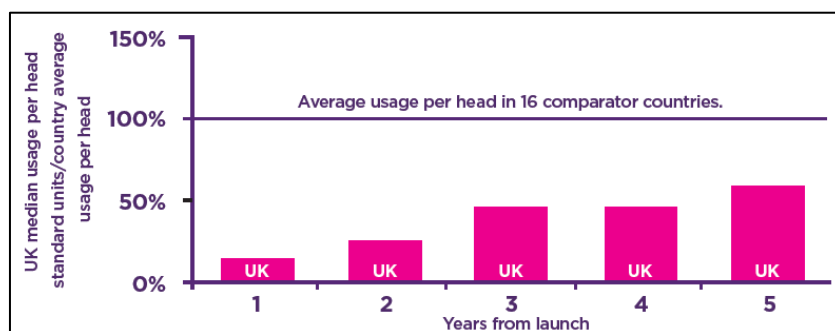


Availability and pricing of branded medicines

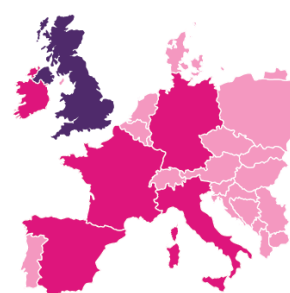
Executive summary

- Through the development of new medicines, the pharmaceutical industry helps to save and improve lives as well as contributing to both NHS and wider economic productivity.
- Fewer patients in the UK are receiving new, innovative medicines than the average in a range of comparable, developed countries. Our recent report¹ shows that the UK remains 9th out of 13 comparable countries across 16 therapy classes surveyed.



- Through the voluntary 2014 Pharmaceutical Pricing Regulation Scheme (PPRS), the pharmaceutical industry has recognised the financial challenges facing the NHS. As a contribution to an exceptional period of austerity we have agreed to keep the branded medicines bill flat for two years, with below 2% growth for a further three years. The industry will underwrite all further expenditure by the NHS, within agreed boundaries.
- The PPRS is an opportunity to drive greater patient access to innovative medicines, since it provides predictability of the bill for branded medicines in the NHS.
- To improve patient access to innovative medicines, we believe that NICE needs to urgently evolve to be fit for the current and future medicines pipeline.
- The NICE appraisal process should be aligned to the wider goals of the NHS. The importance of helping the most vulnerable and those in greatest need, and society's willingness to pay more for medicines at the end of life and for rare conditions, should be recognised. The perspectives of patients and clinicians should also be strengthened in the medicines assessment process.

The UK lags behind Europe in investing in medicines. Expenditure on pharmaceuticals per person*



* Source: OECD Health Data 2012 - currency converted from EUR to GBP using exchange rate of 1 EUR = 0.81 GBP

¹ *International Comparison of Medicines Usage: Quantitative Analysis*, ABPI, 27 November 2014
<http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/271114.aspx>



The value and pricing of medicines

By researching and developing innovative medicines for patients across a huge range of diseases and conditions, the pharmaceutical industry makes an essential contribution to the health and well-being of people in the UK and across the world.

The medicines developed by the research-based pharmaceutical industry provide positive benefits in terms of treating diseases better than before, treating ill health, preventing hospital admissions or other more expensive interventions, and preventing ill health and outbreaks of disease with vaccines. Medicines also support economic growth by helping people to recover from illness, manage chronic conditions and return to work more quickly.

- The estimated number of lives saved through the use of statins has tripled and rates of premature death from chronic heart disease are now lower than ever before.² Around four million people are now receiving statins, saving an estimated 10,000 lives every year.³
- The introduction of antiretrovirals began the transformation of the treatment of HIV infection from a death sentence to a chronic disease.
- In 1992, routine vaccination of babies against Hib commenced in the UK. Within three years, the number of infections fell by 96%⁴

Medicines expenditure in the UK

Medicines represent great value for the NHS and the country. Their many health benefits and knock on benefits for social care, benefits and the economy are obtained very efficiently by the NHS.

- In the UK, the overall spend on medicines represented only 9.6% of total UK-wide NHS expenditure, while medicines from the research-based industry represented 7.1% of total UK NHS spend (2013).
- Total medicine costs in the UK represent only 0.9% of GDP, which compares to 1.2% average across countries including: USA, France, Spain, Germany, Italy, Belgium, Ireland, Austria, Sweden and Denmark (Data assessed December 2013).
- The UK enjoys a highly effective and competitive generics medicines market which means that once patents have expired and research-based companies have made a return on their investment, the NHS reaps considerable savings, estimated at around £7bn a year.⁵
- The Pharmaceutical Price Regulation Scheme (PPRS) controls both the allowable profit by pharmaceutical companies and, in the new scheme which started this year, controls the growth of the medicines bill. It is negotiated by the ABPI on behalf of the industry with the Department of Health and is a four-nations agreement.
- Through the voluntary PPRS, the pharmaceutical industry has recognised the financial challenges facing the NHS. As a contribution to an exceptional period of austerity we have agreed to keep the branded medicines bill flat for two years, with below 2% growth for a further three years. The industry will underwrite all further expenditure by the NHS, within agreed boundaries.
- 93% of the branded market (134 companies) is covered by the voluntary PPRS.

² Healthcare Republic, Shaping the future, progress report, January 2007

³ Department of Health, the Coronary Heart Disease National Service Framework, progress report for 2008, March 2009.

⁴ Department of Health Green Book. Chapter 16. <http://immunisation.dh.gov.uk/green-book-chapters/chapter-16>

⁵ www.britishgenerics.co.uk/about-generics/key-facts Data updated 2010.



Patient access to innovative medicines in the UK

The ability of patients in the UK to access the latest, innovative medicines remains problematic despite a number of policy initiatives and the right of patients under the NHS Constitution to “*drugs and treatments that have been recommended by NICE for use in the NHS, if the doctor says they are clinically appropriate.*”

Patient access to new medicines in the UK is both low and slow compared to other countries. This means that NHS patients are missing out on treatments which are available in other parts of the world (see figure 1).⁶ So, five years after a medicine has been launched, for every 10 patients benefiting from the medicine across the other countries, only 6 UK patients will be receiving it.

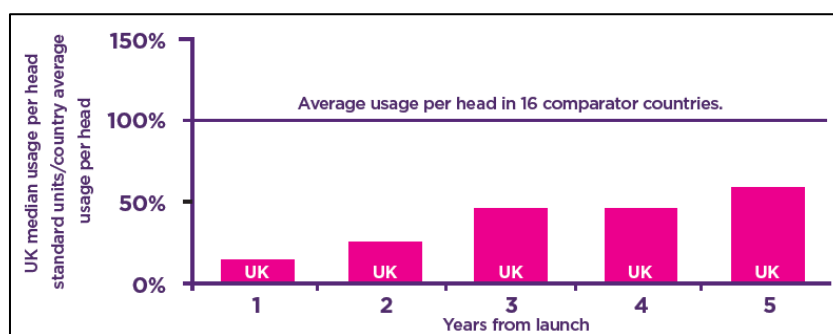


Figure 1

This is confirmed by our report⁷ which shows that the UK remains 9th out of 13 comparable countries across 16 therapy classes surveyed. The report highlights a reliance on older medicines and relatively slow uptake since 2009 of newer, more innovative medicines particularly to treat cancer.

- There was an increase in usage per person for 11 of the 16 therapy classes surveyed from 2008/09, but in seven of these the UK usage per person remained below the international average for 2012/13 – including the latest cancer medicines (less than five years old) and those for dementia, multiple sclerosis and stroke prevention.
- UK usage of HIV medicines is in line with that of other countries; however, its use of diabetes medicine is about a third of that of other countries, close to the international average for insulin and significantly above the average for older diabetes medicines.

Significant barriers exist in the UK which make it difficult to ensure patients receive the newest and most innovative medicines. These include lengthy technology assessment processes and rejections that lead to delays and limited access for patients. Access to innovative medicines still varies considerably according to where you live in England. The *Use of NICE-appraised medicines in the NHS in England* report published in January 2014 showed variations in medicines use across the NHS⁸, including:

- A ten-fold difference in usage between local area teams is shown with *Denosumab*, used to treat osteoporosis.
- A 29-fold difference in usage between local area teams is shown by novel oral anticoagulant drugs (NOACs) data within primary care.

⁶ Office of Health Economics, based on analysis of 61 medicines launched in the UK since 2007, using IMS and ONS/OECD data

⁷ *International Comparison of Medicines Usage: Quantitative Analysis*, ABPI, 27 November 2014
<http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/271114.aspx>

⁸ *Use of NICE-appraised medicines in the NHS in England* HSCIC, 21 January 2014
http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/21012014_a.aspx



Initiatives to improve patient access to innovative medicines

Innovation, Health and Wealth

The Government's *Strategy for UK Life Sciences* and the accompanying NHS *Innovation, Health and Wealth* (IHW) report launched in December 2011 recognised the importance of improving patient access to innovative medicines and technologies in the NHS. There are some early signs of improvement in uptake, utility and international comparisons, but there is further work needed to accelerate those improvements. In the ABPI's response to the NHS England consultation *Incentives, Levers and Sanctions, IHW Refresh* in 2013 we called for:

1. Acceleration of operational accountability and delivery
 - Identify system and organisational leaders accountable and responsible for driving innovation uptake in each organisation and system. Ensure an annual 'innovation report' is integral part of Quality and Annual Accounts.
2. Fast and effective implantation of NICE TAs, NHS England approved medicines and NICE Clinical Guidelines and standards
 - Introduce an integrated national incentive for improved access and uptake of NICE TA and similarly approved medicines, supported by appropriate sanctions
 - The introduction of regular, published, organisational and system audits of all NICE TA and similarly NHS approved medicines through organisational and system formularies audit - incentivised if necessary through joint CQUIN and CCG Quality Premium before becoming standard practice within the Standard Contract, with associated penalties for non-compliance.
 - Develop with NICE and CCGs NICE TA implementation guidance for launch on NICE TA publication. Ensure through national direction the Tariff system is transparent and supportive of rapid take up.
3. Align NHS incentives
 - Align the existing incentive schemes (CQUIN, QoF, Quality Premium, Best Practice Tariffs and the Standard contract incentives and sanctions) to incentive systems and not individual organisations to drive system patient outcomes.
 - Use the PbR tariff system to openly and explicitly incentivise take up of innovative medicines and models of care in support of the wider transformation agenda.
4. Metrics
 - A new set of measures for consistently assessing the appropriate usage of innovative medicines across all NHS localities which enables organisational, system and national data comparison against an agreed set of 'what good looks like' for peer and public scrutiny.

PPRS and Medicines Optimisation

The ABPI and NHS England have in recent months set up a joint PPRS/Medicines Optimisation programme which aims to improve patient outcomes, quality and value of care from medicines use and maximise the benefits of the PPRS. As part of this, roadshows will take place next year to communicate the importance of medicines optimisation and the functioning of the PPRS to operational, clinical and financial staff in the NHS.

Innovative Medicines and MedTech Review

The ABPI welcomed the Innovative Medicines and MedTech Review review announced on 20 November, highlighting the need for a holistic approach to UK life sciences. The review should bring together the life science industrial strategy with the health system, linking licensing, value assessment, NHS commissioning in order to deliver increased patient access to new, innovative medicines. It is essential that the review considers NICE's role in an end to end approach to life sciences, with changes made to the way NICE evaluates new medicines in line with the changing regulatory model and evolving medicines pipeline.



Recommendations for policy makers

The NHS should be a leader in making new innovative medicines rapidly and consistently available, so that the right patient gets the right medicine at the right time. As well as our recommendations for furthering IHW, we believe far more could be done to drive greater patient access to innovative medicines. The PPRS is an opportunity to do this, since it provides predictability of the bill for branded medicines in the NHS during its five-year term.

The ABPI is committed to working with all stakeholders to ensure that the scheme delivers better access to innovative medicines for patients. In looking at this, it will be important to:

- Revamp the NHS Innovation Scorecard to ensure clear, comprehensive published measures on levels of adoption of innovative medicines. The measures should be benchmarked against agreed estimates for their appropriate clinical use, and included in performance reports to the NHS Board and annual reporting to Parliament.
- End NHS activities solely focused on cost containment of branded medicines and resource redeployed to optimise the use of medicines.
- Align incentives to optimise the use of medicines in line with the Principles for Medicines Optimisation, which both the ABPI and NHS England are signed up to.

NICE

- NICE processes, methods and decision-making need to urgently evolve to be fit for the current and future medicines pipeline. Research shows that 60% of the pipeline of new medicines is specialised or stratified (personalised) medicines⁹ so NICE needs to take account of the evolving evidence base and enable earlier access for patients.
- The NICE appraisal process should be aligned to the wider goals of the NHS. The importance of helping the most vulnerable and those in greatest need, and society's willingness to pay more for medicines at the end of life and for rare conditions, should be recognised.
- The perspectives of patients and clinicians should also be strengthened in the medicines assessment process.
- NICE Appraisal Committees should be able to take a realistic, flexible and pragmatic approach in order to bring to patients valuable new treatments that address unmet need.
- A reformed NICE should provide a new single value assessment of all new medicines and indications, with no need for duplication of evaluation by other national or local NHS agencies.

Next steps for the Cancer Drugs Fund

- The Cancer Drugs Fund (CDF) was introduced to enable patients to have access to cancer medicines that are routinely available in other EU countries. The fund has gone some of the way to address this although the UK still lags behind Germany, France and Italy as regards the access to medicines for patients in need.
- The ABPI is concerned that NHS England's new processes for re-evaluating medicines in the Cancer Drugs Fund are crude and likely to result in poorer outcomes for patients. A more sustainable solution is needed.
- The ABPI recommends that greater headroom should be created in the CDF budget by moving some existing medicines into routine baseline commissioning prior to embarking on re-evaluation of medicines. NICE should evolve its appraisal processes by April 2015 to undertake value assessments for CDF medicines.

Before the introduction of the CDF, use of new cancer medicines in the UK was 33% lower than the European average.

⁹ *Securing a Future for Innovative Medicines*, ABPI 10 April 2014 <http://www.abpi.org.uk/media-centre/newsreleases/2014/Pages/100414.aspx>



About the ABPI

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

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90 per cent 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 the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

About the UK pharmaceutical industry

- Our industry invests around £5bn every year in research and development in the UK, or just over £11m a day
- The UK pharmaceutical industry employs 73,000 people, 23,000 of them in research and development jobs
- 25% of all expenditure on R&D in UK businesses is by the pharmaceutical industry, more than any other sector
- We are an important manufacturing sector and generate a trade surplus of £5bn for the UK per year
- One eighth of the world's most popular prescription medicines were developed in the UK

Contact us

For any enquiries please contact the Policy & Public Affairs team:

Audrey Yvernault, Head of Policy & Public Affairs ayvernault@abpi.org.uk

Andy Bolan, Public Affairs Officer abolan@abpi.org.uk

Tel: 0870 890 4333