In 1991, I did a review for the Government, produced a book and reformed the drug pharmaceutical licensing system in Australia. It was a major and successful exercise. In September 1992, I was invited to a meeting of the International Pharmaceutical Manufacturers’ Association in Singapore and set out what I had done in the previous year.

In 1991, Australia began a major reform of its drug licensing system and is implementing the outcomes now. This course of action follows a report done for the Government during the first half of 1991 and accepted by the Australian Government. A public service task force has been established to implement all the recommendations.

Australia’s drug licensing system evolved, like that of other Western industrialised countries, during the 1960s in response to disasters like the thalidomide tragedy. That particular event had impacted heavily on Australia. Indeed, many of the early reports about the adverse effects of thalidomide came from Australian sources. Outsiders—that is, people not trained in pharmacology—understood little about therapeutic drugs generally but could comprehend the adverse effects of thalidomide; it was the dramatic simplicity of the thalidomide disaster that led to action.

In responding to that tragedy an Australian system of drug licensing and evaluation was put in place. It stressed safety and, to a lesser extent, efficacy. It did not stress efficiency or timeliness. It evolved over years, becoming progressively more complex, more bureaucratic, more technical, more idiosyncratic and more difficult.

One result was that Australia became an unsatisfactory market, one to which companies were loath to go. Companies figured that they could market products with less difficulty in other places, that anyway Australia represented only 1 per cent of the world market, that Australian prices for therapeutic drugs were too low, and that there was just too much trouble involved in jumping through the hoops required in Australia, as Australian regulators controlled the licensing process. Although the minister took advice from a committee of experts, that advice went through a delegate who happened to be the senior regulator. The same officer happened to be the person who serviced the expert committee. Certainly he could control the agenda of the committee and the flow of advice to the minister. What happened was that if the regulator was overruled in the expert committee on any matter he could then veto the committee recommendation later in his capacity as ministerial delegate.

Officers developed over time a unique Australian format for new drug applications (NDAs), and built so many steps into the process that it was painfully slow. Further, most therapeutic drugs are supplied to the Australian public on a national formulary for which the Government pays only about half the current world price. So the low price was another disincentive to companies.

Not only that, but the officers were determined to keep the system as it was. They believed fervently that other systems were deficient in not examining the individual data of every patient, and they managed to prevent any action on no less than seven previous inquiries into the licensing system. That there were seven inquiries was itself a measure of industry and political dissatisfaction with the performance of our regulators. Officers managed even to prevent full use being made of opportunities presented by a memorandum of understanding with Sweden.

One main element of the problem, by the time of the 1991 review, was major confrontation between the pharmaceutical manufacturing companies and the industry organisation on one side, and the regulators on the other. The degree of mutual dislike and mistrust became marked. In itself it became one extra Australian problem.

Finally, it got through to very senior officers, and to ministers, that we had a serious problem. It was in light of this that the 1991 inquiry was conducted, culminating in a report that was made public in July 1991. The Government set up the inquiry, funded it and gave it good resources. Consultations were held with most affected parties—regulators, officers, professionals, manufacturers, unions, consumers. One innovative event was a ‘confrontation meeting’ at which various parties were presented with the different things they had asserted—
often about each other—and invited to fight it out there and then. It was a most productive encounter. Another technique was to gather many interested parties together for relatively unstructured public meetings of some hours’ duration.

That report made 164 recommendations for change, all of which were accepted immediately by the Government. Officers had stated confidently during the inquiry that they had beaten the other seven inquiries, and they would beat this one too. They had a formula for beating inquiries but it was possible to short-circuit their process and to prevent their well-tried formula from operating. Each recommendation had a time frame attached and officers are attempting to meet the times laid down. Some rearguard action continues and will result probably in some subversion of some recommendations and reforms.

The outcome of the review was a printed report known to some of you. The process itself, even before any report appeared, started some change, the Government decision to accept the recommendations helped further, officers then dug in to resist what they could, and the implementation team has worked to give effect to much of the report.

Significant recommendations were

- to accept NDAs in European Community (EC) format
- to pursue international harmonisation in relation to requirements for NDAs and for sharing results
- to end the requirement for routine provision of individual patient data
- shortened target times for evaluations
- increased fees, payable in part on performance
- the engagement of a top administrator to run the agency
- an obligation for the agency to achieve the outcomes identified
- simplified arrangements for the very ill
- an end to confrontation between companies and the agency
- an acceptance of the balance between safety and timeliness
- mechanisms to allow recruitment of more academic evaluators.

It is the hope of all concerned that international companies will see again that Australia can be a sensible place in which to seek to market drugs. We hope to re-establish a viable pharmaceutical manufacturing industry in Australia and to allow safe and effective drugs to be available for our community. We hope that effective drugs will be available more rapidly with benefits to ill people—we want to avoid ever having a repeat of the situation in which long-acting oral morphia came on to the United Kingdom market in 1981, but was not available in Australia for another 10 years.
If the licensing system is reformed there will emerge new problems associated with the national formulary. Issues such as which products are listed and what prices are paid remain to be settled. They will occupy more of the attention of industry leaders as questions relating to licensing become less critical.

One gains from an exercise of this kind a certain amount of incremental progress. What varies is the amount of the increment. On the old analogy of the archer who fires an arrow successively halfway to the castle wall, we may never reach a goal of perfect drug evaluation procedures. But while we make progress, things are on the right track. It may be that the Australian reforms of 1991 are no more than one step on the way. But at least we have made a start.
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