

Appendix

Factor (f) Pricing Guidelines issued June 1992

Role of the Authority

The Authority will:

- consider proposals received from companies for price increases under factor (f);
- recommend approval or otherwise to the Minister for Industry, Science and Technology and the Minister for Human Services and where appropriate, the value of any price increases to be offered to companies;
- monitor companies' performance against their proposals to ensure price increases are commensurate with the level of activity companies achieve; and
- discuss with companies additional activity or lower price levels in the event a company's performance is below the level forecast in its proposal.

Principles

The Factor (f) Pricing Guidelines under which higher prices will be paid are based on four fundamental principles:

- prices for pharmaceuticals listed on the Pharmaceutical Benefits Scheme should not be an impediment to the significant development of the industry;
- higher prices should only be recommended if they are likely to contribute to the development of significant internationally competitive activity in Australia;
- Pharmaceutical Benefits Scheme prices should not exceed the average prices of pharmaceutical products in the European Community; and
- a net benefit to the economy should result from any price increases granted on the basis of Australian activity.

Timeframe

Activity undertaken in the period from 1 July 1992 to 30 June 1999 will be eligible for price increases from and including the company financial year in which their proposal is lodged with the Authority.

Definitions

Pharmaceuticals - are human use pharmaceuticals of the type currently available under the Pharmaceutical Benefits Scheme and include biologically active products and systems.

Production - is the manufacture for export or domestic sale of pharmaceutical products, raw materials or material inputs into finished pharmaceutical products. Production is valued at ex-factory prices.

Exports - includes sales from Australia to other countries of products, active ingredients, raw materials for use in pharmaceutical products, and income derived from royalties and similar payments from other countries.

The Authority will consider the inclusion of exports of pharmaceutical related services on a case by case basis. Exports of pharmaceutical products are valued at free on board prices.

Imports - is the landed cost of imported pharmaceutical products, active ingredients, and components used in the production or packaging of pharmaceuticals. Landed cost includes expenditure on royalties and similar payments.

Value added - is the difference between the ex-factory selling price and the landed cost of imported ingredients, materials and royalties and similar payments. Value added can include income from royalties and similar payments.

Turnover - is total sales of pharmaceuticals at ex-factory prices.

Research and development (R&D) - is generally as defined by the Industry Research and Development Board for the purpose of applying the Industry Research and Development tax concession.

To be approved for price increases, R&D will need to have the potential for use in the development of pharmaceutical products and processes, or in the application of pharmaceuticals.

New entrant - is a company which first participates in the Factor (f) Scheme after 1 July 1992.

Continuing participant - is a company which participated in the Factor (f) Scheme before 1 July 1992.

Base year - is the year which is used as the base over which increases in activity are measured.

For new entrants in the scheme, the base year will generally be the company's operating year prior to approval of a factor (f) proposal. Continuing participants in the scheme will generally maintain their existing base year.

Participation requirements

To receive price increases under factor (f), companies must lodge proposals with the Pharmaceutical Benefits Pricing Authority detailing the activity they propose to undertake under the scheme.

Proposals for price increases should be detailed plans for new and expanded R&D and production. Companies will need to demonstrate their proposals are integrated with the long term strategic direction of the company as a whole. Companies must also provide forecast data for activity over the period of the proposal and audited data for activity in the base year.

Once the Authority has reviewed a proposal it will make a recommendation on approval to the Minister for Industry, Science and Technology and the Minister for Human Services and Health. If the Government agrees with the Authority's assessment that a company has demonstrated it can meet the requirements for entry into the scheme, the company will be eligible for price increases under factor (f).

New entrants to the scheme will be eligible for factor (f) price increases if they are able to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. New entrants will either meet specific eligibility criteria or demonstrate their proposal should be eligible on qualitative grounds.

Continuing participants in the scheme will be eligible for additional price increases where they can demonstrate their proposed new activity is internationally competitive and will provide significant net benefits to Australia. The Authority will discuss appropriate performance targets and price increases with these companies and will make a recommendation to the Minister for Industry, Science and Technology and the Minister for Human Services and Health. Details are provided on pages ... and ... of these guidelines.

Eligibility criteria

Proposals from companies entering the scheme after 1 July 1992

All new entrants will be required to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. Companies will generally enter the scheme by demonstrating their commitment to meet two eligibility criteria within five years of approval.

The Authority recognises there may be circumstances in which a company, while making a significant contribution to internationally competitive activity in Australia, is unable to meet these eligibility criteria. In such circumstances, the Authority may recommend price increases on qualitative grounds.

The new entrant must undertake to meet one of the following two eligibility criteria within three years of entry into the scheme, and the other within five years of entry into the scheme.

- **Production**

Increase the value added in Australia on pharmaceutical production by 50 per cent over a three year period.

- **Research and development**

Achieve a level of R&D spending equal to 3 per cent of turnover and maintain R&D spending at 3 per cent of turnover for the remainder of the scheme.

However, a company able to demonstrate it can meet the eligibility will not automatically qualify for factor (f) price increases. Approval of price increases is dependent on the assessment of the international competitiveness of the proposed activity and of the net benefits which will accrue to Australia from the activity.

Where a company is unable to meet the eligibility criteria above, the Authority may recommend price increases if the company is able to demonstrate it is substantially increasing its activity in Australia and the activity is internationally competitive and is likely to lead to significant net benefits for Australia.

The purpose of this provision is not to bypass the stringency or intent of the eligibility criteria, but to provide some flexibility in cases where a company's development strategy is no less ambitious.

In deciding whether to recommend approval of a proposal on qualitative grounds, the Authority will consider the activity proposed by the company including:

- new active ingredient production;
- new investment in production plant, facilities or equipment;
- expenditure on new research and development projects;
- new production for export and domestic sale;
- commitment to best manufacturing practice through measures such as benchmarking, quality program and workplace reform;
- establishment of Australia as a centre for operations in the Asia/Pacific region; and
- other internationally competitive activity.

Once a new entrant has demonstrated it can meet its proposed eligibility criteria, or has been approved on qualitative grounds, the Authority will discuss with the company performance targets for the:

- remainder of the proposal where a company meets the eligibility criteria; or
- entire proposal where a company has been approved on qualitative grounds.

The targets will initially be determined at the time of approval of a proposal. Performance targets will generally be growth rates for increases in research and development and value added production.

New proposals from participants in the scheme prior 1 July 1992

New or revised proposals for price increases under the factor (f) scheme from companies participating in the scheme prior to 1 July 1992, must include a detailed outline of internationally competitive activity the company proposes to undertake under the extended scheme. Continuing participants will not be required to meet the entry requirements for new entrants if they have met all their performance requirements under the 1988 guidelines and the 1990 revised guidelines.

However, to continue to receive factor (f) price increases, these companies will be required to demonstrate their continuing commitment to expanding internationally competitive activity by meeting negotiated performance targets or milestones. Continuing participants in the scheme will maintain their existing base year.

Where a company participated in factor (f) prior to 1 July 1992 and did not meet its performance requirements under the scheme, its eligibility criteria and base year for the extended factor (f) scheme will be negotiated with the Authority, subject to approval by Ministers, based on the company's proposed activity for the extended scheme and its actual performance under past guidelines.

The Authority will evaluate the proposals of all continuing participants to determine whether:

- the company is substantially increasing its level of production and research and development activity in Australia;
- the company's proposed performance targets reflect the increased activity proposed by the company;
- the proposed activity is internationally competitive; and
- the proposed activity will produce significant net benefits for Australia.

If the Authority considers a proposal is insufficient when measured against these criteria, it will discuss additional activity or higher performance targets with the company.

If the Authority determines the proposal is acceptable, it will discuss with the company the payment rate it will recommend to Ministers for approval of the proposal.

Calculation of price increases

Price increases will be calculated on the value of increased activity by the company. The maximum payment rate a company may receive for a proposal will be 25% of the value of the increased activity. The actual level of payment will be based on the Authority's assessment of the benefits to Australia of a proposal.

- **Production**

Price increases for production activity will be paid on the increase over the base year in value added in Australia. The rate will vary up to a maximum of 25% of increased value added in Australia.

- **Research and development**

Price increases for R&D activity will be paid on the increase over the base year in after tax expenditure on R&D. The maximum payment rate a company may receive for R&D activity will be 50% of the increase in after tax expenditure, or 25% of the increase in total expenditure, whichever is the lesser.

Application of price increases

Companies may apply price increases under factor (f) to any of their pharmaceutical products listed on the Pharmaceutical Benefits Scheme with the agreement of the Authority. Price increases will be paid direct to companies based on the activity they identify in quarterly activity reports. Payments will be made one quarter in arrears of reported activity.

Maximum price increase

Factor (f) price increases may not increase the price of a product to more than the average price of the product in the European Community (EC). The EC average price will be based on a simple average of the price of the product in EC countries in which it is sold. Where a realistic EC comparison is not possible, the Authority will determine an appropriate price ceiling.

Performance monitoring

The Authority will monitor the performance of all companies receiving factor (f) price increases to ensure price increases paid to companies are consistent with the actual performance of each company.

Companies will be required to submit an annual monitoring report within three months of the end of their financial year in accordance with monitoring guidelines determined by the Authority. Payments of price increases will be based on activity reported by companies in quarterly activity reports and annual monitoring reports.

Three year review

The Authority will review the performance of each company after three years in the factor (f) scheme. To assist the Authority with its review, companies will be required to submit revised forecasts of activity for the remaining years of the scheme. The review will enable the Authority and companies to review their performance in the scheme and to negotiate revised performance levels and price increases for the remainder of the proposal.

The three year review will not preclude companies from lodging new or supplementary proposals. A company's proposed activity may also be subject to review at any time if performance monitoring establishes a company is performing significantly below forecast target levels.