Chapter 3

Pharmaceutical Industry Development Program

The Pharmaceutical Industry Development Program aims to encourage the development of an innovative and internationally competitive pharmaceutical industry in Australia. The Factor (f) Scheme is a major element of the program. Under the Scheme, participating pharmaceutical manufacturers receive notional and actual price increases for some of their products listed on the Pharmaceutical Benefits Scheme. In return, these companies commit to increases in manufacture, research and product and process development in Australia.

Factor (f) Scheme

Factor (f) is the sixth pricing factor. It requires the Authority to take into account the impact on industry development when recommending the price of pharmaceuticals. The Factor (f) Scheme is an important mechanism the Government uses to deliver on its commitment to industry development.

Phase I of the Scheme was introduced in 1988 and closed to new entrants on 20 May 1991. In light of the success of Phase I, the Government announced in 1992 that the Scheme would extend from 1 July 1992 to 30 June 1999 (Phase II). Phase I terminated in 1994-95.

Participating companies

Ten companies currently participate in Phase II of the Scheme. The companies are:

- 3M Pharmaceuticals (Australia) Pty Ltd;
- AMRAD Corporation Limited;
- Astra Pharmaceuticals Pty Ltd;
- CSL Limited;
- FH Faulding & Co Limited;
- Glaxo Wellcome Australia Limited;
- Merck Sharp & Dohme (Australia) Pty Limited;
- Pfizer Pty Ltd;
- Pharmacia and Upjohn Pty Limited; and
- Rhone Poulenc Rorer Australia Pty Ltd.
  (Formally Fisons Pharmaceuticals Pty Limited)

During 1997-98, the Commonwealth paid Factor (f) price increases totalling $169.7 million. In return, the monitored performance of the Phase II companies for Australian Production Value Added (PVA) activity for the year totalled $787.6 million compared with $613.9 million for 1996-97. This represents a 22.1% increase over the previous financial year's activity and an increase of $654.4 million over the base year level (generally 1991-92). Expenditure on research and development in 1997-98 was $99 million compared with $83.5 million in 1996-97. This represents an increase of 15.7% over the previous year's expenditure and an increase of $87.4 million over the base year level.

The cumulative total of Australian value added production from the commencement of Phase II of the Factor (f) Scheme to 30 June 1998 is $2,826.6 million. The cumulative total expenditure on research and development is $367 million. The amount paid by the Government for Phase II Factor (f) price increases to 30 June 1998 is $550.9 million.

Events

The guidelines for the Government's new $300 million Pharmaceutical Industry Investment Program (PIIP) were released on 6 April 1998. The guidelines outline the principles under which the PIIP will operate and provide details of entry, payment and ongoing administration. The PIIP will run from July 1999 to June 2004 and applications to participate in the program close on 15 August 1998. Entry to the program is competitive, based on an assessment of the relative merits of broad investment and activity programs proposed by companies. Companies will become entitled to partial compensation for the effects of price and volume constraints under the PBS by increasing either or both of their Production Value Added (PVA) and research and development (R&D) activities. Consistent with current arrangements, the PBPA will administer the PIIP and will be supported by a Secretariat located within the Department of Industry, Science and Tourism.

The *Intellectual Property Law Amendments Bill 1998*, was passed through the Lower House of Parliament in March 1998 and it was anticipated that the Bill would complete its passage through both Houses of Parliament in July 1998. The new arrangements recognise long development times and regulatory requirements for new pharmaceuticals, which restrict the time under patent to exploit the invention and gain a return on investment. The Bill's provisions bring Australia into line with the USA, EU and Japan and ensure that pharmaceutical patents grant an 'effective life' similar to that available to inventions in other fields of technology. Existing and new standard 20 year patents for pharmaceutical inventions will be eligible to apply for an extension. Springboarding by generic producers will be permitted from the date the extension of term for a patent is granted.

The Therapeutic Goods Amendment Bill 1997 came into effect on 17 April 1998. The data exclusivity provisions of the Bill ensure that confidential data concerning new chemical entities (NCEs) is protected for five years from the date of registration. During this time, a second company must gain permission from the originator to use the data or develop its own data package. This confidentiality regime rewards the originator company for their time and expense in developing the new drug, and removes the potential for overseas companies to withhold new drugs from the Australian market.

The Pharmaceutical Industry Working Group, established by Minister's Wooldridge and Moore, met for the first time on June 23 1998. Senior industry representatives provided Ministers with an overview of the industry in Australia, its contribution both to the economy and cost-effective healthcare, and the possible impact of the current pharmaceutical pricing structure on future investment. A work program was developed that will assist and resolve some of the issues raised.

In September 1997, the Full Bench of the Federal Court dismissed an appeal lodged by a company regarding its exclusion from the Factor (f) Scheme. In October 1997, the Federal Court formally dismissed another company's application for appeal against exclusion from the Scheme. No further legal action is pending.

Highlights for 1997-98 include:

- 3M undertook a number of capital projects to support the ongoing expansion of its export business. These projects included increasing the capacity of the granulation facility, the first stage of an upgrade of the liquids packaging area, and an upgrade of the aerosol line to allow the production of non-CFC aerosols.

- AMRAD achieved a number of significant advances during the year, including the successful progression of Phase II human clinical trials of AM94, a vaccine for rotavirus infection; the commencement of Phase I human clinical trials in cancer patients of AM424 – a compound under investigation for the treatment of nervous pain; and the commencement of development necessary to enter late stage human clinical trials of AM149 – an injectable anaesthetic. In addition, the AMRAD drug discovery programs yielded exciting potential drug products, two of which have entered into preclinical trials.

- Astra Pharmaceuticals invested a further $60 million in a new, state-of-the-art factory at North Ryde. Covering 17,000 square metres and due to be commissioned in the latter half of 1998, the factory is the largest single sterile pharmaceutical plant in the southern hemisphere. The new factory and two others operating at North Ryde have been designated world-wide supply bases for a number of Astra's products.

- CSL has licensed production technology for incorporation in a new facility to produce bioplasm products in Poland. CSL will also contribute to the design and commissioning of this facility in return for milestone and consultancy fees as well as an ongoing stream of royalty payments. .

- Faulding and CSIRO signed a new agreement to expand research into Faulding's Lipidation technology - a new drug delivery technology that has the potential to alter the way drugs are absorbed, distributed an eliminated by the human body. The technology has the potential to significantly enhance drug therapy in a number of therapeutic areas, with applications in the anti-cancer sphere being of particular interest.

- Glaxo Wellcome Australia filed for approval with Australia's Therapeutic Goods Administration to market the major new influenza drug, Relenza. The company is seeking to supply the Asia/Pacific region and act as back-up supplier for the US market. Australia will be the first country in which the drug is made available commercially. Filings should take place in the USA and a number of European countries later this year.

- In 1997, exports from Merck Sharp and Dohme (Australia) grew by 33% in 12 months to over $250 million, an amount not expected to be reached until the year 2000.

- Rhone Poulenc Rorer's promising anti-cancer drug Taxotere is currently being marketed for late stage metastatic breast cancer. A program has been agreed with the Australian and New Zealand Breast Cancer Institute to trial Taxotere in early stage breast cancer as part of an adjuvant setting. The trial will enter 550 patients over several years.

  New indications for the use of Taxotere are also being investigated. A major trial comprising five hospitals is being commissioned to evaluate effects of Taxotere in combination with Cisplatin in late stage head and neck cancer. In another trial, Taxotere, again in combination with Cisplatin, is being evaluated as a first treatment for lung cancer.

Performance monitoring

Companies participating in the Factor (f) Scheme are required to submit quarterly and audited annual reports on their Factor (f) activity. This enables the Authority to monitor performance.

PVA activity for 1997-98 increased, on average, to 95.4% of forecast performance. R&D expenditure was 111% of forecast expenditure for the year. Overall, activity in Phase II was 91% of the forecast for the period 1992-93 to 1997-98. Delays in obtaining marketing approval for some products both in Australia and overseas, reductions in prices offered under the PBS and the impact on prices from the introduction of the Therapeutic Grouping Policy are reasons given by companies for not meeting PVA targets. Where appropriate, action has been taken to encourage companies to increase activity levels during the remaining year of the scheme.