

## Focus on Pharma

### UK performance in a global context

Estimated total UK pharmaceutical R&D expenditure (including capital) 1987 - 1998e

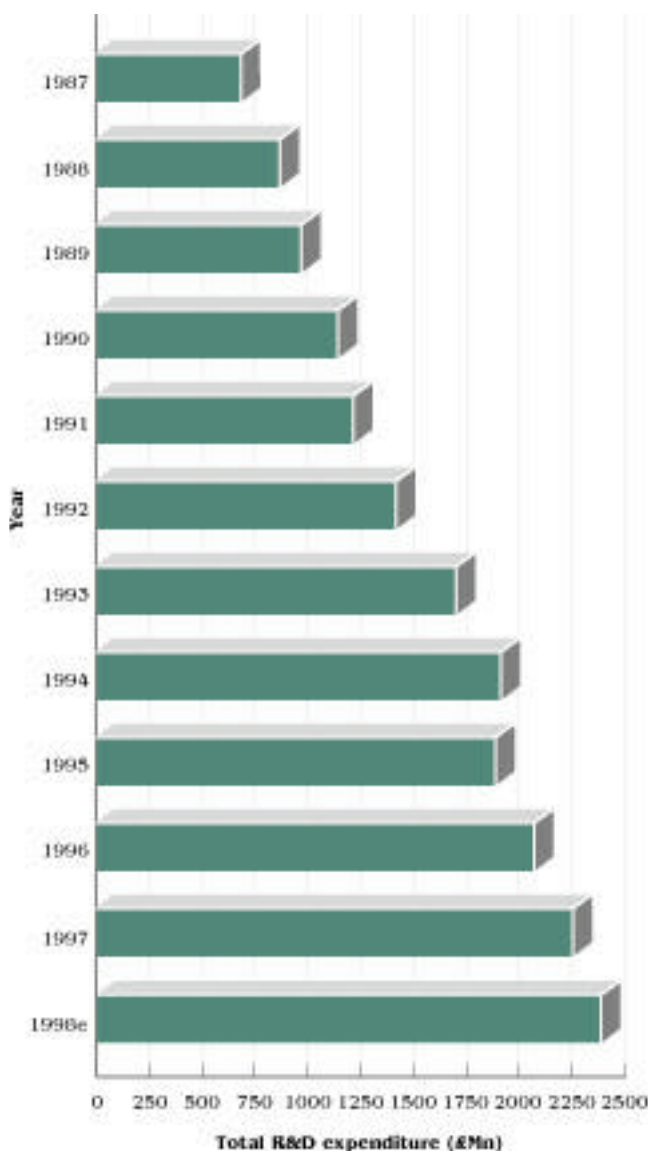


Figure 1 After a short plateau in 1995, total UK R&D expenditure continued to increase in 1996 and 1997.

- The pharmaceutical industry, a key asset to the UK economy, warrants close monitoring to ensure that it maintains its competitive edge under the pressures of globalisation and consolidation.
  
- What is the current level of UK R&D expenditure; does it continue to grow as in the past? How does the UK pharmaceutical industry fare globally? At the same time, how successful is the industry in terms of regulatory submissions and authorisations for new medicines in the UK; how many have appeared on the market?
  
- Armed with the answers to such questions, the industry is in a stronger position to conduct its strategic planning. Therefore, CMR International conducts annual surveys to create an informed profile of the UK pharmaceutical industry. This reveals UK growth in R&D expenditure for 1997 and 1998 to be on a par with that globally.
  
- The UK is still regarded as a desirable place for R&D investment; it will retain this leading position if governmental policy provides the right regulatory and commercial environment for growth.

## Perspective

Investment in the UK by the pharmaceutical industry is tracked by the annual CMR International R&D expenditure survey. Past surveys revealed the substantial growth in UK R&D expenditure that occurred throughout the 1980s and continued into the 1990s (Drasdo et al, 1993, 1994; MacFarlane et al, 1996; Russell et al, 1996; Dorabjee & Lumley, 1998).

Whether this growth will continue so that the UK remains in the forefront of pharmaceutical investment is a matter for concern in the light of globalisation and consolidation pressures. It is therefore increasingly important to assess the performance of the UK pharmaceutical industry in the context of the international industry.

Survey data for 1997, obtained from 34 companies, have been compared with contemporary global data already published by CMR International (Ashton et al

1998). To augment the profile, details of regulatory submissions, authorisations and launch activities over the same period, derived from the CMR International Marketed Medicines Database, are presented.

## Expenditure on R&D

The estimated total UK expenditure on pharmaceutical R&D, which includes capital investment, reached £2,251Mn in 1997; this represents an increase of 9% from 1996 (Figure 1). A similar rate of increase is predicted for 1998 and 1999, suggesting that the UK continues to be an attractive area for investment.

In 1997, pharmaceutical R&D expenditure in the UK accounted for 8.6% of the global R&D expenditure, similar to the level maintained for the past ten years (mean 8.0%). The commitment of the pharmaceutical industry to funding R&D in the UK is underlined by the fact that companies realise only 4% of their global sales in the UK.

R&D expenditure in the UK and other geographical areas, as a proportion of global expenditure (excluding capital)

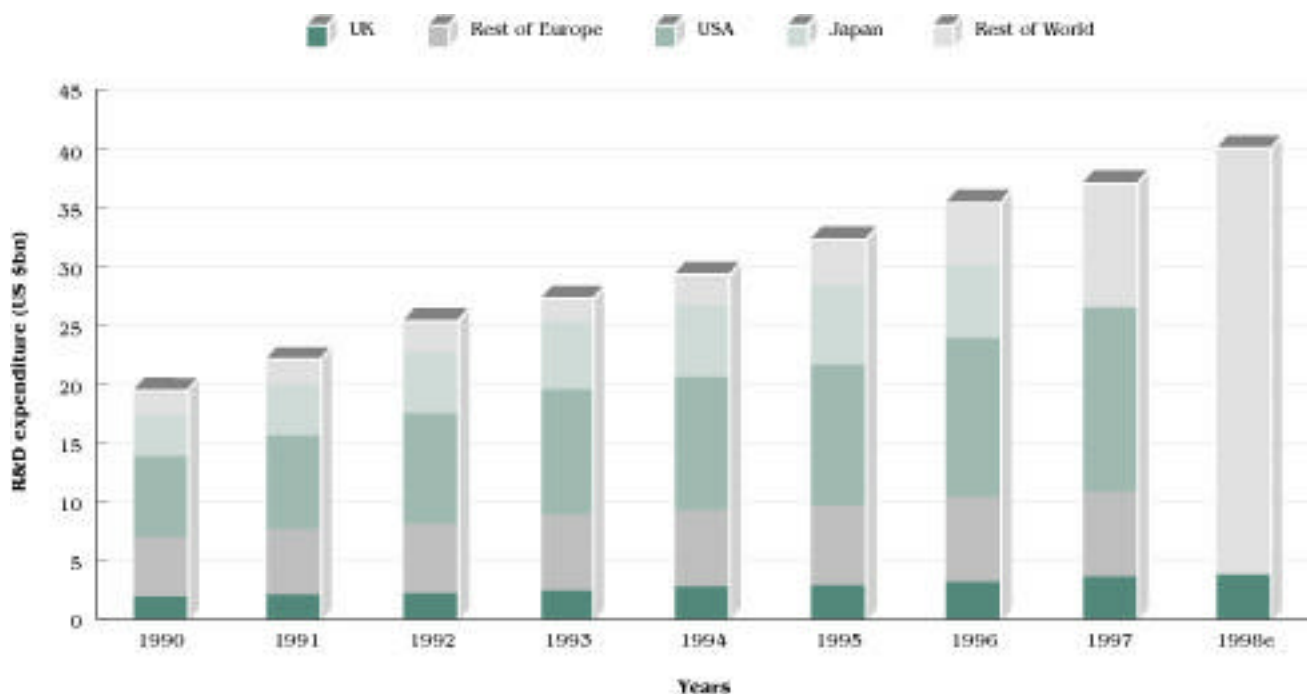


Figure 2 R&D expenditure in the UK has increased at a similar rate as global expenditure over the period 1990-1998e

The rate of growth in R&D expenditure for the UK is the same as that seen globally (Figure 2). In 1997, UK expenditure had grown to represent one third of the R&D investment in Europe as a whole; the relationship between expenditure in the UK and the USA remained at a quarter.

### Where does the money go?

In the UK, a slightly lower proportion of the R&D expenditure is allocated to discovery research than seen globally (Figure 3) while expenditure on development (78%) is proportionally higher than on

The UK remains a centre for innovative R&D, as shown by the products in the pipeline in 1997. These were largely new active substances (74%), of which almost a quarter were biotech products, according to information provided by 20 of the surveyed companies. However, the funding of academic research accounted for only 3% of total UK R&D expenditure, and this was estimated to decrease to 2% in 1998. This suggests reduced support for the UK science base since globally companies allocate 4% of their R&D expenditure to academia.

Breakdown of UK R&D expenditure in 1997 by functional activity: comparison with global R&D expenditure

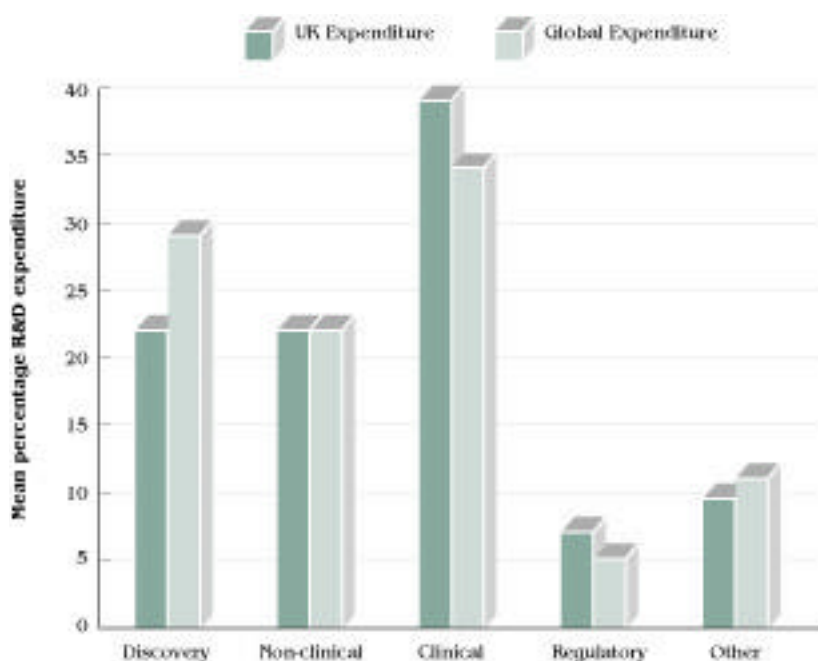


Figure 3 The proportion of the UK R&D expenditure allocated to discovery (22%) is slightly lower than the proportion of global R&D expenditure allocated to this area (29%). However, UK expenditure in development is proportionally slightly higher (78% of UK R&D expenditure compared with 72% of global R&D expenditure).

a global basis (72%). The UK's relatively higher investment in clinical research in 1997 may merely reflect the position of products in the pipeline, or the higher cost of clinical studies in the UK; alternatively, it might point towards increased expertise in clinical testing in this country.

The importance of outsourcing for cost effective development is reflected in the proportion of UK R&D expenditure allocated to external contracts (17%), which in 1997 was the same as that seen globally. However, the UK figure is estimated to increase to 25% in 1998, which might suggest a greater move towards virtuality in the UK.

### The right environment for investment?

To realise the necessary return on pharmaceutical R&D investment requires the right regulatory environment; efficiency in authorisation and marketing activities are therefore of prime importance to the industry. For companies in the UK the performance of the Medicines Control Agency (MCA), both in domestic terms and in relation to the new European procedures, is of particular relevance.

The MCA appears to be a willing partner in the Centralised Procedure, as reflected by the finding that it acted as Rapporteur/Co-rapporteur on ten occasions between January 1995 and September 1998 (Figure 4). During a similar time period the UK

Frequency of selection of the UK compared with other countries, as RMS or Rapporteur/Co-Rapporteur for NASs (1995 - 1998)

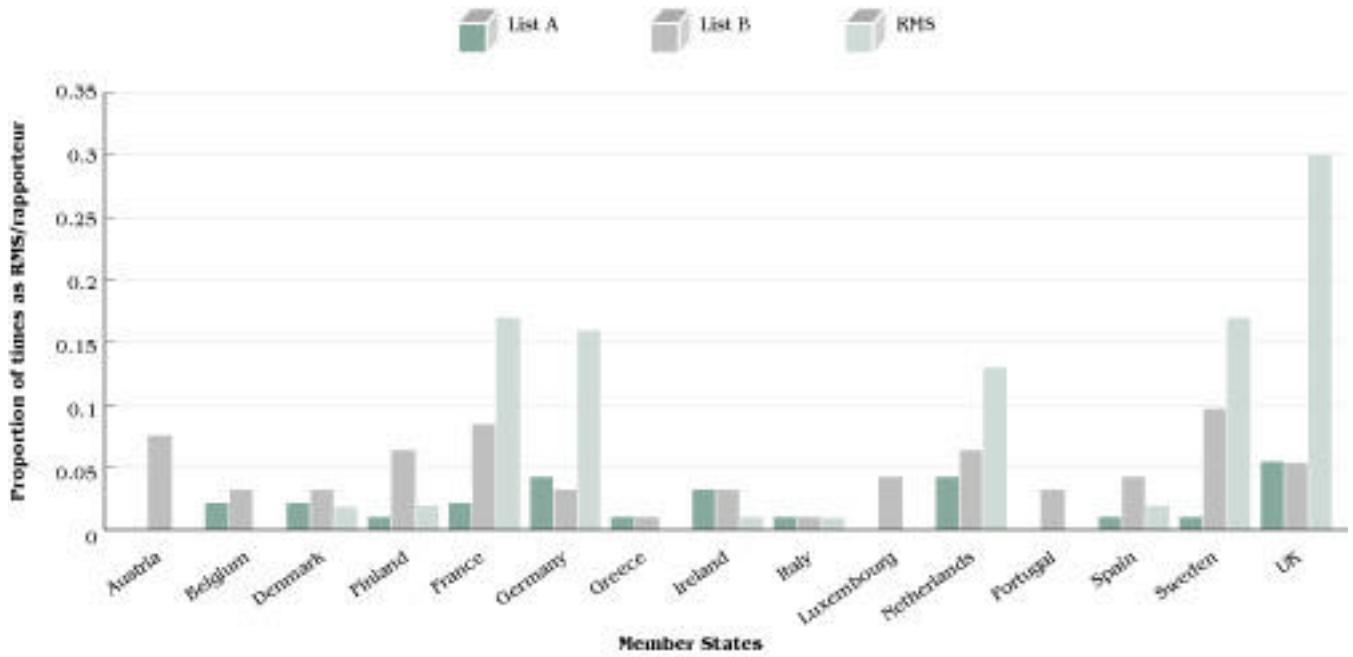


Figure 4 The UK has a leading position in both the Centralised and Mutual Recognition Procedures.

Median NCE approval times in the UK in comparison with other major markets, 1995 - 1997.

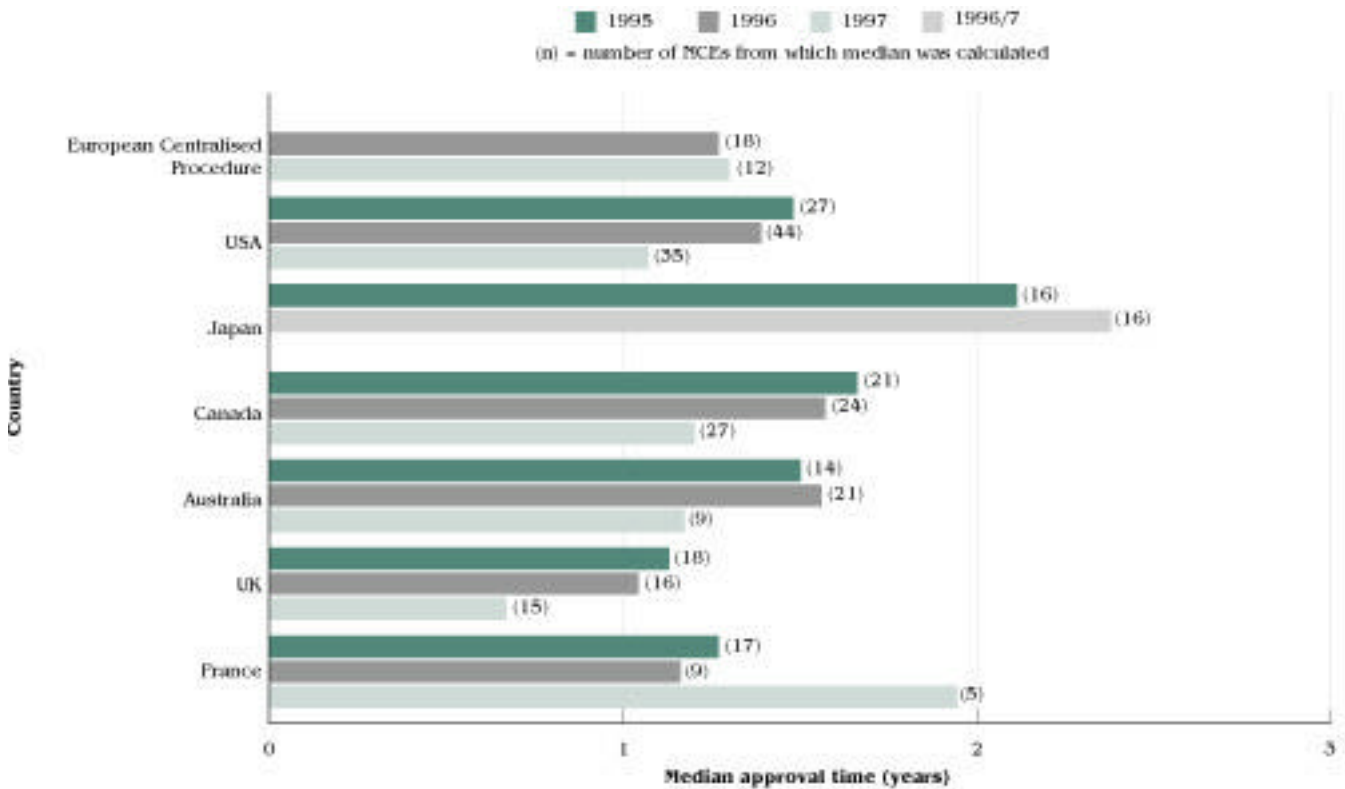


Figure 5 For each year the UK had the quickest median approval time compared with the other countries/procedures included in this analysis.

acted as Reference Member State (RMS) for 30% of 126 Mutual Recognition applications related to new active substances; this reflects confidence in the MCA since the choice of RMS is a company decision.

### The road to product launch

Awaiting regulatory approval is a significant hurdle. In the UK the median approval time for new chemical entities has been decreasing year on year since 1995, reaching 0.6 years in 1997 (Figure 5). Although other countries have experienced reductions in the time from submission to authorisation, the UK remained the quickest over the period 1995-1997 for any of the countries/procedures included in the analysis.

Once approved, the median time to launch of new molecular entities (NMEs) in the UK was just 72 days in 1997 (Figure 6). This is still slower than the time taken in the USA. The numbers of NMEs that have appeared on the market in the UK, USA or Japan between 1989 and 1998 are shown in Figure 7. By the end of 1998,

47% of all NMEs first launched anywhere in the world in that ten year period had appeared on the UK market. The USA was the only country in which a greater proportion of those NMEs first launched during this period was available (50%).

### Remaining competitive

The pharmaceutical industry continues to regard the UK as a desirable place to perform R&D. Investment growth in the UK in 1997 remained in line with global increments and the increase is estimated to continue during 1998 and 1999. At the same time regulatory review times in the UK have decreased each year, reflecting greater regulatory efficiency.

The UK is managing to stay competitive in R&D; it will maintain this leading position so long as governmental policy provides the right environment to encourage innovation and growth.

Time taken from regulatory approval to launch for the EU and six other major markets in 1997

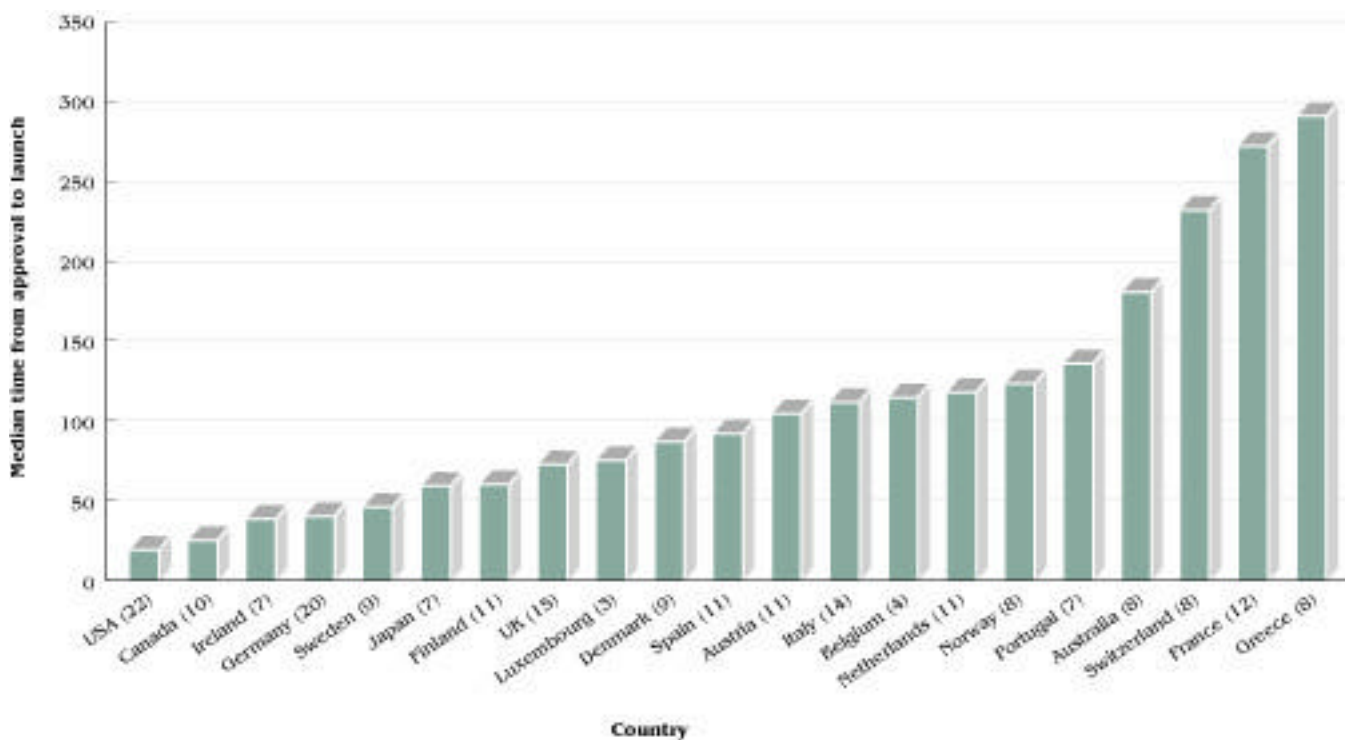


Figure 6 In the UK, the median time taken from regulatory approval to launch was 72 days, compared with 20 days in the USA for NAs launched in 1997.

## Number of NMEs launched in the UK, USA and Japan, 1989 - 1998

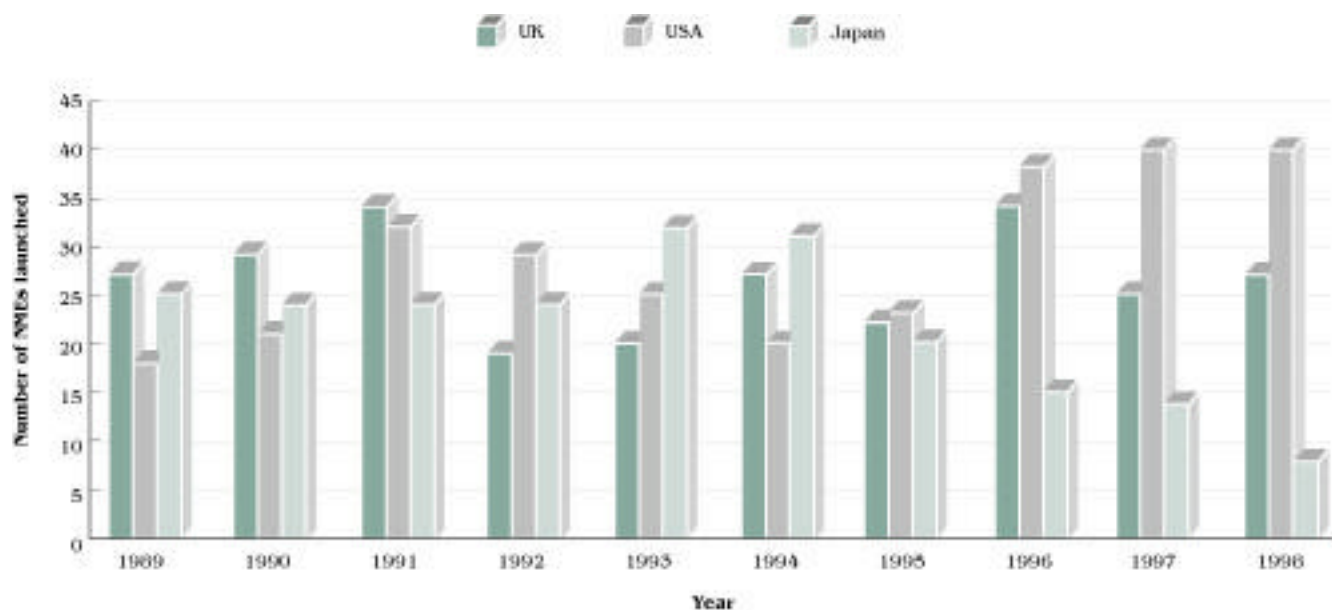


Figure 7 Forty seven per cent of all NMEs that were first launched anywhere in the world between 1989 and 1998 had been launched in the UK by the end of 1998. The USA was the only country in which a greater proportion of those NMEs first launched during this period was available (50%).

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A copy of this R&D Briefing is available on the CMR International web site.

Copies of the full report, "Profile of the UK Pharmaceutical Industry in 1997 and 1998", which contains 45 pages, 24 figures and tables and 2 appendices, are available free of charge to CMR International sponsoring companies. The report can be ordered quoting reference number CMR99-109R

Copies of the full report are also available to sponsoring companies only on the CMR International web site.

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