

# Ministerial Industry Strategy Group Pharmaceutical Industry:

Competitiveness and Performance  
Indicators 2009



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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 to allow Government and industry to monitor the competitiveness of the UK as a location for the pharmaceutical industry.

A review of the indicators took place under the aegis of the Ministerial Industry Strategy Group (MISG) to better benchmark the UK's performance and competitiveness against its major competitors and to improve the presentation of the context of what the indicators are measuring. These would be updated annually to show trends in competitiveness and performance over time. This report contains data collected in 2008.

Websites – Department of Health: [www.advisorybodies.doh.gov.uk/pictf](http://www.advisorybodies.doh.gov.uk/pictf)

– Association of the British Pharmaceutical Industry: [www.abpi.org.uk](http://www.abpi.org.uk)

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## Summary

Since 2001 the Department of Health and the Association of the British Pharmaceutical Industry (ABPI) have collected and published a set of indicators to help in monitoring the competitiveness of the UK relative to other countries as a location for the pharmaceutical industry.

The latest indicators, for the period up to the end of 2008, show that overall the UK remains an attractive location for the pharmaceutical industry. They demonstrate that the UK still has a fairly strong science base and also show a stability in the sector. The indicators also show that the UK is still holds a favourable position in comparison to the rest of Europe. The indicators draw on data covering a period prior to start of the current global economic downturn.

The position for the period of this report is as follows:

- > In 2007, pharmaceutical industry R&D expenditure in the UK increased to over £3.9 billion compared to 3.3 billion in 2006. This is greater than any other country in Europe and third behind only the US and Japan in international terms.
- > The UK's research and development (R&D) infrastructure is strengthened by substantial government investment in health R&D, second only to the US as a share of GDP. UK scientists are more productive than most in terms of published papers and citations of those papers.
- > The industry's contribution to the UK economy continues to be large. There was a positive trade balance of £6 billion in 2008.
- > The proportion of the labour force with science degrees is relatively high in the UK by international standards, and there is an upward trend in annual numbers of new graduates in subjects relevant to the pharmaceutical industry in the UK.
- > Rates of corporate taxation in the UK are relatively favourable; more advantageous than other major markets such as the USA and Japan - but are not as advantageous as in the Republic of Ireland and Singapore.
- > Expenditure on medicines in the UK is low compared with the comparator countries and especially on the newest medicines. The Pharmaceutical Innovation Package, agreed through the PPRS, is aimed at addressing the variable rate of uptake of cost-effective medicines in the NHS.
- > The UK-based pharmaceutical industry remains among the most innovative with 16 of the world's top-selling 75 medicines discovered and developed in the UK, more than any other country except for the USA.

The UK Government and the pharmaceutical industry have a positive working relationship, which is overlooked by the Ministerial Industry Strategy Group (MISG). There is a recognition that if the UK is to maintain its current strong position the UK Government and industry have to continue to work together to improve the environment here, and indeed in Europe, so that it is an attractive location for investment compared to existing and emerging markets such as Singapore and India. The UK Government recognises the importance of the pharmaceutical industry to the UK during the current global economic downturn and has established the Office for Life Sciences (OLS) to develop a strategy to ensure that the UK continues to have a thriving life sciences sector once the economy recovers.



## Introduction and background

1. In order for the UK to maintain a high-performance, wealth-creating, research-based pharmaceutical industry the environment needs to be right. The history of past investment in a country will influence the future scale of activity there, but in a competitive world avoiding disinvestment in the future is as relevant as stimulating expansion. A competitive environment encompassing access to skills and knowledge, support for science and innovation, a positive and stable attitude towards the industry by government, action to reduce red tape, and a competitive fiscal and cost environment would help the UK to maintain its currently strong position in the face of growing international competition.
2. In 2001, the final report of the Prime Minister's joint government and industry Pharmaceutical Industry Competitiveness Task Force (PICTF) recommended regular publication of a set of indicators to help in monitoring the competitiveness of the UK as a location for the industry. A joint review of the indicator set was undertaken by government and industry in 2006. As a result, it was decided to focus on a smaller number of measures than previously, while retaining coverage of a wide range of relevant factors. It was also decided to amend the list of comparator countries to include the emerging markets of China, India and Singapore. This more focused set of indicators is presented in the following pages.
3. 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.
4. The UK is compared with a group of 13 other countries: China, France, Germany, India, Ireland, Italy, Japan, the Netherlands, Singapore, Spain, Sweden, Switzerland and the US. This is not a comprehensive list – other countries outside those covered in this report are also emerging competitors to the UK for some types of R&D and manufacturing investment – but represents a reasonable cross-section of major competitor countries, actual and emerging.
5. The data presented are those that were obtainable at the end of 2008 without undue expense. For some countries, readily available and internationally comparable data are sparse. Nevertheless, the overall set of data provides both a useful snapshot of the current position at the end of 2008 and an indication of emerging trends. However, future figures may be influenced by pressures on the global economy.
6. The following paragraphs provide a commentary on the competitiveness and performance indicators, summarising the main points under each area.

7. The indicators are grouped under the following topics:
  - **Supply factors:**
    - labour and skills (1–2)
    - investment and taxation (3)
    - R&D (4–9)
  
  - **Demand factors (11–16)**
    - demand factors (11-14)
    - regulatory environment 15 – 16)
  
  - **Performance (17 – 23):**
    - innovation (17–19)
    - macroeconomic (20–23)
8. 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 factors

### Labour and skills

9. The first two indicators show that the UK continues to have a fairly good science base. The number of science graduates of all kinds in the 24-34 group of the national workforce has increased and now puts us in a favourable position within Europe. Looking specifically at the annual number of graduates obtaining a first degree in subjects specifically relevant to the pharmaceutical industry ( indicator 1b) the aggregate trend in the UK has been a slow growth overall – but with some significant increase in the number of graduates in anatomy, physiology and pathology and steady or slightly increased numbers in several other areas. However there remains a decline in the number of new chemistry graduates. It is important to note that none of these figures take into account the quality of the graduates which is difficult to measure.
10. The perception by business leaders across all sectors internationally of UK labour regulations has declined. The US and Japan are perceived to have less obstructive market regulations, but the UK continues to be seen as more favourable to business than those in Germany, France and Italy (indicator 2).

### Investment and taxation

11. Rates of taxation on company profits in different countries have a clear influence on international location decisions. The basic rate of corporate taxation in the UK is now at 28% (since April 2008). The Republic of Ireland and Singapore will continue to have lower rates of corporation tax than the UK. R&D tax credits should provide significant support for R&D in the UK. In April 2008, R&D tax credits were raised from 150% to 175% for SMEs, and from 125% to 150% for large companies.

### R&D

12. The UK government spends a greater percentage of the country's national income on publicly funded health R&D than any of the comparator countries outside the US, and this proportion increased slightly in 2006 (indicator 4).

13. In the financial year 2007/08, UK patients made up on average about one in 15 of all patients recruited in international clinical trials, a slightly smaller percentage than in the recent past (indicator 6). There is room for improvement in the speed with which trials are conducted and get started. A little under half of the UK arms of clinical trials are managing to recruit the intended number of patients within the planned timescale (indicator 7), and the median time lag between first submission of the protocol for a proposed clinical trial and the first patient being seen in that trial is 150 days in the UK (indicator 8).
14. The UK continues to see greater pharmaceutical industry R&D expenditure than any other country outside the US and Japan. The UK's share of global R&D expenditure has, however, fallen from 10% in 2000 to 9% in 2007 (indicator 9).

## Demand factors

15. By international standards, the UK devotes a relatively small share of its national income to expenditure on medicines. Pharmaceuticals sales in the UK were 0.8% of GDP in 2007 (indicator 12b). Medicines expenditure per person in the UK is also low relative to other high-income countries: £213 per capita in 2007 (indicator 12a)
16. One of the perceived weaknesses in the UK's competitiveness is the variable rate at which cost effective new medicines (i.e. those launched in the last five years) are taken up in the UK compared with other markets. This is despite there being no regulatory delay in the UK as a result of pricing and reimbursement negotiations, unlike most other countries (indicator 14). On average, the newer a medicine is, the lower its rate of use in the UK relative to that in other countries. This is being addressed through the Pharmaceutical Innovation Package agreed through the PPRS process and is being further considered by OLS. Older, generic medicines have a higher share of the medicines market in the UK than in almost all the comparator countries (indicator 13).

17. The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is the licensing body for all medicines used in the UK. The MRHA is still considered globally as one of the "gold standard" regulatory agencies. 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 as a rapporteur. From September 2006 companies were no longer allowed to nominate Member States as rapporteur for the centralised licensing procedure operated by the European Medicines Agency (EMA). This responsibility now lies with the EU's Committee on Human Medicinal Products. Up to and including February 2008 the United Kingdom remains the major rapporteur for centralised procedures by some 7% (indicator 16a). An efficient regulatory environment can be a major factor in a company's co-decision in locating their business.

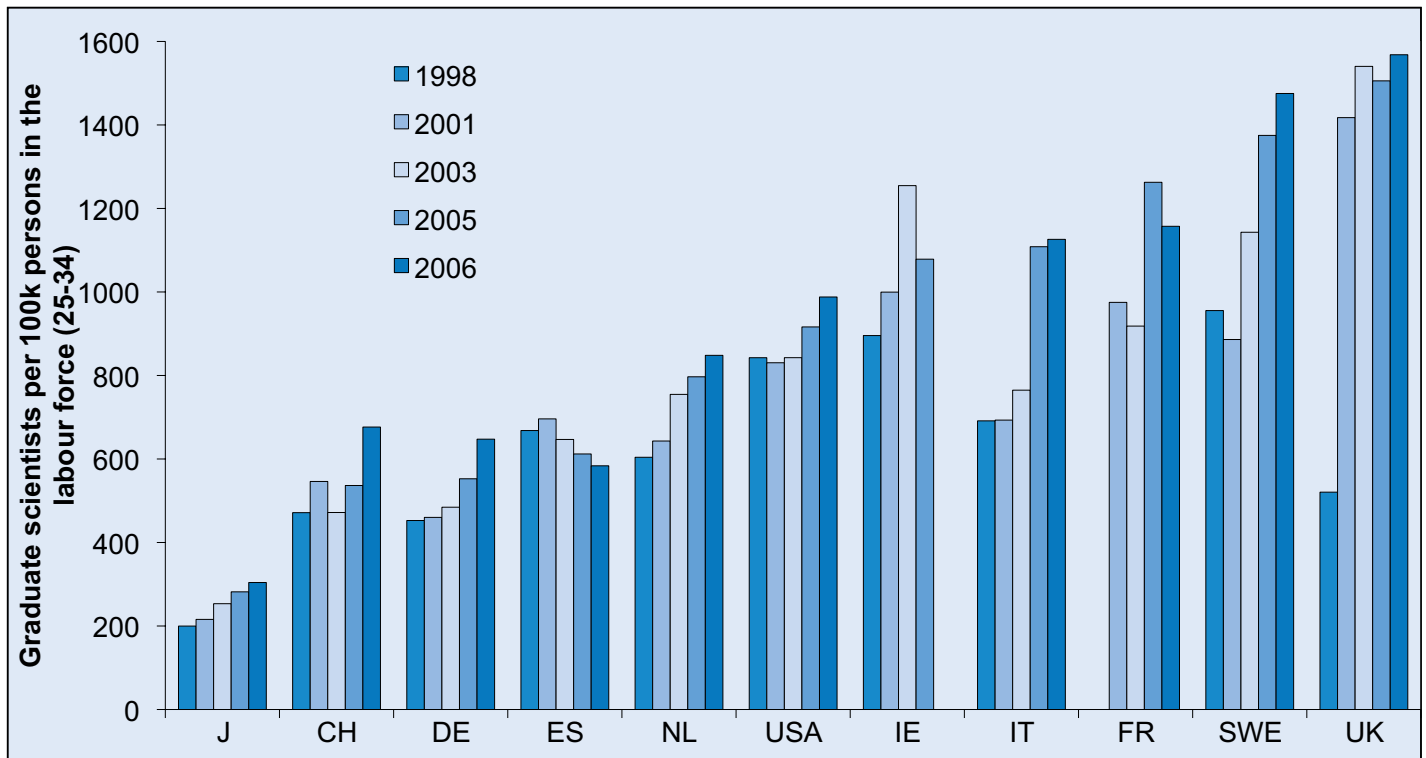
## Performance

### Innovation

18. Indicators of trends in pharmaceutical innovation need to take a long perspective as the R&D process can last 10 years or more from discovery until a product is eventually launched on the market. The UK has long been a comparatively favoured site for pharmaceutical R&D activity. The productivity of UK pharmaceutical research is good. Based on a measure of the number of world first patents filed per R&D pound spent, the UK is third only to the US and Spain, well ahead of the rest of Europe (1998–2007 data – indicator 17). UK-headquartered companies have for several years been producing around one fifth of the world's leading 75 global medicines, both in terms of number of medicines sold and global sales revenues from those medicines (indicator 18). Similarly, UK-headquartered companies 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 19). The overall picture of pharmaceutical industry innovation is therefore that the UK is continuing to hold a strong position relative to most comparator countries, other than the US.

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

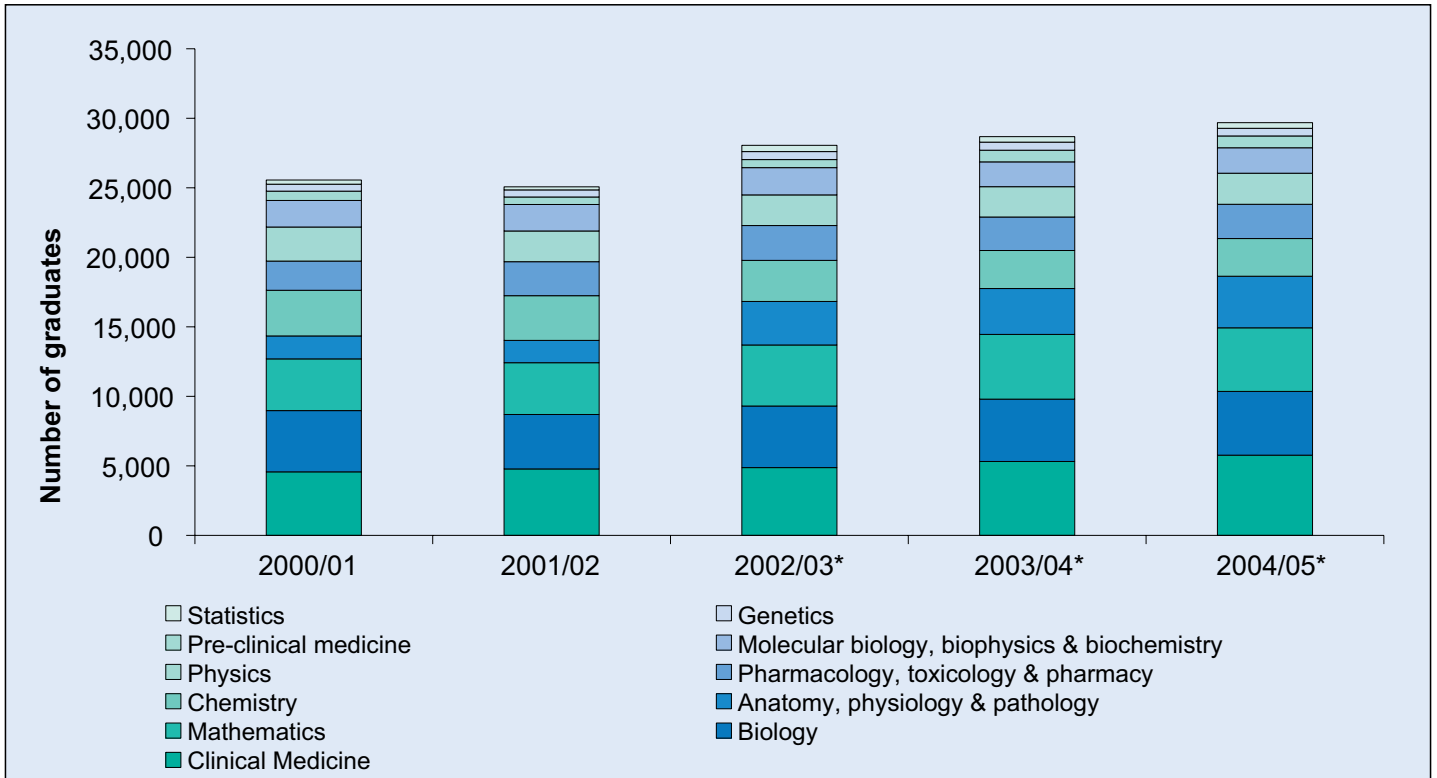
**CHART 1a: Number of graduate scientists per 100,000 persons in the labour force 24-34 years of age (1998, 2001, 2003, 2005, 2006) \***



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

Notes: Definitions of various fields tend to differ across countries and over time  
 time series chosen based on availability of UK data

**CHART 1b: number of people graduating with first degrees relevant to the pharmaceutical industry in the UK†**



†figures include dormant students and exclude visiting exchange students

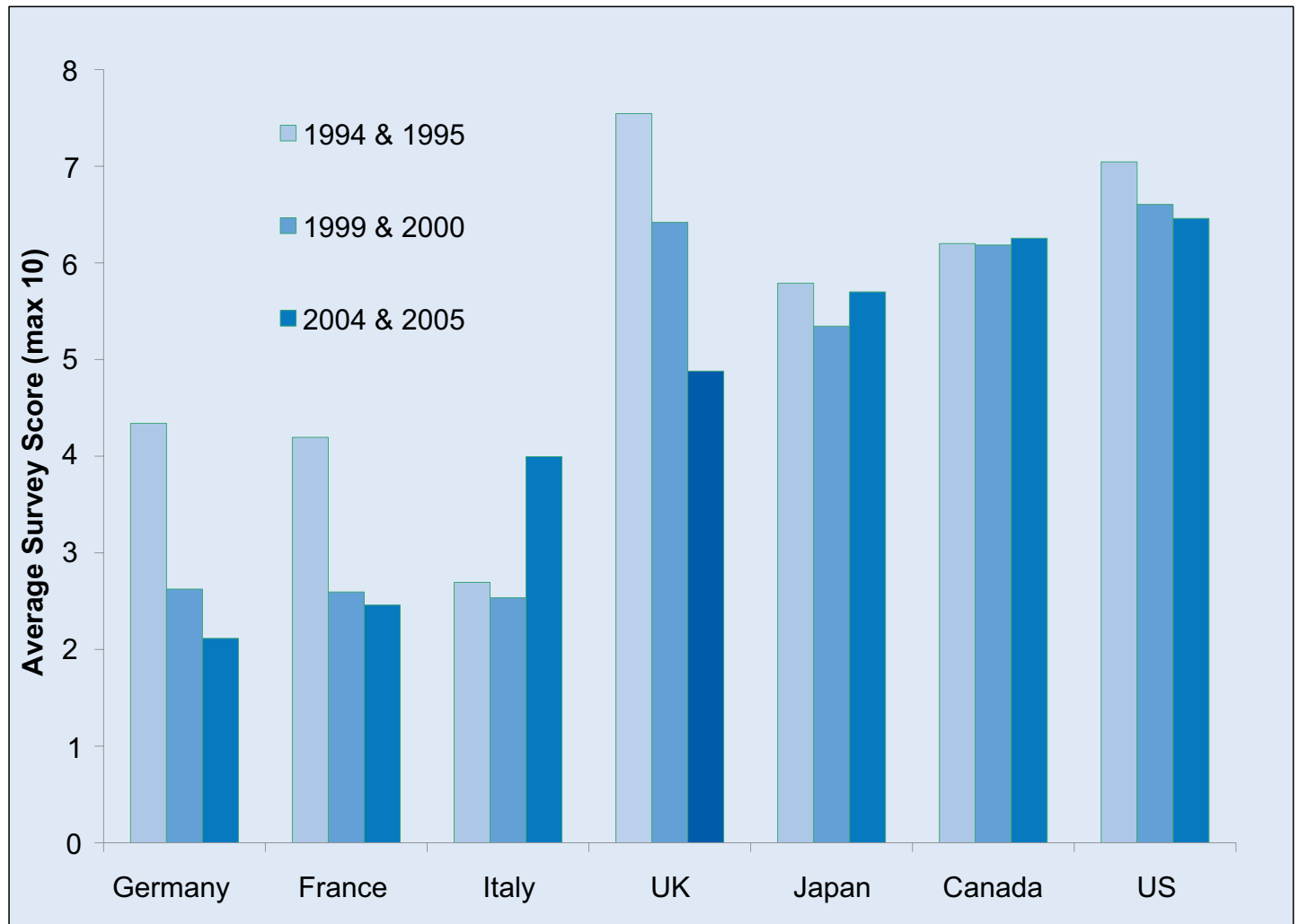
**Notes**

\*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

The subjects above have been selected as being relevant to the pharmaceutical industry

## Indicator 2: Business executive perceptions of labour regulations

CHART 2: Business perceptions of market regulations



Source: World Competitiveness Yearbook, from Institute for Management Development.

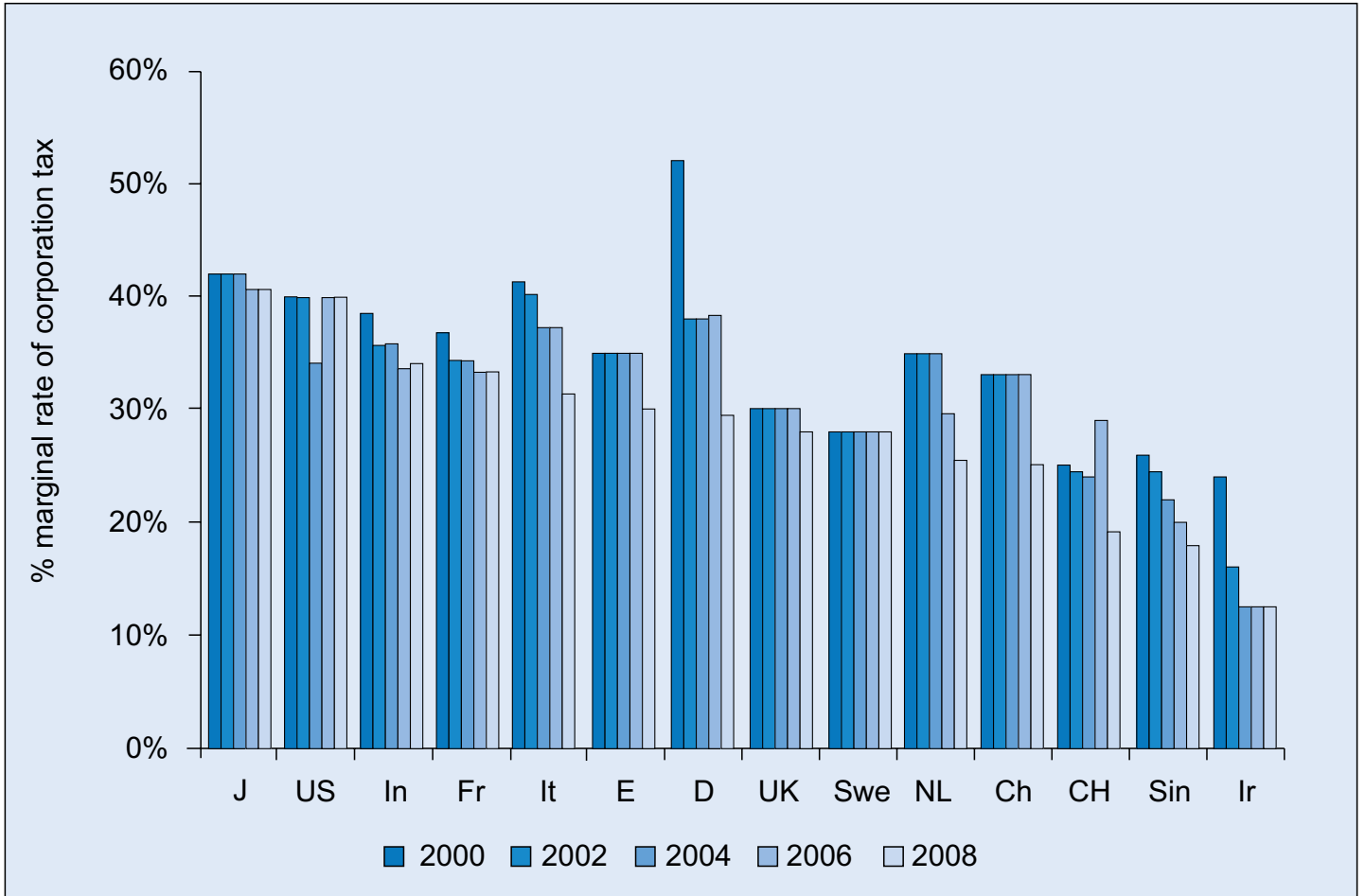
Notes: In the absence of direct measures of the degree of market regulation, the above data is sourced from the International Institute for Management Development's regular survey in the perceptions of "business leaders".

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: Marginal rate of Corporation Tax

CHART 3: Headline marginal rate of corporation tax at January 1st

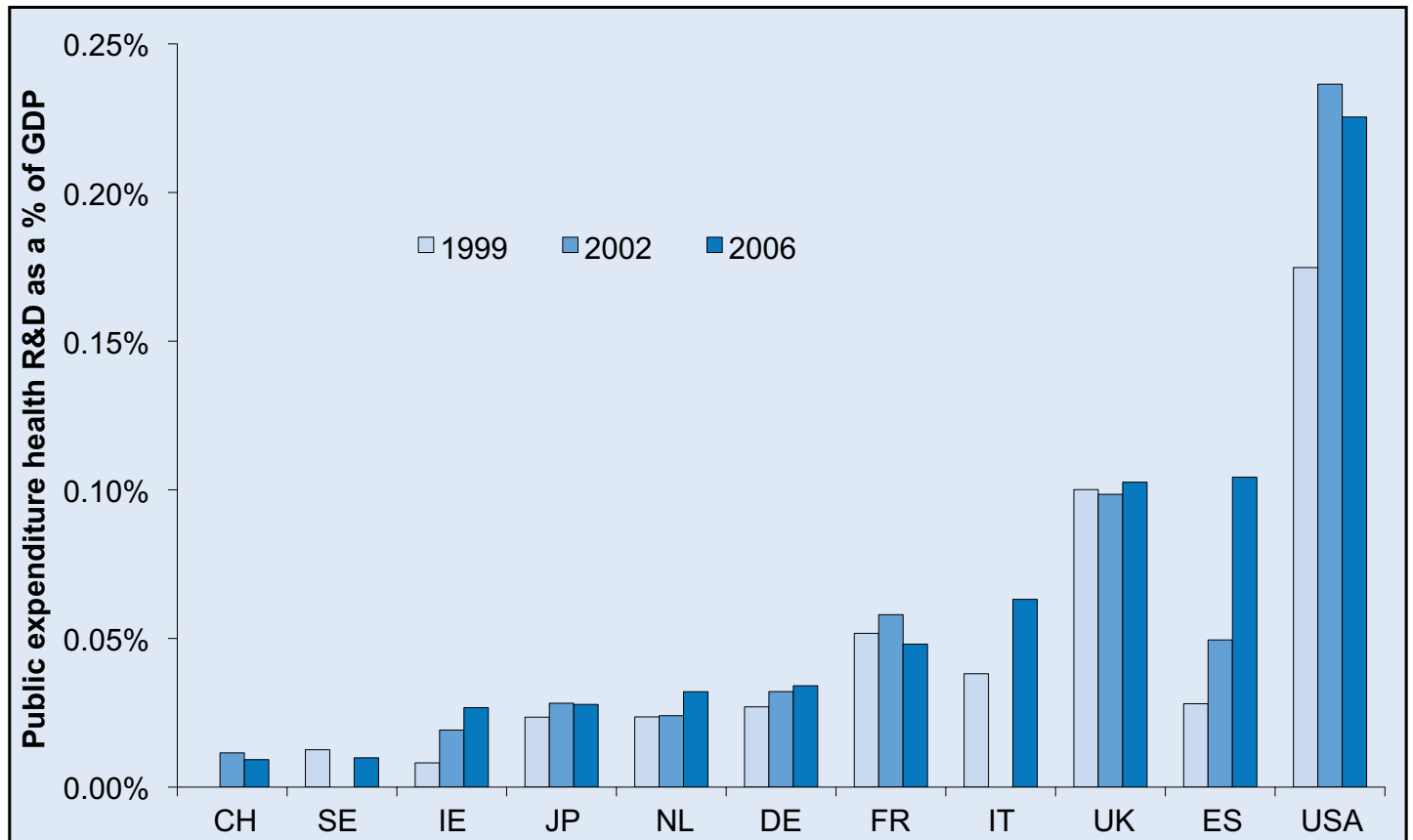


source: KPMG Annual corporate tax rate survey 2000, 2003, 2006, 2008

Note: The reported rates are national averages as at the 1st January for the reported year.

Indicator 4: Government spend on R&D in health

CHART 4: Health R&D in government budget (GBAORD)<sup>(1)</sup> as a percentage of GDP



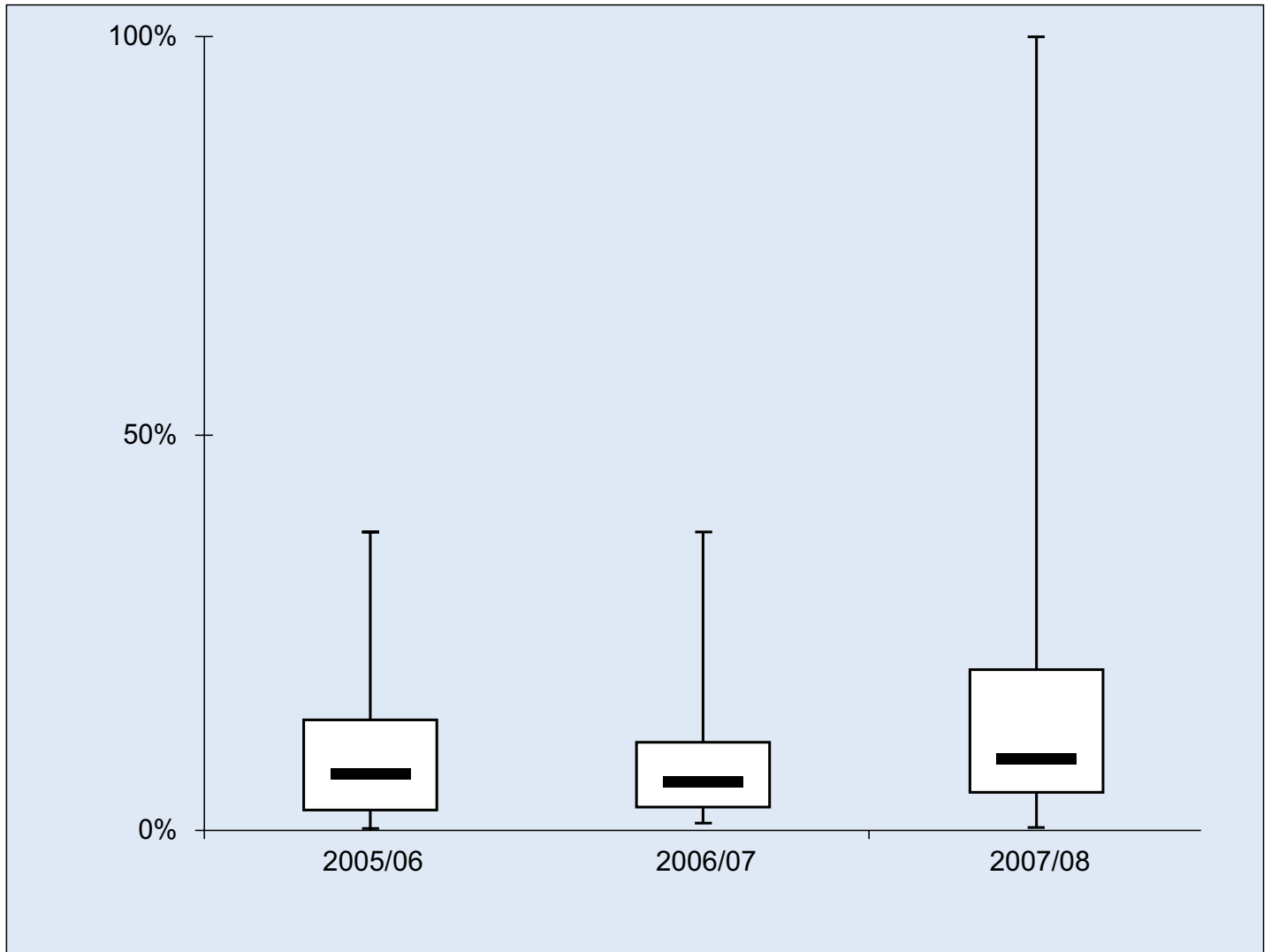
Source: Eurostat

<sup>1</sup> Government budget appropriations or outlays for R&D

Definitions of “Health R&D” and “GBAORD” are taken from the OECD Frascati Manual

### Indicator 5: UK share of patients enrolled in international clinical trials

**CHART 5: UK share of Patients enrolled in international clinical trials  
(median 75 and 25 percentile, with min and max values)**



**Source: ABPI survey**

Notes: The chart is derived from data collected by ABPI from member companies. The results for 2007/08 are based on returns from 82 trials.

The upper edge of the box represents the 75th percentile of the dataset

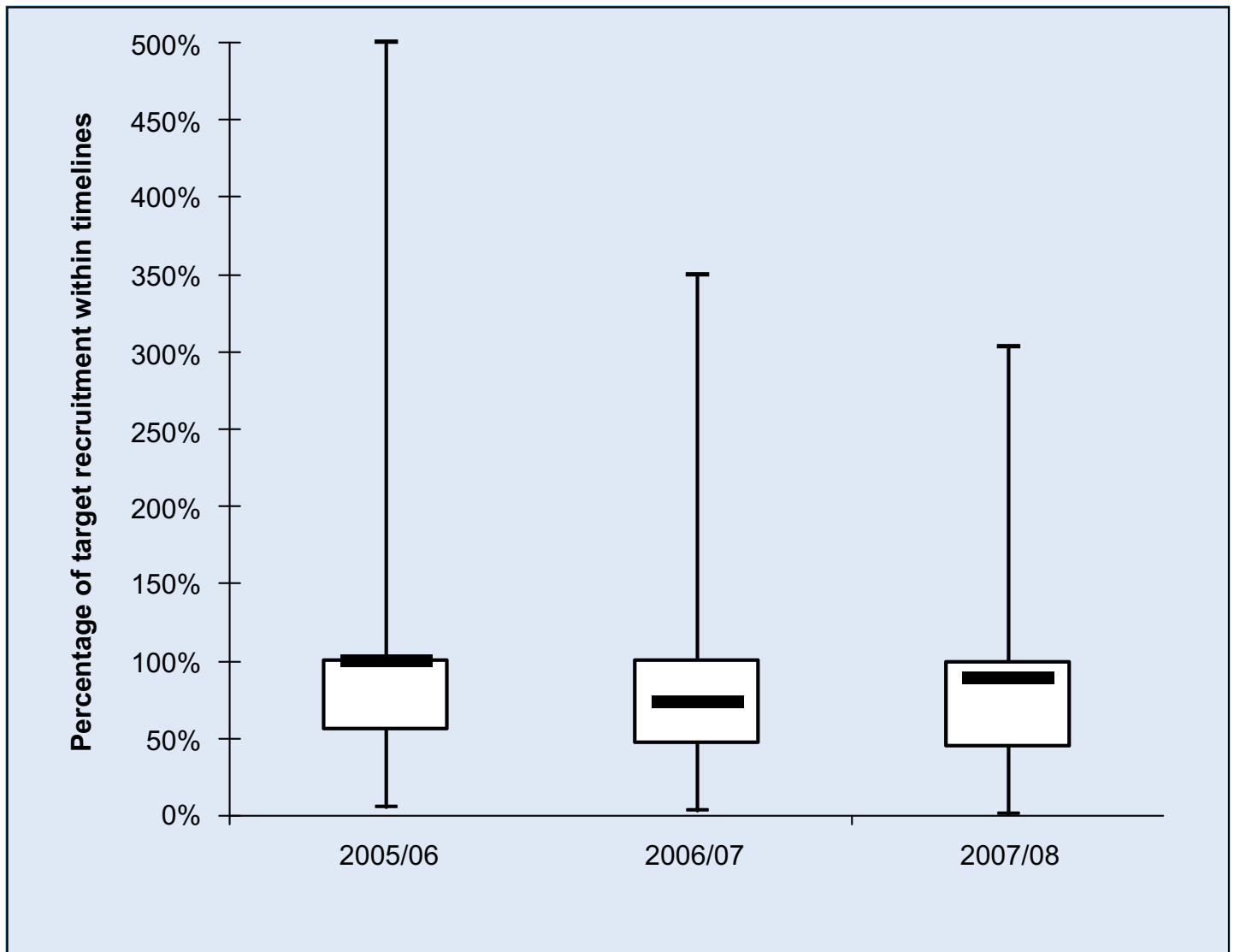
The lower edge of the box represents the 25th percentile of the dataset

The line in the box indicates the median value of the data.

The ends of the vertical lines indicate the minimum and maximum data values.

**Indicator 6: Percentage of recruitment within planned timelines for UK clinical trials**

**CHART 6: Percentage of recruitment within planned timelines for the UK Clinical Trials (median 75 and 25 percentile with min and max values)**



**Source: ABPI survey**

Notes: The chart is derived from data collected by ABPI from member companies. The results for 2007/08 are based on returns from 82 trials.

The upper edge of the box represents the 75th percentile of the dataset

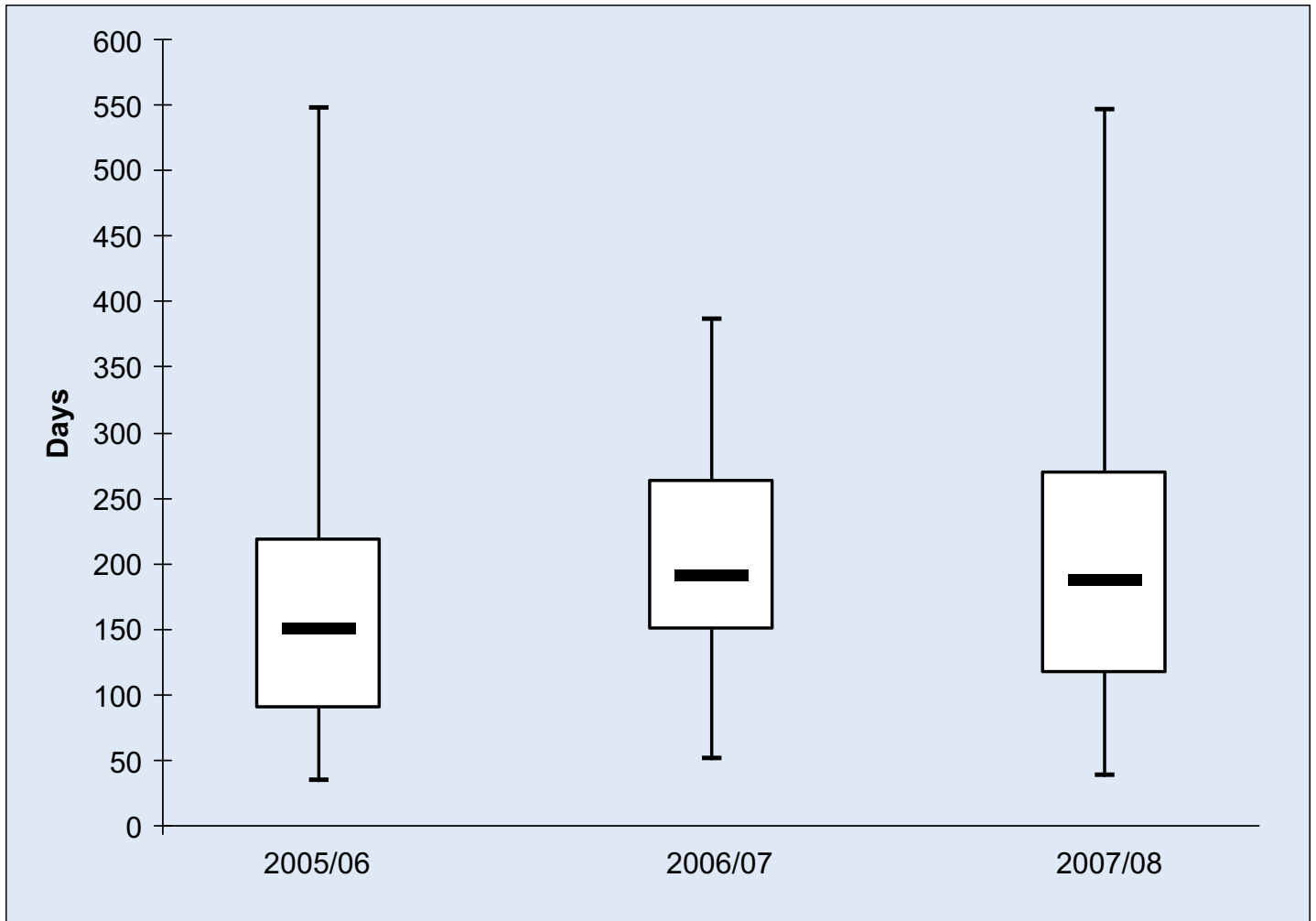
The lower edge of the box represents the 25th percentile of the dataset

The line in the box indicates the median value of the data.

The ends of the vertical lines indicate the minimum and maximum data values.

**Indicator 7: Time from first submission to the first patient visit per site days  
(median 75 and 25 percentile, with min and max values)**

**CHART 7: Median time from first submissions to first patient visit 0 2005/06 - 2007/08**



**Source: ABPI survey**

Notes: The chart is derived from data collected by ABPI from member companies.  
The results for 2007/08 are based on returns from 82 trails.

The upper edge of the box represents the 75th percentile of the dataset

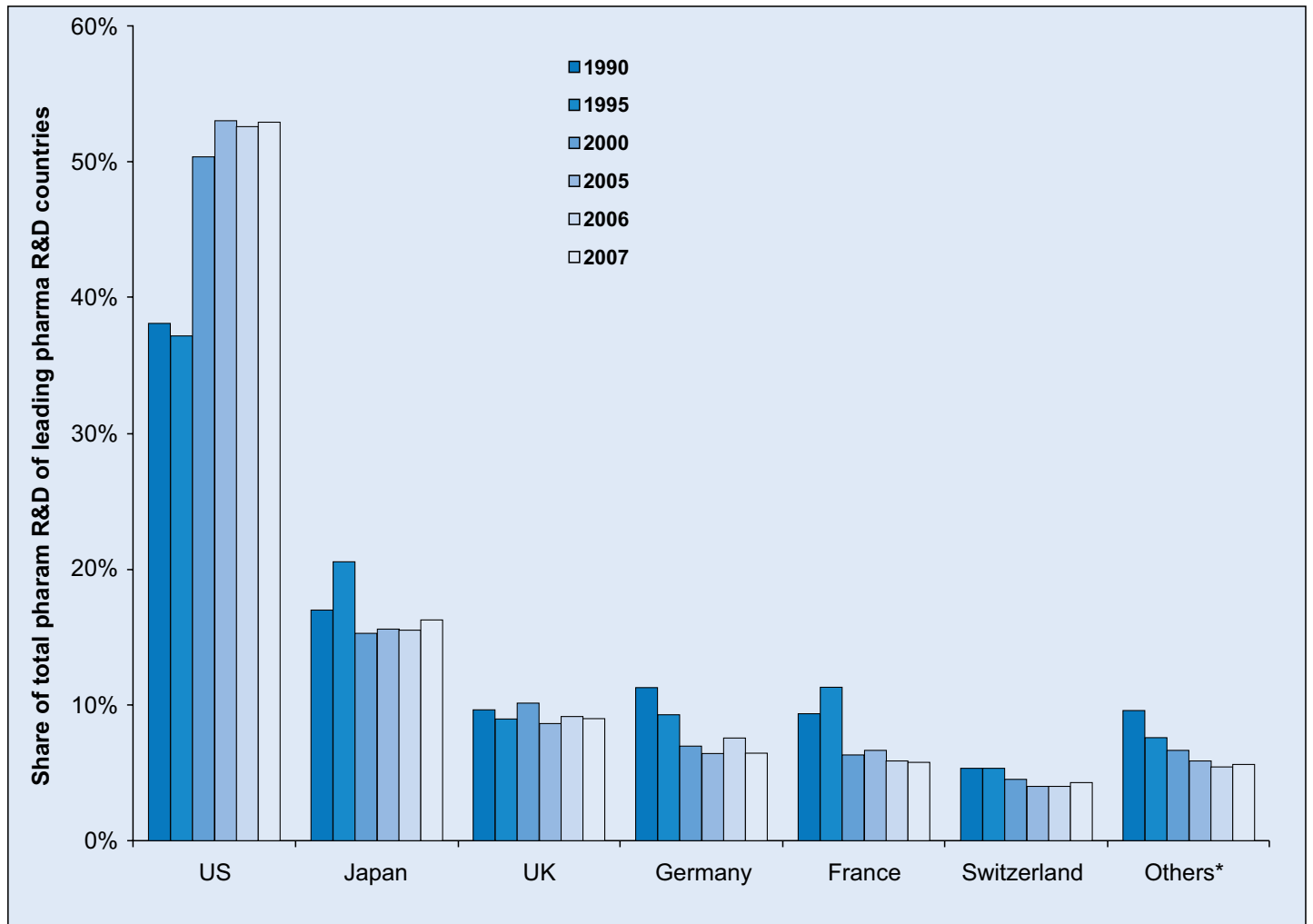
The lower edge of the box represents the 25th percentile of the dataset

The line in the box indicates the median value of the data.

The ends of the vertical lines indicate the minimum and maximum data values.

Indicator 8: Share of total R&D spend of comparator countries

CHART 8: percentage of pharmaceutical R&D spend of comparator countries



Sources: National trade associations

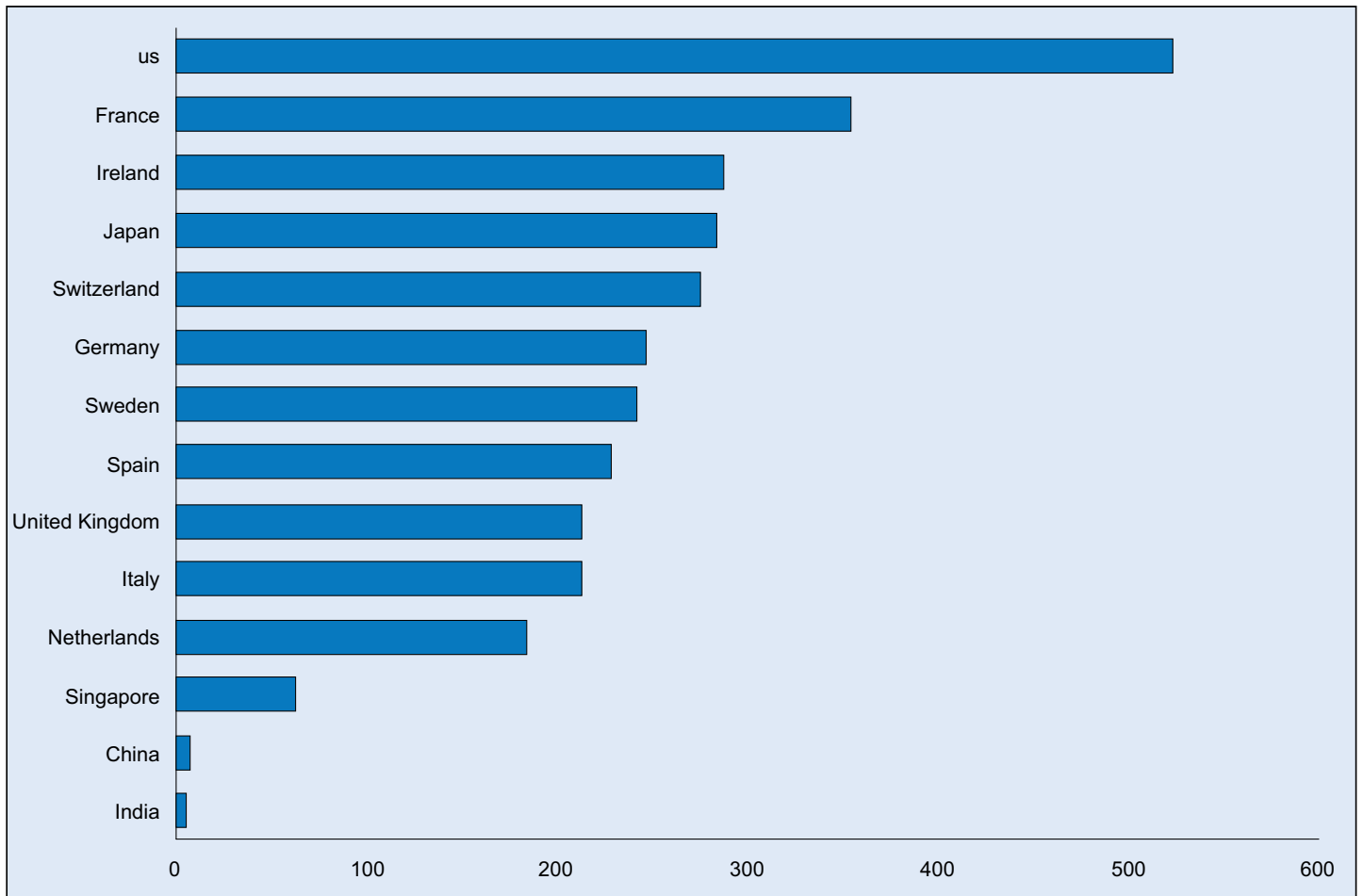
Notes: This is a measure of industry R&D within country boundaries and not of companies' total world R&D expenditure

The comparator countries include all countries where significant R&D investment is made

\*Others are Canada, Ireland, Italy, Spain, Sweden

## Indicator 9a: Medicines expenditure per head of population

CHART 9a: Medicines sales per capita, £, 2008

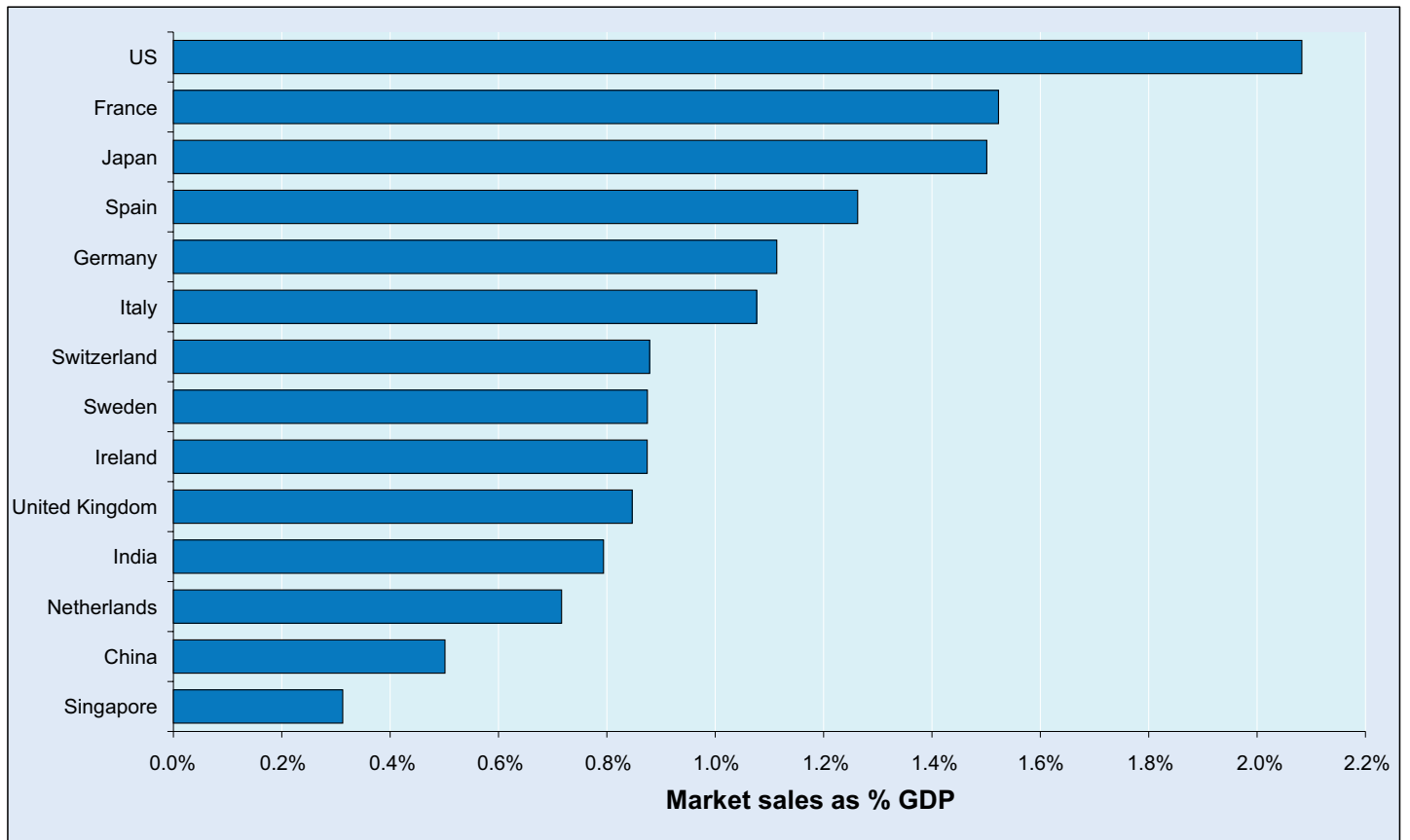


Sources: IMS World Review, OECD, World Bank

Notes: The chart is a measure of value of medicines expenditure per head. Differences in prices will lead to over and under representation of usage.

Indicator 9b: Market sales for pharmaceuticals as a percentage of GDP

CHART 9b: Market sales for pharmaceuticals as a percentage of GDP



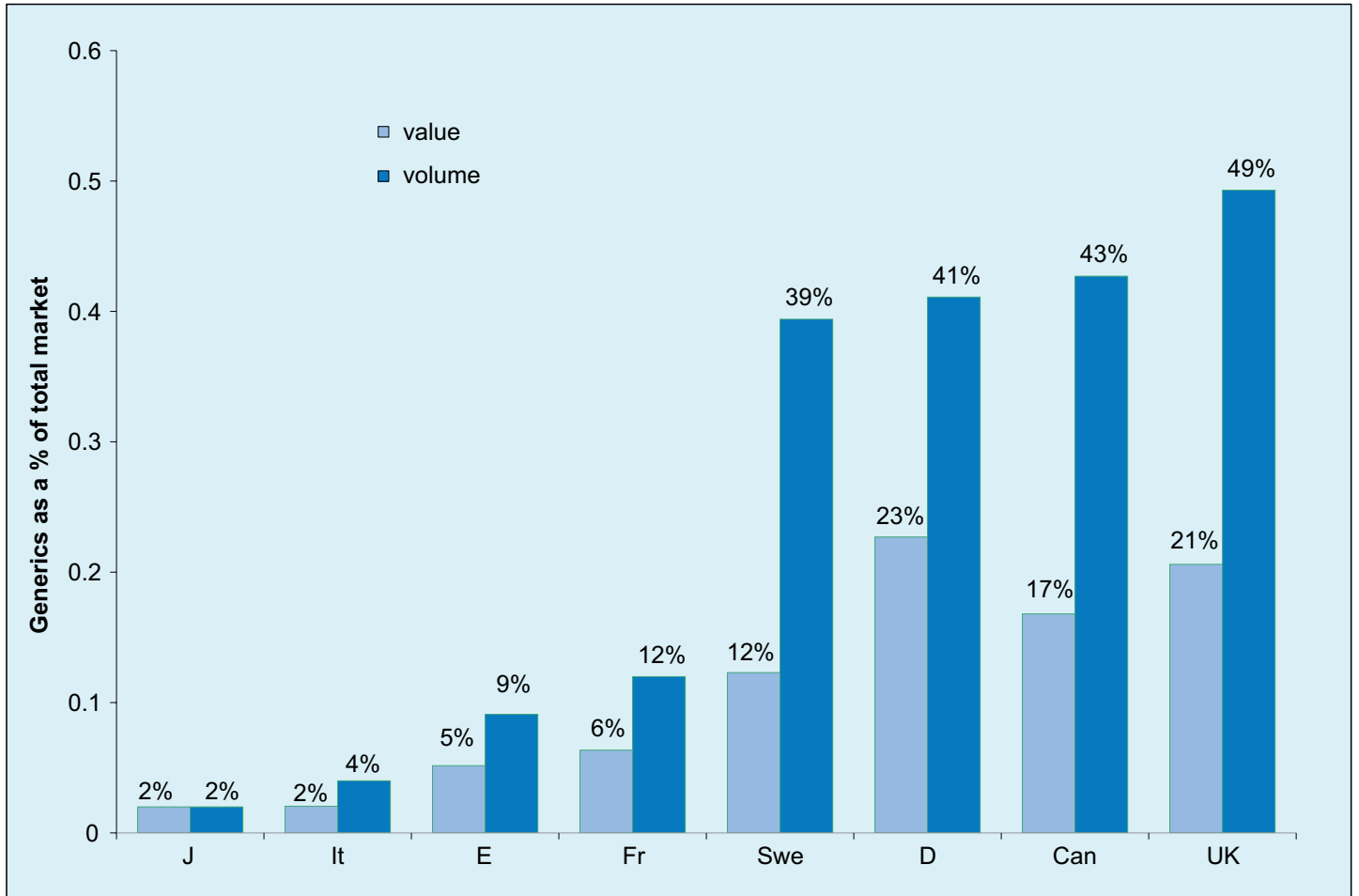
Sources: National trade associations

Notes: The chart is intended to provide an additional view to 9a. The smaller variation is due to the characteristics of national income.



Indicator 10: Generic medicines share of market value and volume

CHART 10: Generic medicines share of market value and volume

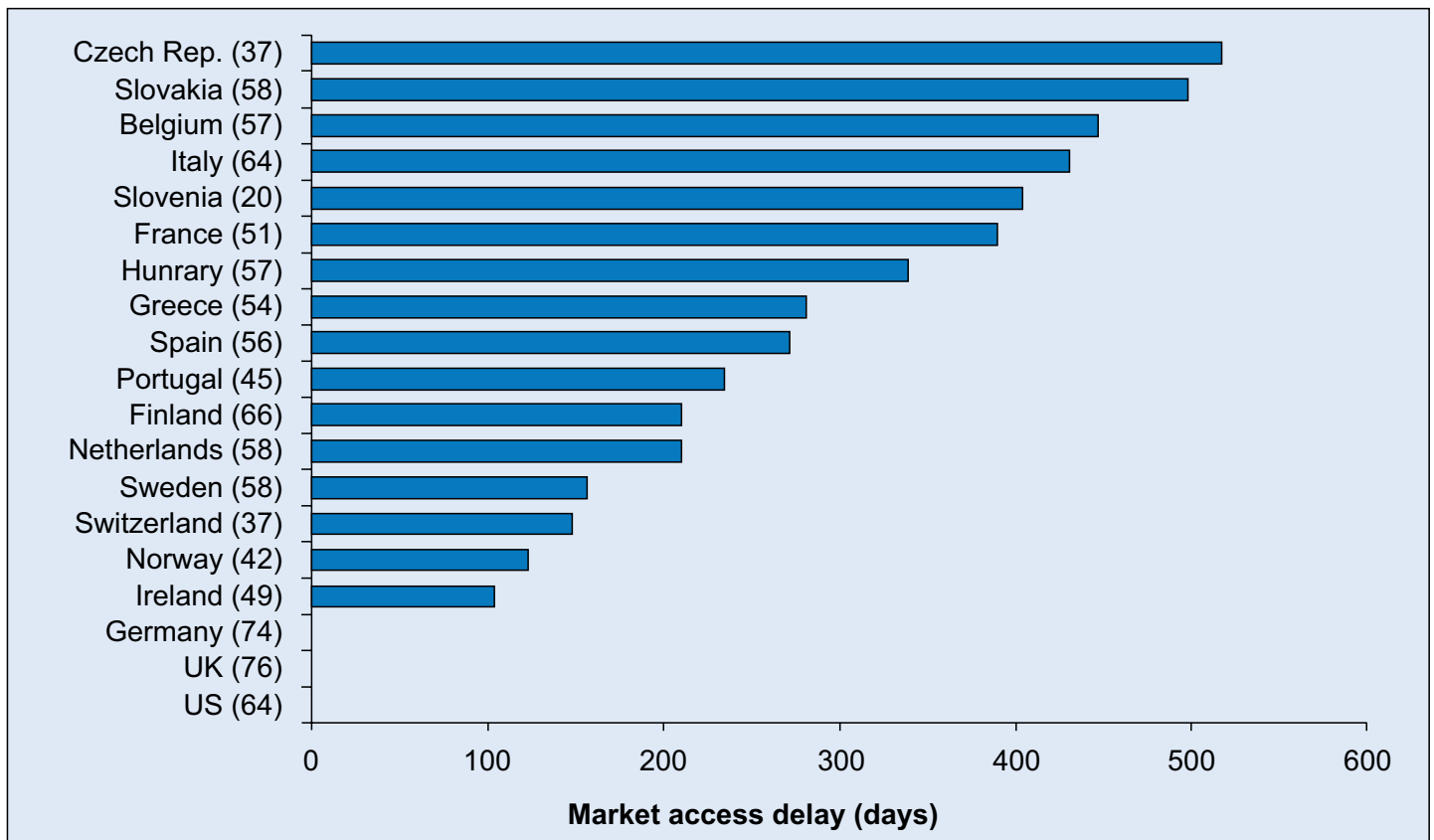


Source EGA

Notes: Generic medicines are generally considered to be cost-effective. It is predicted that there will be greater market penetration for generics as many significant medicines move off patent.

### Indicator 11a: Time elapsed from approval to pricing and reimbursement decisions

**CHART 11a: Average time delay between marketing authorisation and market access**



**Source: Efpia**

Notes: The numbers in brackets after each country name refer to the number of medicines launched on the market in the relevant period. (Hospital and retail delays combined.) All molecules with marketing authorisation between 1 January 2002 to 31 December 2005.

### Indicator 11b\*: Companies free to set the launch prices of new medicines? (Y/N)

#### CHART 11b: Companies free to set the launch prices of new medicines

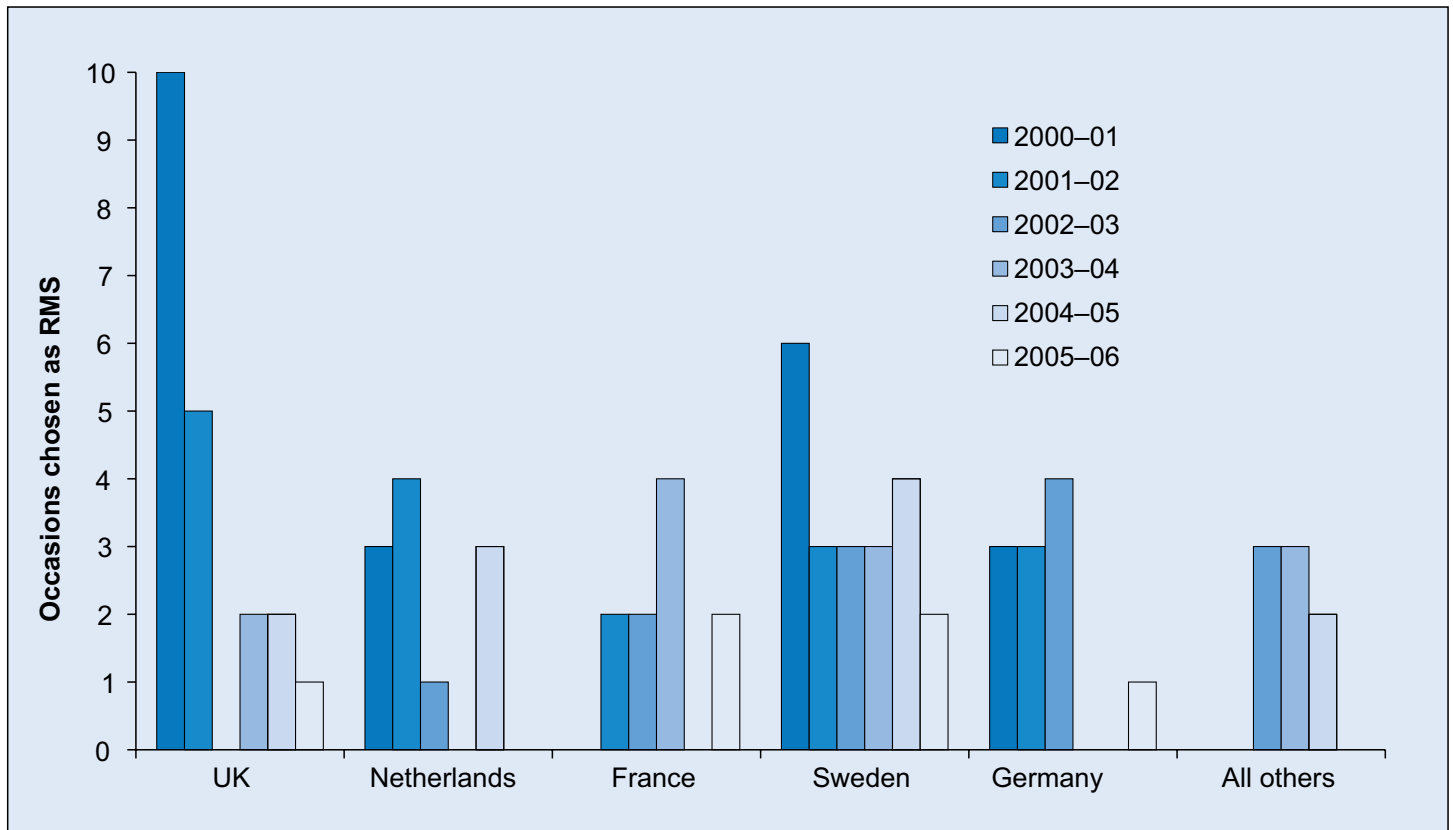
Free pricing at launch December 2008	
Australia	No
Canada	No
France	No
Germany	Yes*
Italy	No
Japan	No
Netherlands	No
New Zealand	No
Spain	No
Sweden	No
Switzerland	Yes
<b>UK</b>	<b>Yes</b>
US	Yes

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

Notes \*Changes to the pricing and reimbursement system in Germany since 2004 have the potential to impact on companies to set launch prices. For most countries medicines need to progress through both a pricing and reimbursement process.

**Indicator 12: In the mutual recognition procedure, the number of times the MHRA is chosen as a reference number state (RMS)**

**CHART 12: Number of time MHRA was chosen as RMS, from 2000 onwards, compared to selected countries**



**Source: MHRA**

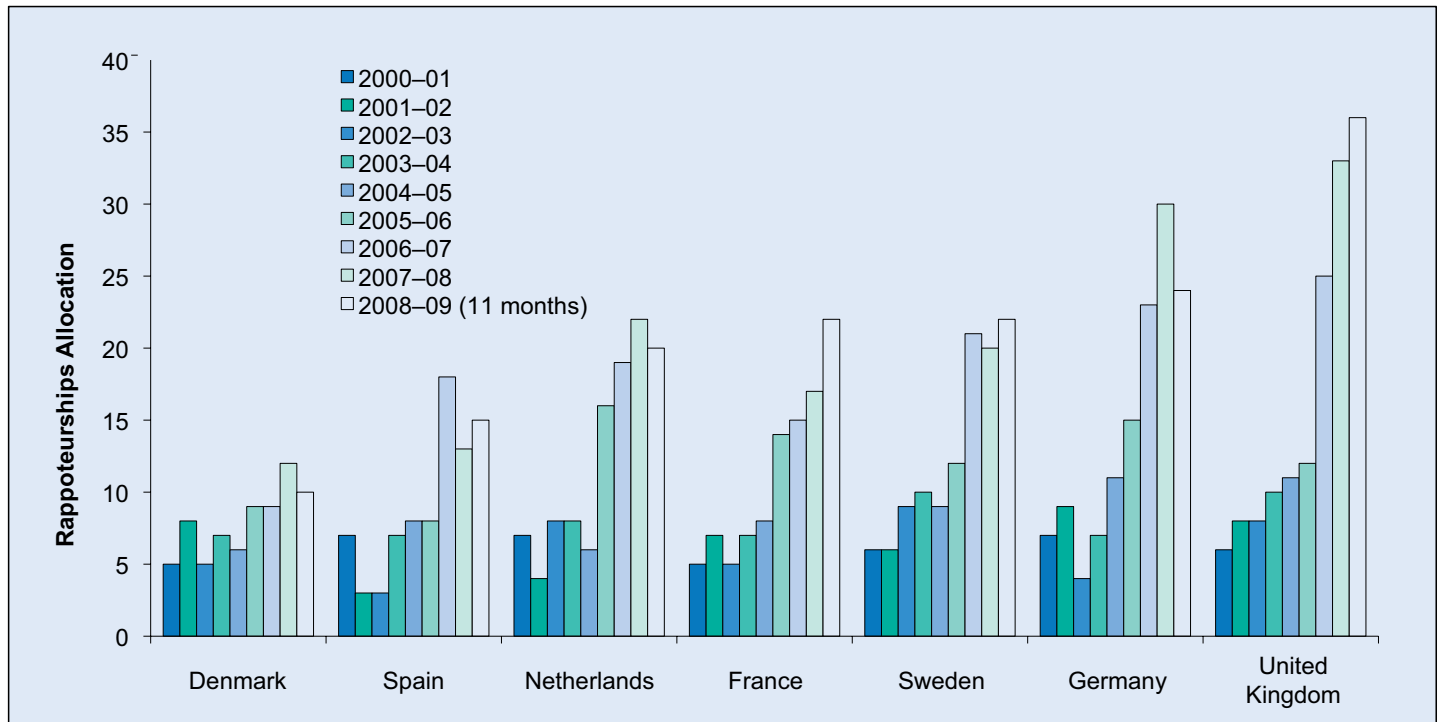
Notes: This indicator shows the degree to which the MHRA is the regulator of choice by companies.

No NASs entered the MR procedure in 2002/03. This continued a downward trend from the previous two years. The underlying cause appeared to be the small number (2) of NASs granted in 2000/01. The number of applications submitted to MHRA had risen for the following two years, which might indicate the number of NASs entering into the MR procedure with the MHRA as RMS would 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 continued to be a major player in the Mutual Recognition procedure and the downward trend continues across Europe in 2005-06 which might reflect the statutory change in regulatory procedure in 2006 when more New Active Substances were processed via the Centralised route rather than the Mutual Recognition procedure.

Where no bar is displayed the country was not chosen as a RMS in that year

### Indicator 13a: In the centralised procedure the number of times the MHRA (and other countries' agencies) appointed as rapporteur

**CHART 13a: In the centralised procedure the number of times the MHRA (and other countries' agencies) appointed as rapporteur**



**Source: MHRA**

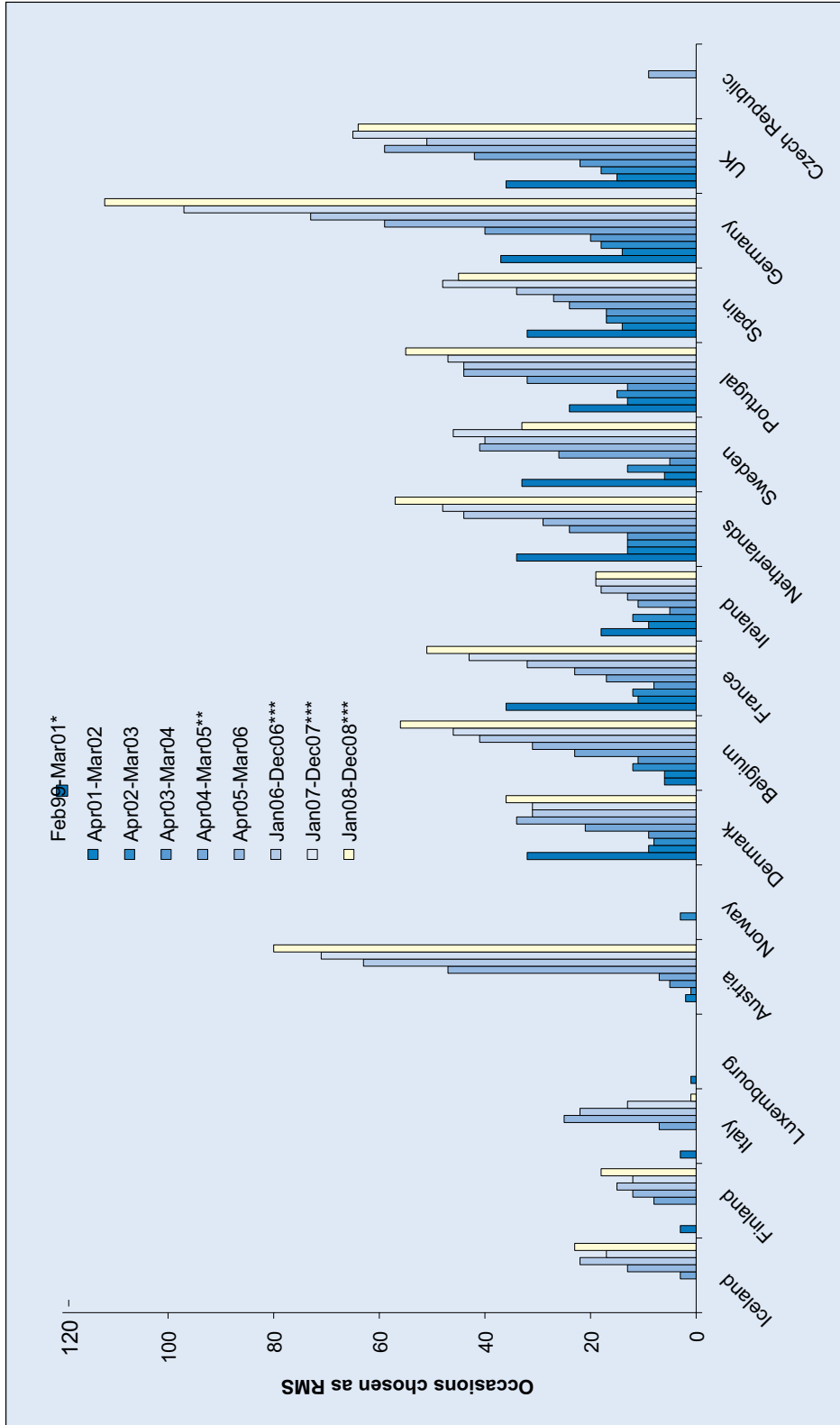
Notes: If a country's agency is believed to provide a high level scientific assessment and is willing to work with industry to achieve European approval, it is more likely to be nominated.

Companies are able to nominate national agencies to act as rapporteur for the centralised licensing procedure operated by the European Medicines Evaluation Agency (EMA). Although the actual selection of rapporteur agencies is a decision of the EMA's CPMP committee, this indicator provides a measure of industry preference. Amongst the countries available, in 2000-01 the UK was the 2<sup>nd</sup> most nominated country. In 2001-02, the UK slipped to 3<sup>rd</sup> behind France and the most nominated country, Sweden. In 2002-03, UK continued to receive a high percentage of rapporteur/co-rapporteur appointments compared with other Member States and remained amongst the leading States. However, there had 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 2<sup>nd</sup> most nominated country. In 2004/05, the industry preference for UK continued and UK levelled with Sweden to become the most nominated countries. In 2005/06, the UK has lost ground with industry nominations but it remained one of the leading rapporteurs.

From September 2006 companies are no longer allowed to nominate MSs for rapporteurship. This responsibility now lies with the EU's Committee on Human Medicinal Products. For the 11 months to February 2008 the United Kingdom remains the major rapporteur for centralised procedures by some 7%.

Indicator 13b: Number of the MHRA (and other countries' agencies) nominated as rapporteur to provide European scientific advice

CHART 13b: Number of the MHRA (and other countries' agencies) nominated as rapporteur to provide European scientific advice

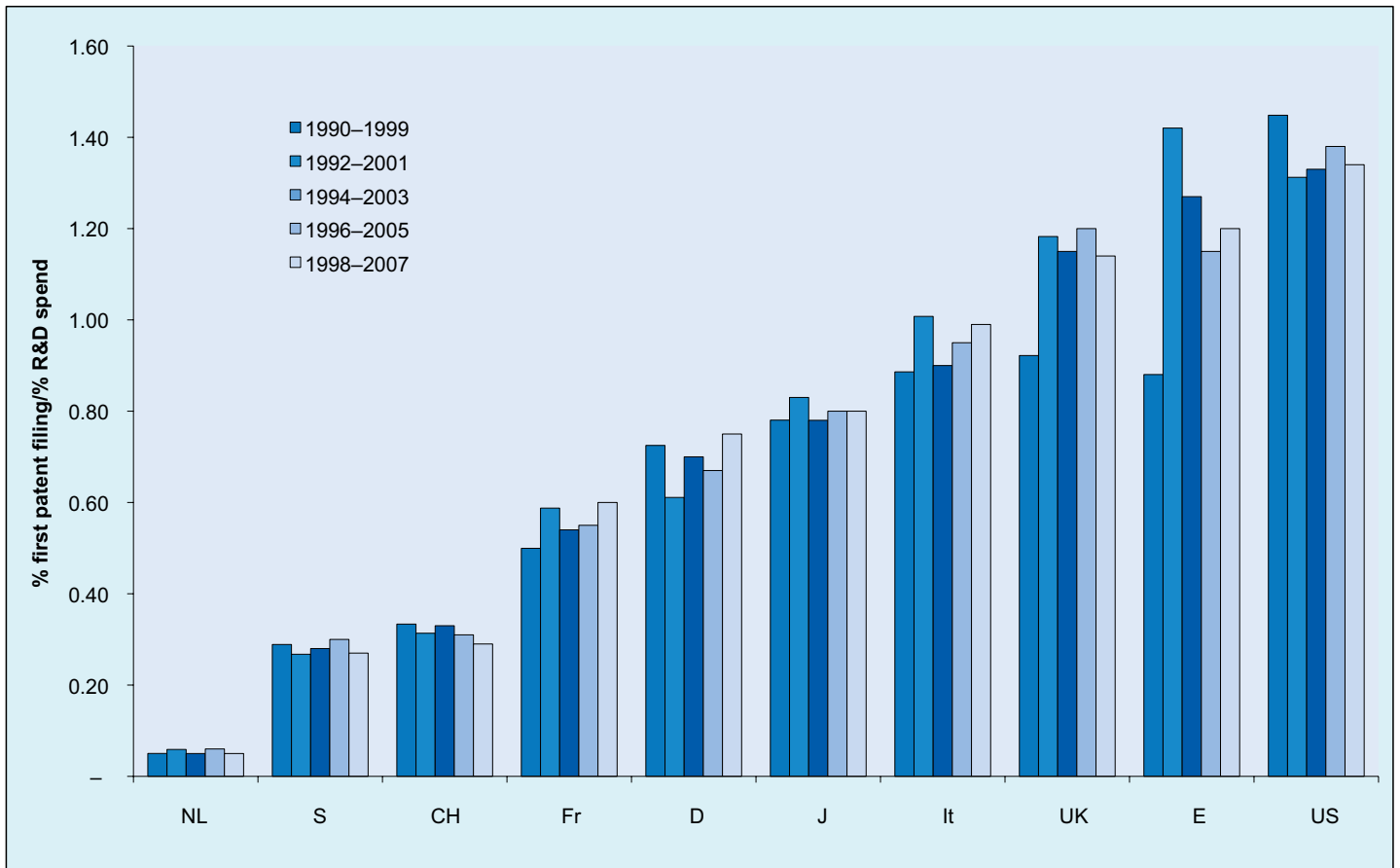


Source: MHRA

Notes: Between Feb 1999 and March 2003 the MHRA was co-ordinator for the greatest number of procedures. In 004-04 and 2004-05, UK again was leading co-ordinator for CPMP Scientific advice. In 2005-06, CPMP Scientific advice group expanded the number of its membership in response to increasing number of scientific advice requests received. Despite the UK having only two members in this group rather than three for some member states, the UK remained a leading co-ordinator appointed for giving scientific advice from 2005-08.

**Indicator 14: Proportion of world first patents filed for marketed New Molecular Entities  $\div$  proportion of world R&D spend**

**Chart 14: % of priority patent filings/proportion of pharmaceutical industry R&D spend 1990–2007**



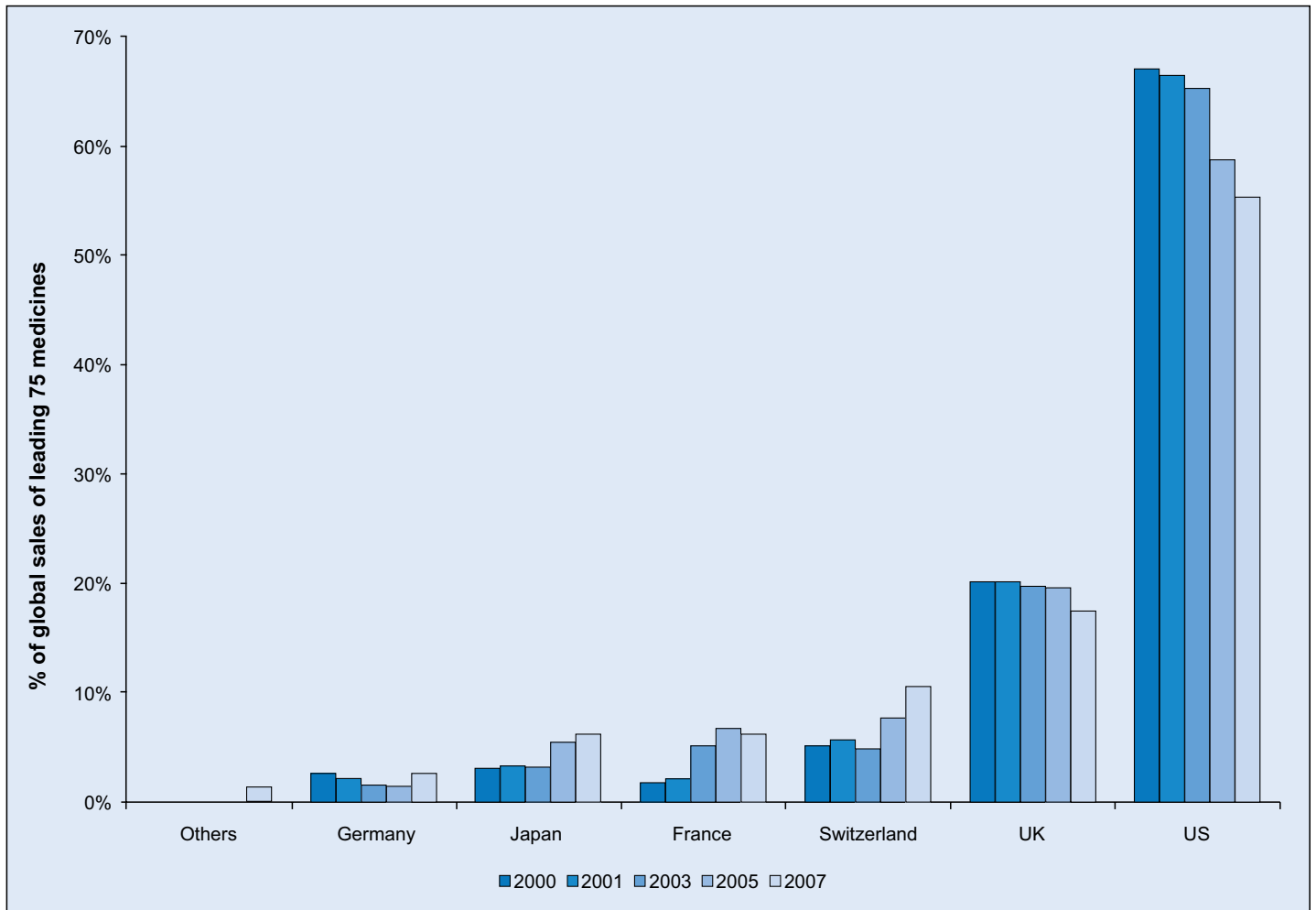
**Source: ABPI calculations**

**Notes:** 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 15: National origin of leading 75 global medicines

Chart 15: National origin of leading 75 global medicines 2000–2007



Source: IMS/ABPI calculations

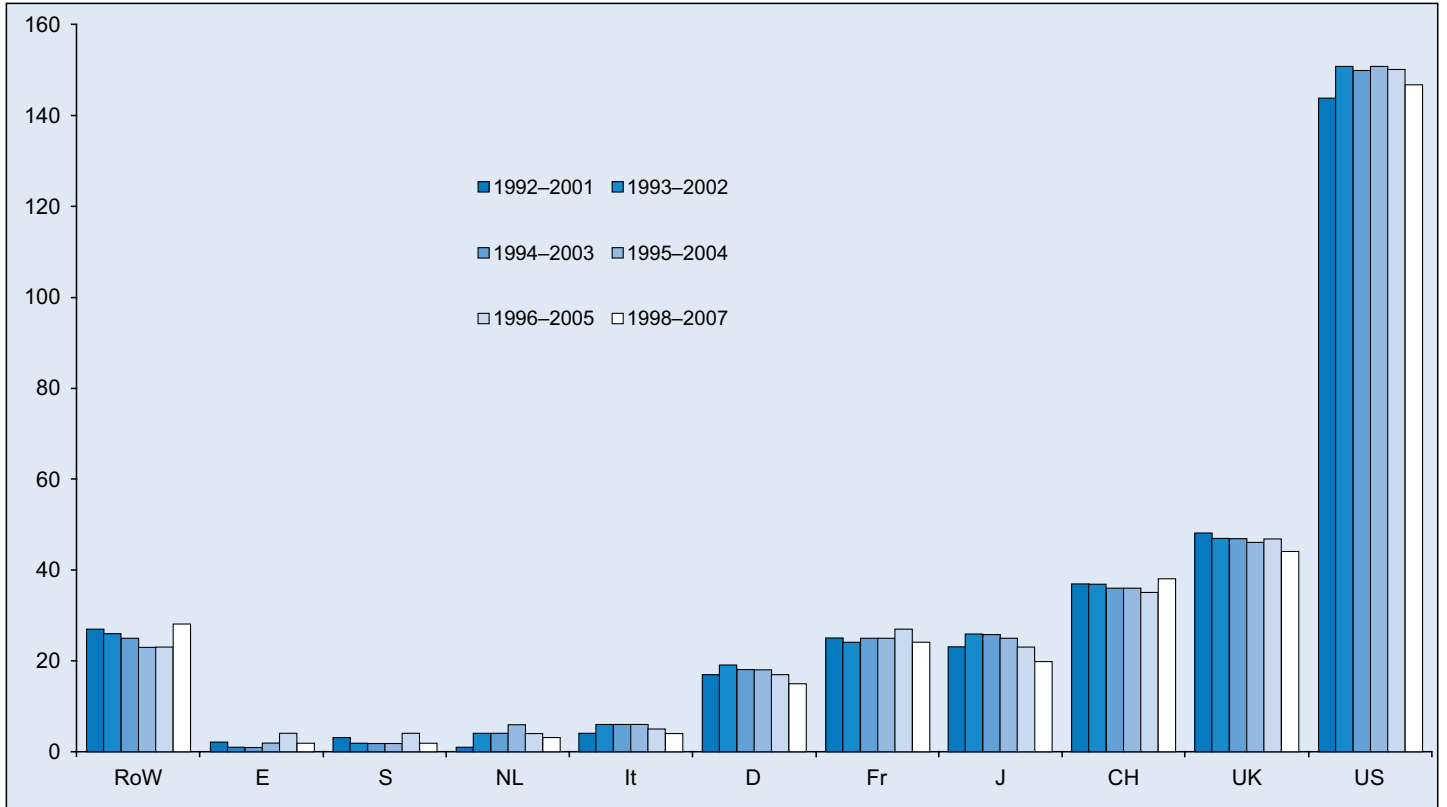
Notes: Top 75 is measured by worldwide sales and national origin relates to location of company HQ.

The chart shows the percentage of the national origins of the top 75 NASs that were produced by companies headquartered in the countries shown.



**Indicator 16: Number of UK-based companies' NMEs launched in all of four major markets: US, Germany, France, UK**

**CHART 16: Number of first in class products launched into four major markets, 1992–2007**

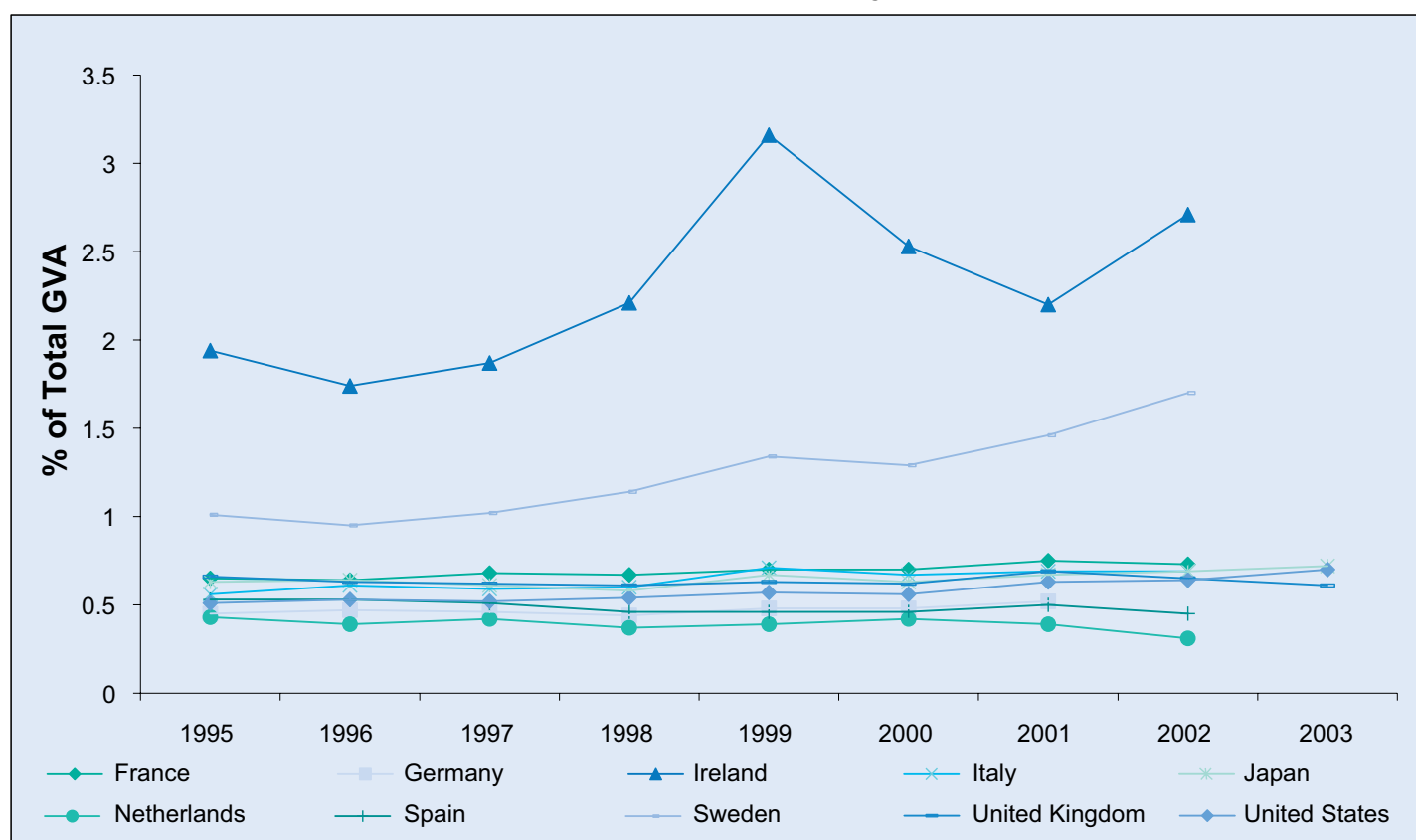


**Source: ABPI, IMS R&D Lifecycle**

Note: This indicator measures how many new medicines (i.e. first in class) are attributable to companies by nationality.

## Indicator 17: Gross Value added

CHART 17: Value added shares relative to the total economy



Source: OECD STAN database

Table 17: Pharmaceutical Industry Value Added

In millions of US\$										
	1980	1985	1990	1995	1998	1999	2000	2001	2002	2003
France	2,884	2,517	5,841	9,383	8,991	9,259	8,415	9,068	9,713	
Germany				10,119	8,873	9,360	8,300	8,973		
Ireland			369	1,207	1,726	2,684	2,153	2,064	2,972	
Italy	2,658	2,645	5,837	6,425	6,704	7,786	6,720	7,038	7,636	
Japan	7,418	9,483	21,145	34,791	23,783	31,010	31,048	29,105	28,622	32,124
Netherlands	452	549	747	1,590	1,327	1,438	1,438	1,369	1,183	
Spain	1,169	913	2,253	2,944	2,561	2,589	2,408	2,749	2,778	
Sweden	407	451	1,186	2,249	2,536	3,011	2,776	2,862	3,683	
UK	2,514	2,344	5,864	6,903	7,967	8,375	8,221	9,176	9,480	10,228
US	8,835	16,130	24,457	37,964	47,139	52,478	55,026	63,620	67,085	77,071

Source: OECD STAN database

Note: Owing 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 are in basic prices.

## 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:

China	CH
France	Fr
Germany	D
India	In
Eire	Ir
Italy	It
Japan	J
The Netherlands	NL
New Zealand	NZ
Singapore	Sin
Spain	E
Sweden	S
Switzerland	CH
United States	US

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 (EMA), 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.

**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 for 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 14 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 17 if it had been discovered and first patented in the UK, as American in indicator 18 if the company headquarters are located in the US.

If the concern is about strength of national innovation, indicator 17 would bolster belief that the UK is a good place for companies to discover new 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	1–16, 19-23
Company headquarters	17, 18



