OnLine Case 2.4
The European Pharmaceutical Industry

The global drugs industry is dominated by powerful American companies, perhaps not unexpectedly as the USA has the world's highest spending ratio for health as a proportion of gross domestic product. But no single company is in a truly dominant position, although individual companies dominate particular segments with patented treatments. There is, in addition, a number of sizeable pharmaceutical companies in the UK, Germany, Sweden, Switzerland and France.

Past, and inevitable, government interest and involvement makes pharmaceuticals a politically sensitive industry. Individual consumers have relatively little influence on the choice of a particular drug, which is prescribed by doctors who are often working under constraints or limitations imposed by their respective governments. This affects the research and marketing strategies of the drug manufacturers. Governments across Europe have frequently agreed favourable prices with international companies who locate and invest in their countries, which has led to the establishment of more plants than are really needed and some loss of production efficiencies**.** The total spend on prescription drugs rose throughout Western Europe in the 1980s and early 1990s. Between 1989 and 1992 it grew by nearly 50% in real terms. Almost all of the cost is borne by the public purse. The main reasons for the growth were ageing populations and medical advances.

However, in the economic recession of the early 1990s, governments became less and less willing to meet an ever-increasing bill; and in 1993 drug spending was deliberately curbed. The pharmaceutical companies were forced to respond, and they reacted in a number of ways. It will be seen in the following examples that national borders are no constraint in this industry.

- Workforces have been reduced and sites closed. Hoechst and Bayer (Germany), Glaxo Wellcome and Fisons (UK) and Ciba (Switzerland) have all followed this strategy.
- In addition, there has been a number of strategic acquisitions and divestments. Two of the UK's leasing companies were sold, Fisons to Rhône-Poulenc Rorer and the manufacturing interests of Boots to BASF. Wellcome was taken over by Glaxo, following a contested bid. In 1998, the two dominant UK companies, Glaxo Wellcome and SmithKline Beecham, were poised to merge, but the two chief executives could not reach agreement on strategic leadership of the new group. However, the strategic logic was always there and the merger went ahead in 2000. Other mergers include:
  Sandoz and CIBA (both Swiss)
  American Home Products, Monsanto and Pharmacia (in two stages)
  Pfizer and Warner Lambert (both US) *followed by*
  Pfizer and Pharmacia in 2003
  Astra (Sweden) and Zeneca (UK and a spin-off from ICI) *and then*
  Astra-Zeneca and Novartis (Switzerland)

  Sanofi and Avensis (2004).

As a result of this consolidation, Glaxo SmithKline became 'number one', but still with only a 7.5% share of the world market, followed by Pfizer-Warner Lambert and Merck.

- As a form of industry restructuring both SmithKline Beecham (Anglo-American) and Merck (US) acquired leading American drugs wholesalers.
- New marketing strategies have been developed, actively promoting to doctors and hospitals those drugs that governments are still willing to pay for. This applies particularly to drugs which are differentiated, protected by patent and not subject to intense competition. Sales forces have also been rationalized

- Research and development has been redirected to focus on:
  (i) programmes which could lead to innovative and high-revenue drugs. The development of 'me-too' brands, which must be sold with lower margins in more competitive markets, is now seen as only low priority. Glaxo SmithKline established six independent internal biotechnology research centres which work autonomously in their prescribed areas. Their role was to develop new drugs to a proof of concept stage, when they are handed over to a centralised unit which manages the final comprehensive testing. The intention was to encourage entrepreneurship, and each group is free to forge alliances with outside research agencies such as Universities anywhere in the world.

  (ii) generic (unbranded) drugs where patents have expired. Margins are low but generic drugs are popular with governments.

- European companies have forged alliances with US companies to obtain their greater expertise in cost management and in the research and development of generic products.
- New joint venture businesses have been set up, such as Rhône-Poulenc (France) and Merck's Animal Health Products division in London and then Rhône-Poulenc with Hoechst (Germany) for all the pharmaceutical interests of these two diversified conglomerates.
- Some manufacturers looked to invest in the new biotech businesses that were emerging but this strategy has not really paid off for any of the major manufacturers.

In the mid-1990s, the UK claimed 40% of those employed in contract research in Europe and was continuing to attract new investment by overseas companies. When Sweden's Pharmacia merged with Upjohn of the USA in 1995, a new corporate head office was opened in London. More recently, Pfizer opened a major research centre in Kent. However, others such as Roche have left the UK to focus their research elsewhere. There were four main reasons why London became 'the centre of the globe in terms of the pharmaceutical industry':

- UK scientists are as good as those in France, Germany, Switzerland and the USA, but the total cost of employing them is lower
- the UK government's regulatory scheme differs from those of certain other countries and allows the drug companies to make between 17% and 21% return on capital employed, thus encouraging more investment
- strong UK capital markets have supported the blossoming biotechnology industry and
- the UK is home to the European Medicines Evaluation Agency, which issues drug licences for the whole EU.

By 2002/3 it was becoming apparent that the cost of developing an testing new drugs was on the increase. The total R&D spend had increased but the number of new drugs had declined. There was a number of causes, the relative signifiance of which is hard to quantify. Legislative requirements have tightened; because of past developments, incremental improvements and further breakthroughs become more complex and therefore expensive, despite the benefits and potential of biotechnology; some technically possible new drugs will not be able to recover the development costs because of the implied research costs. The cost of developing a new drug is now in the region of $800 million to $1.4 billion – to which a further $200 million launch costs can be added. Because patents are taken out before the final clinical trials, the rigorous testing regime means the drug companies have only 8 to 10 years of patent protection, in which time they have to recoup their research, development and launch costs in their prices. After this they are subject to competition from generic drugs.

The general approach to regulation in the UK has typically been one of regulating company profits and not the price of individual drugs, ensuring that companies which do invest in research and development can recover their costs while enjoying patent protection for a period of years. However, the Labour government (elected in 1997) threatened to rein in drug expenditure. The leading companies countered by saying they would relocate abroad. In addition, the formation of a National Institute for Health & Clinical Excellence (NIHCE) which

licenses new drugs provided a new opportunity (for more effective monitoring) but, at the same time, a threat. In 1999 NIHCE refused a licence for Glaxo Wellcome's new influenza drug, Relenza, as it had not been tested on enough elderly people, those most vulnerable to flu. The drug has since received approval from NIHCE.

In 2008 NIHCE refused to support funding for four kidney cancer drugs. These were all tested and approved – and they all worked. But they all cost in the order of £30K per patient per year but prolonged lives for only months. They were not perceived to be cost effective.

Also in 2008 it was reported that the industry was facing serious crisis-times ahead. Basically sales were flat but several important revenue-generating drugs would go out of patent between 2008 and 2012. There were very few potential 'blockbuster' drugs coming through the pipeline to replace them.

questions: How might the UK ensure it retains a leading position in this dynamic, turbulent but very important global industry?

What approach would you suggest any future British government should take?

Competiton authorities in the UK have recommended that resale price maintenance (where manufacturers dictate retail prices) for over-the-counter non-prescription drugs should be abolished. If retailers are free to set their own prices it is assumed that the supermarkets will grow their share of the market at the expense of independent pharmacists. Should this happen, what impact might it have on the drug manufacturers themselves? The public will benefit in terms of prices, but is the situation more complex?