

Towards a socio-political understanding of the pharmaceutical sector

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MUCH IS AT STAKE in scientific and technological, and economic and political, processes pertaining to the biosciences and pharmaceuticals. The value of the global drug industry is approaching US\$500 billion while the health needs of the developing countries are of staggering proportion. From an Australian perspective, opportunities and constraints of medicinal drug policy are associated closely with rapid and possibly fundamental shifts occurring within the worldwide pharmaceutical industry, as well as global regulatory developments. Several articles in this special issue of *Australian Health Review* provide insight into these global dynamics. Other contributions explore policy themes of particular interest to an Australian readership.

Writers on medicinal drug policy and regulation come from a variety of disciplines, including business and management, health and social policy studies, economics, sociology, and political science. The range and volume of the specialised literature on this sector reflects its social and economic significance and its unmatched complexity in terms of interdependencies between business, government, professions, and civil society actors. Most articles in this issue have an emphasis on politics and sociology — this may compensate somewhat for the dominance usually exercised by economists in framing social science research and policy debate on pharmaceuticals.

The articles which follow address mostly under-researched topics. Abraham (*page 150*)

explores the global harmonisation of drug safety regulation. The International Conference on Harmonisation (ICH) process has been under way for well over a decade but is not well understood. It provides a quintessential case of the emergence of a 'global regulatory regime', and the dauntingly technical issues involved are the preserve largely of experts interacting within transnational business–government networks. The implications of the ICH for a wider range of stakeholders — and indeed public health — are not yet on the agenda for research and broad debate, though Abraham has commenced this task.

The huge pharmaceutical companies emerging from mergers and acquisitions operate discovery, development and marketing networks stretching across many countries, linking into the best science anywhere in the world and the most cost-effective locations for production. Growing linkages between these companies and Indian firms, and the broad expansion and upgrading of pharmaceutical research and development (R&D) and manufacturing now occurring in India, will potentially be important drivers of the reshaping of the industry. Research focusing on the Indian pharmaceutical industry's integration into global innovation and production networks has direct pertinence to 'high-tech' industry policy in Australia. India's Central and State governments operate within the same global domain with similar policy aims and apply some of the same policy instruments as their counterparts in Australia. The Indian drug industry will be much discussed in Australia in years to come, most immediately as a low-cost supplier of high-quality generics (see Malhotra & Lofgren *page 182*).

'Big pharma' and its academic supporters emphasise the role of markets and risk taking,

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but Benner (*page 161*) points to the centrality of the state as organiser and source of funding of basic research. He demonstrates that the emerging 'bio-economy' is increasingly dependent on state activity and thus politics. Indeed, 'regulation' is now almost as central a buzzword as 'global'. Competition applies not only in markets but between governments in the provision of favourable conditions for industry development. Australia is competing for pharmaceutical R&D and manufacturing activity with locations around the world, including India and indeed Singapore which is now "one of the world's leading pill producers" as the result of a "unique cocktail of state planning and capitalism" (*The Economist* 14 August 2004). As explained by Benner, competitiveness requires 'clusters' grounded in private-public partnerships. The most striking feature of the process of discovering and developing new medicines is that it brings together a wide range of different private and public actors with fuzzy border lines between public and private. Drug discovery and development is a social undertaking with implications for health and well-being across the globe and must be shaped and regulated ultimately by the people of both developed and developing countries.

Policy-makers in Australia — well aware of international trends in terms of government participation and the significance of 'clusters' — have put in place intricate mechanisms for supporting pharmaceutical industry competitiveness through the Pharmaceutical Industry Action Agenda program. Under this umbrella, the various components of the biotechnology and pharmaceutical industries work in close partnership with the Department of Industry, Tourism and Resources. A major objective is to strengthen opportunities for multinational corporations, local firms, and research bodies to expand activities in Australia on the basis of domestic strength in areas such as basic scientific research, and a capacity to cost-effectively operate clinical trials. The aim is to double Australia's share of the global pharmaceutical

industry by 2010. The Pharmaceutical Partnership Program, providing \$150 million over five years, is expected to drive an increase in R&D investments. Evidently, the focus is on economic development and health and social dimensions are paid little attention. It is conspicuous that groups first and foremost concerned with health and social policy are effectively excluded from the Action Agenda, notwithstanding the growing significance of consumer and patient health advocacy groups within the broader pharmaceutical domain as explored in another article in this issue (Lofgren *page 228*).

Globalisation does not necessarily preclude choice and effective policy interventions within nation states. Davis' analysis of the experience in New Zealand of 'active management of the pharmaceuticals market' through a state agency, Pharmac, demonstrates that there is continued scope for policy innovation even in small countries (see Davis *page 171*). The Pharmaceutical Benefits Scheme (PBS) also illustrates powerfully the possibility of achieving nationally determined health and social policy objectives. Yet the impression from the debate on PBS cost increases and 'sustainability' (which has been going on for decades) is that health and social policy options in this area are now more constrained than in the past due to the cost of new lifestyle drugs, demographic change, and other factors. Sansom (*page 194*) explores the challenge of retaining the PBS as a program grounded in principles of fairness and equity. His particular focus is on the concept and practice of cost-effectiveness analysis as a key step in making decisions on the listing of drugs on the PBS. The concept of cost-effectiveness is relatively easily understood at an abstract level, but complex and conflictive issues arise when this approach is put into practice. Australia is at the forefront of international developments. There is every reason for analysts to continue to monitor closely the PBS listing process and the role of the Pharmaceutical Benefits Advisory Committee (PBAC).

The prospect of a Free Trade Agreement (FTA) with the US (now finalised) has given rise to a

lively policy and political debate on whether cost-effectiveness and rational drug use can be retained as paramount principles underpinning the PBS. Sansom, from his unique perspective of the chairmanship of the PBAC, presents an assessment that differs somewhat from Harvey's analysis which pinpoints the openings provided by the FTA for more effective pressures by the 'big pharma' companies for higher prices and delayed generic competition (see Harvey *page 218*).

There are few analyses of the role of generics in Australia, partly due to the historically marginal presence of generics in the PBS market. The share of generics among dispensed medications is however now above 20%, and the formation in 2001 of the Generic Medicines industry Association (GMiA) signals the emergence of a distinct generics sector (though this lobby group is tiny by comparison to Medicines Australia). Probyn's article (*page 207*) is the first Australian exploration of the shadowy phenomenon of pseudo-generics, a term which refers to drugs that are identical to their brand alternatives in the sense that they are produced by the same manufacturer, probably in the same factory, and simply repackaged. The purpose of introducing such 'fighting-brands' is to manipu-

late competition following patent expiry in order to protect the revenue and de facto market share of the original brand supplier. Policymakers must wish for greater transparency, and further research and more policy debate on the role of generics in Australia is surely warranted.

From time to time a media debate erupts on retail pharmacy regulation or, rather, deregulation. Major change does not seem to be imminent, but the literature on community pharmacy in Australia and its role in health policy and in the drug production and distribution chain is characterised by a paucity of in-depth analysis. The article by Benrimoj and Frommer (*page 238*) provides a convenient overview of the current state and future potential of the pharmacy sector. Even less well understood is the role of consumer groups and the notion of 'patient power', though such groups play an important role in health and drug policy processes in Australia and elsewhere, as explored in the article on this topic (Lofgren *page 228*).

It would be easy to enumerate themes central to an understanding of pharmaceutical policy in Australia that are not addressed in this issue. But the articles published here will hopefully prove useful and stimulate further research and discussion. □