

MAJOR CHALLENGES FOR THE PHARMACEUTICAL INDUSTRY IN THE NEW MILLENNIUM

With the current operating environment characterised by mega-mergers, rising healthcare costs, cost-containment initiatives, changing population demographics and the rapid emergence of new technologies, there has never been a greater need for strategic information on activities of the global pharmaceutical industry.

The fifth annual survey of pharmaceutical investment and output reports information on activities in 1999 concerning:

- International pharmaceutical R&D expenditure and sales;
 - Products in the development pipeline;
 - New active substance activity: submissions, authorisation and marketing.

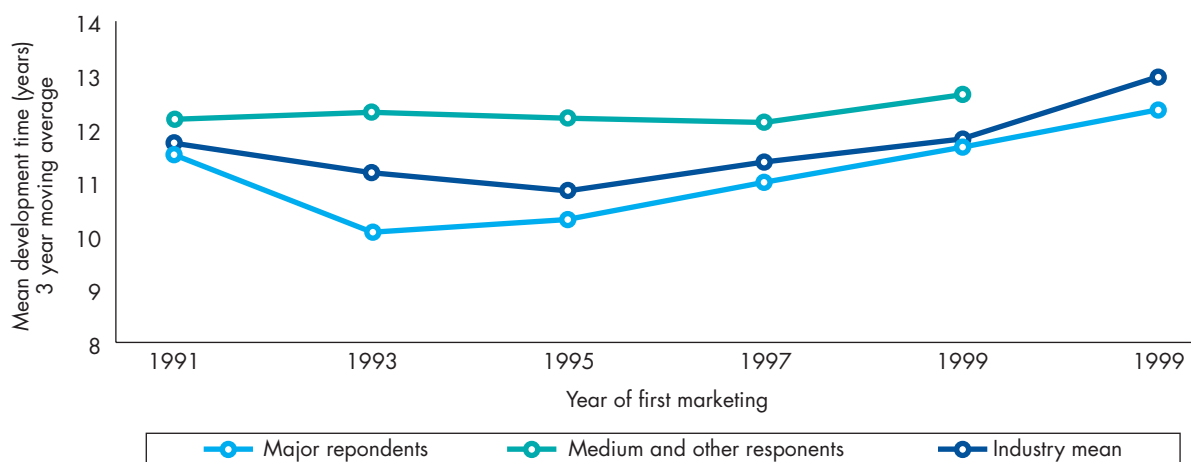
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Fifty-five companies, including 13 Major, 12 Medium and 30 Other companies supplied information*. Between 1998 and 1999, growth in

sales of pharmaceuticals exceeded growth in R&D investment for the first time since 1995. Estimates for 2000 suggest that this will also be the case for 1999 to 2000. This is good news for the pharmaceutical industry; however, some worrying findings are also apparent. Pipeline sizes are not growing, output of marketed New Active Substances (NASs) is static, and a high proportion of NASs are still being terminated at late stages of development.

FIGURE 1

Development times for NMEs launched on to their first world market



Development times (date of first synthesis or isolation to date of first world marketing) have been calculated for 222 (79%) of the 280 NMEs that were first marketed in the period 1st January 1993 - 14th July 2000. "Industry" includes NMEs marketed by companies that did not respond to this survey. Seven NMEs with development times exceeding 25 years, and all vaccines, were excluded from this analysis. NMEs that were marketed as a result of a joint venture between cohorts of companies are excluded from Major and Medium and Other respondent cohorts.

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Key findings of the latest annual survey of pharmaceutical investment and output conducted by CMR International were:

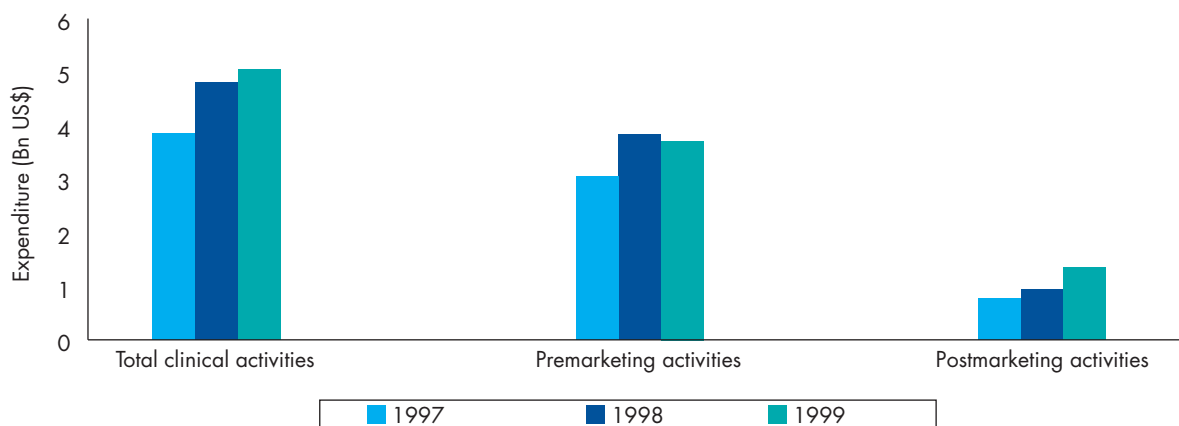
KEY FINDINGS OF THIS SURVEY

- Total development times, from synthesis to first world launch, have increased from an average of just under 11 years in 1996 to 13 years in 1999 (Figure 1).
- The trend in recent years for increases in R&D expenditure to outpace growth in sales (as shown on page 6 Figure 1) has been reversed. Annual growth in sales between 1998 and 1999 was 9.5%, whereas the increase in R&D investment was 4.6%.
- The level of investment in clinical research continued to increase in 1999, largely driven by an increase in post-marketing clinical activities (Figure 2).

- Clinical development pipelines have not increased in size in recent years; the mean number of NASs in development in Major companies was 24 in 1999, compared to 11 for Medium companies and 6 for Others. Companies remain most committed to developing nervous system, cancer and cardio vascular therapies.
- Major companies are not relying solely on NASs to meet their targets, as they continued to invest a third of their R&D expenditure on line extensions in 1999.
- Respondent companies terminated the development of nearly one-fifth of the NASs in their pipelines in 1999. Development of nearly half of the NASs in the presubmission stage was terminated in 1999, by which point over 90% of the total investment in researching and developing a compound will have been committed.
- Over the last two years there has been a marked reduction in the number of submissions, raising concerns that the industry may not be able to sustain the current level of output (Figure 3).
- Many companies are not achieving their stated target of simultaneous submission in major markets. Only one-quarter of the NASs submitted by the survey respondents achieved international submission within one year of first submission, in 1999. (International submission is defined as a dossier submitted to regulatory authorities in two of the three ICH regions of the USA, Japan and Europe. Europe is defined as three from the UK, Germany, France, Italy and Spain).

FIGURE 2

Trend in breakdown of R&D expenditure on clinical activities



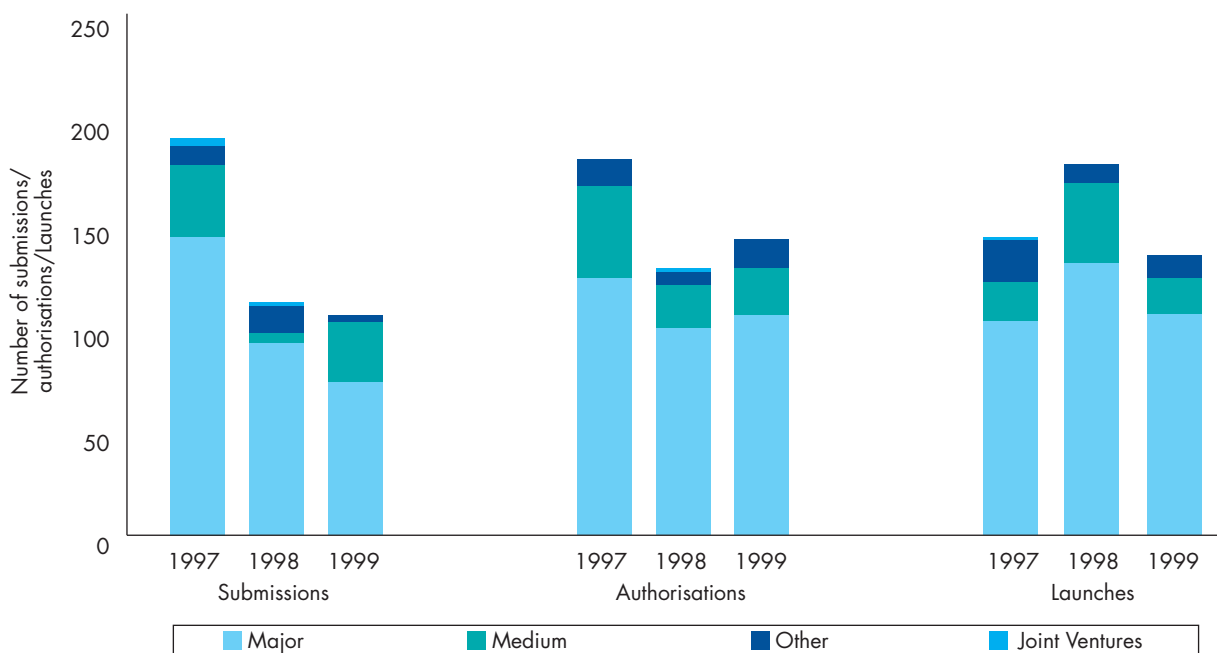
Information on the breakdown of R&D expenditure allocated to clinical activities was provided by 15 companies for 1997, 1998 and 1999.

- Few companies are able to achieve launch of their products as soon as they receive marketing authorisation. In some countries this is due to the time needed to negotiate pricing and/or reimbursement. However, in the UK, the USA and Canada, the median time from approval to launch in 1999 was relatively short, at around 20 days (see page 13).
- 40 NMEs were launched in their first ever world market in 1999, in line with the average output for the 1990s.

It is clear that the industry is currently facing several major challenges. There is an expectation that the industry will continue to achieve the high rate of organic growth observed throughout the 1990s, however this must be achieved in an increasingly competitive environment, in which “fast followers” and the erosion of patent life are threatening market exclusivity. A further challenge is the emergence of the “fourth hurdle” as governments in many countries are beginning to consider cost containment initiatives to combat rising healthcare spending. Many of the industry’s expectations for sustaining revenue in this environment rely on increasing output; there is little evidence from this latest survey that this is likely to happen in the near future.

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FIGURE 3
Regulatory and marketing activities



The number of regulatory submissions, marketing authorisations and launches of new active substances within the EU, Australia, Canada, Japan, Norway, Switzerland and the USA are presented for 22 companies (7 Major, 6 Medium and 9 Other companies) that have participated in each annual survey between 1997 and 1999.