with novel anticoagulants (NOACs).
- The Respiratory Therapy Group succeeded in delivering a partnership between six member companies and five stakeholder groups, as a result of which over 300 community pharmacists were appropriately trained in assessing patient technique during Respiratory Medicines Use reviews.
- The Cancer Therapy Group has been determined to remove the inequality caused by Northern Ireland's

Individual Funding Request (IFR) process, as a result of which cancer patients here have greatly restricted access to innovative medicines readily available to their counterparts elsewhere in the UK. Working alongside patient groups, clinicians, Member of the Legislative Assembly (MLA) and other stakeholders, the group has driven a departmental review of the IFR process, the results of which are eagerly awaited.



The ABPI NI conference captured in picture form by Visual Practitioner Eleanor Beer

Achievements in 2014

Scotland

ABPI Scotland's political engagement this year was dominated by the Scottish Independence Referendum, which took place in September. Leading a Short Life Working Group of ABPI colleagues and member company representatives, the Scotland team investigated the issues presented by the referendum for industry in order to inform the ABPI senior team and the Board of Management. We led scenarioplanning work internally in order to prepare for the outcome of the vote but our strategic position was to remain neutral and uninvolved in the general referendum debate. Following the 'no' vote we continued to input to the Smith Commission process to take forward the devolution commitments on further powers for the Scottish Parliament and expect this to be a considerable focus through 2015.



Delegates at an ABPI event

PPRS funding flows

The Scottish Government expanded its Rare Conditions Medicines Fund (RCMF) into a New Medicines Fund (NMF), which is being funded, currently at £40 million per annum, by the PPRS payments received by the Scottish Government – an idea that was suggested by ABPI Scotland.

Engaging with HIS

Our engagement with Healthcare Improvement Scotland (HIS) significantly improved during 2014, thanks in large part to Acting Director Sandra Auld, to see us working together on issues of mutual interest, and having structured and sustained engagement, including quarterly meetings. This engagement involved working collaboratively on issues such as patient safety/pharmacovigilance, which led to a UK patient safety event taking place in London in September. This slow building of trust has led to further plans for collaborative working into 2015.

Tracking new medicines uptake

The ABPI's work on tracking the uptake of Scottish Medicines Consortium (SMC) approved medicines into local NHS boards continued. This work, which is updated and circulated to ABPI members quarterly, has solicited interest from the Scottish Government which is keen to understand how NHS boards are applying national guidance on new medicines. A second tracker has since been set up to monitor the implementation of the new SMC processes which came into force in mid-2014. Both of these trackers are circulated to the Scottish Access and Value Group, CEOs and HTA groups quarterly.

Working with SMC to inform members

ABPI Scotland's successful annual SMC Training Day took place in October, and was again very well attended by ABPI members. The 2014 event focused on the new SMC processes that came into force in 2014 as a result of the New Medicines Review.

Engaging with patients

Throughout 2014, ABPI Scotland continued its strategic engagement with leading patient group the Health & Social Care Alliance. Three seminars were held on areas of joint interest: Chronic pain, the Ethics of patient groups working with industry, and Rare conditions – in January, February and December respectively. These events continue into 2015.

Delivering objectives via therapy groups

ABPI Scotland therapy groups reaffirmed their focus on delivering our strategic objectives by welcoming a streamlined format for the groups which will allow a responsive approach. Notable 2014 successes include the ABPI Scotland Cancer Industry Group (SCIG) Scottish Cancer Research Working with Industry Forum (SCRWIF) whose prime objective is to increase access for patients to cancer trials in Scotland. A parliamentary motion was raised and supported by over 30 MSPs on this project congratulating the way of working following a successful launch conference. The ABPI Pharmaceutical Industry Alliance has an ongoing work programme of nine collaborative projects which showcase examples of both single and multiple company working and the revitalised Inflammatory Diseases & Rheumatology Group (SIDRIG) has embarked on a topical wastage project centred on patient involvement with their biosimilar medicines.



The ABPI SMC training day

Wales

During 2014 we saw ongoing consultation on the implementation of a new appraisal process in Wales specifically aimed at orphan and ultra-orphan medicines, which will include a stronger voice for patients and clinicians. The first medicines will go through the pilot process in spring 2015. 2014 also saw the announcement of a new co-ordinated approach to the Individual Patient Funding Request (IPFR) process, following a review with stakeholders including ABPI Cymru Wales, which aims to improve transparency and consistency of decision making.



Professor Phil Routledge and Professor Mark Drakeford

2014 saw the end of Professor Phil Routledge's long service as Chair of the All Wales Medicines Strategy Group (AWMSG), with the appointment to the role of Dr Stuart Linton. In October, Professor Routledge delivered the ABPI Cymru Wales' 12th annual lecture entitled *Heroes, villains and the appliance of pharmacological science*. He was introduced by the Welsh Government Health Minister who highlighted Professor Routledge's work to improve transparency and stakeholder engagement with HTA processes in Wales.

New Medicines and the NHS in Wales, a report by the University of South Wales, commissioned by ABPI Cymru Wales, was published in 2014. The report examines decision making around the implementation of access to new medicines in the NHS in Wales following approval by NICE or the AWMSG. The aim was to provide the NHS in Wales and other stakeholders with a better understanding of how new medicines can be best harnessed to its modernisation agenda. ABPI Cymru Wales continues to work with NHS Wales on implementing recommendations from the report.

Prudent healthcare

The ABPI Cymru Wales and the Bevan Commission – a group of international experts established by the Minister for Health and Social Services at the Welsh Government – jointly hosted a conference in July, *Our Prudent Healthcare – Medicine – It's Everybody's Business*.

Attended by more than 80 participants from the NHS, academia, patient organisations and the pharmaceutical industry, the event aimed to discuss and debate the principles of prudent healthcare and its adoption throughout NHS Wales. Prudent Healthcare is modelled on the principles being adopted across countries like the USA and Canada under the 'choosing wisely' banner and aims to increase

doctor-patient communication, reduce waste in healthcare and work towards 'minimum appropriate intervention'.

A publication from the event is available in from the ABPI website alongside a graphical representation of discussions from the day.

R&D - Life Sciences Panel, Hub and NRN

This year the ABPI became a founding member of the Welsh Life Sciences Hub. Sponsored by the Welsh Government, the hub brings together academic, business, clinical and professional services and funding organisations to provide a commercially-driven melting pot of talent supporting the Government's work to encourage the expansion of the life sciences sector in Wales.

The 1st Annual Scientific Congress of the Life Sciences Research Network Wales – Drug Discovery, on which ABPI Cymru Wales holds a seat, attracted the support and attendance of two Welsh Government Ministers. Edwina Hart, Minister for Economy, Science and Transport and Professor Mark Drakeford, Minister for Health and Social Services congratulated the currently-funded 15 PhD and 10 post-doctorate students on their progress to date and confirmed the Welsh Government's commitment to supporting up to 100 students during the course of the scheme.

BioWales 2014 took place in Cardiff in March, focusing on growth and delivery within the life sciences sector and on the opportunities and support available to new investors and established companies in Wales. Dr Louise Leong, Director of Research and Development at ABPI, presented to the conference on 'addressing the translational gap', which highlighted the ABPI's priorities on maintaining a leading environment for the discovery and development of new innovative medicines, and maximising the impact of industry's investment in R&D.

Dr Rick Greville, Director, ABPI Wales Cymru & Distribution Supply Chain, participated in a celebration of the 10th Anniversary of the Wales Cancer Bank in June. As well as chairing a session, Rick participated in an interview with Nick Ross, answering the question 'Stratified medicine – what is it, why do we need it, [what is] the way forward for Wales?'



Delegates at an ABPI Wales event

Member survey 2014

Almost all members surveyed (99%) in 2014 believe that the quality of our services either improved or stayed the same over the year – an achievement of which we are very proud. 90% of members told us that we are always or often professional, with 83% saying we are always or often well informed and always or often provide high-quality services.

As the industry's foremost trade body it is our aim to provide first-class services for our members in order to meet their needs and represent their views as we negotiate on behalf of the pharmaceutical industry. We are delighted to hear that so many members believe that we continued to improve throughout 2014 despite the fact that 'the base line last year was high'.

In particular, members told us that they particularly valued: the core messaging on topical issues, networking opportunities, analysis and response to government consultations, policy briefings and the in-house experts that we provide.

However, despite these high levels of satisfaction we know that we have areas of improvement. Members have told us that we should concentrate on: consolidating, clearly publicising and communicating the work of our various groups; developing resources that promote the value of industry to people's lives; communicating our government affairs activity; and improving networking opportunities.

We will be implementing a programme of improvement across our service areas throughout 2015 in order to address these concerns and provide an even better member experience.



Events

Throughout 2014 the ABPI events team delivered a total of 37 events for more than 2,000 delegates. This was a mixture of member-only events, workshops, information-sharing days and industry and stakeholder events as well as a number of additional events specifically for the devolved nations.

Member-only events included a legal day for in-house counsel of member companies, finance directors' forums, corporate affairs network, CEO forum dinner, regional roadshows, code of practice consultations, and workshops on joint working, understanding value-based assessments, implementing PPRS, and patient safety.

Industry-wide events included workshops on clinical trial transparency and understanding EU and UK requirements,

early access to medicines and its impact on the R&D environment in the UK, engaging with real world data, public disclosure of payments to healthcare professionals and NICE submissions and technical appraisal programmes.

The ABPI's two major events remain the annual and R&D conferences.



Annual conference: Securing a future for innovative medicines

In April 2014 almost 400 delegates attended the ABPI's annual conference at Westminster Park Plaza where they came together to consider how best to secure a future for innovative medicines in the UK, given the shift in medicines development.



























R&D conference: Stratified Medicine – from Discovery to Patient – Mind the Gap

Almost 200 delegates attended the Royal College of General Practitioners in November 2014 for the annual ABPI R&D conference which brought together a wide range of cross-sector stakeholders from academia, the NHS and industry to discuss the opportunities and challenges that the science of stratified medicine presents.



























Publications

We published around 36 publications during 2014, ranging from research reports and position statements to industry information and guidelines.

In addition to our publicly available publications, the ABPI provides a number of regular member-only publications including the daily Government Affairs Report, weekly Media Update and quarterly Environment Update.

All of the ABPI's public reports are available to download from our publications library on our website.

Some of the key publications of 2014 include:



Understanding the 2014 Pharmaceutical Price Regulation Scheme

This guide was developed as an overview for members and other stakeholders covering the key points and themes in the new PPRS which came into effect on 1 January 2014.

RAising the game: translating national policy into local action for rheumatoid arthritis services

Developed and funded by the ABPI's Rheumatology Initiative, in association with the National Rheumatoid Arthritis Society (NRAS), this research report assesses the extent to which government policies are having an effect and, more broadly, the priority attached to rheumatoid arthritis by local commissioners

Innovation in medicine: R&D and access

This single-page infographic shows the cost and process of 'bench to bedside' development of medicines.

Priorities for 2015

The ABPI has set its strategic priorities for 2015 and is working towards achieving these for the benefit of members as well as patients nationwide.

Our priorities for 2015 fall into three broad categories:

- To improve the UK environment for research, development and manufacturing
- To improve the commercial environment in the UK, building on the platform of the PPRS
- To improve the perception of industry in the eyes of our stakeholders.

Our priorities for 2015 include:

To improve the UK environment for research, development and manufacturing

- · Create a favourable research and policy environment for personalised medicines
- Improve the UK clinical research environment and performance
- · Demonstrate the link between the UK R&D and access/uptake of new, innovative medicines
- · Encourage the effective operation of the early access and adaptive licensing schemes
- Support the utilisation of the big data opportunity in the UK

To improve the commercial environment in the UK, building on the platform of the PPRS

- Ensure PPRS commitments are met and ensure industry confidence in the scheme
- Deliver pro-innovation HTA reform to drive improved access
- · Break the NHS barriers to uptake in England, Wales, Scotland and Northern Ireland
- Demonstrate the value of medicines to the healthcare system
- · Address affordability challenges with innovative solutions
- Establish key issues for consideration before the next PPRS negotiation

To improve the perception of the industry in the eyes of our stakeholders

- Create and deliver an integrated, proactive policy, public affairs and communications plan to underpin the ABPI Strategy for 2015
- Drive reputation through disclosure of individual payments to healthcare professionals and progress clinical trial transparency
- · Deliver a compelling story around the value of our industry
- · Strengthen the ABPI story and refresh corporate materials
- Collaborate with members and stakeholders including patient organisations
- Build communications excellence and move from reactive to proactive in media relations

ABPI Board of Management (as of 31.12.14)



ROW 1 (Left to right)

Jonathan Emms Pfizer Ltd President

Lisa Anson AstraZeneca UK Ltd

Steve Arnold *UCB Pharma Ltd*

Robin Bhattacherjee Actelion Pharmaceuticals UK Ltd

Nick Bruce Pfizer Ltd

Nick Burgin *Eisai Europe Ltd*

ROW 2 (Left to right)

Pete Butterfield *Alliance Pharmaceuticals Ltd*

Jean-Michel Cosséry *Eli Lilly & Co. Ltd*

Frederic Guerard Novartis Pharmaceuticals UK Ltd

Mark Hicken Janssen-Cilag Ltd

John Kearney Amgen Ltd

Nicola Massey Shire Pharmaceuticals Ltd

ROW 3 (Left to right)

Johanna Mercier Bristol-Myers Squibb Pharmaceuticals Ltd

Michael Nally

Merck Sharp & Dohme Ltd (MSD UK)

Matt Regan

AbbVie Ltd **Tarja Stenvall**Sanofi Ltd

Steve Turley Lundbeck Ltd

Nikki Yates GlaxoSmithKline Plc (GSK)

ABPI Senior Leadership Team (as of 31.12.14)



ROW 1 (Left to right)

Stephen Whitehead Chief Executive

Geoff Bailey Finance Director

Carol Blount

NHS Partnership Director (Scott Purdon from January 2015)

Paul Catchpole

Value and Access Director

Alison Clough

Executive Director - Commercial UK

ROW 2 (Left to right)

Colette Goldrick

ABPI Northern Ireland and International Affairs Director

Dr Richard Greville

ABPI Cymru Wales and Distribution and Supply Director

Samantha Ogden

Chief of Staff and Operations

Andrew Powrie-Smith

ABPI Scotland Director (Sandra Auld, Acting Director from January 2015)

Dr Bina Rawal

Research, Medical and Innovation Director (Virginia Acha from March 2015)

ROW 3 (Left to right)

Heather Simmonds

Director of the Prescription Medicines Code of Practice Authority

Aileen Thompson

Executive Director Communications

Professor Adrian Towse

Director of the Office of Health Economics

Carol Wilson

Legal Director and Secretary to the Association

We bid a fond farewell to some esteemed colleagues in 2014 including: Andrew Powrie-Smith, Louise Leong, Esteban Herero-Martinez and Catherine Meaden. The majority of them remain within the pharmaceutical industry, working closely with us and member companies.

We also welcomed some key new colleagues to the ABPI including: David Watson as Head of Commercial and Chris Rowland as Value and Access Manager; Ruth Wilson leading our work with therapy groups, Sunayana Shah managing regulatory affairs and James Christie heading up our newlyformed Medicines Manufacturing Industry Partnership (MMIP).

On the SLT we welcomed Aileen Thompson as Executive Director Communications. Aileen joined from Innovate UK. Joining her on the team were also Dr Virginia Acha, Executive Director Research Medical and Innovation from Amgen and Scott Purdon, NHS Partnership Director from ViiV Healthcare.

The ABPI team, its expertise and experience, continues to grow in order to deliver a first-class service for members and we look forward to working with and for you during 2015.

Membership (as of 31.12.14)

We welcomed nine new members to the ABPI in 2014 – two full members and seven general affiliate members:

Full members:

- · Alimera Sciences Limited
- · Allergan Limited

General affiliate members:

- Binleys
- · Clifford Chance LLP
- Eight Days A Week Printing Solutions Limited
- · Healthcare 21 Communications Limited
- · Health IQ Limited
- nspm UK ltd
- · Why Health Limited

In total we had 126 members:

Full members

A. Menarini Farmaceutica Internazionale S.r.l.

Abbott Laboratories Limited

AbbVie Limited

Actelion Pharmaceuticals UK Limited

Alexion Pharma UK Limited

Alimera Sciences Limited

ALK-Abello Limited

Allergan 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

BioMarin Europe Limited

Boehringer Ingelheim Limited

Bristol-Myers Squibb Pharmaceuticals Limited

Celgene Limited

Chiesi Limited

Chugai Pharma Europe Limited

Daiichi Sankyo UK Limited

Daval International Limited

Eisai Limited

Eli Lilly & Company Limited

Fresenius Medical Care (UK) Limited

GlaxoSmithKline Plc

Grünenthal Limited

Ipsen Developments Limited

Janssen

Leo Pharma

Lundbeck Limited

Merck Serono Limited

Merck Sharp & Dohme Limited

Merz Pharma UK Limited

Mitsubishi Tanabe Pharma Europe Limited

Napp Pharmaceuticals Limited

Novartis Pharmaceuticals UK Limited

Novo Nordisk Limited

Orion Pharma (UK) Limited

Otsuka Pharmaceutical Europe Limited

Pfizer Limited

Pierre Fabre Limited

Quintiles UK

Rosemont Pharmaceuticals Limited

Sanofi Limited

Servier Laboratories Limited

Shionogi Limited

Shire Pharmaceuticals Limited

Sunovion Pharmaceuticals Europe Limited

Takeda UK Limited UCB Pharma Limited ViroPharma Limited

Warner Chilcott Pharmaceuticals UK Limited

General affiliate members

1HQ Limited

American Express Europe Limited

Amygdala Limited

Arnold & Porter (UK) LLP Ashfield In2Focus Limited Atlantis Healthcare UK Limited

Aurora Healthcare Communications Limited

Baker & McKenzie LLP Banks Sadler Limited

BCD Meetings and Incentives Limited

Binleys

Bird & Bird LLP BMI System Limited

Bristows

BTG plc (British Technology Group) Cegedim Relationship Management

Clifford Chance LLP

CMS Cameron McKenna LLP Compliance Hub Limited Covington & Burling LLP Creston Health Limited

Datapharm Communications Limited

Deloitte LLP

DHR International Life Sciences Europe

DLA Piper UK LLP

Eight Days A Week Printing Solutions Limited

Ernst & Young LLP Eversheds LLP

Five Hats International Limited

Galbraith Wight Limited

Hayward Medical Communications Limited

Healthcare 21 Communications Limited

Healthcare at Home Limited

Health IQ Limited

Hogan Lovells International LLP

IMS Health Limited

KPMG LLP

Linklaters LLP

M D Events Limited

Norton Rose Fulbright LLP

nspm UK ltd

PA Consulting Group Limited

Packer Forbes Communications Limited

PH Associates Limited

Policy Matters LLP

PricewaterhouseCoopers LLP

Simmons & Simmons LLP

Star Medical Limited

Taylor Wessing LLP

Trinity Events Solutions Limited

Trio Media Limited

Virgo Health Limited

Why Health Limited

Wragge Lawrence Graham & Co LLP

Research affiliate members

Axess Limited

Charles River Laboratories

Covance Laboratories Limited

Life Sciences Research Limited

Marshall BKU

NDA Regulatory Science Limited

ORION Clinical Services Limited

Parexel International Limited

PrimeVigilance Limited

Quintiles Limited

Quotient Clinical Limited

Randox Laboratories Limited

Sequani Limited

Sucampo Pharma Europe Limited

Takeda Development Centre Europe Limited

TranScrip Partners LLP

ABPI – a voice for industry

The ABPI represents innovative research-based biopharmaceutical companies, small, medium and large. Our members supply 90% of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI is recognised by government as the industry body negotiating on behalf of our members and the branded pharmaceutical industry in relation to the PPRS. The ABPI is also consulted on content and changes to the statutory scheme alternative.

Working together with members we provide a strong voice, ensuring that members and industry are heard through advocacy and engagement with key stakeholders including policy makers, government and regulators to ensure that the pharmaceutical industry is recognised as a key sector for the UK economy and positioned as a partner in the wider healthcare system.

We keep members informed and up to date with policy briefings and updates, supporting engagement at the highest levels on all the key issues including:

- Animal research and the 3Rs (Replacement, Refinement and Reduction)
- Clinical research infrastructure and governance, covering all phases of clinical development, real world data studies, experimental medicine and research using electronic health records
- · Education and skills
- Joint working between companies and the NHS

- Manufacturing and product quality
- Market freedoms, including the supply of medicines
- Medical affairs and patient engagement
- NHS commissioning
- Open innovation
- Patient access to innovative medicines
- Pharmacovigilance
- · Prescribing guidance to healthcare professionals
- Purchasing behaviour within the NHS
- Regulatory affairs
- · Stratified medicine
- Taxation
- The operation of Health Technology Assessment (HTA) throughout the UK including National Institute for Health and Care Excellence (NICE) in England, Scottish Medicines Consortium (SMC) in Scotland and All Wales Medicines Strategy Group (AWMSG) in Wales
- The operation of the Pharmaceutical Price Regulation Scheme (PPRS) 2014
- The value and pricing of innovative medicines.

For more information on membership services please contact

membership@abpi.org.uk 0207 930 3477

Association of the British Pharmaceutical Industry 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT Tel: 0207 930 3477 Email: abpi@abpi.org.uk

ABPI Cymru WalesFloor 4, 2 Caspian Point, Pierhead Street, Cardiff Bay CF10 4DQ
Tel: 0207 930 3477

ABPI Northern Ireland The Mount, 2 Woodstock Link, Belfast BT6 8DD Tel: 0207 930 3477

ABPI Scotland3rd Floor Crichton House, 4 Crichton's Close, Edinburgh EH8 8DT Tel: 0207 930 3477