abpi

Bringing medicines to *life*

Delivering value to the UK

The contribution of the pharmaceutical industry to patients, the NHS and the economy

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Amended January 2016

Our value in numbers

£11.5 million invested in the UK per day on research and development[1]

73,000 people employed directly in the UK[2]

Each employee contributing £149,000 to GDP per year[3]

The industry generates a trade surplus of £3bn for the UK per year[4]

25% of all expenditure on R&D in UK businesses is by the pharmaceutical industry[5]

[1] Office for National Statistics (ONS), Business Enterprise Research and Development 2012, November 2013
[2] Office of Health Economics (OHE) calculations based on ONS, Business Enterprise Research and Development (2008, 2009, 2010, 2011, 2012), accessed December 2013
[3] ONS, Annual Business Survey 2012 Provisional, November 2012 (Section C, Manufacturing) and BERD 2012 released November 2013
[4] HM Revenue and Customs, UK Trade Info 2013, February 2014
[5] ONS, Business Enterprise Research and Development, 2012, November 2013

An asset to be proud of

The pharmaceutical industry is one of the UK's most valuable assets. Through researching and developing innovative medicines for patients, across a huge range of diseases and conditions, the industry makes an essential contribution to the health and wellbeing of people in the UK and across the world.

With the UK's strong science base, an innovative pharmaceutical industry and the enormous potential of the NHS as an engine for research, the UK is in a strong position to continue to lead in the development and delivery of medicines.

We are also an important partner for the NHS, academia and the research community. In partnership with the NHS, we are working hard to encourage the adoption and diffusion of innovation within the NHS. By working together in partnership, we can provide the strongest foundation for developing innovative medicines and ensuring that patients receive the most appropriate medicines when they need them.

The industry also makes a vital contribution to the UK's economy and has the potential, within the right environment, to continue to flourish and generate further growth – but this potential needs to be nurtured.

The challenges the industry faces in the UK

The UK is in a tough global race to attract investment and compete with other economies across the world in order to sustain its vibrant and innovative research community and advanced manufacturing expertise.

We cannot underestimate the growing challenges for innovation in the UK. The UK's global share of clinical trials has fallen in recent years and the UK is slipping down the table in terms of the national origin of the leading 100 global medicines by sales. Together, we must reverse these trends if we are serious about maintaining the UK's global position.

Failing to nurture such a valuable industry will make global pharmaceutical companies think twice before investing in the UK. In addition, for the many small and medium-sized enterprises (SMEs) in our sector, the economic downturn and the current business environment pose significant challenges.

Today, UK patients are denied access to medicines that are routinely available in other countries. We have among the lowest usage of innovative medicines compared to other comparable countries, despite us having among the lowest priced medicines in Europe. We need to ensure that a brighter future awaits UK patients. Our industry's commitment is clear, we are determined to continue to work together with UK Government and the NHS to deliver better patient access to innovative medicines and to ensure that innovation and research are rewarded, and continue.

Sustaining economic growth – an industry to nurture

As well as bringing life-saving and life-enhancing medicines to patients, our industry is a major contributor to the economy of the UK

A great track record

The pharmaceutical industry remains a jewel in the UK's scientific and industrial crown. Britain's future economic prosperity depends on fostering strong, vigorous and well-supported knowledge intensive industries.

By most measures, the pharmaceutical sector is Britain's most successful research-based industry. Indeed, pharmaceutical companies collectively add more economic value than any other sector.

The commercial and policy environment in the UK has encouraged pharmaceutical R&D, manufacturing and marketing for many decades. In turn, the pharmaceutical sector's importance has bolstered the economy, generated high-quality jobs, and supported local communities across the UK.

The industry has been the driving force in a remarkably successful R&D programme for many decades in the UK that has produced numerous medicines responsible for reducing mortality and morbidity, while enhancing quality of life, for countless patients. This has also contributed heavily to Britain's collective scientific knowledge. The opportunity to participate in clinical studies keeps our UK-based healthcare professionals at the cutting edge of medical science and practice, as well as augmenting their knowledge, for the benefit of all patients.

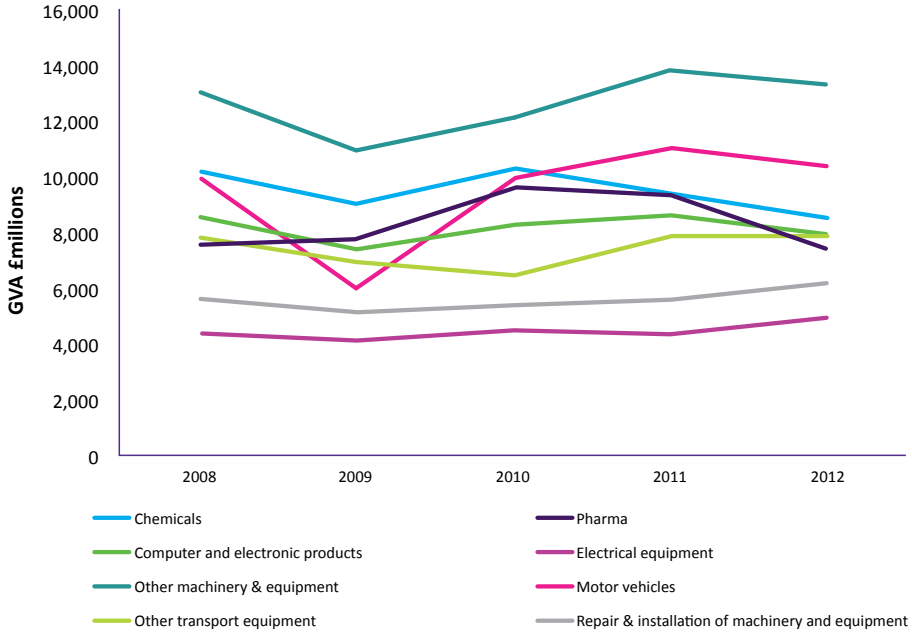
A vital contribution to the UK economy

The pharmaceutical industry delivers a significant contribution to the UK economy and the population as a whole.

As this diagram shows, the pharmaceutical sector makes a greater contribution than many other major high-tech industries in the UK.

Gross Value Added (GVA) is the contribution made by businesses, industries or sectors to the UK's national income – in other words, an industry's contribution to Gross Domestic Product (GDP).

Gross Value Added (GVA) for high and medium-high tech sectors (£millions) 2008-2012



Note for graph: Using the new definition of high and medium high tech sector (SIC2007)

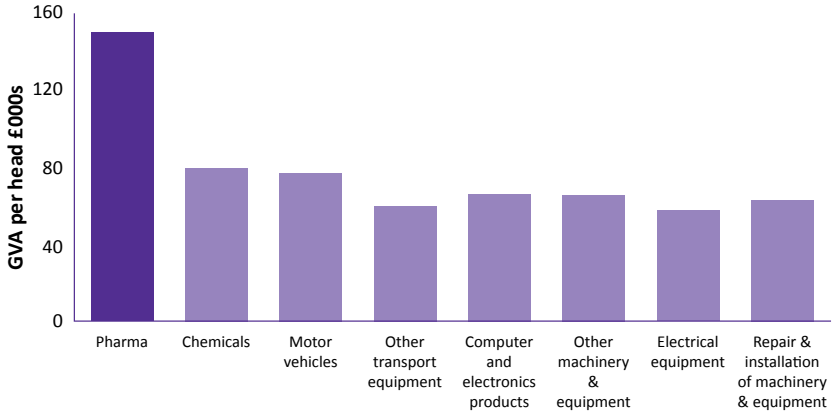
Source for graph: ONS Annual Business Survey (provisional) 2012, Section C Manufacturing. Release date 14th Nov 2013

Adding to the UK's national income

The pharmaceutical sector's relative importance becomes even more obvious when looking at the productivity – or GVA generated by each employee. According to the latest figures, this shows that GVA per employee in the industry was £149,000[7] in 2012 – significantly higher than high and medium-high tech sectors such as chemicals, motor vehicles and computer products.

Given the current economic situation, these figures highlight the vitally important contribution of the pharmaceutical industry to the UK's economic recovery, as is shown in this chart.

GVA per head for high and medium-high tech sectors (£000s) 2012



Note for graph: Using the new definition of high and medium-high tech sector (SIC2007)
Source for graph: ONS Annual Business Survey 2012 (provisional), Section C, Manufacturing, Release date 14th November 2013

[7] ONS Annual Business Survey 2012 (provisional), Section C, Manufacturing, Release date 14th November 2013

Generating a positive trade balance

The pharmaceutical sector has, over the past decade, consistently generated a large trade surplus for the UK – at £3bn per annum, according to the latest figures.[8]

In 2013, the pharmaceutical sector's contribution to the balance of trade was the 3rd greatest of nine major industrial sectors, up from 5th in 1975.[9]

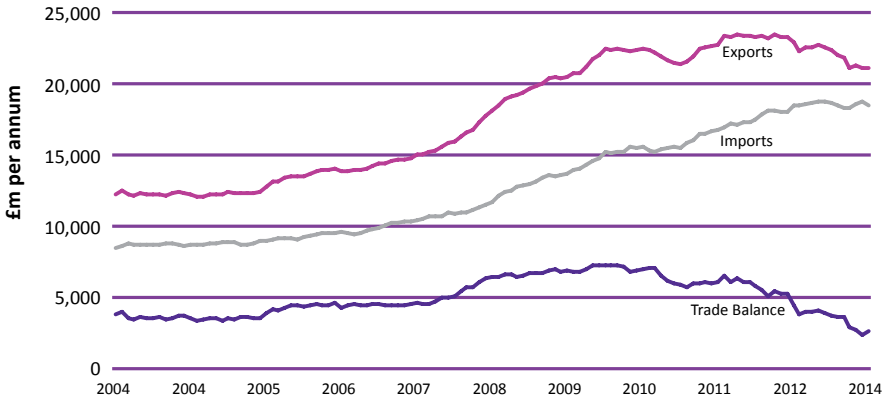
The trade balance refers to the difference between the value of UK exports to other countries and the value of imports from them.

As the diagram below shows, over the past decade the trade balance in pharmaceuticals has seen a small overall increase.

In 2013, the UK's trade deficit for all goods and services was on average around £2.5bn per month.[10]

The pharmaceutical industry generates a positive trade balance for the UK

UK Pharmaceutical trade, February 2004 to February 2014 (12 month moving total).



Source for graph: HM Revenue and Customs, UK Trade Info, released March 2014

[8] HM Revenue and Customs, UK Trade Info 2013, February 2014

[9] OHE figures based on HM Customs and Excise data

[10] ONS, UK Trade, December 2013

A source of highly skilled jobs

The pharmaceutical industry employs around 73,000 people directly in the UK – 23,000 of which are in highly skilled research and development roles[11].

Pharmaceutical R&D and manufacturing create many highly-skilled jobs across the country – as well as supporting local communities and economies in many other ways. This contribution is made not only by global pharmaceutical companies but also by numerous SMEs based across the UK.

In addition, the industry generates thousands of jobs in related industries across the broad life sciences sector, which includes the biotechnology, medical technology and diagnostics industries. The industry is part of a much wider ecosystem which extends across universities, charities, research bodies and numerous collaborative projects and networks across the UK.

[11] OHE calculations based on ONS, Business Enterprise Research and Development (2008, 2009, 2010, 2011, 2012), accessed March 2013

Creating a significant spill-over effect from R&D

The UK's pharmaceutical sector invests approximately £11.5 million every day in R&D.

In fact, there was more R&D investment performed in the pharmaceutical sector than any other sector in 2012, representing 25% of all expenditure on R&D in UK businesses[12].

Knowledge generated by R&D can flow from one organisation to other companies in the same sector. At the simplest level, scientists employed by the pharmaceutical sector share knowledge at congresses and in publications. In many cases, the flow of cutting-edge knowledge benefits other business sectors as well as public, academic and charitable organisations.

These investments not only benefit the pharmaceutical companies that make them. R&D investments made by one pharmaceutical company often stimulates innovation elsewhere in the sector or in the economy more widely.

The spill over effect to the rest of the economy generated by pharmaceutical R&D is estimated to be more than double the return that is captured by the company actually making the pharmaceutical R&D investment[13].

The UK pharmaceutical industry provides medicines to UK patients at some of the lowest prices in Europe[14]

[12] ONS, Business Enterprise Research and Development 2012, November 2013

[13] Garau M and Sussex J, Estimating Pharmaceutical Companies' Value to the National Economy Case Study of the British Pharma Group, OHE 2007

[14] Department of Health, PPRS Report to Parliament, 6th, 10th and 11th reports, 2002, 2009 and 2012

Delivering improved outcomes for patients

The pharmaceutical industry brings life-saving and life-enhancing medicines to patients who need them, improving the health and wellbeing of people in the UK and across the world

Value in health – better outcomes for patients

Medicines developed by the pharmaceutical industry have helped to change the healthcare landscape through the prevention or cure of previously life-threatening diseases.

Developments in medicines have also changed a number of acute 'death sentence' illnesses to manageable chronic conditions (such as HIV and AIDS).

Colorectal Cancer

- The five-year relative survival rates for both male and female colon and rectal cancer have doubled between the early 1970s and mid 2000s[16, 17, 18, 19, 20].

Cardiology

- The death rate from heart disease and related diseases among the under-75s has fallen by 44% since 2000.
- Medical and surgical treatments for chronic heart disease can together be directly credited with saving 28,520 lives in the year 2000 – roughly equivalent to one life saved every 20 minutes[21, 22].

[16] Coleman M, Babb P, and Damiecki P, Cancer Survival Trends in England and Wales, 1971-1995: Deprivation and NHS Region. Vol. 1999: TSO

[17] Rachet B, et al., Population-based cancer survival trends in England and Wales up to 2007: an assessment of the NHS cancer plan for England The Lancet Oncology (2009). Standardised figures were provided by the author on request

[18] ONS, Survival Rates in England, patients diagnosed 2001-2006, followed up to 2007

[19] Richard MA., Trends and inequalities in survival for 20 cancers in England and Wales 1986-2001: population-based analyses and clinical commentaries. Foreword. Br Journal Cancer, 2008, Vol. 99, Supplement 1, September

[20] Rachet B, et al., Population-based cancer survival trends in England and Wales up to 2007: an assessment of the NHS cancer plan for England, The Lancet Oncology (2009)

[21] NCSI, Coronary Heart Disease, David Wood, HCNA

[22] Unal B, Critchley JA, Capewell S, Explaining the decline in coronary heart disease mortality in England and Wales between 1981 and 2000, Circulation, 2004;109:1101–1107

Rising life expectancy

During the course of the 20th century, healthcare underwent dramatic and lasting changes which have had fundamental impacts on how care is delivered and how health services are managed and funded. A steady increase in life expectancy was one of the most fundamental and striking of these changes. Advances in medical care, including pharmaceuticals and other medical technologies, have played a significant part in this increase[23].

Helping people to live longer

Between 1891 and 1900, in England and Wales, a boy and girl born could expect to live for 44.1 and 47.8 years, respectively[24].

By 2011, life expectancy at birth had risen to 78.96 years for men, and 82.79 years for women in England and Wales[25].

Just over a century ago, in the early 1900s, more than half of deaths occurred among people aged under 45. By 2012 this figure had dropped to just 3.8%[26, 27, 28].

Our society's needs are also rising. Patient and public expectations for better care are increasing, driven by greater access to information, international comparisons and an increasing desire for choice. The health needs of the population are also changing as the population ages and, in addition, advances in technology can sometimes bring with them additional costs. Together these factors pose major challenges to health systems today.

The pharmaceutical industry is already helping to address major societal costs and the burden of certain long-term conditions such as heart disease. However, continued medical innovation is vital – and must be supported – if health services in the UK are to cope with the burden of an ageing population and the increasing demands for healthcare caused by long-term conditions.

[23] Baillie L and Hawe E, (2012) Causes of Death: A study of a Century of Changes in England and Wales, OHE, 2012
[24] ONS, Interim Life Tables, 2011
[25] ONS, Interim Life Tables 2010-12, 2013
[26] ONS, Mortality Statistics: Deaths Registered in England and Wales, 2012
[27] General Register Office for Scotland, Vital Events Reference Tables, 2012
[28] Northern Ireland Statistics and Research Agency, Deaths by Cause, 2012

Transforming HIV

The introduction of antiretrovirals began the transformation of the treatment of HIV infection.

In 1987, the first antiretroviral, AZT, was approved[29]. Saquinavir, the first protease inhibitor, was approved for use in the USA in 1995[30]. The introduction of this new class of drug began the pattern of 'combination treatment' to attack the virus.

The rapid adoption and uptake of new classes of innovative therapies used in combination with existing treatments transformed HIV treatment. This treatment success story was clinically driven responding to a large unmet need.

Between 1996 and 1999, the mortality rate among people with HIV was 16.3 per 1,000 person years. This declined to 10.0 per 1,000 person years over the two year period 2003-2005.

Over the same period, the potential years of life lost decreased from 366 to 189 per 1,000 person-years. Life expectancy for a HIV-positive 20-year old increased from 36.1 to 49.4 years[31].

Pharmaceutical innovation and investment has helped to transform health outcomes in the UK

[29] Kaiser Family Foundation, The Global HIV/AIDS timeline, www.kff.org/hivaids/timeline/hivtimeline.cfm, accessed March 2013

[30] Kaiser Family Foundation, The Global HIV/AIDS timeline, www.kff.org/hivaids/timeline/hivtimeline.cfm accessed March 2013

[31] Boerma JT, Nunn AJ and Whitworth JA, Mortality impact of the AIDS epidemic: evidence from community studies in less developed countries AIDS 1998;12 Suppl 1:S3–14

Cancer

Between 2000 and 2011, age-standardised mortality rates for all malignancies fell by around 12% for men and 9% for women[32].

Of the most common cancers, stomach and cervical cancer showed the greatest improvements. In stomach cancer, mortality rates decreased by 35% and 31% in males and females, respectively. In cervical cancer, mortality rates decreased by 24% in the last decade[33].

Looking ahead, two vaccines that protect against the two strains of human papillomavirus (HPV 16 & 18), responsible for more than 70% of cervical cancers, look set to herald a further significant decline in mortality from these particular cancers[34].

Despite falling mortality rates in many cancers, mortality from some cancers continues to rise in areas such as liver cancer[35] and uterine cancer[36].

To add to this burden, a number of cancers become increasingly common with advancing age, so with the lengthening of life expectancy the incidence of some cancers looks set to increase.

This highlights the importance of continuing to support pharmaceutical research into better treatments to increase both the quality of care (such as reduced side effects and easier modes of delivery) and life expectancy – as well as new treatments for as yet untreatable diseases.

[32] Cancer Research UK, Cancer mortality for all cancers combined, http://www.cancerresearchuk.org/cancer-info/cancerstats/mortality/all-cancers-combined/, accessed January 2014

[33] Cancer Research UK, Cancer mortality for common cancers, http://www.cancerresearchuk.org/cancer-info/cancerstats/mortality/cancerdeaths/, accessed January 2014.

[34] Cancer Research UK, HPV vaccines, www.cancerhelp.cancerresearchuk.org/about-cancer/cancer-questions/cervical-cancer-vaccine, accessed March 2013

[35] Cancer Research UK, Liver cancer mortality statistics, www.cancerresearchuk.org/cancer-info/cancerstats/types/liver/mortality/#trends, accessed March 2013

[36] Cancer Research UK, Uterine cancer mortality statistics, www.cancerresearchuk.org/cancer-info/cancerstats/types/uterus/mortality/, accessed March 2013

Vaccinations have helped to confine numerous diseases to history.

This point is illustrated by the story behind the Hib vaccination programme. Haemophilus influenzae type b (Hib) is a bacterium that can cause a number of clinical diseases including childhood meningitis, pneumonia and blood poisoning.

Hib vaccination
In 1992, routine vaccination of babies aged between two and four months against Hib commenced in the UK.

Within three years, the number of children who contracted Hib before their first birthday had fallen by 96%[37].

Appropriate use of innovative medicines is part of the solution for improved patient outcomes

[37] Department of Health Green Book. Chapter 16. Haemophilus influenzae type (Hib). http://immunisation.dh.gov.uk/green-book-chapters/chapter-16/

Cardiovascular disease

Pharmaceuticals are central to the treatment of both chronic heart disease (CHD) and stroke, and have made a significant contribution to improvements in morbidity and mortality.

Statins
The estimated number of lives saved through the use of statins has tripled and rates of premature death from CHD are now lower than ever before[38]. Around 4 million people are now receiving statins, saving an estimated 10,000 lives every year[39].

The Liverpool study

A study from Liverpool University (published in 2004, but which still represents the most comprehensive up-to-date study in this area) estimated that CHD mortality rates in England and Wales for people aged 35 to 84 years old decreased by 62% in men and 45% in women over the course of just two decades[40]. The authors estimated that 68,230 fewer people died from CHD in 2000 than expected based on forward projections using 1981 figures.

The study[41] estimated that overall, medical and surgical treatments accounted for 41.8% of this decrease in expected CHD mortality rates between 1981 and 2000:

- Aspirin accounted for around 42% of the reduction due to improved treatment of acute myocardial infarction, and approximately 32% through secondary prevention following a heart attack
- Fibrinolytics – which dissolve blood clots that form in the coronary arteries after a heart attack – accounted for 27% of the reduced mortality following acute myocardial infarction
- Fibrinolytics and antihypertensives accounted for 2.1% and 3.1% of the total improvement in mortality, respectively

Therefore, based on the percentage increase attributable to medical and surgical treatments for CHD, the authors suggested that these could together be credited with saving 28,520 lives in the year 2000.

[38] Healthcare Republic, Shaping the future, progress report, January 2007
[39] Department of Health, The Coronary Heart Disease National Service Framework, Progress Report for 2008, March 2009
[40] Unal B, Critchley JA, Capewell S Explaining the decline in coronary heart disease mortality in England and Wales between 1981 and 2000 Circulation 2004;109:1101–1107
[41] Unal B, Critchley JA, Capewell S Explaining the decline in coronary heart disease mortality in England and Wales between 1981 and 2000 Circulation 2004;109:1101–1107

Contributing to efficiencies and savings

Appropriate use of medicines can deliver patient benefits and cost savings to the NHS

Helping to fight the economic burden of illness

The pharmaceutical industry not only provides positive benefits in terms of helping to improve health outcomes and support economic growth, it also contributes to addressing future financial challenges.

Many chronic conditions place a huge economic burden on society through, for example[42]:

- Employee absenteeism and lost productivity due to illness
- The long-term medical, in-patient hospital and surgical costs typically associated with late treatment and worsening disease
- The significant cost to the NHS and local communities associated with permanent disability; and ultimately the costs of premature death
- The societal (psychological, family and community) costs associated with illness

Appropriate use of medicines can deliver patient benefits and consequent cost savings to the NHS.

The greatest positive economic impact which the industry brings, however, is in its contribution to the overall improvement in the health of the UK population, which helps people to recover from illness and return to work quicker.

The burden of illness on the economy[43] CBI research found that:

- In 2010, on average, each UK employee took 6.5 days sick leave which cost the economy £17bn that year
- Long-term absence accounts for nearly one-third (32%) of lost working time
- Stress, anxiety and depression remain the main causes of long-term absence
- Musculoskeletal disorders are the second most commonly identified cause of long-term absence for manual workers (44%) closely followed by chronic back pain (42%)

Through the development of new medicines, the pharmaceutical industry helps to improve both NHS and wider economic productivity

[42] CBI, Healthy returns? Absence and workplace health survey 2011, May 2011

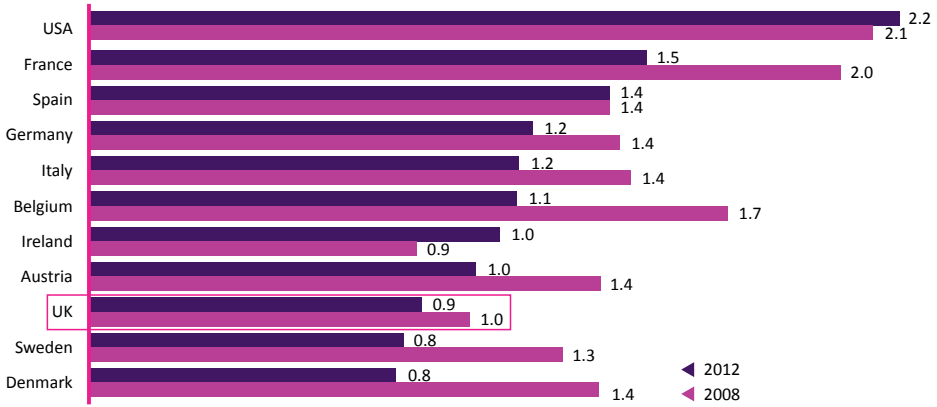
[43] CBI, Healthy returns? Absence and workplace health survey 2011, May 2011

Medicines deliver value for money for the NHS

In 2013, 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[44]. Total medicine costs in the UK represent only 0.9% of GDP, which compares to 1.2% average across countries shown in the chart below (excluding the UK)[45].

Under the new five year voluntary PPRS, the pharmaceutical industry has agreed to keep NHS expenditure on branded medicines flat for two years, with the pharmaceutical industry underwriting any further expenditure by the NHS within agreed boundaries.

Spending on medicines as a percentage of GDP in various countries in 2012[46]



Note: All data accessed December 2013
Source: IMS World Review Analyst, 2013. OECD Helath Database

[44] OHE, UK NHS medicines bill projection 2012 – 2015, analysis for the ABPI, June 2012

[45] OHE, UK NHS medicines bill projection 2012 – 2015, analysis for the ABPI, June 2012

[46] IMS Health, World Review Analyst 2013, OECD Health Database. All data accessed December 2013

Helping the NHS to achieve efficiencies

There are also significant hidden benefits of pharmaceuticals in terms of improvements in NHS productivity and the UK economy as a whole.

Other studies and analyses show more clearly that pharmaceuticals can – and do – directly save the NHS money, as shown below.

Hypertension
In 2009, following publication of clinical guidance on the treatment of hypertension – and despite an increase in NHS expenditure on antihypertensives – NICE estimated savings of £446,627 per 100,000 of the population in relation to the reduced treatment costs associated with fewer heart attacks and strokes. This amounted to an overall saving of over £200m per year across the NHS in England and Wales[47].

Severe eczema
NICE suggested that using a new treatment for severe eczema might reduce the demand on dermatological services. A shift away from PUVA (psoralen + UVA) could result in a saving of £5,962 per 100,000 of the population, equivalent to a saving of £3.3 million for the NHS per year.

[47] NICE, How NICE could help the NHS save millions, website, April 2010, www.nice.org.uk/newsroom/features/HowNICECouldSaveTheNHSOver600million.jsp and Cost Saving Guidance, NICE website at: www.nice.org.uk/usingguidance/benefitsofimplementation/costsavingguidance.jsp

Working in partnership with the NHS

Increasingly, pharmaceutical companies are working with the NHS to ensure local health priorities are met, patient outcomes are improved and local NHS organisations can meet their objectives. Guided by appropriate governance, including the ABPI Code of Practice, these joint-working projects ensure a win: win for patients, the NHS and the industry.

Local examples of joint working between the NHS and industry can demonstrate multiple benefits to patients and the NHS – if we can scale such examples to national level then the impact could be substantial.

Greenwich PCT worked with MSD on their *Evidence into Practice*™ Diabetes Programme[48]

- Delivered as a free-of-charge pilot across 14 practices in Greenwich
- 12% decrease in numbers of diabetes attendances from 2009/2010-2010/2011 vs 1% increase in non-pilot group
- 12% decrease in diabetic medicine outpatient attendances (compared to 1% increase in the non-pilot group) saving £23,385
- 8% decrease in number of cardiovascular disease (CVD) attendances from 2009/2010-2010/2011 vs 2% increase in non-pilot group
- 8% decrease in all CVD attendance (compared to 2% increase in non-pilot group) saving £177,734
- A total of £201,119 was saved (average of £14,366 per practice)

Wearside practice based commissioning consortium and GSK worked together on improving chronic obstructive pulmonary disease (COPD) care,[49] resulting in:

- Patients receiving an annual COPD review increased from 44% to 74%
- Patient's understanding of their condition increasing from 64% to 76%
- A 12% reduction in year-on-year non-elective COPD admissions in the period July 2009 to June 2010. In comparison, the other practices in Sunderland PCT recorded a 2% increase over the same period
- A 6% increase in the proportion of patients receiving combination therapy, in line with NICE COPD guidelines

[48] www.evidenceintopractice.com and www.greenwich.nhs.uk

[49] NICE, Shared Learning Database, Improving COPD patient care in line with NICE recommendations, http://www.nice.org.uk/usingguidance/sharedlearningimplementingniceguidance/examplesofimplementation/eximpresults.jsp?o=420

Continuing the success story – helping the industry to meet the challenges of the future

The success of the pharmaceutical innovation model relies on a holistic approach

The success of the pharmaceutical innovation model relies on a holistic approach across the lifecycle of medicines development, from high-risk upfront investment to delivery of efficiencies upon loss of exclusivity.

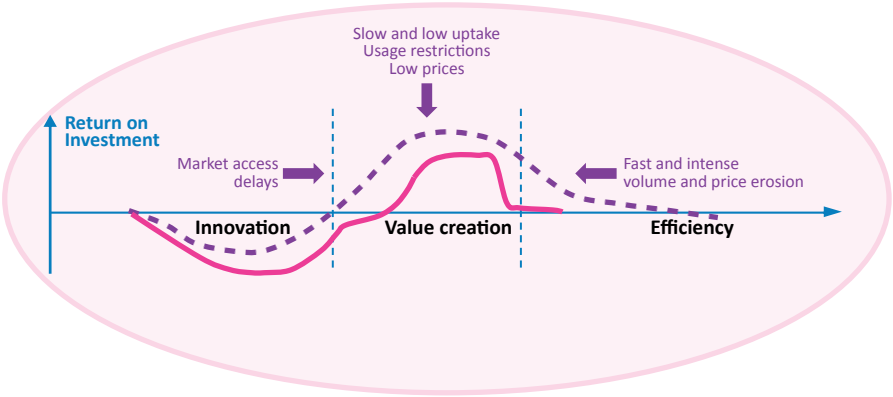
There are three distinct stages to this cycle.

1. Innovation – this is capital intense and high risk. Only 1 in 10,000 molecules screened ever reaches the market
2. Value creation – during this stage, manufacturers benefit from intellectual property protection and can recover a fair return on their investment
3. Efficiency – this model has in-built efficiencies. After loss of exclusivity, genericisation follows with consequent price reductions

The pharmaceutical innovation model is under pressure

However, the lifecycle for innovation in the UK is 'squeezed' on all sides

This model is affected by a number of challenges from delays in products reaching the markets, restrictions in patients being able to access them and continued pricing pressures.



The medicine development process

Bringing new medicines to patients is a lengthy, risky and costly process. It takes over 12 years and typically costs £1.15 billion to research and develop one new medicine from thousands of candidates and ensure that it meets the required quality, efficacy and safety standards. Only then will a new medicine be made available to patients and even then further barriers such as value and cost-effectiveness assessments may need to be overcome.

Stage of development	**Pre discovery** Based on their disease focus companies' scientists work to understand the disease	**Drug discovery** Researchers select a 'target', such as a gene or protein, then search for a molecule or compound that may act on the 'target' to alter the disease	**Pre-clinical testing** Early safety and efficacy tests are undertaken in computational models, cells and in animals
Average number of years taken at each stage to develop successful medicine[50]		**4.5 years**	**5.5 years**
Average cost to research and develop successful medicines[51]		**£436 million**	**£533 million**
Number of medicinal candidates tested to achieve one approved medicine[52]		**5,000 – 10,000 candidates**	**10-20 candidates**

Phase 1 clinical trial	**Phase 2 clinical trial**	**Phase 3 clinical trial**	**Licensing approval**	**Medicine available for patients**
The candidate medicine is tested in people for the first time. Studies are conducted with about 20 to 100 healthy volunteers	Researchers evaluate the candidate medicine's efficacy in about 100 to 500 patients with the disease	Researchers study the candidate medicine in about 1,000 to 5,000 patients to generate data about safety, efficacy and the overall benefit-risk relationship of the medicine	Information and results from all the studies is compiled and submitted to the regulatory agencies	The medicine is now licensed for use and patients may benefit from it, subject to value and cost-effectiveness assessments and local health budget availability
7 years	**8.5 years**	**11 years**	**12.5 years**	
£710 million	**£916 million**	**£1.1 billion**	**£1.15 billion**	
5-10 candidates	**2-5 candidates**	**1-2 candidates**	**1 medicine**	

[50] Paul S et al. How to improve R&D productivity: the pharmaceutical industry's grand challenge, Nature Reviews Drug Discovery, Volume 9 March 2010 (in 2010 prices based on Bank of England exchange rate)

[51] Paul S et al. How to improve R&D productivity: the pharmaceutical industry's grand challenge, Nature Reviews Drug Discovery, Volume 9 March 2010

[52] PhRMA analysis, updated for data per Tufts Center for the Study of Drug Development (CSDD) database (1995)

A 'tipping point' is approaching

The UK innovation lifecycle is currently being 'squeezed' on all sides. The UK medicines market is already very efficient, with branded medicines prices among the lowest in Europe[53].

Companies are finding the UK commercial environment increasingly challenging and this is demonstrated in a number of ways:

- Between 2000 and 2010, the UK's global share of patients in clinical trials fell by 14%[54]
- The UK's position as the country of origin of the leading 100 global medicines by sales declined between 2004 and 2011[55]
- The UK is an early launch market in global pharmaceutical launch sequences, but companies are starting to consider delaying launches in the UK because of the challenges they face
- Uptake of innovative medicines is poor
- Prescribing savings pressures in the NHS are significant and have increased

The industry is also making a significant contribution to efficiency savings. The UK has a highly efficient generic market, partly explained by high generic prescribing rates – at around 85%[56]. In addition, the UK has among the highest penetration, and use of, generic medicines across European countries – at around 65% of current market share[57].

Since the start of 2009, the pharmaceutical industry has helped the NHS to secure efficiencies of at least £3 billion, during a period when other areas of NHS expenditure have increased dramatically[58].

Looking ahead, loss of exclusivity of some major branded medicines is projected to yield £3.4bn of cumulative savings to the NHS across the UK between 2012 and 2015[59].

[53] Department of Health, PPRS Report to Parliament, 6th, 10th and 11th reports, 2002, 2009 and 2012
[54] Centre for Medicines Research (www.cmr.org); Global Clinical Performance Metrics Database; Kinapse report
[55] Department of Health, MISG, Pharmaceutical Industry: Competitiveness and Performance Indicators 2009
[56] IMS, PPA, OHE Analysis 2012; prices are based on drug tariff (actual net prices after discounts to pharmacy erode faster)
[57] IMS 2012 (2011 data)
[58] OHE, Estimates of efficiencies in the UK Medicines Bill in the four year period – 1 January 2009 to 31 December 2012, analysis for the ABPI, January 2013
[59] OHE, UK NHS medicines bill projection 2012 – 2015. Results – Four Nations, October 2012

Market share of innovative products in the UK lags behind comparable countries

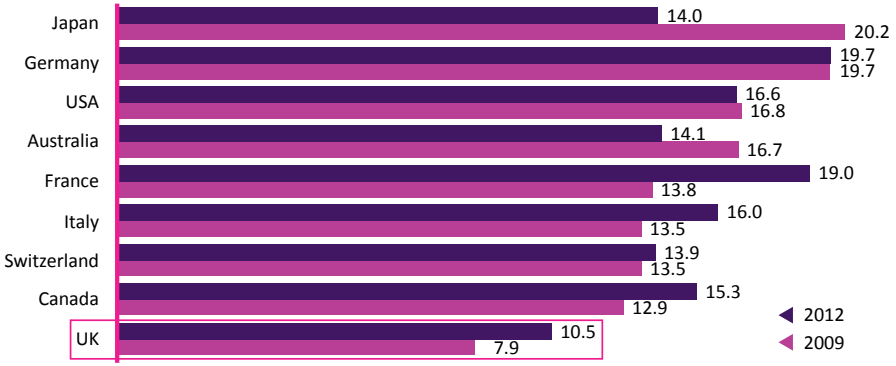
When we examine the market share of the newest pharmaceutical products in comparable EU and developed countries, it is clear that patients in the UK are not able to access these medicines as readily as elsewhere.

Significant barriers exist in the UK which make it difficult to ensure that patients receive the newest and most innovative medicines.

Lengthy health technology assessment processes and rejections lead to:

- Delays and limited access for patients
- Poor performance in innovation uptake[60]

Market share for pharmaceutical products, brands and generics, launched in the past 5 years by value (%)[61]



[60] OHE analysis 2012

[61] IMS, World Review Analyst 2013, accessed December 2013

Slow and low uptake

2010 saw the publication of the first international report, Extent and Causes of International Variation in Drug Usage, prepared by Professor Sir Mike Richards[62]. This compared the usage of medicines in the UK with that of 14 comparable European and developed countries. The report showed that out of 14 countries, the UK ranked lower in seven areas in terms of medicines usage:

- Cancer drugs launched within the last five years ranked 12th
- Cancer drugs launched more than 10 years ago ranked 10th
- Drugs for dementia ranked 11th
- Drugs for hepatitis C ranked 13th
- Drugs for multiple sclerosis ranked 13th
- Drugs for rheumatoid arthritis ranked 10th
- Second generation antipsychotics ranked 11th

Poor uptake of innovative medicines in the UK leads to poor patient outcomes, with, for example, five year cancer survival rates in the UK[63] being lower than most other European countries.

The latest analysis from the Office of Health Economics in 2013 confirms this picture.

The analysis compares the uptake (in volume terms) of 61 branded medicines launched in the UK since 2007 with 16 other comparable countries.

The results show that on average UK uptake for new medicines is at 14% of the median for the comparator countries in the first year from launch and 58% after five years.

Uptake of new medicines in the UK is, therefore, still well below the average for comparable countries[64].

[62] Department of Health, Extent and causes of international variations in drug usage: a report for the Secretary of State for Health by Professor Sir Mike Richards CBE, July 2010

[63] Eurocare 4 2009

[64] OHE analysis for the ABPI, Benchmarking the uptake of new medicines in the UK – international perspective, 2013

The UK pharmaceutical industry – a trusted and valued partner

A pivotal role in improving health

It is clear that medicines have a major role to play in improving the health of our nation by:

- Preventing life-threatening diseases
- Helping to change previously life-threatening illnesses to long-term conditions
- Improving the quality of life for people with long-term conditions
- Reducing mortality across a wide range of diseases and thereby helping to increase life expectancy

However, this is only part of true value that medicines provide to people and society, since they also help to:

- Improve NHS productivity – by reducing the need for longer term, more expensive treatment (surgical treatment and in-patient stays, for example)
- Help to shift care from hospitals into the community
- Improve health outcomes
- Reduce absenteeism due to illness
- Improve our society's sense of wellbeing

- The pharmaceutical industry in the UK has consistently contributed to the health and economy of the nation
- The pharmaceutical industry in the UK must remain a world leader and needs to be supported
- The pharmaceutical industry is worth investing in for the UK's future

Looking ahead – an industry ready to help grow the economy out of recession

The value provided by the UK's pharmaceutical industry extends beyond developing life-extending and life-transforming, innovative medicines.

From supporting ongoing medical professional education, to joint working projects that help the NHS achieve better patient outcomes, to supporting local communities and partnering with international organisations to supply vaccines to the developing world, the industry's contribution can be seen in numerous ways.

The UK pharmaceutical industry is playing its part in bringing value to patients in the UK and to the country's economy, working with one of the UK's greatest assets – the NHS. Together, we are working to ensure that patients receive the most modern medicines at the time when they need them most.

We also need to recognise that the business environment in the UK is very challenging – and the external perception of the UK as a place to invest is not always a positive one. As this document has shown, the UK continues to lag behind in the adoption of new medicines compared to many other European countries and the UK's global share of patients in clinical trials has fallen in recent years. The pharmaceutical industry in the UK is now at a crucial moment and we must reverse these trends if we are serious about maintaining the UK's position.

The industry stands ready to be a continued driver for economic recovery, but our message is simple: the industry needs to be supported and nurtured. To generate growth and nourish innovation, different elements need to be right in terms of the fiscal, R&D and the commercial environment affecting pricing, access and use of medicines by patients. This means that the UK needs to ensure that innovative medicines are reimbursed at a fair price and used rapidly and consistently throughout the NHS.

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