

Australian pharmaceutical industry observed

Jeremy Wurm

Multinationals are investing increasingly in local operations, with indigenous rather than expatriate managements. Scientific jobs are mainly filled by Australian graduates, many with overseas experience.

WHETHER Australia likes it or not, the country is competing in the global marketplace, and Australians have been forced to forsake a long-standing preoccupation with "the tyranny of distance". The fact is that Australia is now firmly entrenched as a Pacific Rim nation, and the pharmaceutical industry has adapted to enable it to prosper. Major changes in the regulatory and pricing regulation systems have increased the local industry's international competitiveness, and Australian scientific, manufacturing and clinical research standards are second to none.

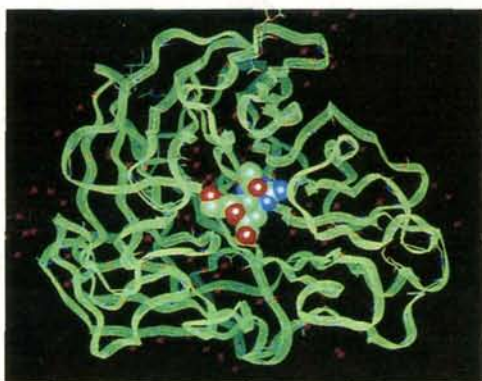
Every organization operating in Australia has to contend with major issues raised by the geographic and demographic characteristics of the continent itself. A highly urbanized country with only 17 million inhabitants, Australia is making progress in its transition into the international mainstream.

Sydney and Melbourne account for over half of the country's population. In terms of pharmaceutical activity, most organizations are located in Sydney, and to a lesser extent in Melbourne. However, Adelaide, Brisbane and Perth can all legitimately claim to be Head Office locations for a handful of pharmaceutical and related organizations.

Foreign ownership

Most Australian pharmaceutical companies are foreign owned, with a few notable exceptions. Off-shore decision making is further complicated in some instances by the fact that a number of Australian subsidiaries report to international headquarters through a regional office, in a city such as Singapore or Tokyo. Physical distance from the centre of international decision making can pose a real problem, especially when compounded with the modest commercial value of the Australian marketplace in relation to the United States, Japan and Europe.

A major disincentive to involvement by foreign companies in the Australian marketplace has always been the volume of the market itself (less than 2 per cent of the world market). Transport costs between Australia and other markets are significant, as are freight charges within the country itself. Transfer pricing repre-



Glaxo's sialidase inhibitor, now under development for the treatment of influenza, was designed by scientists at the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the Victorian College of Pharmacy (Monash University). See Nature 363, 418-423 (1993).

sents another area where potential investors in Australia have often found obstacles to entering the local market. Relatively high total employment costs in Australia contribute further to the dilemma.

Counterbalancing all of these issues, however, is the government's Factor F Programme, which has been implemented with the aim of providing manufacturers with financial incentives to invest in local operations. At least until 1999, the pharmaceutical industry has been afforded the opportunity to overcome many of the

barriers to investment which have existed in the past.

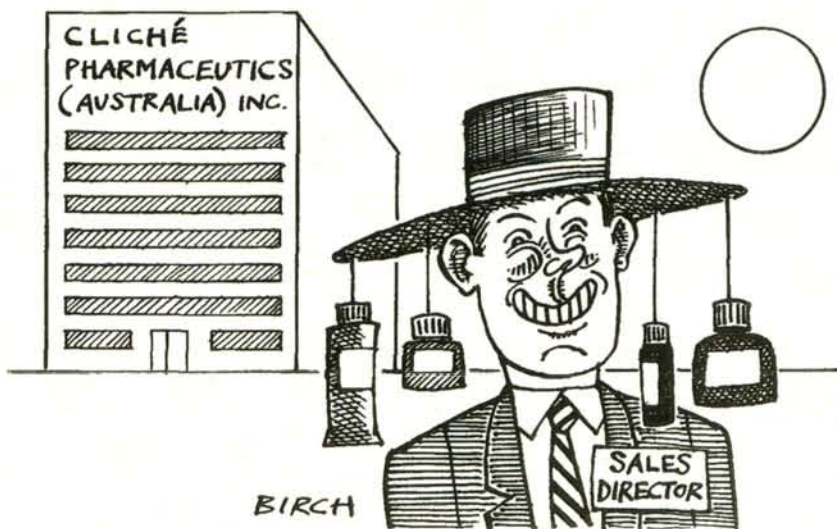
Harmonization

'Harmonization' has been a feature of the past few years, not only in the production context, but also in the broad areas of research and development, regulatory affairs and clinical medicine. In each of these fields, Australia can claim to have satisfied or exceeded the most stringent international performance criteria.

In recent years, the Australian industry has demonstrated a genuine commitment to self-regulation. This has had a range of positive benefits, which include an overall increase in product quality, together with an improvement in the standards applied to product promotion.

The drug evaluation process in Australia has been streamlined and is now compatible with the procedures applied in major world markets. The Therapeutic Goods Act of 1989 represented a major step in improving the relationship between industry and government. In 1991, an independent review was commissioned, and Professor Peter Baume assessed the drug evaluation system, identifying areas for further rationalization.

The Baume report concluded with a range of recommendations, all of which were accepted by the government. The implementation of these recommendations has seen Australian regulatory re-





Glaxo Australia's principal production site and headquarters at Boronia, Victoria.

quirements achieve consonance with European standards. Approval times have been reduced, administrative procedures simplified, and the whole process has become more effective.

The net result is that the relationship between government departments and the industry as a whole has improved considerably. These fundamental changes have encouraged foreign companies to launch new products in Australia, and facilitated the participation of local manufacturers in other world markets.

Manufacturing

Many foreign companies have taken the view that it is not cost effective to maintain full-scale local production facilities, despite the incentives offered by the Factor F pricing scheme. The result is that manufacturing in Australia is often confined to the less complex formulations, or the organization restricts itself to local packaging of imported finished product.

Until a decade ago, there had been a trend for pharmaceutical companies in Australia to wind down their production facilities. In the light of Factor F and other fundamental changes, there are now clear signs of reinvestment in pharmaceutical manufacturing. There is a concerted effort to achieve compliance with international standards of good manufacturing practice, encouraged by tax concessions which are available to pharmaceutical producers who have gained accreditation.

Australia is a signatory to the Pharmaceutical Inspection Convention. From a commercial point of view, an obvious advantage has been the facilitation of a genuine export market for the Australian industry, and the ability of Australian companies to import from overseas.

Historically, Australia has been a net importer of pharmaceutical specialities,

although there is now a real opportunity for companies to take advantage of the much larger potential markets for pharmaceuticals, in South-East Asia, and beyond. Exporting from Australia has grown dramatically, and the Pacific Rim represents a vast, and previously overlooked, source of income; better pricing has been a major supporting influence and improved regulatory procedures have also had a positive effect.

Scientific development

In almost every case, multinational pharmaceutical companies which have a research base have established subsidiaries in Australia. However, only a few of these organizations carry out basic research in the country, and those who do have a scientific presence here concentrate on development rather than pure research. Carrying out research and development in Australia is far less expensive than in the United States, for example. However, in preference to establishing research facilities in Australia, many organizations nowadays choose to fund universities and research institutes in their own research programmes. In human terms, Australia has no shortage of highly qualified scientists, and the quality of preclinical and clinical research is of the highest order.

When it comes to clinical trials, Australia is a favoured location for studies, on the basis of costs and medical expertise. This has come about through close collaboration between the industry as a whole, and independent research centres, including hospitals, universities and specialised research establishments.

Significant breakthroughs in Australian research in recent years have been the "gene shears" project, and the development of relaxin. In each case, Australian researchers can claim credit for the initial

work, although support for the advanced stages of many developmental programmes has to originate overseas. While these two projects, among others, have created interest in the broader scientific arena, there are a number of other promising new projects being undertaken, both within the Australian pharmaceutical industry, and in organizations funded by it.

A notable recent development within the Australian pharmaceutical industry has been the burgeoning of the regulatory and clinical functions. Regulatory affairs specialists and clinical research associates have proliferated, whereas the headcount in a number of other functions in the local industry has declined. Australia has seen a trend towards 'de-layering', which has led to flatter reporting structures in many organizations. Middle management functions in many sales and marketing departments have disappeared, with a need for marketing executives to become better negotiators who see international business development as a genuine opportunity.

There has been a trend away from management of Australian subsidiaries by expatriates from Head Office, and the local industry is now run by managers who combine familiarity with the local marketplace with an understanding of international issues which affect Australia. In an industry with a commitment to self-regulation, there is widespread participation in continuing education among pharmaceutical executives, and high levels of tertiary education can be seen in all functions, from sales, through to administration, production and general management. In scientific functions, the industry has continued to attract local graduates of the highest calibre, many of whom have benefited from overseas experience.

Conclusion

The Australian pharmaceutical industry has emerged from the tough economic climate of recent years, and the future outlook is generally positive. Standards which operate in all disciplines within the industry have now achieved parity with the highest international requirements. The local industry is well staffed by executives who are conscious of the need to compete internationally, and who are capitalizing on the country's developing ability to penetrate foreign markets. □

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1. Australian Pharmaceutical Manufacturers Association—Annual Report 1992, 1993 (APMA Inc., Sydney).
2. *Scrip Review* (APJB, London, 1993).
3. *Australian and New Zealand Biotechnology Directory 1993* (Australian Biotechnology Association Melbourne, 1993).