Pharmaceutical Industry Competitiveness Task Force

Competitiveness and Performance Indicators 2005

The Pharmaceutical Industry Competitiveness Task Force (PICTF) was a joint Government and industry task force set up by the Prime Minister in 2000 to look at ways of ensuring that the UK remains an attractive location for the R&D pharmaceutical industry. An important outcome of PICTF was agreement to collect and publish data on a set of competitiveness and performance indicators. These are to allow Government and industry to monitor the competitiveness of the UK as a location for the pharmaceutical industry. Baseline data were published in a first report in December 2001 and it was agreed these would be updated annually to show trends in competitiveness and performance over time. This report contains data collected in 2005.

Websites – Department of Health: www.advisorybodies.doh.gov.uk/pictf
– Association of the British Pharmaceutical Industry: www.abpi.org.uk

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Pharmaceutical Industry Competitiveness Task Force

Competitiveness and Performance Indicators 2005

Contents

Note:

While it was agreed that no single indicator dominated as a measure of competitiveness or performance, certain indicators were regarded as particularly important. These indicators are marked with an asterisk and appear in chart form on pages 3-5, as well as in the main set of indicators.

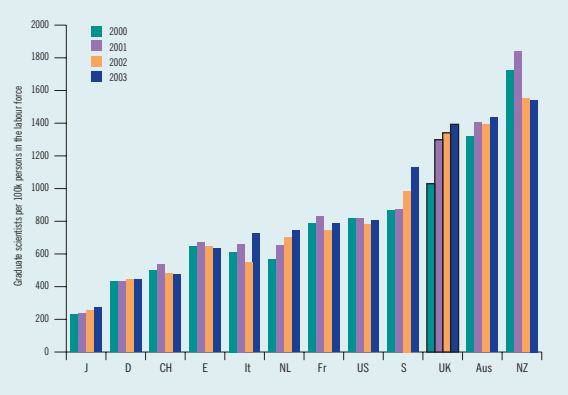
Where charts do not precisely match the corresponding PICTF indicators, this is either because the data specified were not available or because the chart was considered to present the point behind the indicator in a more relevant way (eg additional data in Indicator 8).

Quick View of Main Indicators

The Pharmaceutical Industry Competitiveness Task Force agreed that of the forty-six indicators, twelve should be considered as "main indicators", as recognition of their significance in affecting overall competitiveness. These pages bring together those main indicators.

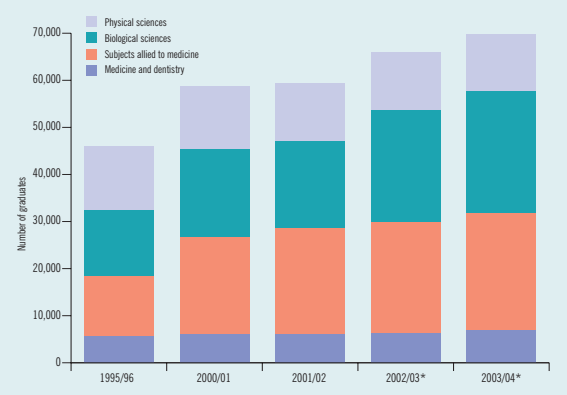
Indicator *1: Number of new graduates with degrees in science relevant to the pharmaceutical industry

Chart a: Number of graduate scientists per 100,000 persons in the labour force 24-34 years of age (2000–2003)



Sources: Data on the number of graduates taken from OECD Education Database.
Labour force figures taken from OECD Labour Force Statistics Database

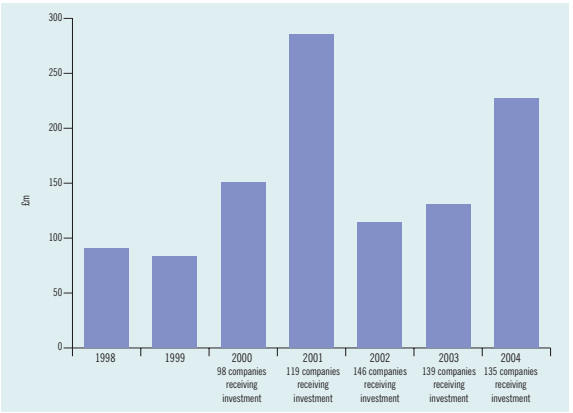
Chart b: Number of people graduating with first degrees relevant to the pharmaceutical industry in the UK



Pages 16 and 17

Indicator *4: Venture capital invested in the pharmaceutical/biotechnology industry

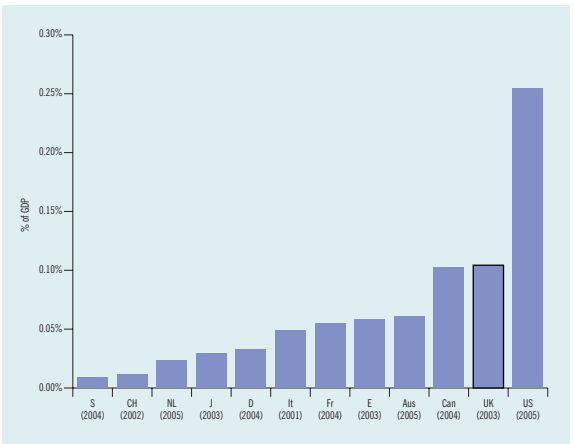
Chart: Venture capital (and buy-outs) investment in UK in pharmaceuticals by BVCA members



Page 21

Indicator *9: Government expenditure on R&D in medical and biological sciences

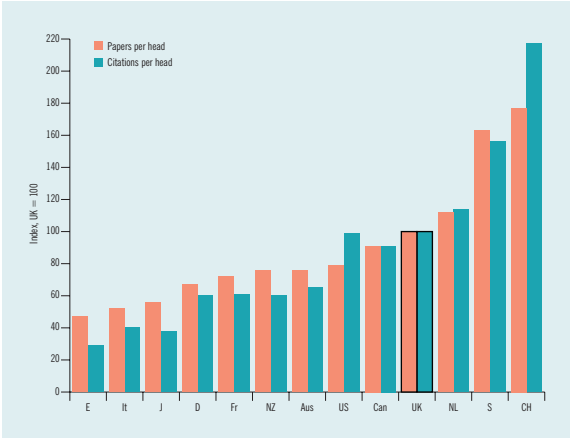
Chart: Health R&D in government budget (GBAORD)[1] as a percentage of GDP, 2005



Page 26

Indicators *10 and 11: Scientific research papers/citations per head

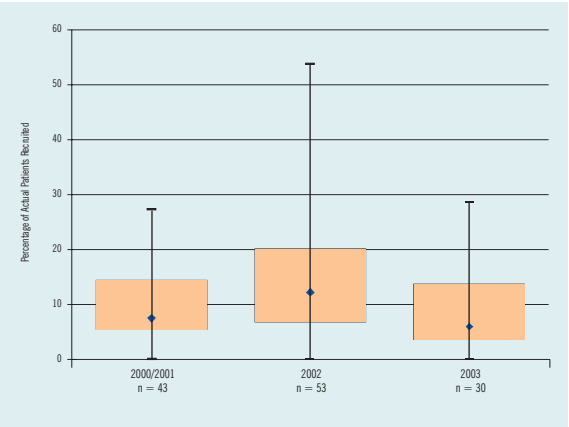
Chart: Scientific research paper citations and scientific research papers per head of population 1994–2003



Page 27

Indicator *12: Percentage of UK patients recruited in international studies where UK patients were involved

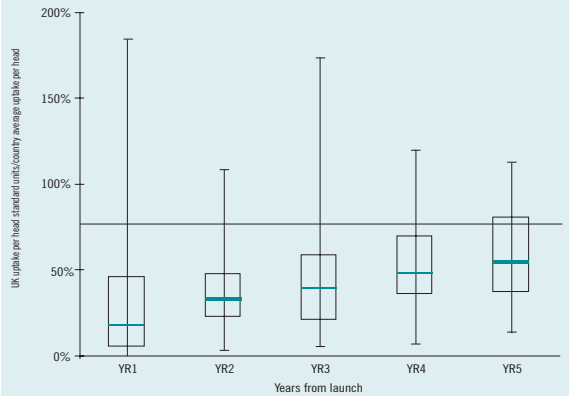
Chart: Percentage of UK patients recruited in international studies



Page 28

Indicator *16: Population-adjusted standard units sold per month of a sample of major new NHS-reimbursed products launched within the last 5 years, monthly sales measured at 1 and 3 years after launch in the UK and comparator countries

Chart: UK uptake of 40 medicines launched in the UK since 2000 compared to average for other PICTF countries



Page 32

How to read this chart

The values used to generate this chart are UK average monthly consumption per head for each year since launch, measured in standard units, of fifty-five medicines, launched in the UK since 1998, divided by average consumption in all other PICTF comparator country markets where the medicine is available.

A value above 100% would mean that UK per head consumption is above the average.

The box represents the interquartile range, which contains the middle 50% of values. The whiskers are lines that extend from the box to the highest and lowest values.The line across the box indicates the median.

Indicator * 21: Companies free to set the launch prices of new medicines? (Y/N)

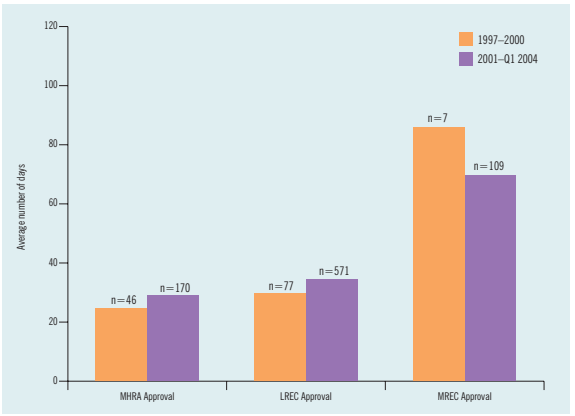
	Free pricing at launch July 2005
Australia	No
Canada	No
France	No
Germany	Yes*
Italy	No
Japan	No
Netherlands	No
New Zealand	No
Spain	No
Sweden	No
Switzerland	Yes
UK	*Yes*
US	Yes

Sources: Various trade associations, public domain sources e.g. Pharmacoeconomics

Page 37

Indicator *22: Overall time taken from first submission of protocol to final medicines regulatory approval (CTX), REC approval and NHS hospital approval to proceed with clinical trial at first site

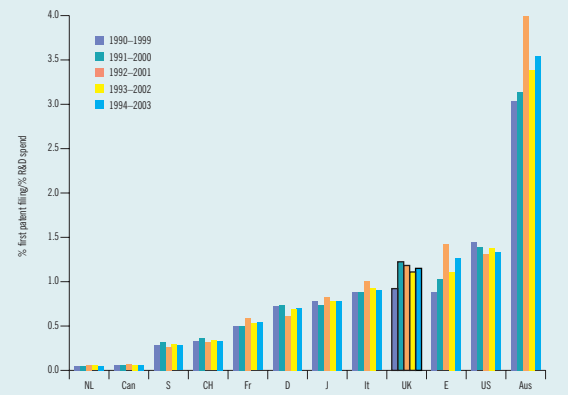
Chart: Average time from first submission of protocols to approval for MHRA (previously MCA), MREC, LREC between 1997-2000 & 2001-Q1 2004



Page 38

Indicator * 33: Proportion of world first patents filed for marketed NMEs ÷ proportion of world R&D spend

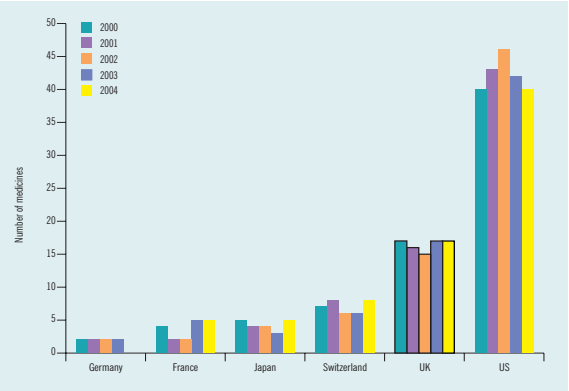
Chart: Proportion of PICTF priority patent filings/proportion of PICTF pharmaceutical industry R&D spend 1990-1999, 1991-2000, 1992-2001, 1993-2002, 1994-2003



Page 48

Indicator *34: National origins of 'global top 75 NASs'

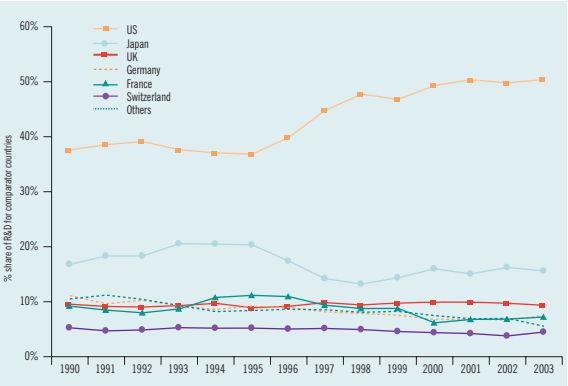
Chart: National origins of leading 75 global medicines – 2000–2004



Page 49

Indicator *35: Percentage of world pharmaceutical R&D expenditure

Chart: Percentage of "world" pharmaceutical industry R&D spend



Page 50

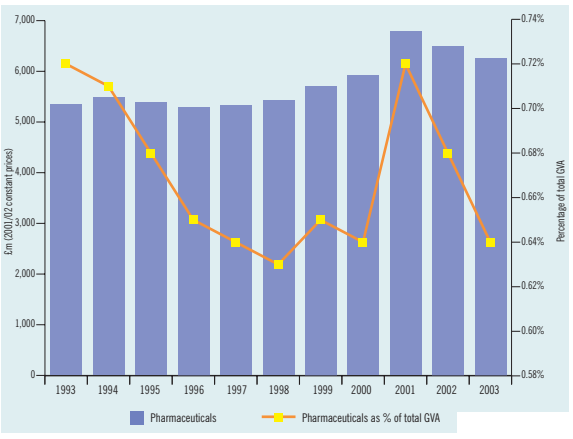
Indicator *43: Gross Value Added

Table: Pharmaceutical Industry Valued Added

In millions of US$	1980	1985	1990	1995	1998	1999	2000	2001	2002
Canada	444	906	1,892	1,761	1,234	1,531	1,766	2,228	
France	2,884	2,517	5,841	9,305	8,982	9,261	8,397	9,065	9,678
Italy	2,658	2,645	7,257	5,763	6,717	7,788	6,706	7,035	7,609
Netherlands	452	549	696	1,647	1,324	1,438	1,435	1,369	1,179
Spain	1,169	913	2,828	2,964	2,562	2,589	2,403	2,748	2,768
Sweden	407	451	1,182	2,251	2,537	3,011	2,772	2,865	3,668
United Kingdom	*2,514*	*2,344*	*5,831*	*6,902*	*7,963*	*8,372*	*8,204*	*9,172*	*9,456*
Japan	7,418	9,483	21,060	34,759	23,754	30,953	31,053	29,086	28,539
United States	8,835	16,130	27,477	43,441	52,812	58,807	64,122		
Germany	0	0	0	10,420	8,860	9,361	8,283	8,970	

Source: OECD STAN database

Chart: UK pharmaceutical GVA 1993-2003 (constant 2003/04 prices)



Source: United Kingdom Input-Output Analyses 2005 Edition (www.statistics.gov.uk)

Page 57

Section 1

Commentary

Summary

This is the fifth annual set of competitiveness and performance indicators prepared and published jointly by the Association of the British Pharmaceutical Industry (ABPI) and the Department of Health. It presents the latest data available in autumn 2005. The indicators help in monitoring the competitiveness of the UK relative to other countries as a location for the pharmaceutical industry. The overall position for the UK shown by the indicators is that:

- The number of graduate scientists already in the labour market in the UK is relatively high by international standards. Trends in the overall numbers of new science graduates in the UK may mask significant changes in some subject areas that may be more or less relevant to the pharmaceutical industry, and say nothing about quality.
- The UK is about average relative to its comparator countries in terms of labour costs and business perceptions of labour market flexibility.
- Corporate tax rates are unchanged in the UK and most comparator countries over the last year and although foreign direct investment into the UK economy continues to decline the same trend is seen in most comparator countries too. Venture capital invested in the pharmaceutical sector increased significantly in 2004.
- Take up of new medicines in the UK continues to be slow by international standards
- Generic penetration in the UK market is high by international standards.
- The UK pharmaceutical industry remains among the most innovative, behind the US.
- The industry's contribution to the UK economy continues to be large, including a positive trade balance of £3.7 billion in 2004, and a contribution to national income approaching £7 billion in 2002 (the most recent data available on gross value added).

Introduction and Background

As recommended by the final report of the joint government and industry Pharmaceutical Industry Competitiveness Task Force (PICTF) in March 2001, a set of competitiveness and performance indicators has been published annually. Forty-six indicators were defined by PICTF, covering a wide range of relevant factors. Twelve of these were highlighted as being "main indicators". To supplement the indicators, a table is also published which summarises factors that are less amenable to statistical presentation but which are nevertheless significant for the competitiveness of the UK through their impact on the market for medicines.

The indicators and table of factors affecting the market for medicines are updated annually as part of the process of monitoring the relative attractiveness of the UK as a location for the pharmaceutical industry. For this purpose the UK is compared with a group of 12 other countries: Australia, Canada, France, Germany, Italy, Japan, the Netherlands, New Zealand, Spain, Sweden, Switzerland and the US. Other countries outside those covered in this report are increasingly important competitors to the UK for R&D and manufacturing investment. It is intended that the scope and content of the competitiveness and performance indicator report will be reviewed during 2006.

This report presents the fifth, 2005, set of PICTF indicators. As before, the indicators have been prepared jointly by the Association of the British Pharmaceutical Industry (ABPI) and the Department of Health. The data presented were the latest available in late 2005. In a few cases new data have not become available since the 2004 indicators were collected. Where previously used data series have become unavailable, it has sometimes been possible to find alternative sources. Inevitably, data from different sources will not be entirely comparable, and even data series from a single source are liable to be updated. Nevertheless, the overall set of data provides both a useful snapshot of the current position and an indication of emerging trends.

The following paragraphs provide a commentary on the competitiveness and performance indicators, summarising the main points revealed by them. The commentary follows the structure of the indicator set (numbers in parentheses refer to the indicator number, from 1 to 46, as shown in Table 8.2 of the PICTF Final Report of March 2001; numbers preceded by an asterisk * are the 12 main indicators among the total, as highlighted in Table 8.1 of that report):

Supply conditions:

- **labour supply (*1-3)**
- **capital supply and taxation (*4-8)**
- **research infrastructure (*9-15)**

Demand and regulatory conditions:

- **uptake of medicines (*16-20)**
- **price/profit regulation (*21)**
- **research and medicines regulation (*22-32)**

Industry outputs:

- **innovation (*33-42)**
- **macroeconomic contribution (*43-46)**

No single indicator dominates as a representation of competitiveness or performance. It is important to consider the overall picture presented by the indicators and table of other factors taken as a whole.

Supply Conditions

Labour supply

A strong and reliable supply of good quality science graduates, available at reasonable cost, is a major attraction to R&D investment. Indicator *1 shows that the UK continues to have a relatively high number of science graduates in the workforce. Only New Zealand and Australia have higher proportions of science graduates in the 25-34 age group of the labour force. These figures should be treated with some caution, however, as definitions of 'graduate scientist' are likely to differ between countries (although the data are consistent within countries, they are not necessarily consistent across countries). The indicator used here of the UK supply of new science graduates increased in total in 2002/03 and again in 2003/04. Note that neither of the indicators 1a and 1b necessarily takes quality of graduates into account. Also, these are broad indicators covering a number of subject areas, hence trends in these two indicators may mask significant changes in some subject areas that may be more, or less, relevant to the pharmaceutical industry. A study carried out by the ABPI examining the skills landscape in the pharmaceutical and biopharmaceutical industries – *Sustaining the Skills Pipeline in the Pharmaceutical and Biopharmaceutical Industries* – was published in November 2005 and has flagged industry concerns in a number of areas.

Year by year, business executives perceive labour market regulations in the UK as increasingly restrictive, although still less so in 2004 and 2005 than in Germany, France and Italy (indicator 2). The US and Canada continue to be seen as having the most flexible labour markets. Unit labour costs in the UK in 2003 continued to be in the middle of the range across the comparator countries: slightly lower than in France and the US and much lower than in Germany.

Capital supply and taxation

Flexible and accessible capital markets are vital to the pharmaceutical sector with its long-term and risky research and development (R&D) investment needs. There was a large increase in the amount of venture capital invested in the pharmaceutical sector in 2004, up to £227 million from £131 million in 2003, but this is still somewhat below the peak level of £285 million achieved in 2001 (indicator *4 – all figures in money of the day). Updated figures show that the number of pharmaceutical sector companies in the UK has been increasing gradually since 1999 (indicator 7).

Rates of taxation of company profits in different countries have a clear influence on international location decisions. The basic rate of corporate taxation in the UK has remained at 30% for some years and is still towards the lower end of the range among the comparator countries (indicator 5). In most countries, corporate tax rates are being held constant, as in the UK, or are reducing over time. Switzerland and Sweden currently have lower corporation tax rates than the UK. So too do some countries not shown in the list. R&D tax credits should provide significant support for R&D in the UK. A small or medium sized company (SME) can claim 150% R&D tax relief (on staff and material costs) if it incurs qualifying R&D expenditure, or receive a payable cash element of up to 24% of that expenditure if it is loss-making. A large company can claim 125% R&D tax relief. This means it can deduct 125% of the qualifying current spending on R&D when it calculates its taxable profits, instead of the normal 100%.

The quantity of foreign direct investment (FDI) into the UK, across all sectors of the economy, fell in 2003, but that experience was common across most of the comparator countries. (Specific pharmaceutical industry FDI data are not available). Only New Zealand and Switzerland had more FDI in 2003 than in 2002. FDI across all sectors of the economy was equivalent to just 0.8% of UK GDP in 2003, putting it ahead of Germany and the US but below most other comparator countries (indicator 8). In absolute (dollar) terms, in 2001 the UK ranked second as a destination for FDI in all sectors, well behind the US but ahead of all the other comparator countries. However, by 2003 the UK had fallen to sixth among the comparator countries in absolute terms.

Basic research infrastructure

Indicator *9 shows that the UK government continues to spend more on research and development in health than does any other government outside the US. The extent to which UK scientists – whether publicly or privately funded – produce published work is shown by indicator 11, while indicator *10 proxies how widely that work is recognised as valuable by measuring the rate at which UK-authored scientific papers are cited. Over the decade 1994-2003 inclusive, the UK produced more scientific research publications per head of the population than the US or any of the other comparator countries, with the exception of Switzerland, Sweden and the Netherlands. For citations of such papers per head, the UK was again in fourth place behind the same three countries.

• Clinical research infrastructure

Medicines are required to undergo a long and costly, multi-stage process of testing and development, including clinical trials, before they can be authorised for use by patients. The cost, quality, timelines and degree of international acceptance of trials undertaken in one country relative to another will affect the amount of investment in that country. Indicator *12 shows that in the median international trial in which the UK was one of the countries involved, around 10% of the total number of patients recruited were in the UK, although this proportion fluctuates from year to year. The UK component of international studies of medicines in development that completed patient recruitment in 2003 was completed on time in 71% of cases (indicator 13). Studies being conducted in the UK only were rather less punctual, however: only 29% completed their patient recruitment within the planned timescale. (2003 is the last year for which data are available for these indicators.)

Demand and Regulatory Conditions

• Uptake of medicines

Along with the supply side factors so far discussed, pharmaceutical companies attach importance to the size, rate of growth and openness to new products of medicines markets. Indicator 18 shows that although medicines expenditure is increasing gradually as a share of GDP in the UK, it is also growing in all of the comparator countries. The UK continues to spend a relatively small fraction of its national income on medicines: 0.94% in 2004. This is very close to, but fractionally greater than, the share of GDP being spent on medicines in Sweden, Australia and Switzerland and is substantially greater than in the Netherlands. Medicines expenditure in all the other comparator countries was a considerably higher percentage of national income than in the UK.

Within this relatively modest market, UK spend specifically on new medicines remains low. In 2004, 17% of UK medicines expenditure went on products launched during the previous five years, a lower share than in all other comparator countries except Japan (16%) and well below the 27% seen in the US (indicator 19). Indicator *16 shows that the newer a medicine is, the lower is its rate of use in the UK relative to that in other countries. In the first year after their launch, the median rate of use per person of new medicines in the UK was only 17% of mean per capita use in the first year after launch in the comparator countries taken together. The median rate of uptake of new medicines in the UK relative to other countries increases as the time from the medicine's launch increases but is still only 39% of international levels three years after launch and 54% five years after launch. However, in each year a small minority of new medicines are being used in the UK at rates above the international average.

At the other end of the product life cycle, after patent expiry the opportunity arises for considerable cost savings from generic competition. A market that maximises generic competition once the innovator company's patent has expired may be able to invest the savings in paying for newer medicines. Generic penetration in the UK market is

relatively high: 49% in volume terms, only slightly lower than in the US, which has the highest generic penetration in volume terms among the comparator countries in this report (indicator 20).

There has been no great overall change during the last year in the UK's relative position internationally in terms of the qualitative features of health care systems that affect the demand for medicines, which are summarised in the table at the end of this commentary. However an increased role for pharmacoeconomics in German formulary decisions, and the spread of reference pricing there to include some on-patent medicines, has reduced the attractiveness of Germany to the pharmaceutical industry relative to the UK. Overall the picture continues to be that access to medicines is subject to a wide range of influences in the UK – more than in most of the comparator countries.

• Price/profit regulation

Under the terms of the current (2005) Pharmaceutical Price Regulation Scheme (PPRS), pharmaceutical companies continue to have freedom in the UK to set launch prices of new medicines as they wish within the overall cap placed on the rate of return they are permitted to earn from the totality of their branded medicine sales to the National Health Service. The PPRS only allows subsequent price increases when company profits fall below a threshold level. UK prices of on-patent medicines are, on average, towards the top end of the range across comparator European countries because UK prices include a significant contribution to the research and development of new medicines. UK prices remain much lower than those in the US. The US, Germany and Switzerland also allow freedom of pricing at launch, although in Germany this may not be the case for all future new launches as some on-patent products are now being included in reference pricing groups (indicator *21). This continues to make the UK a more attractive market to innovative pharmaceutical companies than countries where launch prices are regulated. To the degree that market attractiveness influences decisions on location, this may influence companies' investment in the UK.

• Research and medicines regulation

The speed and efficiency with which medicines are able to pass through the various regulatory stages between discovery and launch onto the market have a major impact on the returns to pharmaceutical companies' investments. Indicator *22 shows that in the slightly more than three years 2001-Q1 2004 (latest available data), when compared with the four year period 1997-2000, the time taken for ethical approval has improved significantly for multi-centre research ethics committees (down from 86 days to 70 days and close to 60 days by Q1 2004) but has worsened slightly (by around four days in each case) for local research ethics committees and the MHRA (previously the MCA). The time taken to obtain approval for animal experimentation fell to its lowest level – 22 clock days – in 2004 and well within the target level of 35 days (indicator 24).

Indicators 25-27 taken together show the total time that elapses between the date of the first application anywhere in the world for market authorisation for a new medicine, to the date on which it is finally approved for launch in each national market. The three indicators individually break down the overall time elapsed into key stages. Overall for the most recent five-year period for which data are available, 1999-2003 inclusive, the UK has the third shortest average time to market among the comparator countries, very close behind Germany, although the US enjoyed considerably shorter time lapses. The UK, like Germany and the US, requires no agreement of reimbursement prices for newly launched products, which removes one source of delay to patient access to new medicines that exists in many other countries.

Since the financial year 2001/02 the UK, or more specifically the MHRA, has ceased to be the first choice among companies to be reference member state under the EU mutual recognition procedure for authorising medicines for the market (indicators 29 and 30). The two referrals to the MHRA in 2004/05 compares with four to Sweden, three to the Netherlands and two to all other countries in total, but none to either France or Germany. The MHRA's reputation appears to be reasonably strong, however. The MHRA was, along with the Swedish authority, the most popular choice of rapporteur in 2004/05 under the centralised procedure for market authorisation (indicator 31). The MHRA remained in 2004/05 the most frequently nominated rapporteur among the EU member states to provide scientific advice (indicator 32).

Industry Outputs

• Innovation

Indicators of trends in pharmaceutical innovation necessarily take a long perspective as the R&D process can last 10 years or more from discovery until a product is eventually launched onto the market. Some of the indicators reported here are therefore 10-year moving averages. If the latest data in those cases are for the 10-year period 1994-2003, for example, compared with 1993-2002 average data presented in last year's indicators report, then changes in the indicator reflect how far the experience in 2003 differed from that in 1993.

The UK has long been a comparatively favoured site for pharmaceutical R&D activity. The productivity of UK pharmaceutical research is good, putting the UK in fourth place among the comparator countries, a little behind the US (indicator *33). The two other more highly placed countries – Australia and Spain – spend comparatively little on pharmaceutical R&D. The UK has for some years ranked third, behind the US and Japan in terms of the amount of pharmaceutical R&D expenditure that takes place within its borders and in 2003 provided 9% of world pharmaceutical industry R&D (indicator *35). This should be seen in the context of the UK being less than 4% (source: IMS World Review, 2005) of the global market for medicines.

UK headquartered companies produced over 10% of all new pharmaceutical products launched in the decade 1995-2004, which puts them in third place internationally, behind the US and Japan (indicator 36). In the same decade, the UK ranked fourth, just behind France and considerably behind Japan and the US, in terms of the number of first in class medicines launched by its companies (indicator 39). UK companies have a somewhat higher share, however, of the best selling medicines. UK companies produced 17 (23%) of the world's top 75 selling medicines in 2003 (indicator *34) and took 19% of the total value of global sales of those top 75 medicines (indicator 38), second only to the US industry in each case.

UK companies continue to achieve greater penetration of the dominant US market than those of any other country apart from US companies (indicator 40), and continue to have more new medicines launched in all four major markets (US, Germany, France and the UK) than any other country's companies apart from the US (indicator 41). The number of new medicines from UK companies that have been accorded US Food and Drug Administration (FDA) priority status up to 2004 puts it in third place, behind the US and Switzerland (indicator 42).

The overall picture on innovation is thus that the UK is broadly continuing to hold a fairly strong position relative to most comparator countries, other than the US.

• Macroeconomic contribution

The UK pharmaceutical industry was the world's fourth largest in 2002 (the latest year for which internationally comparable data are available) in terms of gross value added (indicator *43). It produced a positive trade balance of £3.7 billion in 2004, putting the UK in fourth place behind Switzerland, France and Germany among the comparator countries in terms of net pharmaceutical exports (indicator 44). The total value of UK pharmaceutical production (i.e. the UK industry's total domestic and export sales) in 2003 was £15.7 billion (indicator 45).

The UK pharmaceutical industry directly employed 73,000 people in 2004. The UK industry is the sixth largest in employment terms among the comparator countries (indicator 46).

Features of Healthcare Systems Most Likely to Influence Access to Markets and Patient Access to Medicines

Influencing Factors	Australia	Canada	France	Germany	Italy	Japan	NL	NZ	Spain	Sweden	Switz	UK	US
Speed of regulatory approval	2	2	1	1	1	3	1	2	1	1	1	1	1
Complexity of pricing/ reimbursement procedure	3	3	2	2	3	2	2	3	2	2	2	N/A	N/A
Downward pressure on launch prices	3	3	2	1	2	2	2	3	3	1	1	N/A	N/A
Conditional/limited reimbursement	3	2	2	2	2	1	3	3	3	1	1	2	3
Level of generic penetration	Medium	High	Low	High	Low	Low	High	High	Low	Low	Low	High	High
National guidelines using pharmacoeconomics	Yes	No	Planned	Yes	No	No	Some products	?	No	No	No	Yes	No
Pharmacoeconomics used in pricing/reimbursement decision	Yes	Some provinces	Possible	Possible	Some products	Not usually	Some products	Yes	No	Yes	Some times	Not directly	National No/ Private Yes
Drugs budget funded by:	National	Provincial	National	National	Regional	National	National	National	Regional	Local	Local	National	Mix
% of population covered	1	2	1	1	2	1	1	1	2	1	1	1	3
Copayment culture exists	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Level of copayment	1	1	1	1	1	1	1	2	1	1	1	1	3
Capped budgets for GPs	1	1	1	2	1	1	1	3	1	1	1	2	1
Influencing of GP prescribing	1	2	1	2	1	1	2	3	2	2	1	3	2
Capped profits/sales – rebates	No	Possible	Yes	No	Yes	No	No	Yes	Yes	No	No	Yes	No
Private market: 'lifestyle' drugs	1	?	1	?	?	3	?	2	1	2	1	3	1
Private market: other drugs	3	?	3	?	2	3	3	2	3	3	2	3	1
DTC advertising allowed	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes

The combination/aggregate policy mix is unique to each country

Key: 3 = High potential for impact on access 2 = Some potential to affect access 1 = Unlikely to significantly affect access
N/A = Not applicable (ie not a feature of this market) ? = Not known

Section 2

Supply Conditions

Labour		Notes
*1	Number of new graduates with degrees in sciences relevant to the pharmaceutical industry	
2	Business executive perceptions of labour regulation	
3	Total hourly labour costs in UK versus comparator countries	

Capital		
*4	Venture capital invested in the pharmaceutical/biotechnology industry	
5	Marginal rate of Corporation Tax	
6	Market capitalisation of pharmaceutical, including biotechnology firms, on second tier capital markets	Statistics for pharmaceuticals for NASDAQ no longer available
7	Number of new pharmaceutical/biotech businesses created minus existing such businesses closed	
8	Foreign direct investment as % of GDP	

Basic research infrastructure		
*9	Government expenditure on R&D in medical and biological sciences	
*10	Scientific research paper citations per head	
11	Scientific research publications per head	Combined with indicator *10

Clinical research infrastructure		
*12	UK % of patients enrolled in international studies, normalised for population	
13	Proportion of studies completed within planned timelines	
14	Average industry grant cost per patient recruited to clinical trials	not available
15	% of international studies undertaken partially or wholly in the UK	not available

Indicator *1: Number of new graduates with degrees in science relevant to the pharmaceutical industry

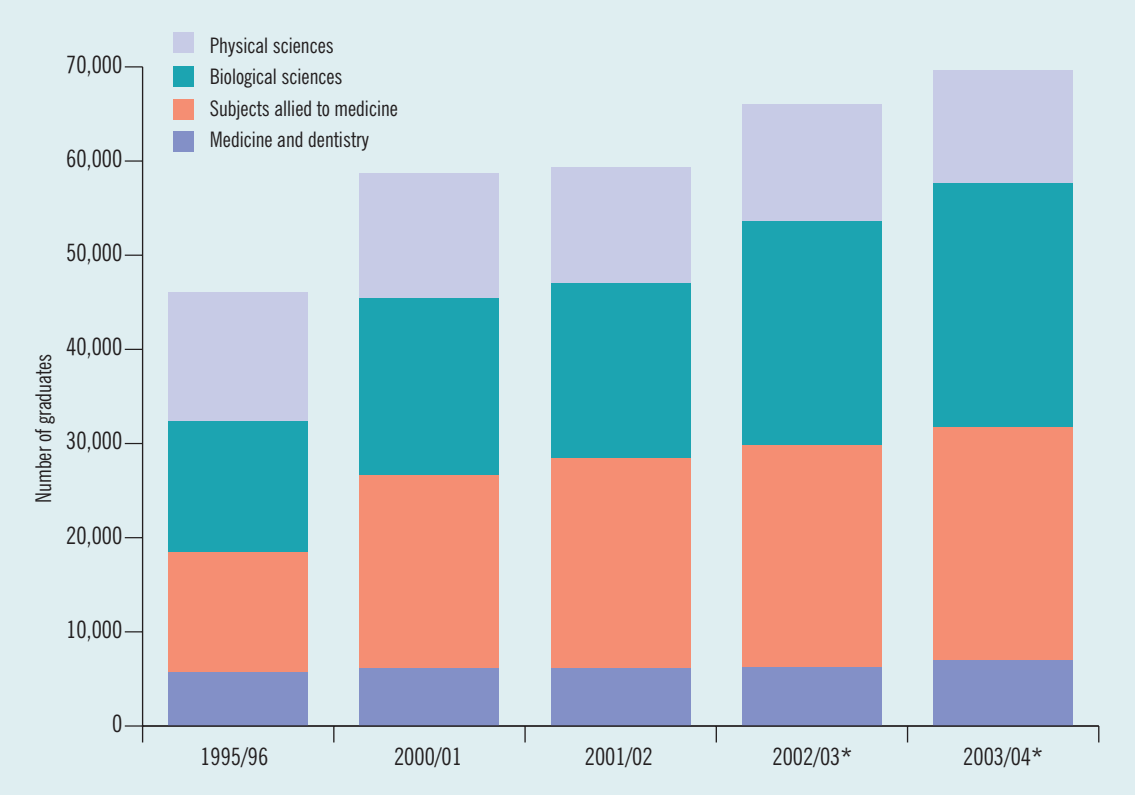
Chart a: Number of graduate scientists per 100,000 persons in the labour force 24-34 years of age (2000–2003)

Sources: Data on the number of graduates taken from OECD Education Database.
Labour force figures taken from OECD Labour Force Statistics Database

Note

Note that definitions of various fields tend to differ across countries and over time.

Chart b: Number of people graduating with first degrees relevant to the pharmaceutical industry in the UK



Source: Higher Education Statistics Authority

Note

Figures in previous publications include overseas students and exclude "dormant" students. This year the figures (for all years) include dormant students and exclude visiting exchange students.

*From 2002/03, HESA has moved over to the new JACS subject coding system which has replaced the HESA subject codes. However, the subject groups have not changed significantly.

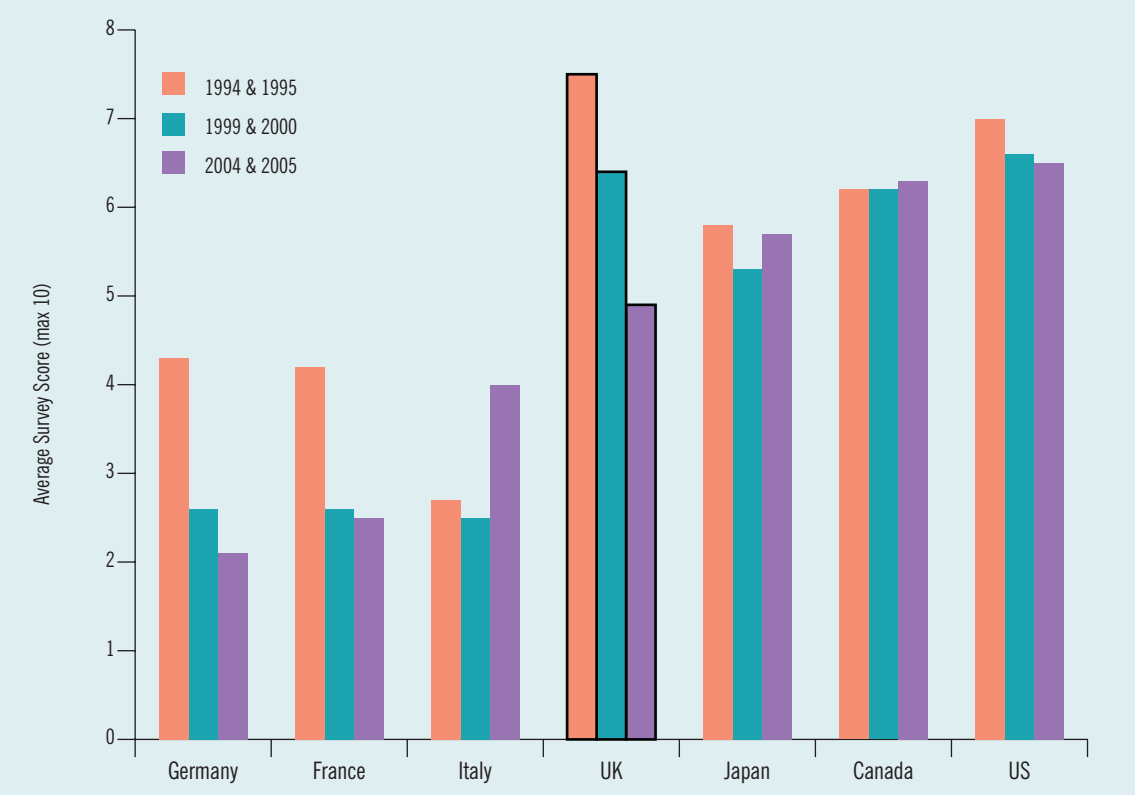
These four categories of science graduates cover a number of subject areas, hence trends within the general subject areas may mask significant changes in some specific subject areas that may be more, or less, relevant to the pharmaceutical industry. Growth in some subjects within the general categories that are not relevant to the pharmaceutical industry might mask a reduction in other subjects of greater relevance.

The four categories in the chart include the following subjects:

Medicine & Dentistry	Subjects allied to medicine	Biological sciences	Physical sciences
Pre-clinical dentistry	Anatomy	Biology	Chemistry
Clinical medicine	Physiology & Pharmacy	Botany	Material science
Clinical dentistry	Complementary medicine	Zoology	Physics
Others in medicine & dentistry	Nutrition	Genetics	Forensic & Archaeology sciences
Pre-clinical medicine	Ophthalmics	Microbiology	Astronomy
	Aural & oral sciences	Sports science	Geology
	Nursing	Molecular biology	Oceans sciences
	Medical technology	Biophysics & Biochemistry	Physical & terrestrial
	Others in subjects allied to medicine	Psychology	geographical & environmental sciences
	Broadly-based programmes within subjects allied to medicinene	Others in Biological Sciences	Others in Physical sciences
		Broadly based programmes within biological sciences	Broadly based programmes within physical sciences

Indicator 2: Business executive perceptions of labour regulations

Chart: Business perceptions of market regulations



Source: World Competitiveness Yearbook, from Institute for Management Development

Note

In the absence of direct measures of the degree of market regulation, the above data derives from the International Institute for Management Development's regular survey of the perceptions of "business leaders".

From and including 2004 the survey scores range from zero to ten, where zero (0) indicates that regulation hinder business activity and ten (10) that regulation do not hinder business activity. The survey questions up to 2003 were slightly different, with zero meaning that "labour regulations are too restrictive" and ten "labour markets are flexible enough".

Indicator 3: Total hourly labour costs in UK versus comparator countries

Table: Manufacturing unit labour costs per hour (£)

Labour costs per hour (UK £)											
	1985	**1990**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**
New Zealand	3.41	4.60	6.28	6.93	6.60	5.44	5.65	5.22	5.21	5.74	6.79
Spain	3.63	6.41	8.11	8.60	7.43	7.28	7.44	7.07	7.51	7.94	9.18
Italy	5.95	9.83	10.28	11.38	10.26	9.87	9.81	9.3*	9.6*	10*	11.3*
Canada	8.53	8.98	10.20	10.67	10.06	9.42	9.63	10.91	11.26	11.14	11.81
Australia	6.40	7.46	9.86	11.04	10.33	9.19	9.88	9.58	9.24	10.34	12.3*
Japan	4.94	7.21	15.09	13.46	11.94	11.04	12.87	14.48	13.41	12.34	12.30
UK	*4.89*	*7.15*	*8.73*	*9.13*	*9.52*	*10.11*	*10.53*	*11.10*	*11.47*	*11.94*	*12.48*
France	5.86	8.72	12.26	12.22	10.51	10.56	10.66	10.25	10.91	11.41	12.91
US	10.14	8.40	10.89	11.34	11.18	11.26	11.80	12.89	14.11	14.07	13.46
Sweden	7.53	11.79	13.59	15.62	13.57	13.35	13.39	13.29	12.79	13.47	15.18
Netherlands	6.82	10.17	15.28	14.89	12.72	12.92	13.26	12.76	13.62	14.41	16.4*
Switzerland	7.53	11.75	18.57	18.16	14.78	14.72	14.56	13.88	15.01	15.87	17.07
Germany	7.40	12.28	19.18	19.06	16.10	15.87	15.92	14.94	15.64	16.21	18.30

Source: Economist Intelligence Unit, Country reports (30.9.05)

Note

Includes pay and non-pay costs.

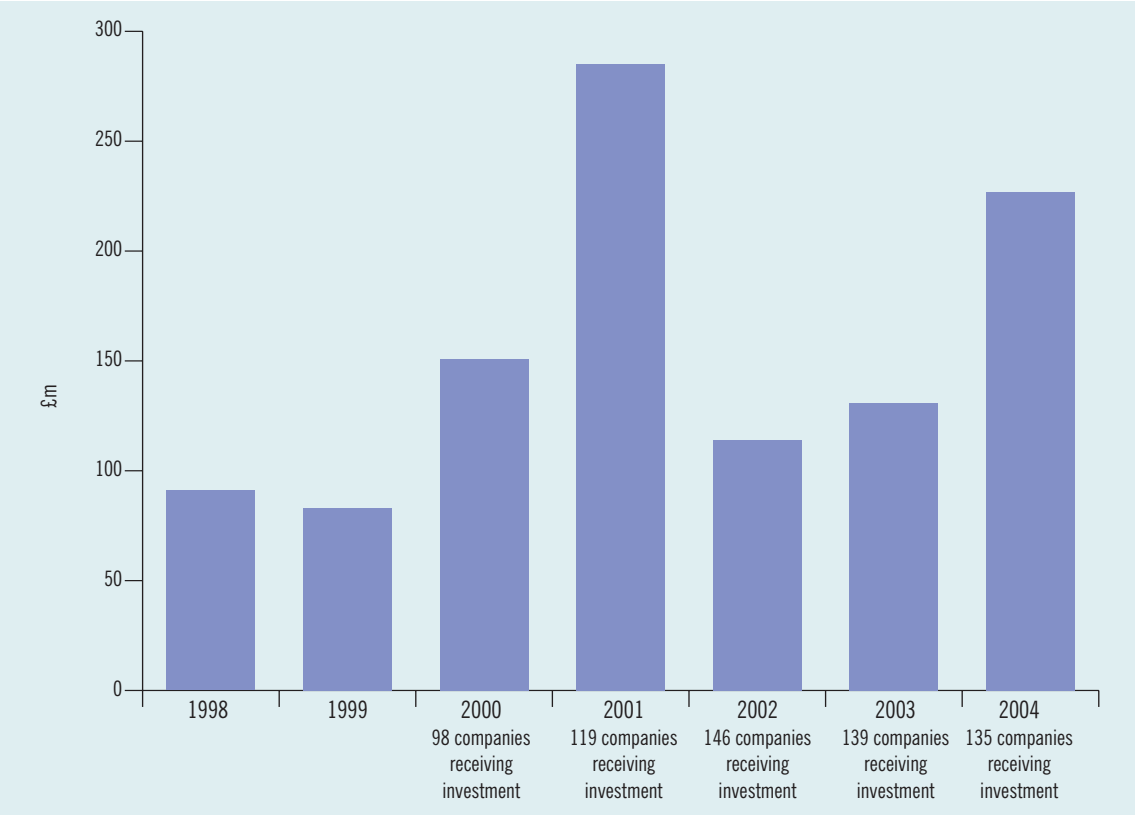
Manufacturing unit labour costs per hour are derived by dividing the total payroll by the number of employees in manufacturing enterprises.

Due to revisions some figures have changed a little from those published last year.

*These figures are estimates

Indicator *4: Venture capital invested in the pharmaceutical/biotechnology industry

Chart: Venture capital (and buy-outs) investment in UK in pharmaceuticals by BVCA members



Sources: British Venture Capital Association Reports on Investment Activity 2000, 2001, 2002, 2003, 2004

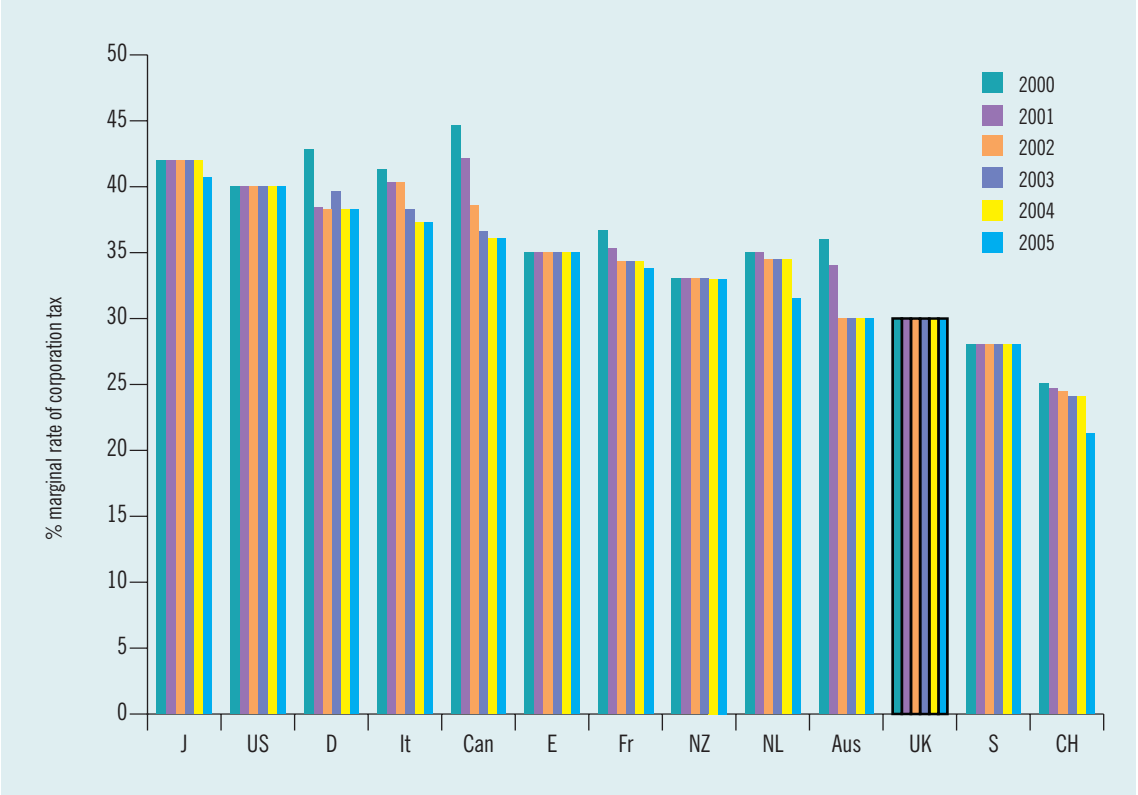
Note

Amounts shown are investments in the UK by members of the British Venture Capital Association. Sector definition 'pharmaceuticals' is based on the FTSE Actuaries Industry Classification System.

Average venture capital invested per company has fluctuated from £1.5m in 2000 £2.4m in 2001 £0.8m in 2002, £0.9m in 2003 and £0.6m in 2004. The BVCA note that investment in technology sectors have fallen to a third of the value in 2001.

Indicator 5: Marginal rate of corporation tax

Chart: Headline marginal rate of corporation tax



Sources: KPMG annual corporate tax rates surveys 2001, 2002, 2003, 2004 and 2005

Note

All rates at January 1st.

Indicator 7: Number of new pharmaceutical/biotechnology businesses created minus existing such businesses closed

Table: VAT (de)registrations in the UK pharmaceutical industry

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Stock (at 1st Jan)	400	415	415	430	425	425	430	440	440	460	465
Registrations	40	30	40	30	35	45	40	35	50	35	*
De-registrations	25	25	30	30	40	40	30	30	35	30	*
Net change	*15*	*0*	*10*	*0*	*0*	*5*	*10*	*0*	*15*	*5*	*

Source: Small Business Service, "Business Start ups and Closures: VAT Registrations and De-Registrations 1994-2003" (published November 2004 – www.sbs.gov.uk)
Three digit SIC level, SIC 24.4 manufacture of pharmaceuticals and medicinal chemicals.

Note

* not currently available

Due to revisions some figures have changed a little from those published last year.

All figures rounded at source to nearest five.

VAT registration and deregistration serves as a proxy to measure businesses opening and closing. Note that some companies may not be registered for VAT.

The SIC classifies industries by product and while it captures some biotech companies it may not capture them all, as their "product" is often knowledge so they may be picked up in other categories.

Indicator 8: Foreign Direct Investment as a % of GDP

Table a: Foreign Direct Investment inflows (as a % of GDP)

	1990	1995	1997	1998	1999	2000	2001	2002	2003
Japan	0.1%	0.0%	0.1%	0.1%	0.3%	0.2%	0.1%	0.2%	0.1%
United States	0.8%	0.8%	1.3%	2.0%	3.1%	3.2%	1.6%	0.6%	0.3%
Germany	0.2%	0.5%	0.6%	1.1%	2.6%	10.4%	1.1%	1.8%	0.5%
United Kingdom	*3.1%*	*1.8%*	*2.5%*	*5.2%*	*6.0%*	*8.3%*	*3.7%*	*1.8%*	*0.8%*
Canada	1.3%	1.6%	1.8%	3.8%	3.8%	9.3%	3.9%	2.9%	0.8%
Sweden	0.8%	5.8%	4.4%	8.0%	24.2%	9.7%	5.4%	4.8%	1.1%
Italy	0.6%	0.4%	0.3%	0.2%	0.6%	1.2%	1.4%	1.2%	1.1%
Australia	2.6%	3.2%	1.8%	1.6%	0.7%	3.4%	1.1%	3.4%	1.5%
New Zealand	4.0%	6.0%	3.9%	2.2%	2.5%	6.4%	3.7%	1.4%	2.5%
France	1.3%	1.5%	1.6%	2.1%	3.2%	3.3%	3.8%	3.4%	2.6%
Spain	2.7%	1.0%	1.1%	1.9%	2.5%	6.5%	4.6%	5.2%	2.9%
Switzerland	2.3%	0.7%	2.5%	3.3%	4.4%	7.8%	3.5%	2.0%	3.8%
Netherlands	3.6%	3.0%	3.0%	9.4%	10.3%	17.2%	13.5%	6.1%	3.8%

Sources: UNCTAD website 25th August 2005 http://stats.unctad.org/fdi/eng/TableViewer/wdsview/dispviewp.asp
GDP values from OECD Statistics Portal

Note

Expressing FDI as a percentage of GDP can show the importance of foreign direct investment (FDI) to the receiving country.

Due to data revisions all figures may have changed compared to last year's publication.

All countries have experienced a decline in FDI inflows since 2000. Driving the decline in FDI flows in 2001, 2002, and 2003 is a combination of macro and micro economic factors (weak economic growth, falling stock markets, and low corporate profit) and institutional factors (winding down of privatisation). The slow down in the world economy has led to a fall in cross border mergers and acquisitions which account for the bulk of FDI. The number of mergers and acquisitions has fallen for all the comparator countries since 2000, and this may explain the relatively low figures for FDI inflows.

Indicator 8: Foreign Direct Investment as a % of GDP – *continued*

Table b: Foreign direct investment inflows (in millions of dollars)

	1990	1995	1997	1998	1999	2000	2001	2002	2003
New Zealand	1,735	3,659	2,624	1,191	1,412	3,347	1,911	823	2,017
Sweden	1,971	14,448	10,968	19,835	60,926	23,242	11,910	11,647	3,296
Japan	1,753	41	3,224	3,192	12,741	8,323	6,241	9,239	6,324
Canada	7,582	9,255	11,527	22,809	24,743	66,791	27,487	21,030	6,580
Australia	8,128	11,970	7,657	6,015	2,924	13,071	4,006	13,978	7,900
Switzerland	5,484	2,223	6,636	8,941	11,719	19,255	8,856	5,648	12,161
Germany	2,962	12,025	12,244	24,593	56,077	198,276	21,138	36,014	12,866
United Kingdom	*30,461*	*19,969*	*33,227*	*74,321*	*87,979*	*118,764*	*52,623*	*27,776*	*14,515*
Italy	6,411	4,842	3,700	2,635	6,911	13,375	14,871	14,545	16,421
Netherlands	10,514	12,301	11,132	36,964	41,205	63,854	51,927	25,571	19,674
Spain	13,984	6,285	6,387	11,797	15,758	37,523	28,005	35,908	25,625
United States	48,422	58,772	103,398	174,434	283,376	314,007	159,461	62,870	29,772
France	15,614	23,676	23,174	30,984	46,545	43,250	50,476	48,906	46,981

Source: UNCTAD website 29th September 2005 http://stats.unctad.org/fdi/eng/TableViewer/wdsview/dispviewp.asp

Note

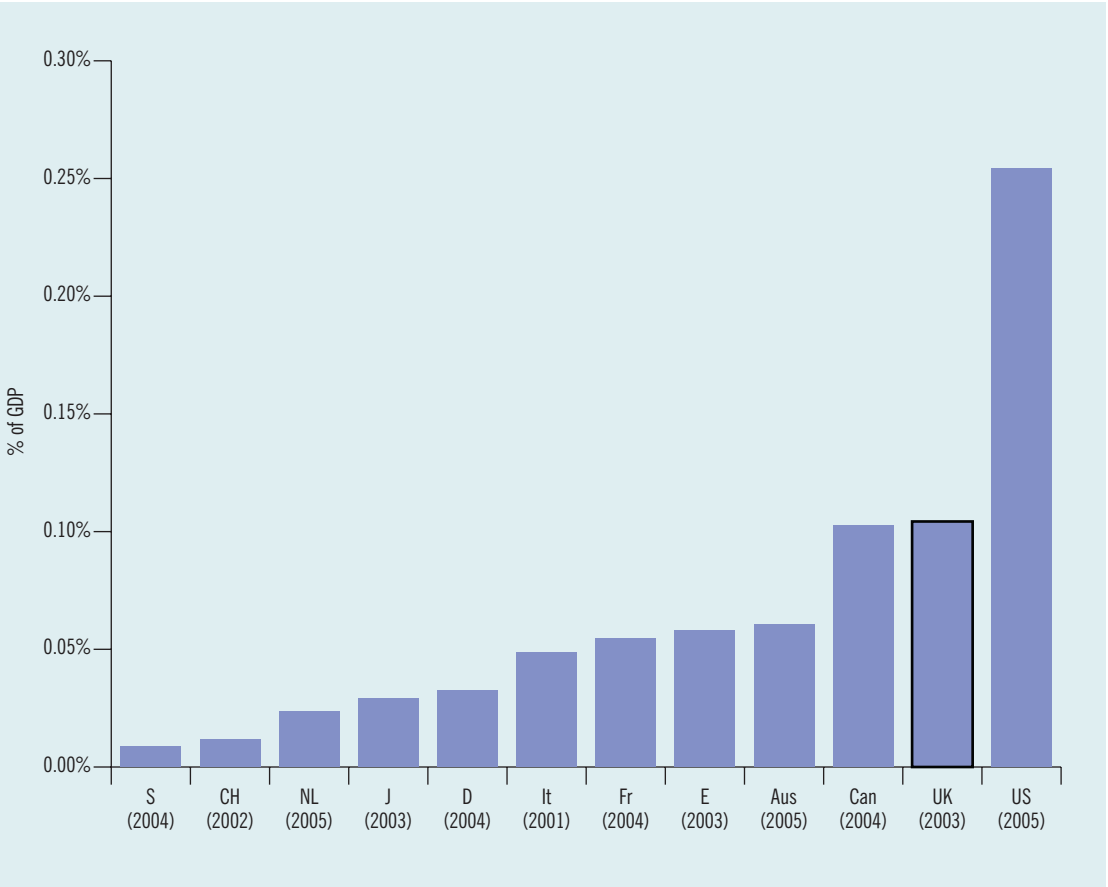
Cash inflows are an indicator of the attractiveness of an economy to the rest of the world, as a location for investment.

Some data may differ slightly from the figures presented in last year's publication due to subsequent adjustments.

It is also important to note that some of the variability in the data across countries and over time could be caused by exchange rate fluctuations.

Indicator *9: Government expenditure on R&D in medical and biological sciences

Chart: Health R&D in government budget (GBAORD)[1] as a percentage of GDP, 2005



Source: OECD and Eurostat R&D Databases, September 2005

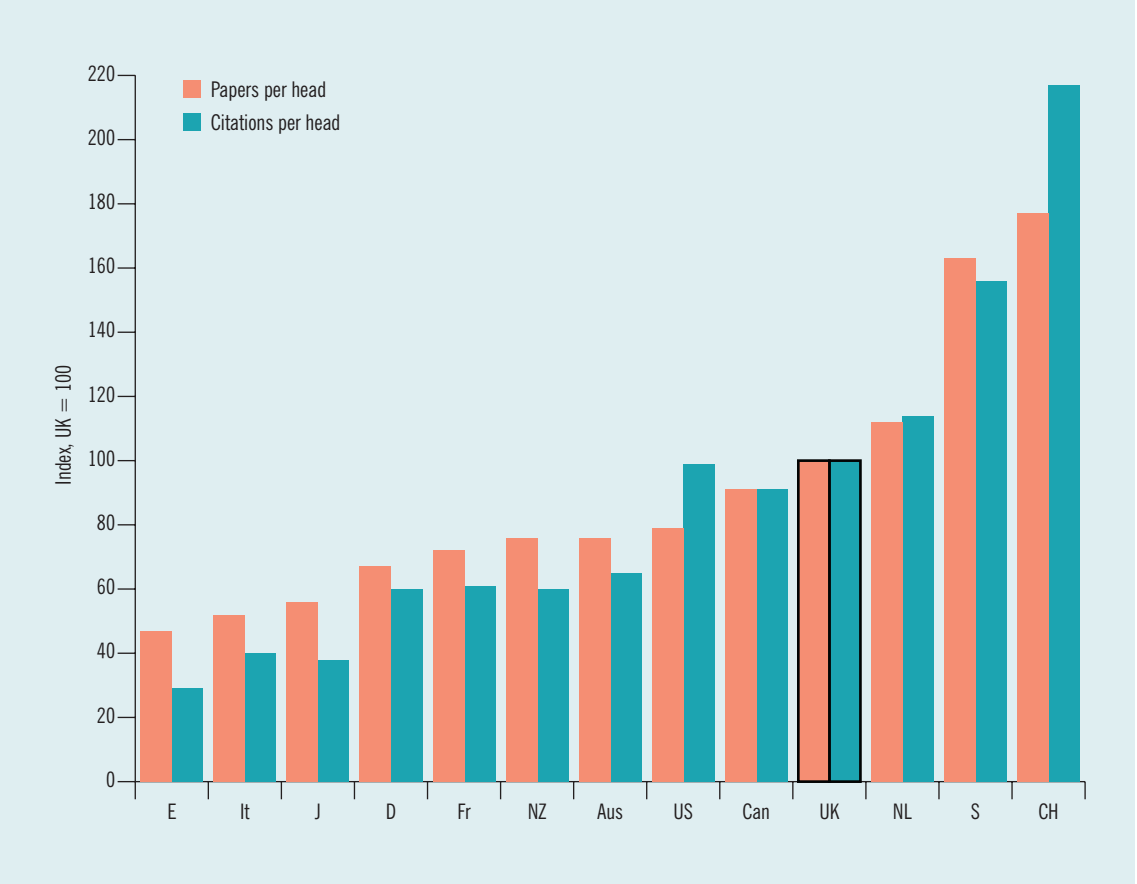
Note

[1] Government budget appropriations or outlays for R&D

It was not possible to present data on medical and biological specific R&D.

Indicators *10 and 11: Scientific research papers/citations per head

Chart: Scientific research paper citations and scientific research papers per head of population 1994–2003



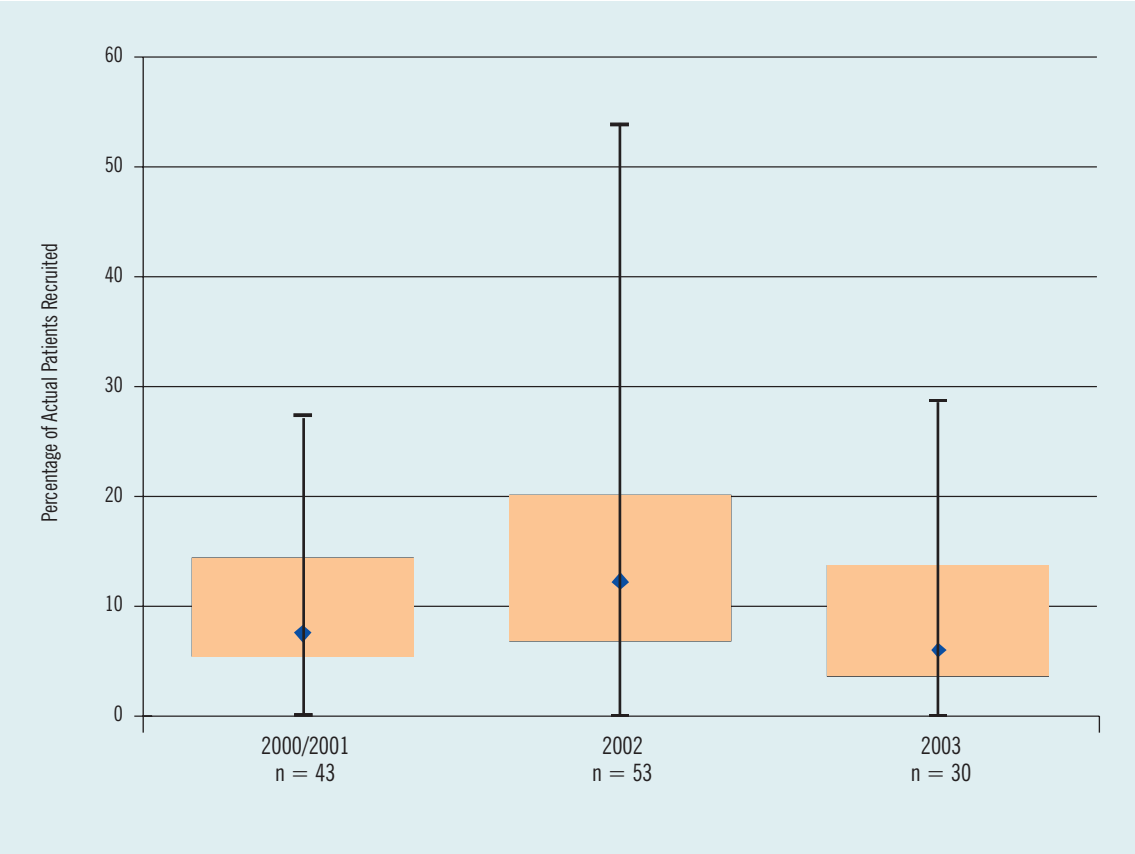
Source: Evidence Ltd, Thomson ISI

Note

Over the decade 1994–2003 inclusive, the UK produced more scientific research publications per head of the population than the US or any of the other comparator countries, with the exception of Switzerland, Sweden and the Netherlands.

Indicator *12: Percentage of UK patients recruited in international studies where UK patients were involved

Chart: Percentage of UK patients recruited in international studies



Source: CMR International

Note

The chart presents three "box-whisker" plots and provides data to measure the success of the UK in attracting international clinical trials, showing recruitment rates of UK patients in international trials.

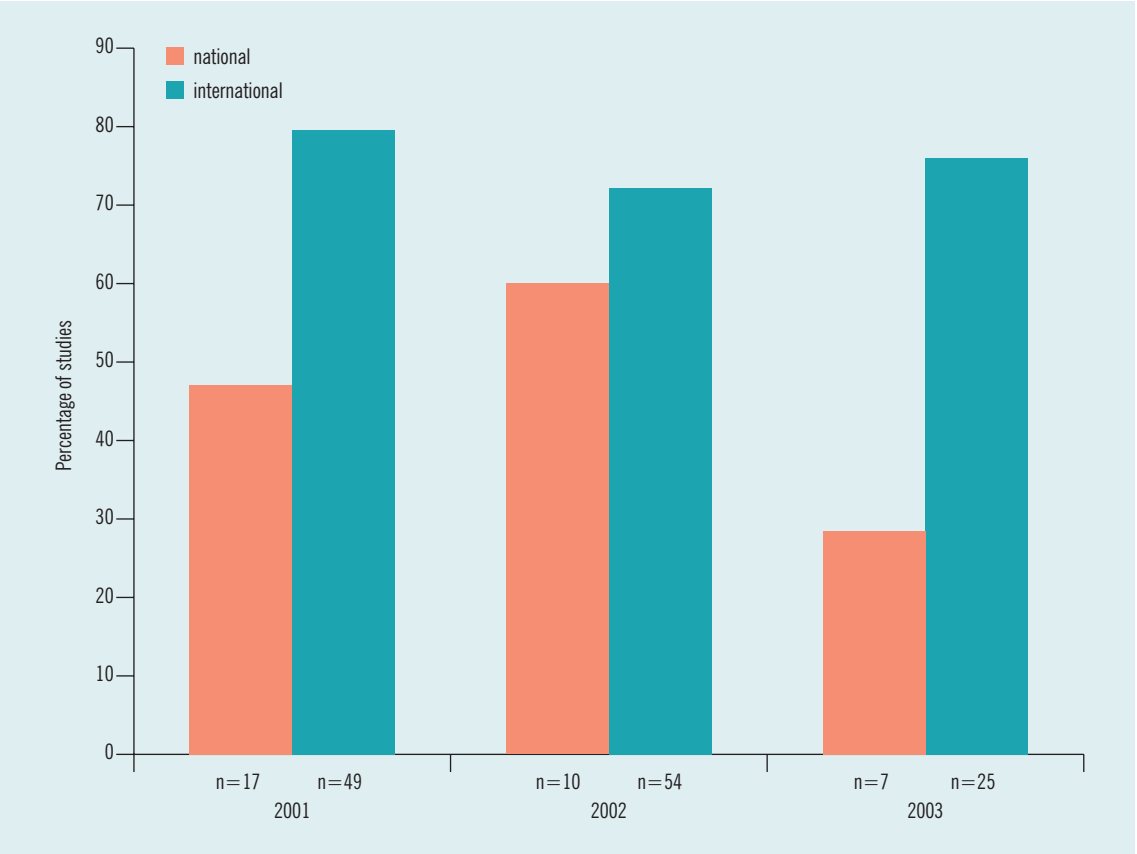
A box whisker chart is a way of representing the distribution of a set of data; the top and bottom edges of the box correspond to the quartiles, with a mark inside it to show where the median is. Two 'whiskers' are attached to the sides of the box, to show the overall range of the data.

Comparing several box-and-whisker charts can be a useful way of spotting differences in distributions.

This indicator is not updated from last year's publication.

Indicator 13: Proportion of studies completed within planned timelines

Chart: Proportion of studies completed within planned timelines



Source: CMR International

Note

A little over 80% of studies undertaken in the UK are international.

“n” refers to sample number.

This chart has not been updated from last year's publication.

Section 3

Demand and Regulatory Conditions

Uptake	Notes
*16 Population adjusted standard units sold per month of a sample of major new NHS-reimbursed products launched within last 5 years, monthly sales measured at 1 year and 3 years after launch in the UK and comparator countries	
17 Population adjusted standard units sold per month of a sample of new non-reimbursed products launched within last 5 years, monthly sales measured at 1 year and 3 years after launch in the UK and comparator countries	No-new non-reimbursed products in the UK
18 Pharmaceutical sales as % of GDP	
19 % (by value) of national pharmaceuticals market accounted for by NMEs launched within last 5 years	
20 % (by value) of national pharmaceuticals market accounted for by generics	

Price/profit regulation

*21 Companies free to set the launch prices of new medicines? (Y/N)	

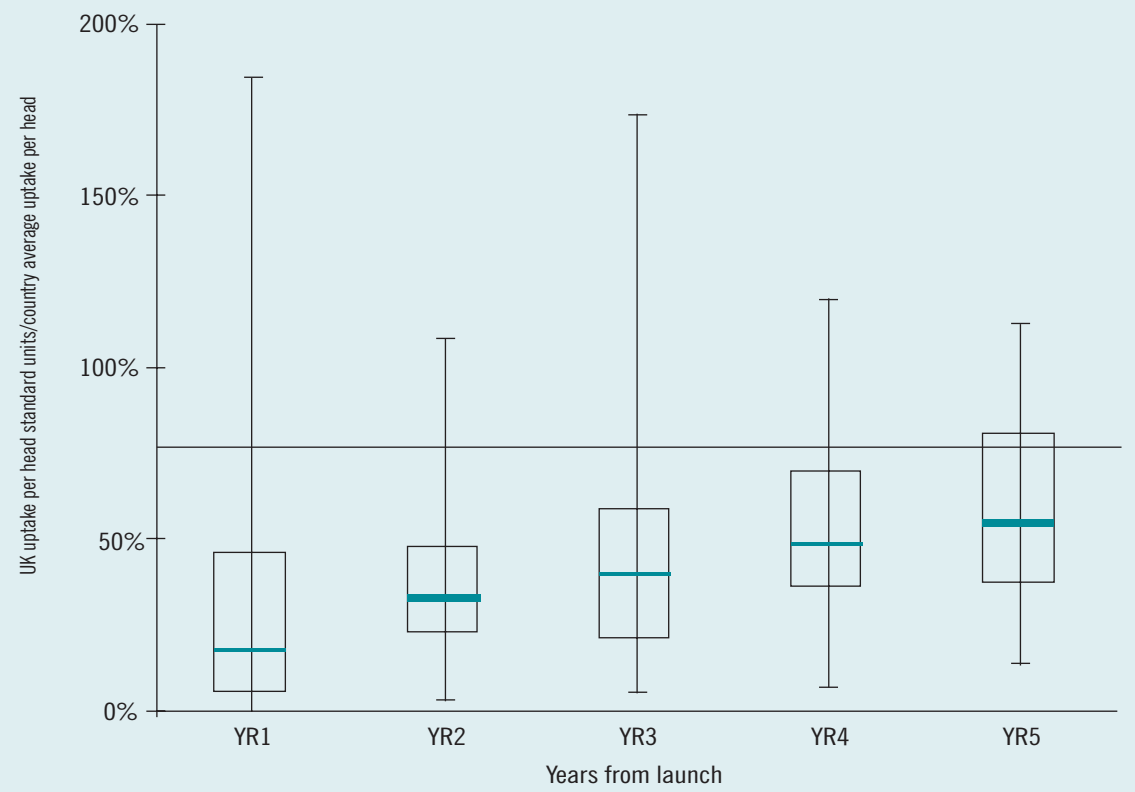
Research and medicines regulation

*22 Overall time taken from first submission of protocols to final medicines regulatory approval (CTX), REC approval and NHS hospital approval to proceed with clinical trial at first site	
23 Proportion of studies approved by Research Ethics Committees (MRECs and LRECs) without deferral	
24 Average approval time for licence for animal experimentation	
25 Average time from first world application for market authorisation to application in the particular market	
26 Average time from application for market authorisation to approval, in the particular market	
27 Average time from approval to launch, in the particular market	

28 Number of regulatory and scientific advice opportunities between the MCA (now MHRA) and the pharmaceutical industry	not available
29 In the mutual recognition procedure, the number of times the MCA (now MHRA) is chosen as the Reference Member State (RMS)	
30 In the mutual recognition procedure, the number of times applications to other EU member states are withdrawn from the procedure following a positive UK opinion when the MCA (now MHRA) is the RMS	
31 In the centralised procedure, the number of times the MCA (now MHRA) is nominated by industry as the rapporteur	
32 In the centralised procedure, the number of times the MCA (now MHRA) is nominated as rapporteur to provide European scientific advice	

Indicator *16: Population-adjusted standard units sold per month of a sample of major new NHS-reimbursed products launched within the last 5 years, monthly sales measured at 1 and 3 years after launch in the UK and comparator countries

Chart: UK uptake of 40 medicines launched in the UK since 2000 compared to average for other PICTF countries



Sources: Sales volume data, IMS; population data, OECD; prescribing data, BNF, EMC; Launch data, IMS Lifecycle

Note

How to read this chart:

The values used to generate this chart are UK average monthly consumption per head for each year since launch, measured in standard units, of forty-nine medicines, launched in the UK since 1999, divided by average consumption in all other PICTF comparator country markets where the medicine is available.

A value above 100% would mean that UK per head consumption exceeds the average.

The box represents the interquartile range which contains the middle 50% of values. The whiskers are lines that extend from the box to the highest and lowest values. The line across the box indicates the median.

Table a: Selected statistics for UK uptake of medicines compared to PICTF average – 2005

Years from launch					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
25% of cases at or below	4%	21%	20%	35%	36%
median	**17%**	**32%**	**39%**	**48%**	**54%**
75% of cases at or below	46%	48%	59%	70%	81%
Number of cases	51	41	35	22	18

Table b: Selected statistics for UK uptake of medicines compared to PICTF average – 2004

Years from launch					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
25% of cases at or below	4%	16%	27%	26%	21%
median	**13%**	**27%**	**36%**	**43%**	**47%**
75% of cases at or below	41%	41%	47%	54%	56%
Number of cases	44	47	36	28	19

Table c: Selected statistics for UK uptake of medicines compared to PICTF average – 2003

Years from launch					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
25% of cases at or below	7%	21%	24%	28%	28%
median	**21%**	**31%**	**34%**	**40%**	**44%**
75% of cases at or below	44%	49%	61%	59%	72%
Number of cases	49	49	46	37	27

Table d: Selected statistics for UK uptake of medicines compared to PICTF average – 2002

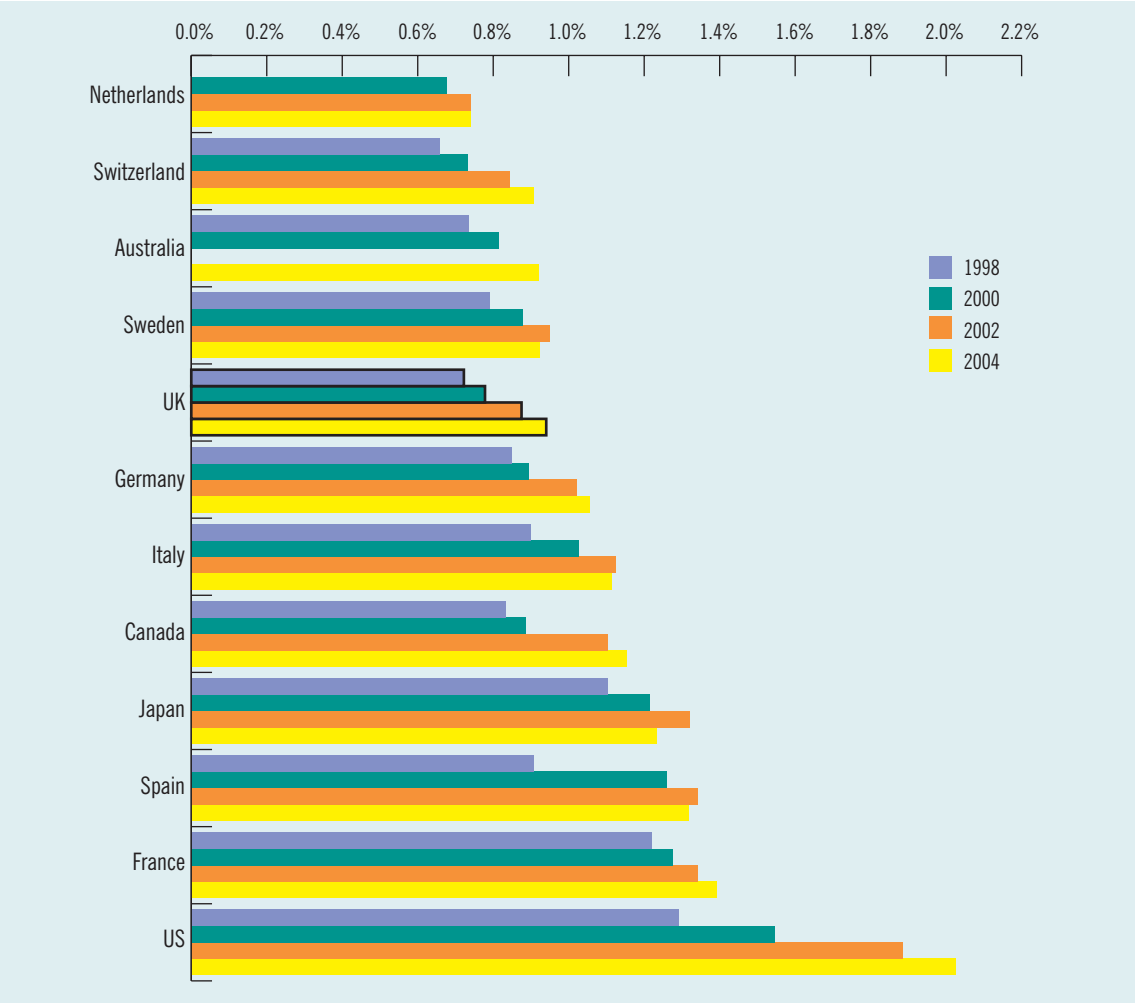
Years from launch					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
25% of cases at or below	8%	17%	20%	22%	30%
median	**25%**	**31%**	**34%**	**34%**	**62%**
75% of cases at or below	39%	57%	55%	63%	177%
Number of cases	35	41	31	24	10

Table e: Selected statistics for UK uptake of medicines compared to PICTF average – 2001

Years from launch					
	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
25% of cases at or below	12%	16%	20%	19%	21%
median	**26%**	**29%**	**34%**	**35%**	**53%**
75% of cases at or below	45%	49%	47%	53%	66%
number of cases	46	45	39	30	16

Indicator 18: Pharmaceutical sales as a % of GDP

Chart: Pharmaceutical sales as a percentage of GDP for selected countries



Sources: ABPI calculations using IMS World Review 2004 market data and OECD data for GDP

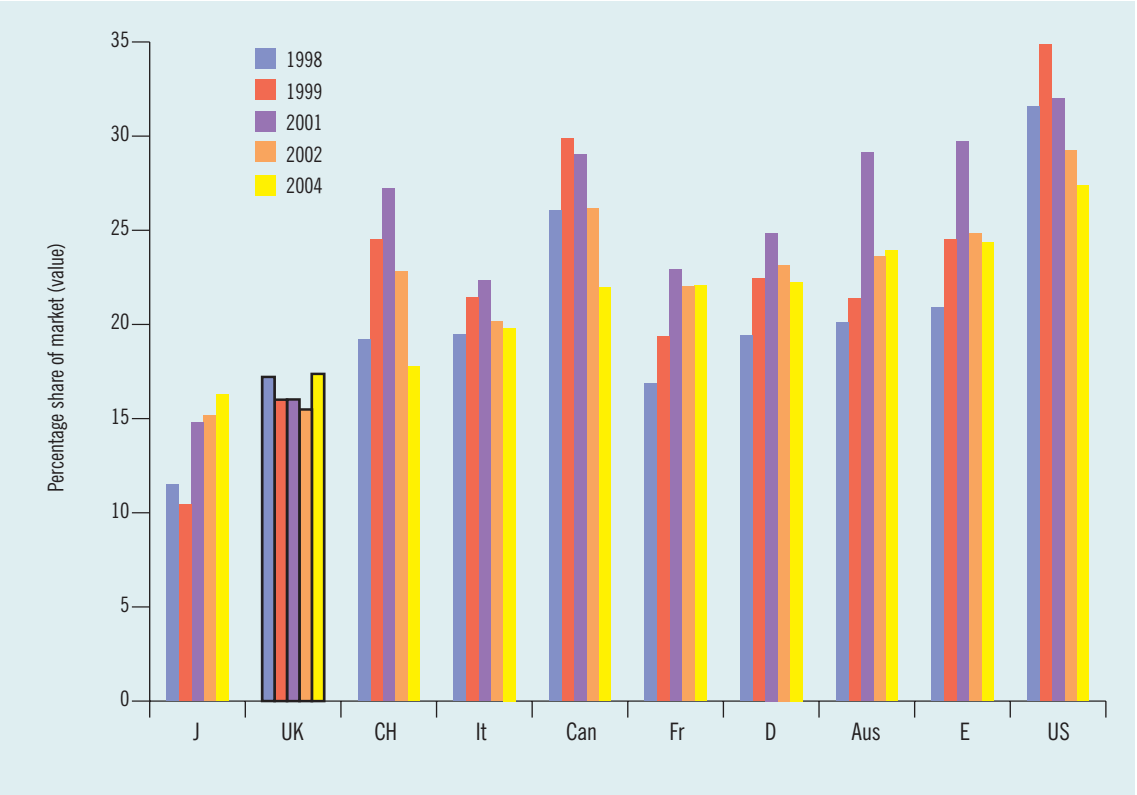
Note

These figures include prescription and hospital medicines.

Data are not available for Australia for 2002, nor for the Netherlands for 1998.

Indicator 19: Percentage (by value) of national pharmaceuticals market accounted for by new products launched within the last 5 years

Chart: Percentage (by value) of national pharmaceuticals market accounted for by products launched within the last 5 years (1998-2004)



Source: IMS World Review

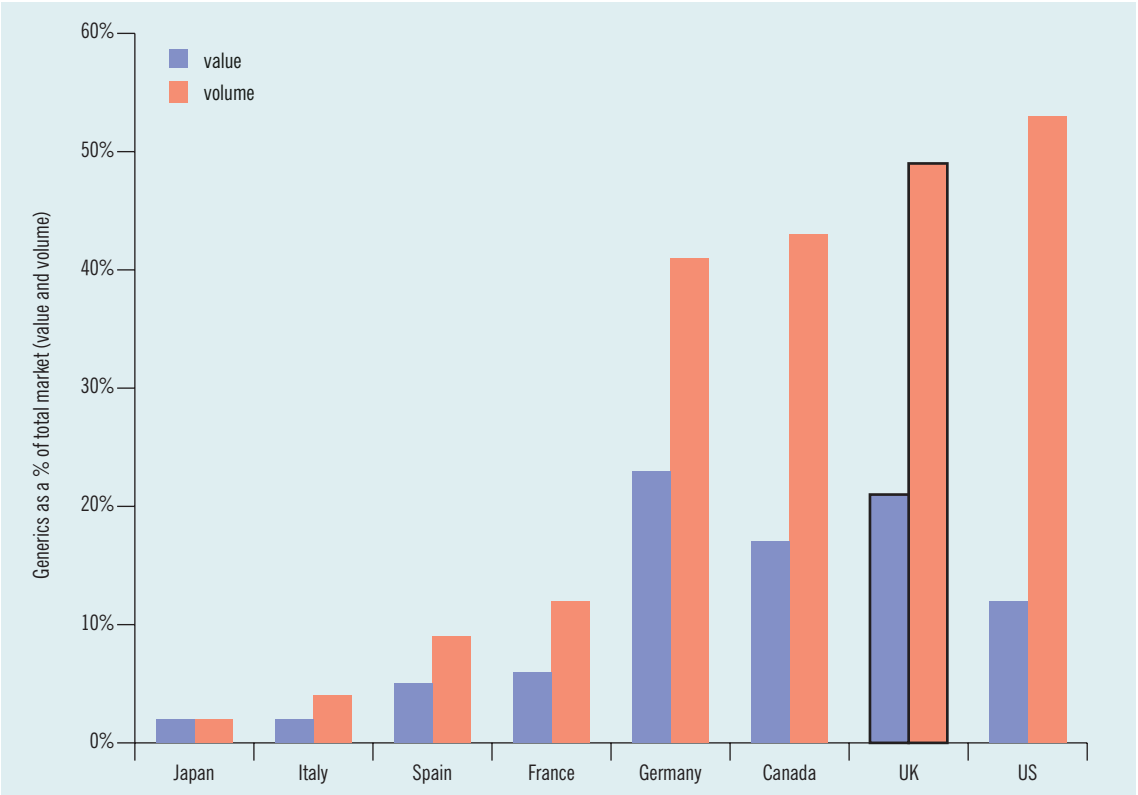
Note

This measure is an alternative to indicator 16 as a way of assessing uptake of new medicines.

Please note that the data used captures all new products including new generic products.

Indicator 20: Percentage of national pharmaceuticals market accounted for by generics

Chart: Generic market share by value and volume for comparator countries 2004



Source: www.egagenerics.com/doc/fac-GxMktEur_2004.pdf, http://www.canadiangenerics.ca/en/resource/market_trends.shtml, http://gphaonline.org/policy/pdf/2005-05-18-testimony.pdf

Note

This year this indicator shows the generic market share by value and volume.

The sources for the data has changed from 2004 PICTF.

Indicator * 21: Companies free to set the launch prices of new medicines? (Y/N)

	Free pricing at launch July 2005
Australia	No
Canada	No
France	No
Germany	Yes*
Italy	No
Japan	No
Netherlands	No
New Zealand	No
Spain	No
Sweden	No
Switzerland	Yes
UK	*Yes*
US	Yes

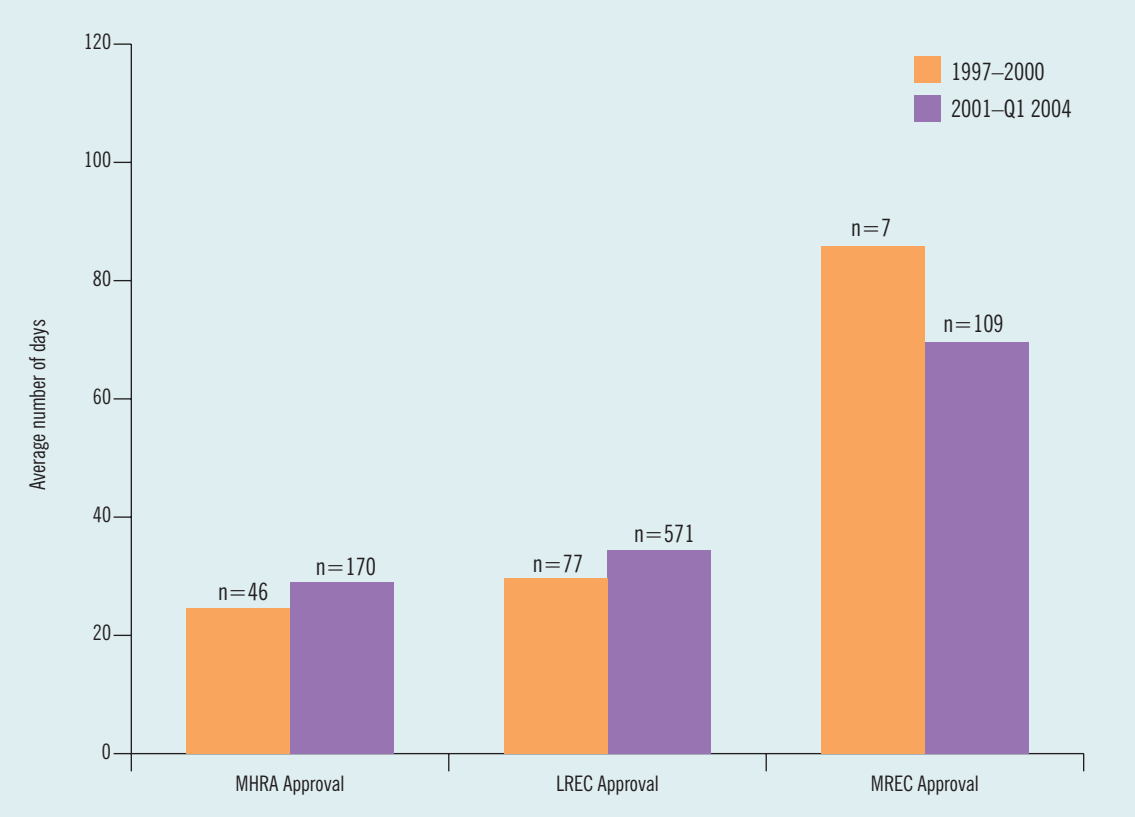
Sources: Various trade associations, public domain sources e.g. Pharmacoeconomics

Note

* Changes to the pricing and reimbursement system in Germany during 2004 and 2005 have the potential to companies are free to set launch prices.

Indicator *22: Overall time taken from first submission of protocol to final medicines regulatory approval (CTX), REC approval and NHS hospital approval to proceed with clinical trial at first site

Chart: Average time from first submission of protocols to approval for MHRA (previously MCA), MREC, LREC between 1997-2000 & 2001-Q1 2004



Source: CMR International

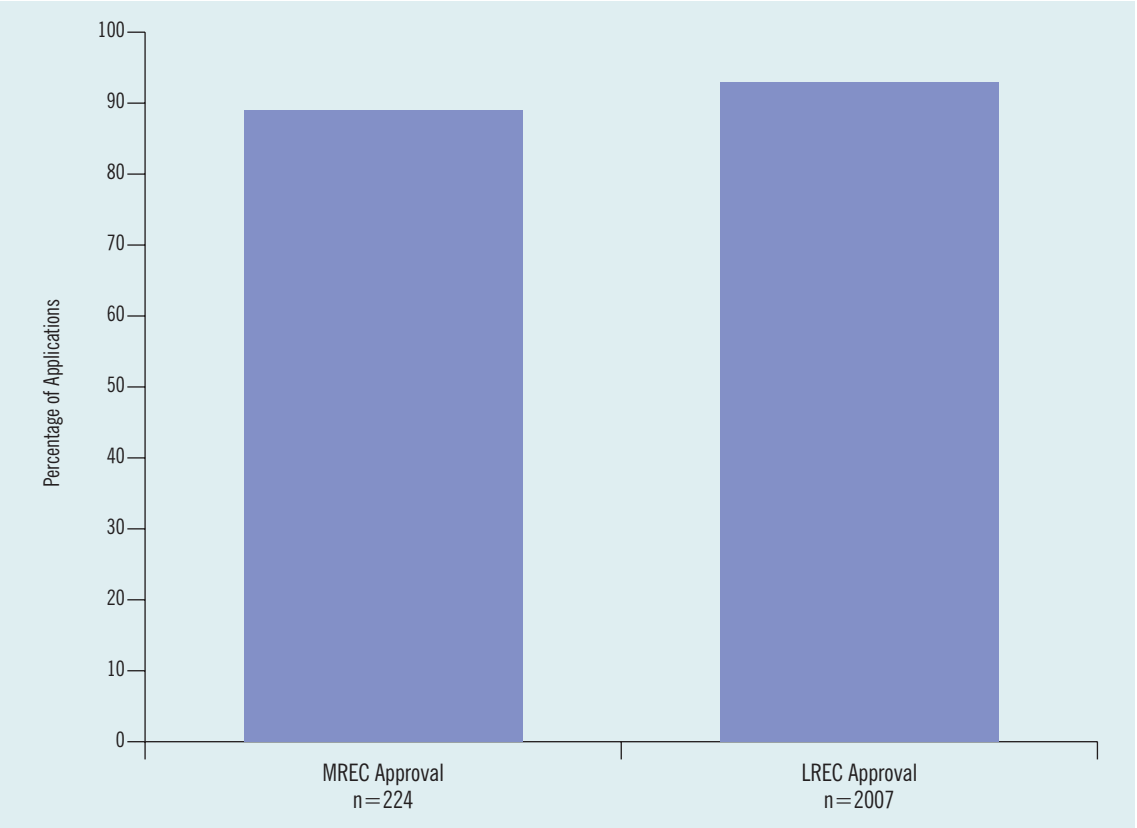
Note

In order to work towards compliance with the EU clinical trials directive, which have come into force in May 2004, a target time from submission to approval of 60 days had been set.

Due to lack of data this indicator has not been updated since 2004 PICTF.

Indicator 23: Proportion of studies approved by Research Ethics Committees (MRECs and LRECs) without deferral

Chart: Percentage of applications to Research Ethics Committees (MRECs and LRECs) between 1997 and December 2003 that are approved at the first meeting



Source: CMR International

Note

Data for this indicator was not collected during 2004, and will be superceded by a new indicator in the future.

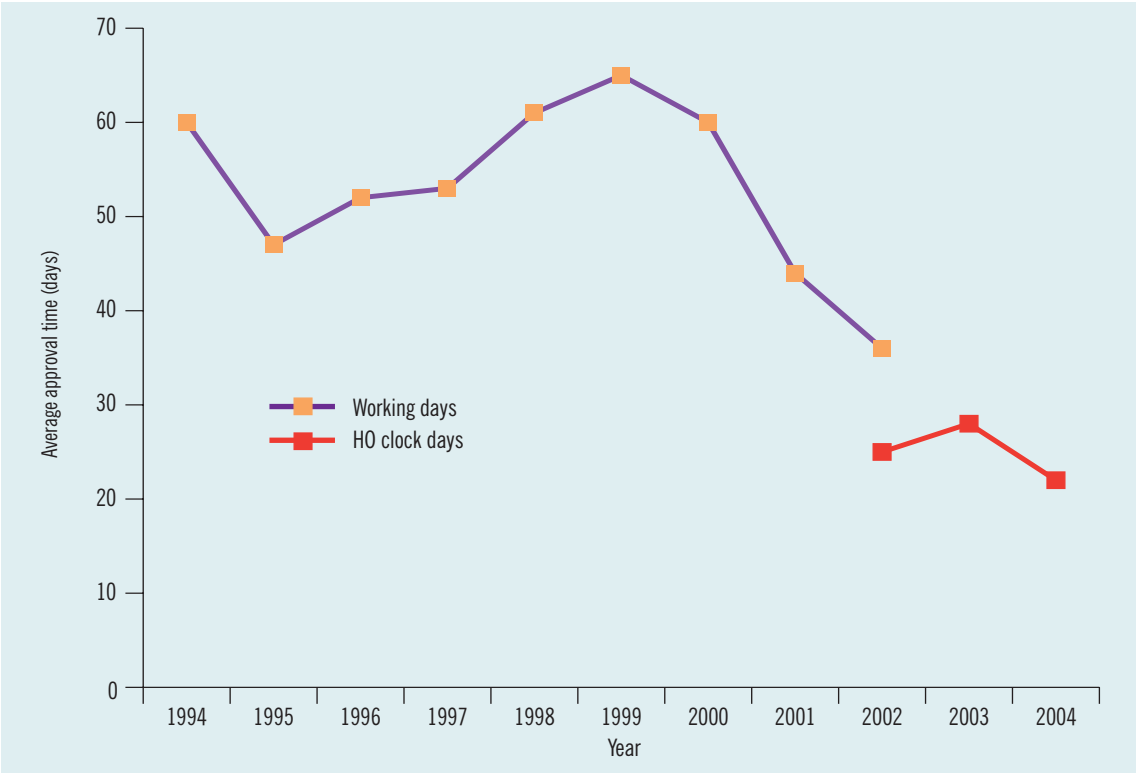
Submissions were between 1997 and December 2003 inclusive.

Multicentre trials (where there are five or more centres participating) are more likely to raise questions than trials involving four or fewer centres.

Due to lack of data this indicator has not been updated since 2004.

Indicator 24: Average approval time for licence for animal experimentation

Chart: UK average approval time for licence for animal experimentation



Source: Home Office

Note

*From 2002 approval time measured in HO clock days – this excludes any delays on the Industry's behalf, providing a more accurate and reliable indicator of the efficiency of the regulator.

The Home Office has an agreed target of dealing with 85% of Project Licence applications within 35 "clock days", meaning total working days taken for processing a request, but excluding any time spent waiting while further information is obtained from the applicant. For the 12 months January to December 2003 an application received in its final form was with the Home Office for an average of 28 "clock days", and 74% were processed within 35 "clock days".

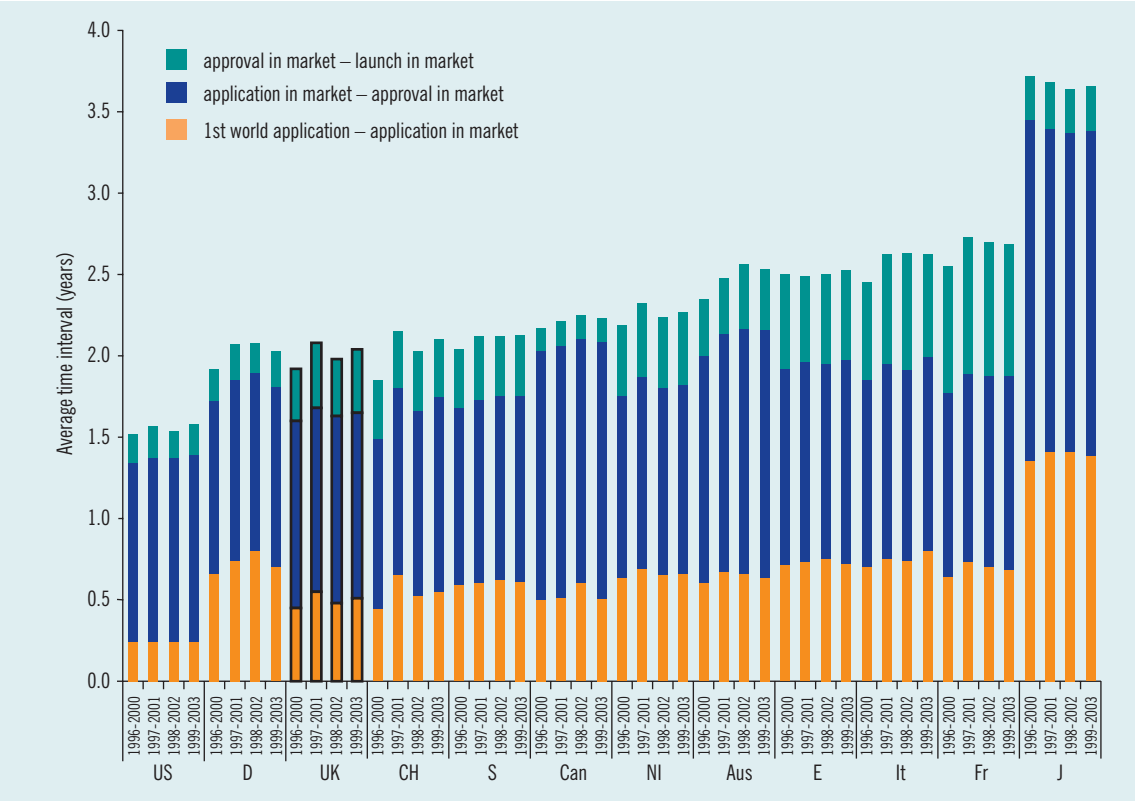
The data shows that approval times have decreased by 6 clock days from 2003 to 2004.

Indicator 25: Average time from first world application for market authorisation to application in the particular market

Indicator 26: Average time from application for market authorisation to approval, in the particular market

Indicator 27: Average time from approval to launch, in the particular market

Chart: Time elapsed between first world application in any market and launch in particular market 1996-2000, 1997-2001, 1998-2002, 1999-2003



Sources: ABPI calculation. Pharmaprojects

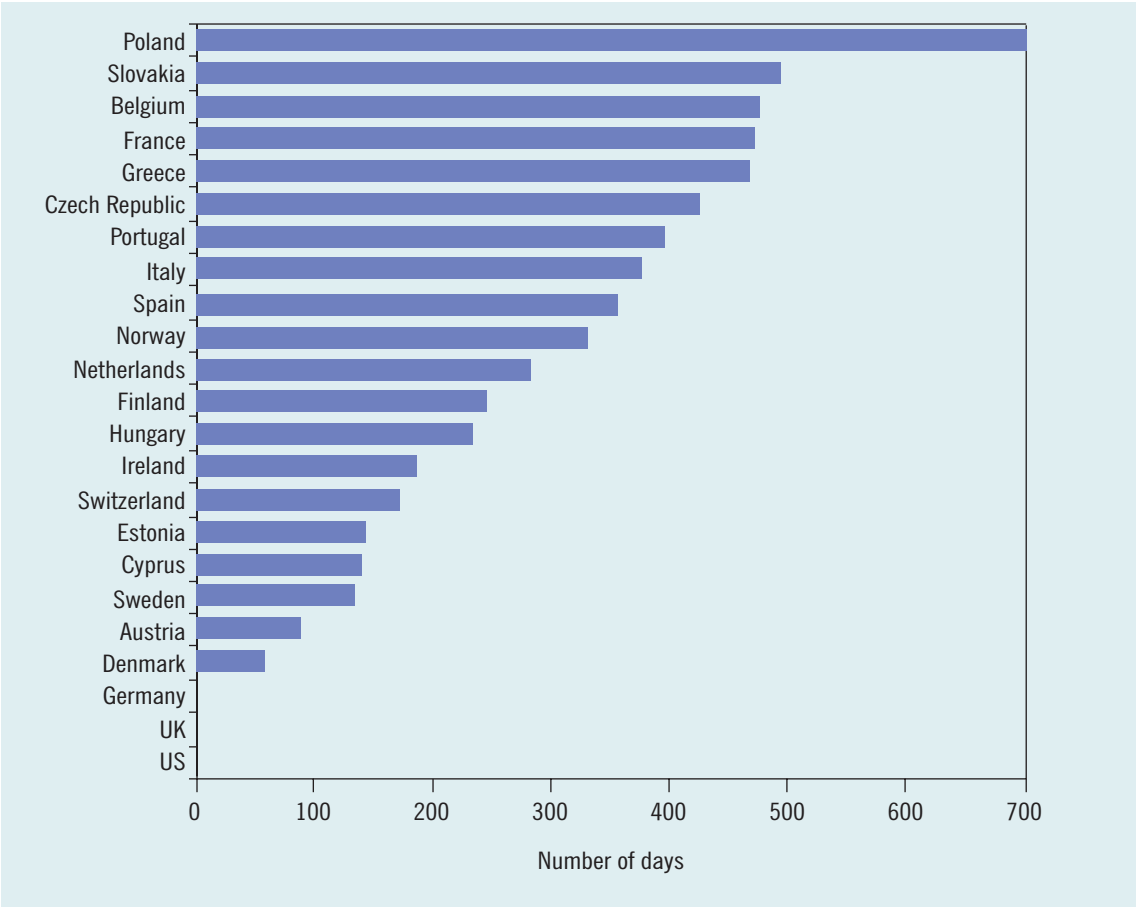
Note

This measure captures the lag between application for launch in any market to launch in specific markets for products launched in the various periods.

The three main reasons for delay are company strategy (when to apply, when to launch), length of regulatory process, length and pricing and reimbursement process.

Due to lack of data this indicator has not been updated since 2004.

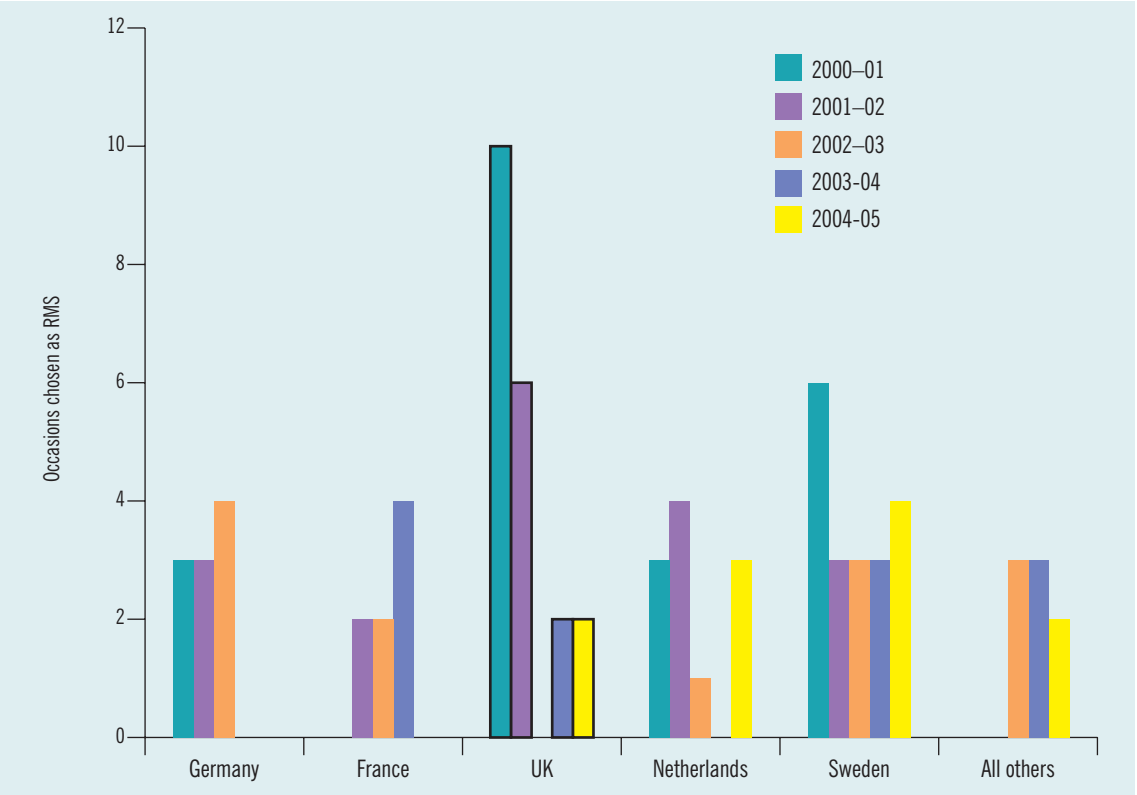
Chart b: Average pricing and reimbursement delay for EMEA and non-EMEA approved molecules (May 2004)



Source: Efpia

Indicator 29: In the mutual recognition procedure, the number of times the MCA (now MHRA) is chosen as the Reference Member State (RMS)

Chart: Number of times MHRA (previously MCA) was chosen as RMS, 2000-01, 2001-02, 2002-03, 2003-04, 2004-05 compared to selected countries



Source: MHRA

Note

This indicator shows the degree to which the MHRA is the regulator of choice by companies.

No NASs entered the MR procedure in 2002/03. This continues a downward trend from the previous two years. The underlying cause appears to be the small number (2) of NASs granted in 2000/01. The number of applications submitted to MHRA has risen for the following two years, which may indicate the number of NASs entering into the MR procedure with the MHRA as RMS will pick up in the following few years when these applications are granted. In 2003-04 there was a fall in applications community wide as reflected in the table above. The trend continued in 2004-05. UK continues to be a major player in the Mutual Recognition procedure.

Indicator 30: In the mutual recognition procedure, the number of times applications to other EU member states are withdrawn from the procedure following a positive UK opinion when the MHRA is the RMS

Table: Total withdrawals where the UK was the RMS

	2000-01	2001-02	2002-03	2003-04	2004-05
Applications where the UK is the RMS (Number of New Active Substances)	10	6	0	2	2
Total applications (including all procedures of the same active drug substance) to other members states	100	80	0	30	74
Withdrawals	15	2	0	2	5

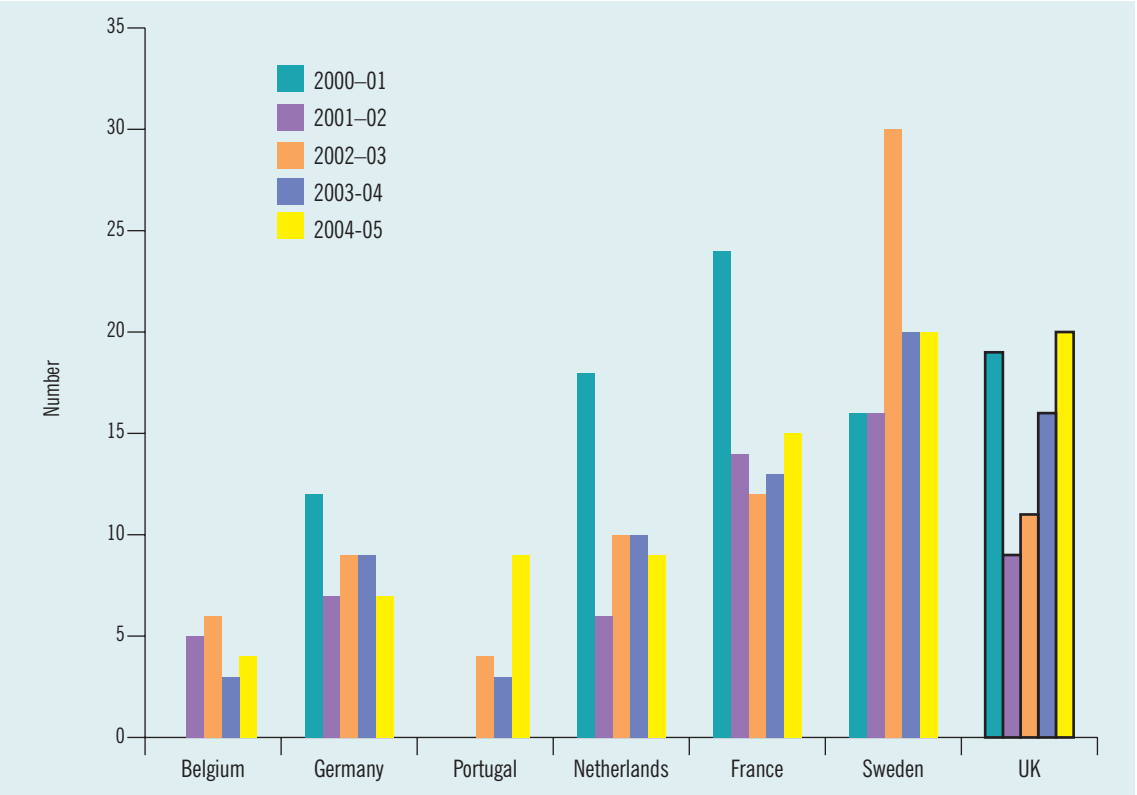
Source: MHRA

Note

The number of withdrawls from the mutual recognition procedure following a UK approval should be low if the MHRA has predicted potential issues. The data in 2000-01 show a 15% withdrawal rate. This improved significantly in 2001-02 with a withdrawal rate of only 2.5%. In 2002-03, no UK application has entered the mutual recognition procedures because the five new drug applications submitted to the UK have not yet completed the UK authorisation stage. In 2003-4 the withdrawal rate remains low at 6%. Similarly in 2004-2005, about 6% of the applications were withdrawn. There is no readily available equivalent data for other European countries.

Indicator 31: In the centralised procedure, the number of times the MHRA is nominated by industry as the rapporteur

Chart: Number of times MHRA (and other countries' agencies) nominated by industry as rapporteur



Source: MHRA

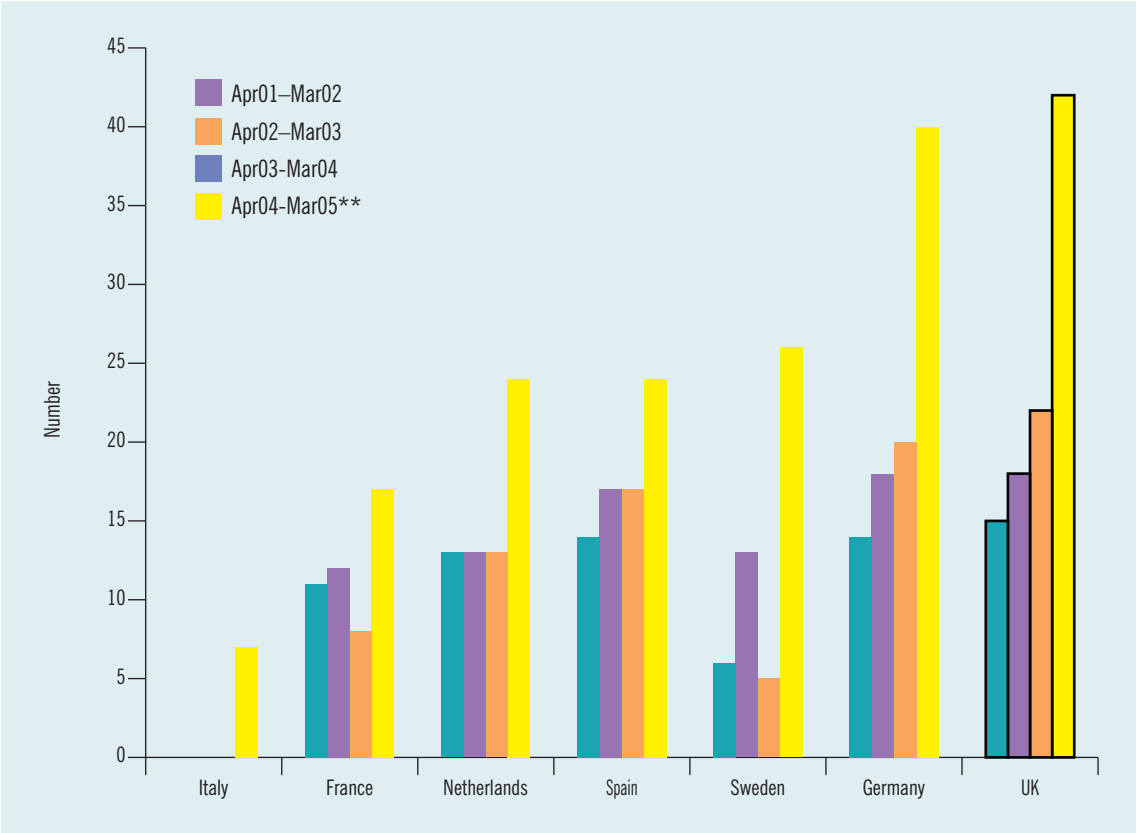
Note

If a country's agency is believed to provide a high level scientific assessment and is willing to work with industry to achieve European approval, it is more likely to be nominated.

Companies are able to nominate national agencies to act as rapporteur for the centralised licensing procedure operated by the European Medicines Evaluation Agency (EMEA). Although the actual selection of rapporteur agencies is a decision of the EMEA's CPMP committee, this indicator provides a measure of industry preference. Amongst the countries available, in 2000-01 the UK was the 2nd most nominated country. In 2001-02, the UK slipped to 3rd behind France and the most nominated country, Sweden. In 2002-03, UK continues to receive a high percentage of rapporteur/co-rapporteur appointments compared with other Member States and remains amongst the leading States. However, there has been a greater distribution amongst the smaller countries for example Portugal and Belgium who have received 25% and 20% respectively compared to 8% and 10% respectively in 2001/2002. In 2003/2004 industry preference for UK was most obvious and UK was the 2nd most nominated country. In 2004/05, the industry preference for UK continued and UK levelled with Sweden to become the most nominated countries.

Indicator 32: In the centralised procedure, the number of times the MHRA (previously MCA) is nominated as rapporteur to provide European scientific advice

Chart: Number of the MHRA (and other countries' agencies) nominated as rapporteur to provide European scientific advice



Source: MHRA

Note

Data includes follow up advice.

If the MHRA is seen to be actively engaged in co-ordinating CPMP scientific advice procedures then companies will be more likely to nominate MHRA as rapporteur when they come to apply for a licence in the centralised procedure. Between Feb 1999 and March 2003 the MHRA was co-ordinator for the greatest number of procedures. As we are approaching the end of the three-year term, these results show that in the current term, the UK maintains its leading position as a co-ordinator for CPMP Scientific Advice. In 2003-04, UK again was the leading coordinator for CPMP Scientific advice. In 2004-05, UK continued to be the leading coordinator.

Section 4

Industry Outputs

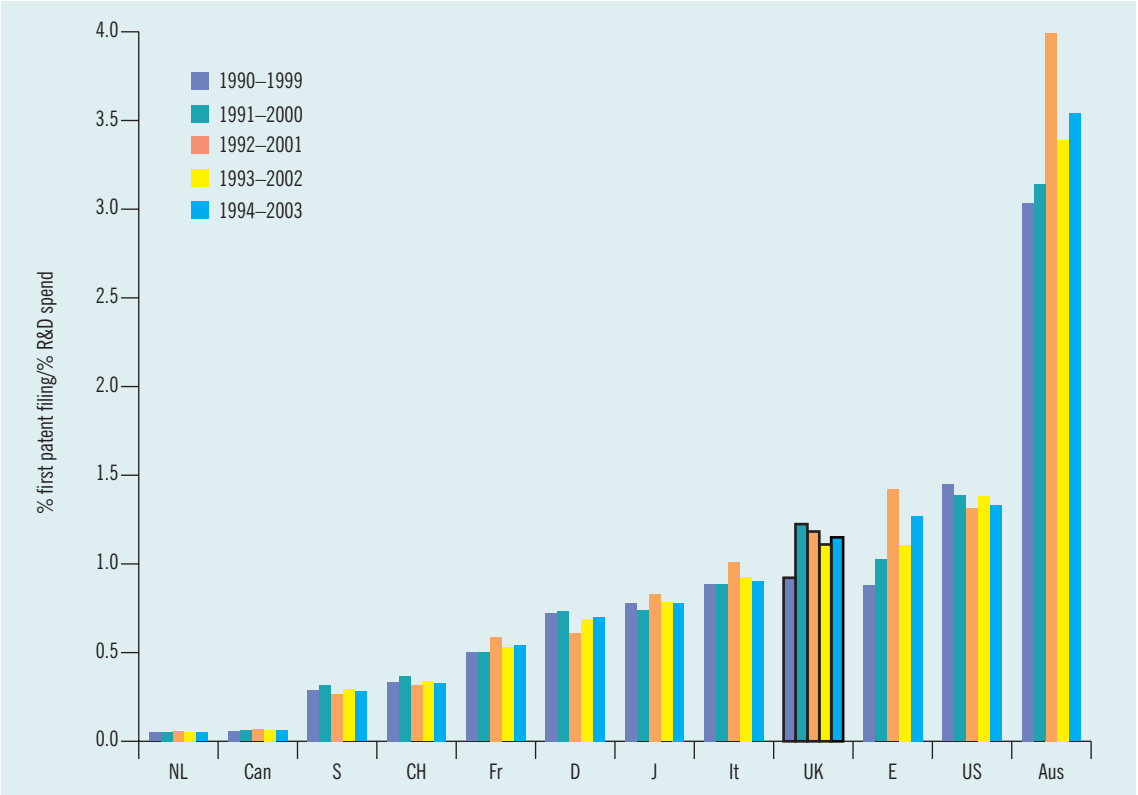
Innovation	Notes
*33 Proportion of world first patents filed for marketed NMEs ÷ proportion of world R&D spend	
*34 National origins of 'global top 75' NASs	
*35 % of developed world pharmaceutical R&D spend	
36 Proportion of NMEs launched in the world by UK-based companies	
37 % of sales by UK-based companies attributed to NMEs first launched during the previous 5 years	Data no longer available
38 UK-based companies' % of global sales of 'top 75' NASs	
39 Number of UK-based companies' NMEs that were first or second launches in class (by mechanism of action)	
40 UK-based companies' share of the US market	
41 Proportion of UK-based companies' NMEs launched in all of the 'top 4' markets: US, Germany, France, UK	
42 Number of UK-based companies' NMEs launched that received FDA priority review	

Macroeconomic contribution

*43 Gross value added	
44 Pharmaceutical trade balance	
45 Share of world pharmaceutical industry production	
46 Pharmaceutical industry employment	

Indicator * 33: Proportion of world first patents filed for marketed NMEs ÷ proportion of world R&D spend

Chart: Proportion of PICTF priority patent filings/proportion of PICTF pharmaceutical industry R&D spend 1990-1999, 1991-2000, 1992-2001, 1993-2002, 1994-2003



Source: ABPI calculations

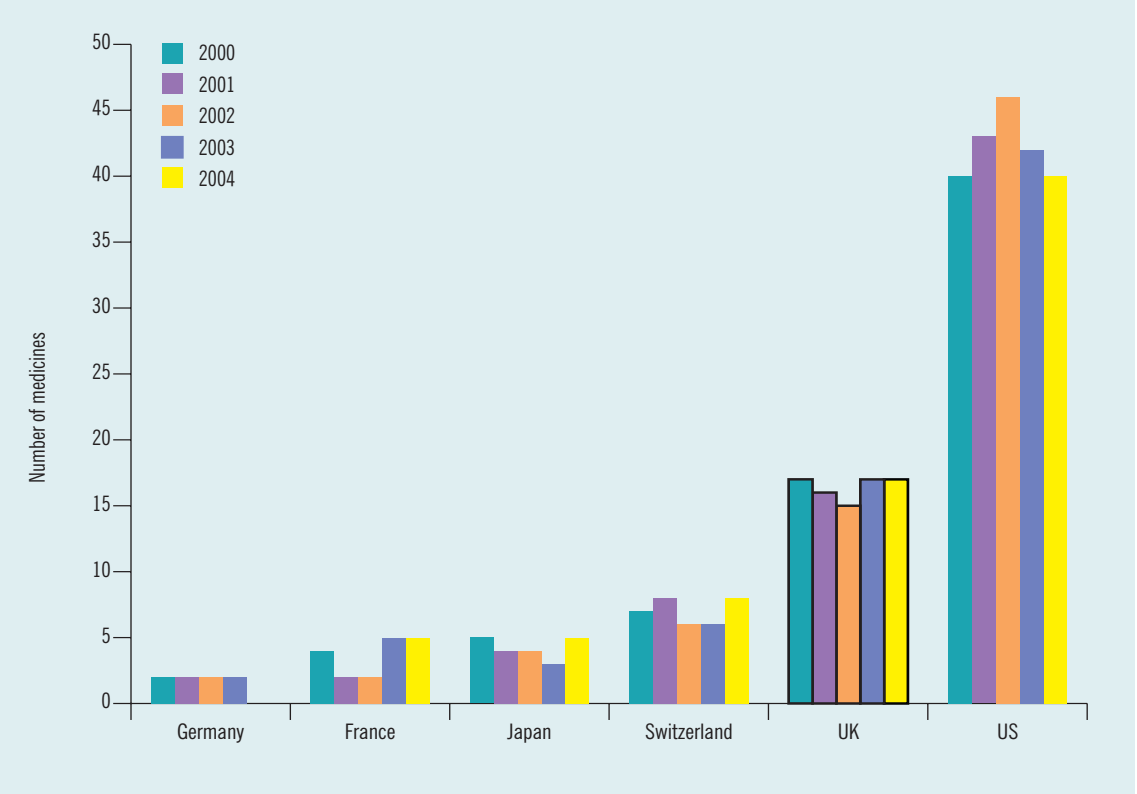
Note

This indicator is a measure of the relative productivity of R&D expenditure, measured as a ratio of share of patents to share of R&D expenditure. Nationality is location of first world patent filing.

Countries with a low pharmaceutical R&D base can appear relatively productive. Comparing the countries with significant levels of pharmaceutical R&D activity the UK is among the most productive by this measure.

Indicator *34: National origins of 'global top 75 NASs'

Chart: National origins of leading 75 global medicines – 2000–2004



Sources: IMS World Review and includes primary and hospital markets

Note

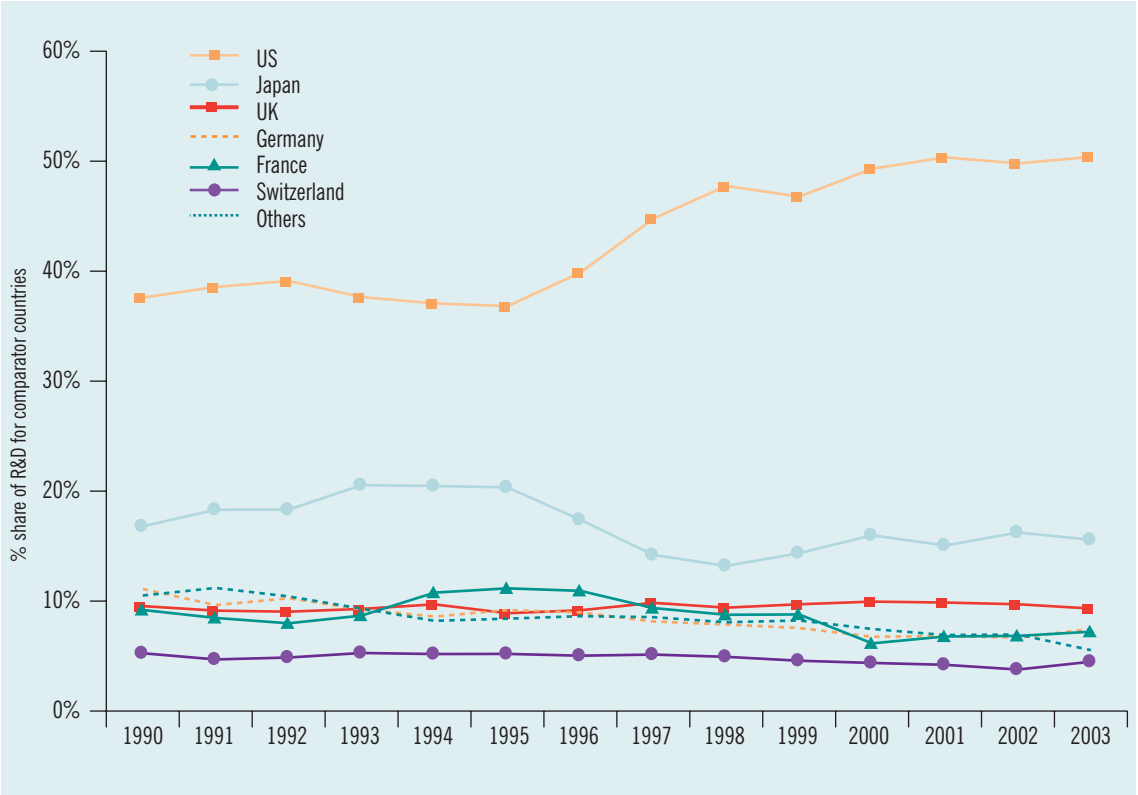
This chart shows the national origins of the global top 75 medicines, where top 75 is measured by worldwide sales and national origin relates to location of company HQ.

The range of sales in 2004 for the medicines included was US$1,030m–US$11,930m.

The figure for Germany for 2004 is zero.

Indicator *35: Percentage of world pharmaceutical R&D expenditure

Chart: Percentage of "world" pharmaceutical industry R&D spend



Sources: National trade associations

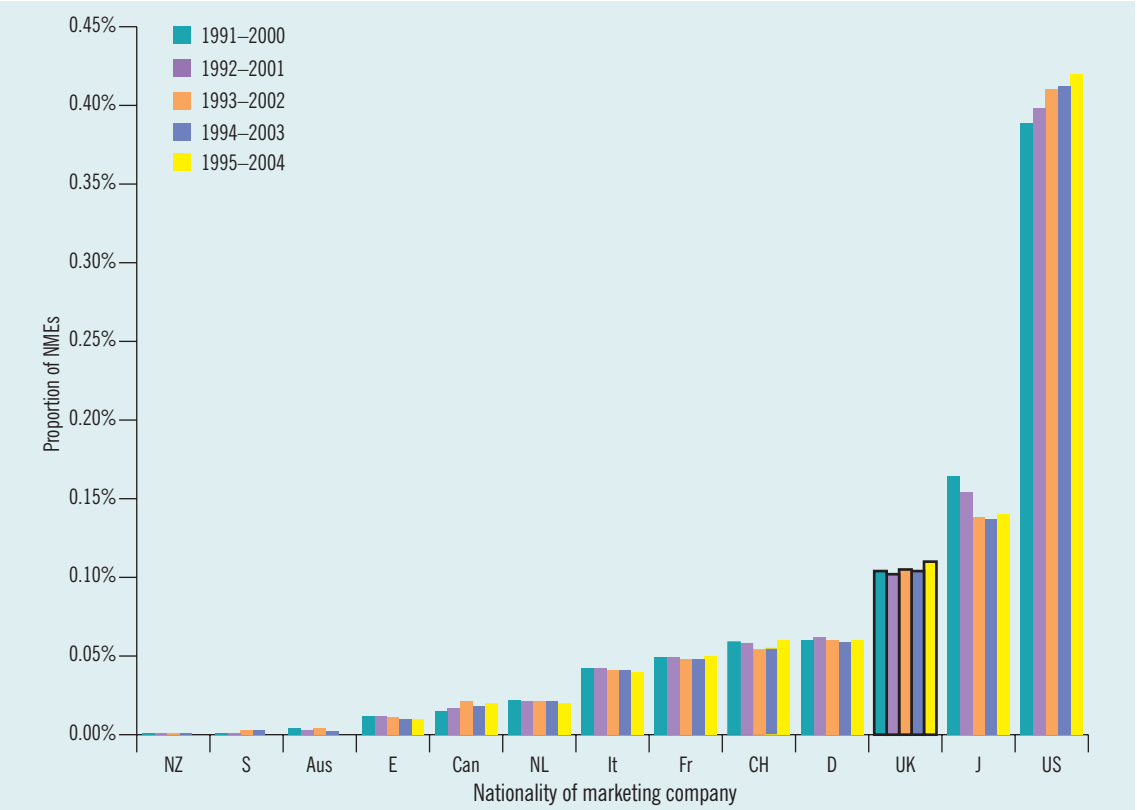
Note

'World' spend is defined here as total spend in PICTF comparator countries apart from Australia and New Zealand.

This is a measure of industry R&D within country boundires and not of companies' total world R&D expenditure.

Indicator 36: Proportion of NMEs launched in the world by UK-based companies

Chart: Proportion of products, first marketed during 1991-2000, 1992-2001, 1993-2002, 1994-2003, 1995-2004 by nationality of marketing company



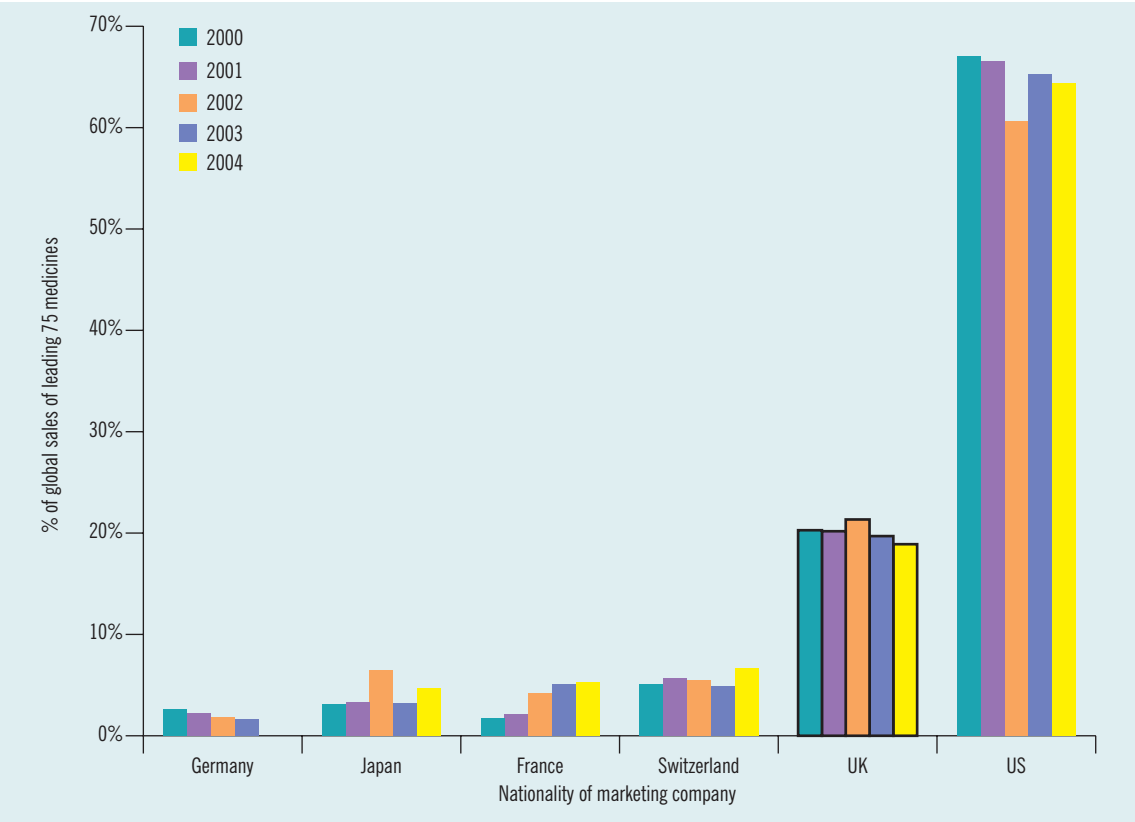
Source: IMS World Review

Note

This indicator is the first and crudest of the indicators assessing national company performance measured in terms of output. It is crudest because it is a simple count of NMEs by marketing company and does not attempt to measure importance of NMEs marketed.

Indicator 38: UK-based companies' % of global sales of "top 75" NASs

Chart: % of global sales of leading 75 medicines, by nationality of marketing company, 2000-2004



Source: IMS World Review and includes primary and hospital markets.

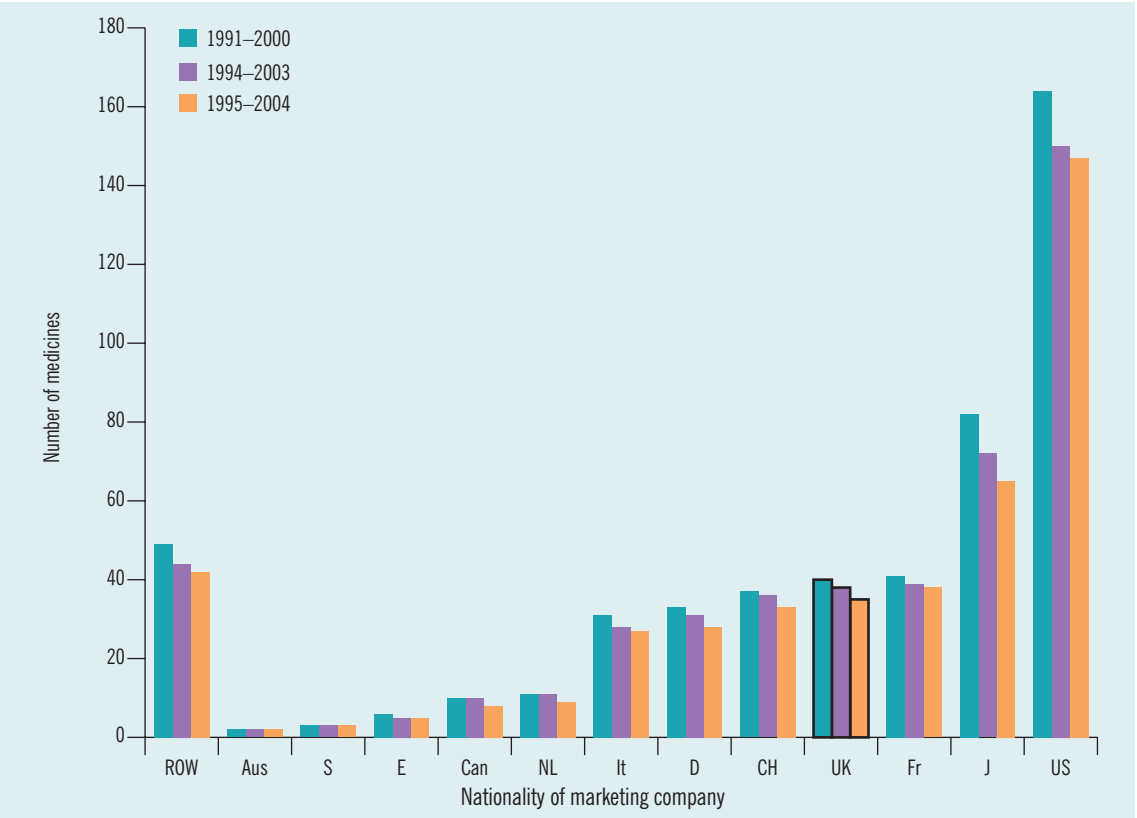
Note

This measure counts the number of 75 leading products, weighted by worldwide sales for companies grouped by nation where headquarters are domicilied. It is a complementary indicator to 34.

The figure for Germany for 2004 is zero.

Indicator 39: Number of UK-based companies' NMEs that were first or second launches in class (by mechanism of action)

Chart: Proportion of medicines by nationality that were first in class (by mechanism of action)



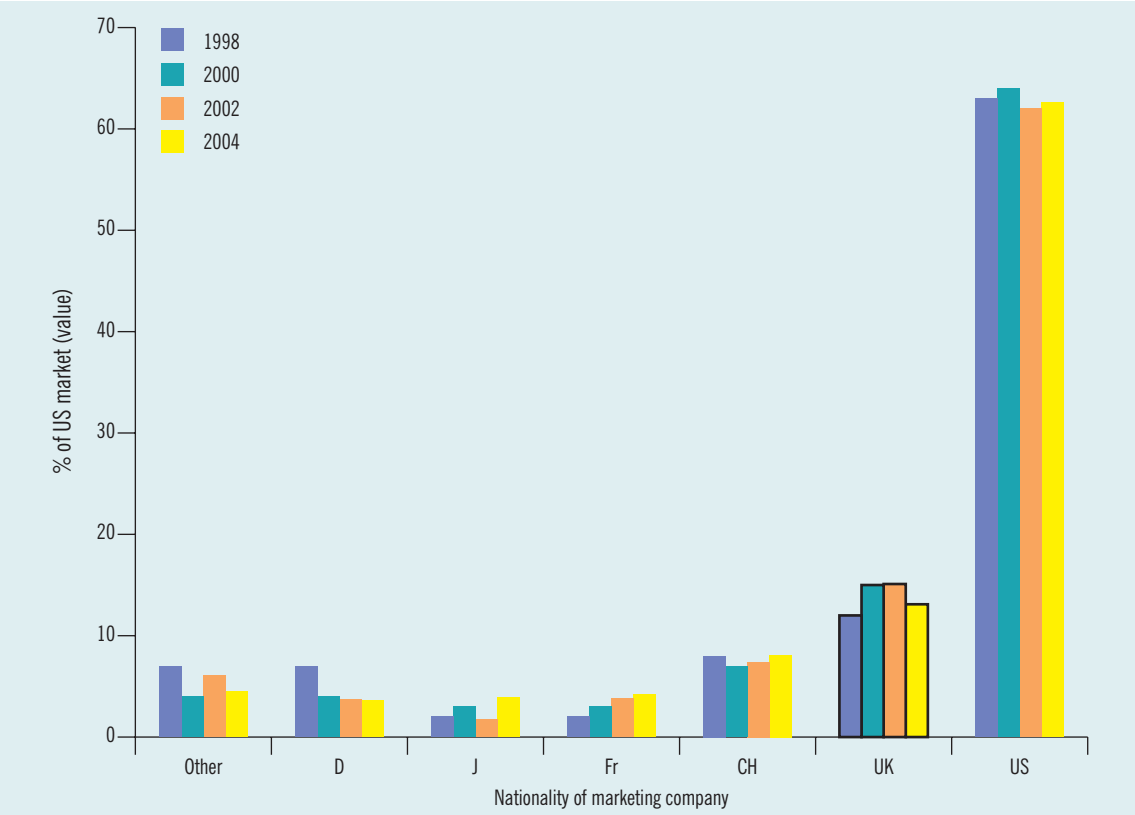
Source ABPI, IMS R&D Lifecycle

Note

This indicator measures how many new medicines (ie. 1st in class) are attributable to companies by nationality

Indicator 40: UK-based companies' share of the US market

Chart: Share of US market by corporate nationality



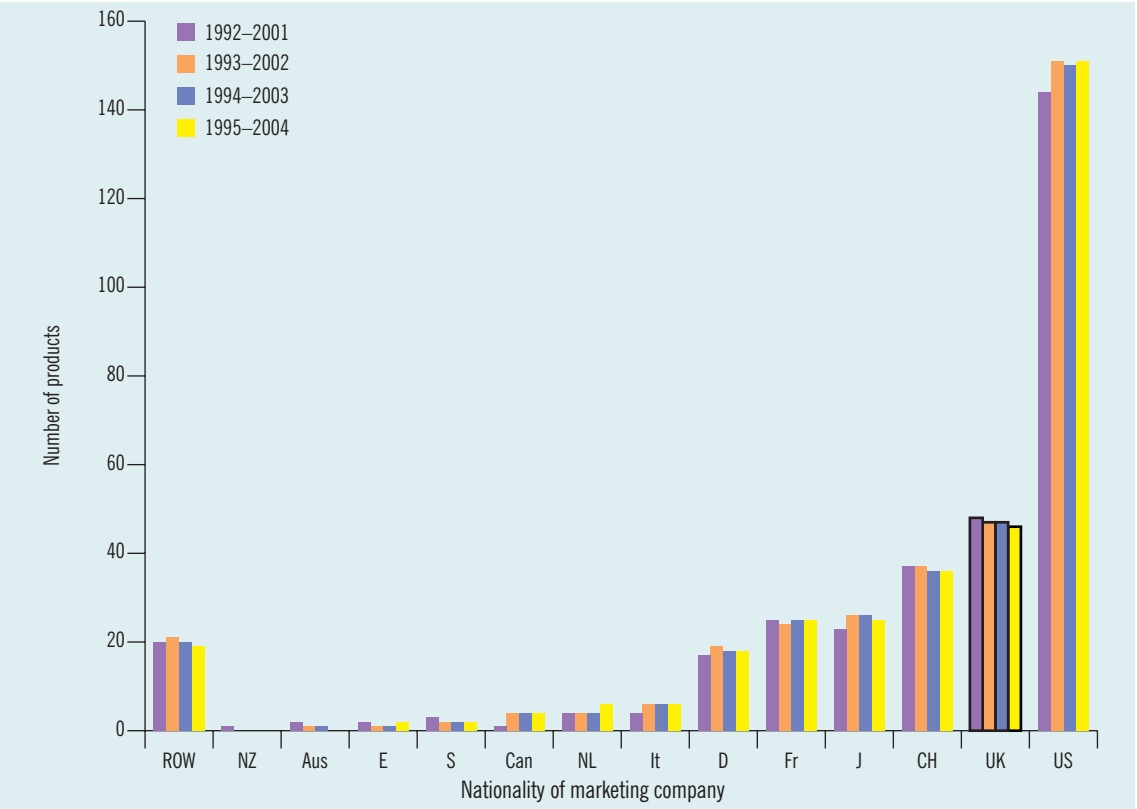
Source: IMS world review

Note

Because of its size and recent growth the US market is seen as the most important single country market for companies.

Indicator 41: Number of UK-based companies' NMEs launched in all of four major markets: US, Germany, France, UK

Chart: Number of products launched onto four major markets



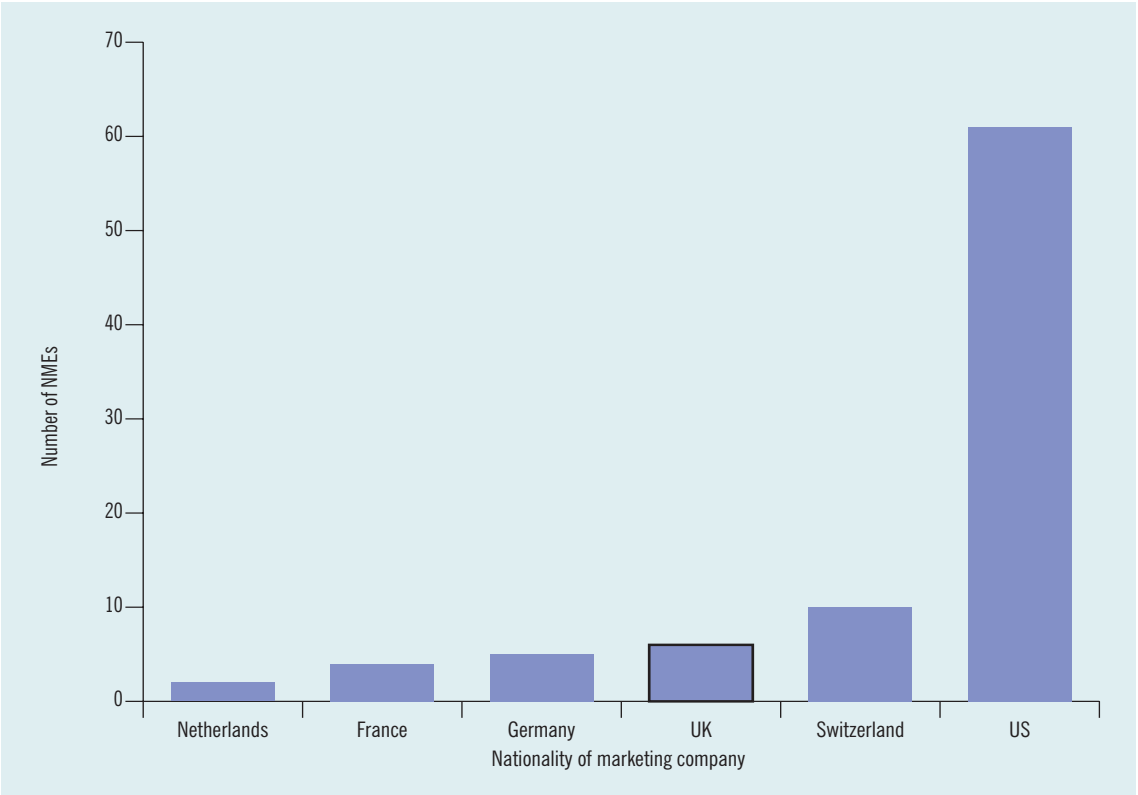
Source: Pharmaprojects, ABPI, IMS R&D Cycle

Note

This indicator is another measure of successful output by national companies and measures proportion of products launched in the US and three important markets in Europe.

Indicator 42: Number of UK-based companies' NMEs launched that received FDA priority review to 2004

Chart: Number of NMEs launched that received FDA priority review by nationality



Source: FDA

Note

FDA priority review is a process designed to enable important new medicines to pass through the US regulatory process rapidly. Medicines given such status are defined by the FDA as "a significant improvement compared to marketed products in the treatment, diagnosis or prevention of disease".

Indicator *43: Gross Value Added

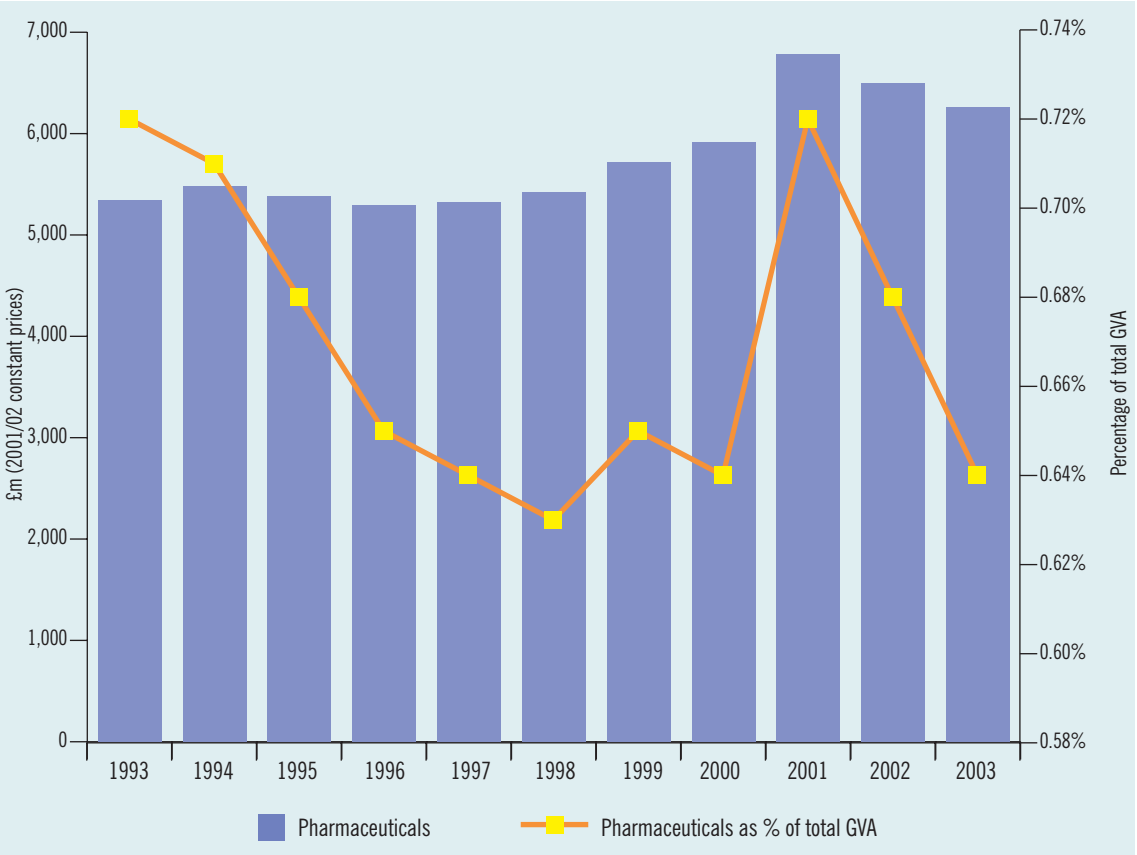
Table: Pharmaceutical Industry Valued Added

In millions of US$	1980	1985	1990	1995	1998	1999	2000	2001	2002
Canada	444	906	1,892	1,761	1,234	1,531	1,766	2,228	
France	2,884	2,517	5,841	9,305	8,982	9,261	8,397	9,065	9,678
Italy	2,658	2,645	7,257	5,763	6,717	7,788	6,706	7,035	7,609
Netherlands	452	549	696	1,647	1,324	1,438	1,435	1,369	1,179
Spain	1,169	913	2,828	2,964	2,562	2,589	2,403	2,748	2,768
Sweden	407	451	1,182	2,251	2,537	3,011	2,772	2,865	3,668
United Kingdom	*2,514*	*2,344*	*5,831*	*6,902*	*7,963*	*8,372*	*8,204*	*9,172*	*9,456*
Japan	7,418	9,483	21,060	34,759	23,754	30,953	31,053	29,086	28,539
United States	8,835	16,130	27,477	43,441	52,812	58,807	64,122		
Germany	0	0	0	10,420	8,860	9,361	8,283	8,970	

Source: OECD STAN database

Note Due to revisions some figures have changed a little from those published last year. The data for Japan and the USA are in producer prices whereas the rest of the data are in basic prices.

Chart: UK pharmaceutical GVA 1993-2003 (constant 2003/04 prices)



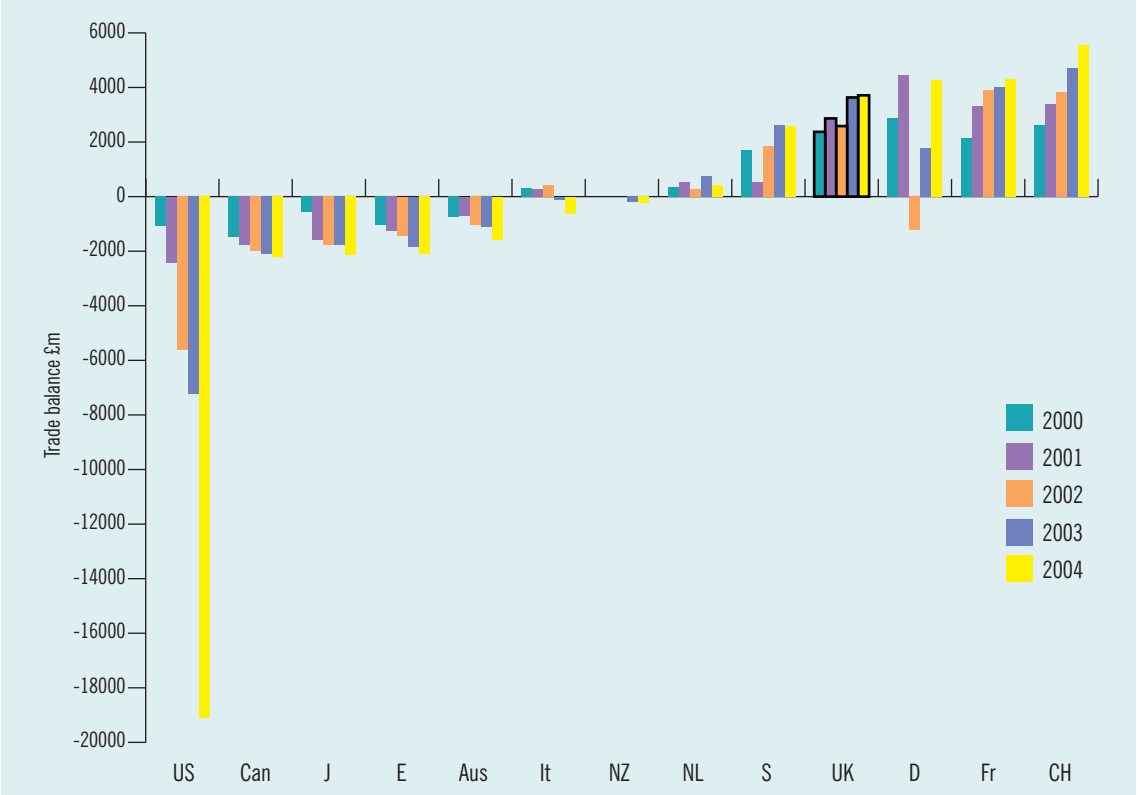
Source: United Kingdom Input-Output Analyses 2005 Edition (www.statistics.gov.uk)

Note Due to revisions in the data there are small discrepancies with the figures published last year and the current estimates.

GDP deflators were not available for calendar years, hence financial year deflators have been used.

Indicator 44: Pharmaceutical trade balance

Chart: Trade balance in pharmaceuticals 2000–2004



Source: Global Trade Information Services Database

Note

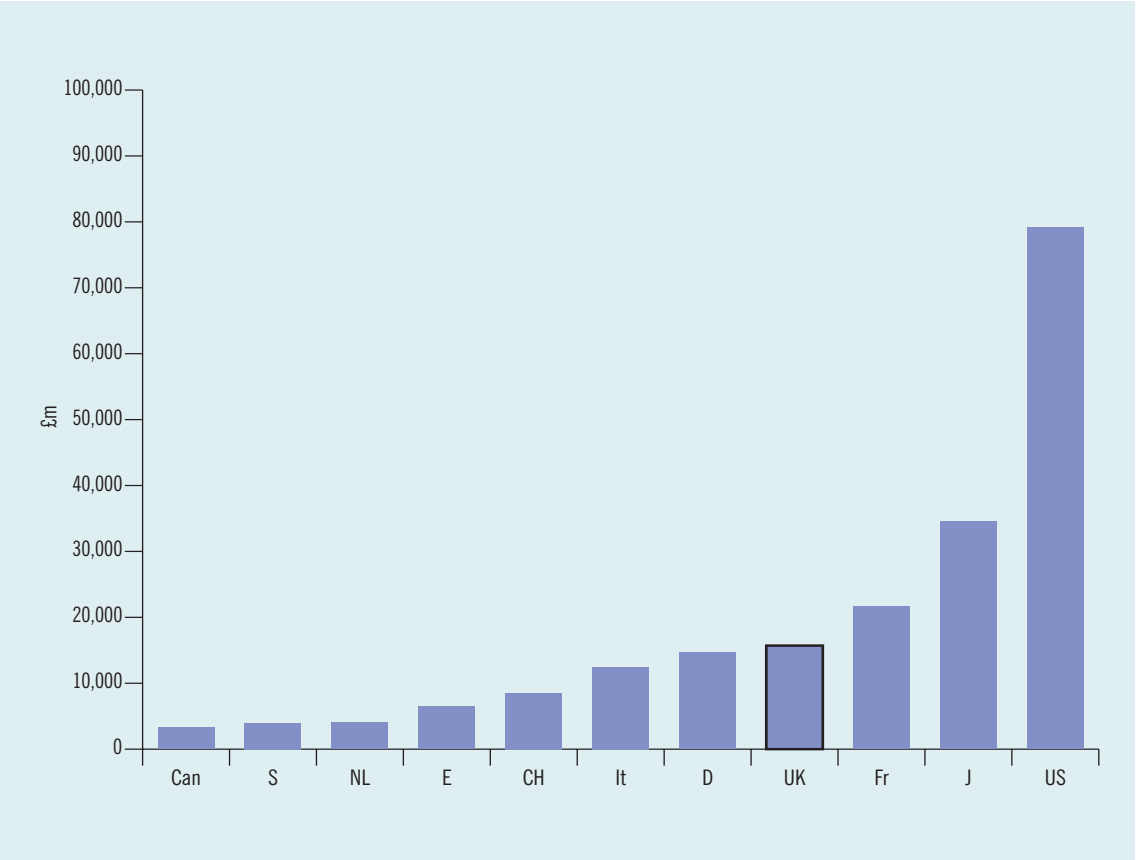
This measure indicates exports minus imports.

The source for the data is Government reported trade activity.

Puerto Rico is included within US reported trade activity but will be separately identified by other countries.

Indicator 45: Share of world pharmaceutical industry production

Chart: Pharmaceutical production for selected countries – 2003



Sources: For Europe (excluding UK) and Japan figures from national trade associations.
For USA, Canada and UK figures from national government statistics.

Indicator 46: Pharmaceutical industry employment

Thousands																
	1985	**1990**	**1991**	**1992**	**1993**	**1994**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**
Australia	10	10	10	11	12	11	12	12								
Canada		21	21	21	20	19	21	21	22	23	25	27	25		29	
France	71	80	80	81	82	83	84	86	88	90	92	95	96	98	99	
Germany	90	120	123	126	125	118	123	121	116	114	113	115	115	115	120	
Italy	63	70	70	69	69	64	63	64	64	65	70	73	79	84	84	
Japan	188		206	149	160	160	245	193	192	210	197	210				
Netherlands	12	13	13	13	13	13	13	13	14	13	13	13	15	16	16	
Spain	41	39	39	39	40	39	38	38	38	38	39	39	39	38	39	
Sweden	9	9	11	10	12	14	15	15	16	16	16	19	19	21	22	
Switzerland	31	30	30	29	29	29	28	27	27	27	26	26	29			
UK	*67*	*71*	*73*	*74*	*69*	*69*	*62*	*59*	*55*	*68*	*70*	*66*	*71*	*84*	*72*	*73*
USA		183	184	194	200	231	228	229	236	247	261	274	283	291	294	

Sources: For Europe (excluding UK) and Japan figures from national trade associations. For USA, Canada and UK figures from national government statistics

Note

The UK figures from 1998 are from ONS Annual Business Survey;
For previous years source was ONS employment survey.
UK figures for 2004 and 2003 subject to change.

Annex 1

Selected Glossary

Countries

In this publication, the names of countries are spelled out in full. Otherwise, abbreviations are used as set out below.

The PICTF Report identified thirteen countries (sometimes referred to as "PICTF comparator countries") considered to be the world leaders in the global pharmaceutical industry. This group of thirteen countries – or as many of them for which data were available – is used for the majority of the indicators in this publication:

Australia	Aus
Canada	Can
France	Fr
Germany	D
Italy	It
Japan	J
Netherlands	NL
New Zealand	NZ
Spain	E
Sweden	S
Switzerland	CH
United Kingdom	UK
United States	US

Indicators 29, 31 and 32 measure the performance of the UK in comparison with the other members of the European Union's medicines licensing system.

In some charts, ROW is used to refer to the Rest Of the World.

Other definitions

ATC: Anatomic, therapeutic, chemical. International system for classification of medicines – ATC3 roughly corresponds to specific therapy classes of medicines.

BNF: British National Formulary. Joint publication by British Medical Association and Royal Pharmaceutical Society of Great Britain providing up-to-date information on the use of medicines.

CMR: CMR International – a research organisation who products include the International Marketed Medicines Database (IMMED).

CPMP: Committee for Proprietary Medicines Products – an expert committee of the European Agency for the Evaluation of Medicinal Products (EMEA), which coordinates the EU medicines licensing system.

DTI: Department of Trade and Industry.

EMC: Electronic Medicines Compendium. Industry – sponsored internet resource publishing Summary of Product Characteristics (SPC) sheets for UK medicines.

IMS: IMS Health – a company providing information on pharmaceutical products.

LREC: Local Research Ethics Committee – committee used to approve clinical trials where there are up to four centres participating.

MCA: Medicines Control Agency – the authority in the UK responsible for licensing medicines (up to 31st March 2003).

MHRA: Medicines and Healthcare products Regulatory Agency – formed on 1st April 2003 from the merger of the UK Medicines Control Agency and the Medical Devices Agency.

MREC: Multicentre Research Ethics Committee – committee used to approve clinical trials where there are five or more centres participating.

National origin: the home-base of the company responsible for the first synthesis, or where not known, the country of patent priority for an NME.

Nationality of Marketing Company: the home-base of company responsible for marketing a medicine.

New Active Substances (NASs): chemical, biological or radiopharmaceutical substances that have not been previously available for therapeutic use in man and are destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in man.

The term NAS also includes:

- an isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available;
- a biological substance previously available as a medicinal product, but differing in molecular structure, nature of source material or manufacturing process;

- a radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

New Molecular Entities (NMEs): products (including new chemical entities (NCEs), biological products, vaccines and products of biotechnology) that have not been previously available for therapeutic use in man and are destined to be made available as a 'prescription only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in man. New salts, pro drugs and esters of existing products and certain biological compounds (e.g. antigens) are excluded. Combination products are also excluded unless one or more of the active constituents has never been previously marketed.

ONS: Office of National Statistics.

PMPRB: Patented Medicines Prices Review Board (of Canada).

SIC: Standard Industrial Classification (90) – Industry taxonomy used in UK and harmonized with Europe.

VAT: Value Added Tax.

Annex 2

Definition of nationality for Indicators

Where possible the UK indicators provide comparable data for the 13 PICTF countries – and in some cases more. This annex clarifies what is meant by "nationality" in each case.

Definitions

There are two major concepts of nationality used in this report.

- *The geographic boundary of a nation*. This definition means that the indicator includes all activity undertaken within the boundaries of a particular country. All the supply and demand and regulatory conditions indicators are defined in this way, and some of the output indicators.
- *Nation where a company is headquartered*. This definition means that the indicator is defined according to the location of the company headquarters. This definition applies to the output indicators that are based on company product data.

An example: Is it British, American or French?

It is important to be aware of these distinctions when comparing indicators. This is because some products can be categorised to different nationalities depending on which indicator is considered.

For example, a product would be classified as British in indicator 33 if it had been discovered and first patented in the UK, as American in indicator 38 if the company headquarters are located in the US, and as French in indicator 45 if it is being manufactured there.

If the concern is about strength of national innovation, indicator 33 would bolster belief that the UK is a good place for companies to discover new products, if the concern is about manufacturing, indicator 45 would bolster belief that France is a good place for companies to manufacture products.

Changes over time

The pharmaceutical industry is a dynamic and increasingly global industry. The indicators here present the situation in the year concerned; we do not retrospectively alter data to account for new ownership or location patterns. It is important to realise this when considering time-series data presented in the report.

Classification of all PICTF indicators

Table 1: Classification of indicators according to nationality

Definition	Indicator
Geographic boundary	1–33, 35, 43–46
Company headquarters	34, 36–42