A consumer comment

The Australian consumer movement is deeply concerned about the Industries Assistance Commission (IAC) draft report on pharmaceutical products because: 1. It threatens to abandon a drug approval system which has served Australia well, to follow the lead of other countries which generally do not have as good a record as Australia does in protecting patients from unsafe and ineffective drugs; 2. It threatens an "Americanization" of pharmacy through an onslaught of mass media advertising of potent drugs and a retreat from a professional model of pharmaceutical retailing in favour of a chain-store model; and 3. In spite of evidence that many poor consumers economize by not purchasing the drugs that are prescribed by their doctor, it contributes to the momentum for recouping an ever increasing proportion of the cost of drugs from consumers.

Drug evaluation procedures

The most irresponsible of the Commission's recommendations is that Australia should relinquish its national sovereignty in protecting Australian consumers. If any one of a number of other countries on an unspecified "list of designated countries" has approved a drug for marketing, then Australia would be expected to approve it automatically. The IAC does not suggest which or how many countries would be on this list. For the sake of argument, let us assume that it is a list of 10 countries which are believed to have the tightest drug control policies.

The IAC proposal would mean that if nine of the 10 countries banned the drug, Australian consumers would still get it because just one country had approved it. The Commission has not considered the fact that this might be a country with a much more sophisticated system of postmarketing surveillance than we can afford. Even though the one country of 10 which permits marketing might do so under tightly monitored conditions, the IAC proposal implies "open season" on Australian consumers.

The IAC approach is unreasonable because Australia has a superior system of drug evaluation compared to that of many developed countries. The cautious approach that is taken by the Australian Drug Evaluation Committee (ADEC) has protected Australians. Benoxaprofen is a well documented case. ADEC did not approve marketing: Britain did, resulting in 61 known patient deaths. (The IAC describes this reaction in these 61 deaths as something of a "panic" because there were so many users of the product. For a critique of this aspect of the Report, copies of the Australian Federation of Consumer Organizations — Australian Consumers' Association [AFCO-ACA] submission to the Commission are available from the author.)

In its recommendations the Commission does not recognize the need for the Commonwealth Department of Health to monitor the standards that have been adopted by so-called designated countries. Language barriers will make continuing monitoring of the evaluation standards of a country such as Japan difficult and expensive.

The proposal fails to understand the politics of the regulation of pharmaceutical products in many of the countries whose lead we would be forced to follow. Often products are approved for marketing in the home country of a transnational corporation because industry ministries have lobbied successfully for marketing on the basis that, unless the home country approves the product, other countries will not buy it. This is particularly so now that many Third World countries with no drug regulation resources have a policy of prohibiting imports of drugs unless the product has been approved for marketing in the country of origin.

What often happens then is that approval is granted in the home country of the transnational company for reasons of industry policy rather than for health reasons. The health departments of the home country then use extraordinary measures to restrict the practical levels of exposure of their own consumers and to monitor carefully such exposure as does occur by means of extensive postmarketing surveillance. Of course, other countries which assume wrongly that the home country approved the product for sound health reasons do not impose these extraordinary postmarketing controls.

One of the reasons why Australia has a balanced drug approval system is that we do not have this special kind of industry policy pressure for marketing approval on behalf of indigenous transnational corporations that one can observe in Switzerland, Germany, Japan and other countries.

Drug marketing decisions in Australia are made more competently and less corruptly (see page 3 and Appendix 1 of the AFCO-ACA submission to the IAC for the considerable evidence of massive corruption in the pharmaceutical industry overseas which has been largely avoided in Australia) than in other countries, and on the basis of sound health policy rather than profligate industry policy.

Faster access to new drugs is not always to the benefit of consumers. There is no guarantee that doctors will acquire accurate knowledge of how to use such drugs more quickly and appropriately. Until there is an adequately organized way of providing doctors with unbiased postgraduate education on new drugs, there is every chance that drugs will be misused and cause more drug-induced illness. Deaths that have been induced by adverse reactions to

prescription drugs have been estimated variously as ranging from 30,000 to 130,000 a year in the United States. It would be hoped that this problem is less severe in Australia, although no one really knows. Fast access to drugs that represent major therapeutic breakthroughs is imperative, but we have seen no evidence of tardiness by the Department of Health with genuine breakthroughs.

The consumer movement view of the Commission's analysis of drug evaluation procedures is that it is long on deregulatory rhetoric and short on evidence. If the Commission feels that there has been an unreasonable delay in marketing some drugs, it should list these drugs so that those who are concerned with the protection of consumers can subject them to critical scrutiny. If the Commission knows of drugs that would be of great benefit and minimal risk to consumers that are being excluded from the Australian market, we would appreciate this information being made public, so that we can lobby the Minister for Health to make them available. If, as the Commission claims, consumers are being forced into "more expensive and/or less satisfactory [non-drug] treatment" because of delayed access to new drugs, we would appreciate being informed about these cases also so that we can protest to the Minister.

Advertising and retailing

The Commission proposes the removal of regulations that restrict the sale of Schedule 2 and 3 products to pharmacies and of regulations that restrict the advertising of these products. Favorable consideration has also been given to allowing advertising of prescription drugs in the mass media. The implications of this proposal are frightening. For example, nitrazepam can be sold without prescription in Victorian pharmacies as a Schedule 3 drug. The effect of the IAC's proposal would be to allow Coles and Woolworths to sell nitrazepam in Victoria and to advertise the product on television.

Advertising of drugs in the mass media is the vanguard of the pill-popping culture. Young people need to develop a tolerance of frustration by following adult role models who withstand and cope with the stresses of everyday life. However, drug advertising in the mass media in countries such as the United States exposes young people commonly to opposite role models — adults who resort to chemical solutions for frustrations that range from headaches to insomnia and mild anxiety. The advertising is pervasive. Senator Gaylord Nelson in his Senate hearings found that the annual expenditure on the advertising of psychoactive non-prescription drugs in the United States exceeded the government's allocation of funds to combat drug abuse? How the importance of adult role models in...
This situation is now fairly well established.

Evidence exists that parents who are users of tranquilizer, barbiturate and stimulant drugs are more likely to have children who are users of marijuana, LSD, and other drugs.4

The consumer movement favours strategies to provide more objective information about drugs to medical practitioners, by means other than advertising, and it favours the retention of a professional delivery model for pharmacy.

The Pharmaceutical Benefits Scheme

The consumer movement also generally supports the status quo on the pharmaceutical Benefits Scheme, although we strongly support the recommendations of the Commission in favour of generic prescribing as a way of reducing the cost burdens on taxpayers. There is no way in which the industry can guarantee that the higher prices that are paid by Australian taxpayers for brand-name drugs will be converted into life-saving research and development in the Southern Hemisphere.

Direct government grants for research and development are the only way to do so.

The IAC is concerned to make consumers, particularly pensioners, more price conscious by having them pay more of the costs of drugs. Consumers are concerned at the trend to make them pay a higher and higher proportion of drug costs. In 1980, when the patient contribution was five shillings (50 cents), this represented 22% of the average cost of drugs; today, at $5, consumers are paying 74% of the cost.

A study of low-income families in Sydney has indicated that less than half the families bought the medicines that had been prescribed for them.5 Worse, some families who could not afford to fill their prescriptions borrowed what they thought were equivalent drugs from others. In another study of 800 families, 25% of respondents had difficulty in affording pharmaceuticals.

Conclusion

The IAC Draft Report on Pharmaceutical Products is a classic illustration of how the rhetoric of industry deregulation can be carried to irresponsible lengths. Australian patients will be the victims of any dismantling of our drug evaluation system, of a jettisoning of restrictions on mass media advertising of drugs, and of a shift to the American model of pharmaceutical marketing and retailing. The entrepreneurial spirit of drug marketing includes risks that the IAC report does not fully recognize.

References