Consumers' Health Forum

Submission

Cost Recovery Inquiry
Productivity Commission

1 December 2000

Introduction

Consumers' Health Forum (CHF) is the peak organisation representing consumers on national health care issues on behalf of more than one hundred health consumer organisations. These member organisations represent a range of consumer interests including specific disease groups such as diabetes, asthma and HIV/AIDS; population groups for older people, women, young people or men; special interest areas such as consumer rights, carers, maternity and chronic conditions; and state based or local community health organisations.

CHF has been involved as a stakeholder in developing and implementing the National Medicines Policy since its ground-breaking work in 1988[1] and 1989[2] to obtain recognition of the value of developing a more rational drug policy for Australia. CHF has participated in the debate around many aspects of the regulatory process for medicines, which is central to achieving the central objectives of Australia's National Medicines Policy:[3]

- timely access to the medicines that Australians need at a cost individuals and the community can afford;
- medicines meeting appropriate standards of safety, quality and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable industry.

Cost Recovery by the Therapeutic Goods Administration

CHF believes that its work to identify, preserve and strengthen the community service obligations of the Therapeutic Goods Administration (TGA) is of particular relevance to the current Productivity Commission Inquiry into Cost Recovery.

Consumers' concerns before the TGA change to full cost-recovery

In the August 1996 Federal Budget, changes were announced to increase the operational cost recovery from industry for the national regulation of therapeutic products to achieve full cost-recovery from 1998-99. CHF's 1997 discussion paper[4] recognised that these changes may result in benefits to consumers from more timely access to new products and information. Funding of the TGA through industry contributions was also recognised as being in the public interest through facilitating efficient and effective operation of the TGA. However it was considered important that cost recovery from industry did not result in interpretation by Government, industry or the community as industry "ownership" of the regulator's policy or practice.

CHF identified the need to distinguish certain community service obligations of the TGA from services to industry undertaken by the TGA, albeit in the public interest, around the pre-market evaluation and post-market surveillance of therapeutic goods. These community service obligations of the TGA were seen as including but not limited to ensuring:

- consumer input to policy development, standard setting and decision making processes
- ongoing safety, quality and efficacy of therapeutic goods after marketing approval, for example through tracking and recall of unsafe or faulty products and consideration of consumer reports on adverse reactions
- community access to information about medicines
- accountability to the community of TGA's independence from industry influence.

How well have consumers concerns been addressed?

The TGA has made some steps to address the community service obligations summarised in the bullet points above. Consumer representatives are involved on a range of TGA and industry committees. These include TGA committees such as the National Drugs and Poisons Scheduling Committee, co-regulatory committees such as the Therapeutic Goods Advertising Code Council, and the TGA Industry Consultative Committee which provides an opportunity for industry representatives to comment on and provide input to the TGA's policy development and financial management.

However, as outlined in a recent submission made by CHF in collaboration with the Australian Consumers' Association (ACA) to the Regulatory Reform Taskforce,[5] consumers have a range of problems with public health and safety regulation, including the TGA. The TGA is complex, confusing and inaccessible to consumers and is not consumer focused, although working 'for the good of consumers'. This paper outlines several specific examples where the TGA's cost recovery relationship with industry appears to have accentuated these problems for consumers.

Examples of the impact of cost recovery on consumers

Example 1- consumer input to policy development and decision making

The TGA, while working 'for the good of consumers' has not actively sought to engage with them in the regulation of products over the years. This has changed somewhat in recent years with consumer representatives being appointed to a number of committees, but there is still a long way to go before the TGA and its processes can be described in any way as being consumer focused.

Consumer input to regulatory processes is important to ensure that the decisions that are made really are in the best interests of consumers. For example, some years ago the TGA's Australian Drug Evaluation Committee (ADEC) rejected a marketing application for a new drug to treat endometriosis. The application was rejected on the grounds that one of the side effects was the later development of osteoporosis, which ADEC considered to be unacceptable. However, the drugs already being used to treat this condition caused unpleasant hormonal side effects for women affected by endometriosis. For many consumers, the side effects caused by the unapproved drug were preferable to those caused

by the approved drug, and the organisation representing consumers with endometriosis moved to lodge an appeal against the decision. The TGA then called a round table meeting, and the ADEC decision was changed to allow the new drug on the market under limited conditions. While this was a clear example of why consumer input into the drug evaluation process is important, there is still no process for consumers to have a voice in the drug evaluation process.

As noted in the Australian National Audit Office *Drug Evaluation by the Therapeutic Goods Administration – Follow-up Audit* in July 2000 (3.42, page 55):

"In late 1999, TGA advised ANAO that it had reached agreement with the Consumers' Health Forum on an initial framework for piloting inupt on consumers' perspectives on applications involving new chemical entitities. The Consumers' Health Forum advised the ANAO that TGA and the pharmaceutical industry do not appear to have considered consumer consultation in the cost recovery equation for drug evaluation."

It would appear that the move to full cost recovery has meant no action because the TGA is solely funded through cost recovery from industry. Industry does not see this type of consultation with consumers as part of the cost of drug regulation and the TGA does not appear to be able to ensure that this occurs, despite an ANAO recommendation in 1996.

Example 2 – Information for consumers
CHF is concerned that even where the TGA recognises the need for consumers to be informed, the TGA does not ensure resources are available to consult with consumers or to employ communications expertise to convey very important health messages and warnings to consumers.

For example, labelling is an important source of information for consumers. CHF noted in a submission to the Labelling Project[6] that there is too much complexity for consumers, which stems from having a number of different regulatory codes, guidelines and schedules from a range of sources that all influence labelling requirements. Problems with labelling are compounded because they are designed by people who are not experts in communication. The move towards performance-based labelling of medicines may have some positive advantages for consumers, but effective monitoring and evaluation is essential. CHF has given cautious support to moves to performance based standards for labelling and packaging of medicines, on the proviso that there be effective consumer participation in all decisions about the content and form of regulations.

However CHF is concerned that despite its advice to the Labelling Project that the labelling requirements were not well understood by consumers and the importance of interactive consumer consultations in this area, which was recognised by the TGA, no funding was available for consumer consultations or information.

Since that time, CHF has also raised further information needs for consumers around tamper-evident packaging, knowing to look for it, what to look for, making sure that consumers

understand the wording of the cautions used. Once again the source of funding seems unclear although both industry and TGA would recognise the need.

CHF is concerned that in the cost recovery environment, industry does not see information for consumers as part of the regulation process it should pay for, and the TGA does not have access to funding sources for consumer information and consultation to ensure community access to information about medicines.

Example 3 – Making the TGA transparent and accessible to consumers
Although the TGA and industry have agreed on a number of streamlined regulatory processes including risk-based assessment, which must result in efficiencies for both, consumers are still not well aware of the processes nor are they easily accessible. This becomes a particular issue for consumers when things go wrong, and yet with the shift to risk-based assessment, surely this is where consumers really have a role in early advice of problems.

It is hard for consumers to find where to report their perceived problems with therapeutic goods. There are no real avenues for consumer reporting and further it is hard for consumers to find out about problems that are arising. CHF sees the TGA as having a much greater role in providing consumer friendly safety updates about products which are discovered to carry a health risk after marketing has been approved. For example, the TGA could have played a much greater role in alerting consumers to the risks of using St. John's Wort, rather than relying on information being conveyed through adverse events bulletins and health care providers.

However in a cost recovery environment, it would appear to be easier for the TGA to spend money on making the regulatory processes more accessible for industry, for example through the "TGA Information Kit," rather than on making the regulatory processes accessible to consumers. And the other barrier that consumers often face is the use of commercial-in-confidence exclusions. It is imperative that the TGA only applies this exemption to openness where it is really necessary. Otherwise, industry may try to minimise information for the public, such as early safety alerts, by claiming this as broadly as possible.

Principles for accountability to consumers for cost recovery by the TGA

CHF wishes to commend to the Productivity Commission the principles for consumer focused administrative arrangements for the regulation of public health and safety made by ACA and CHF to the Regulatory Reform Taskforce. These principles[5] are also considered relevant in developing a stronger focus on accountability to the community when cost recovery is used by regulatory agencies such as the Therapeutic Goods Administration and are summarised below.

The twelve principles recommended to underpin the regulatory processes are:

1. The prime objective of the administrative arrangements for the regulatory system should be the protection and enhancement of public health and safety, including protection of the environment, and must not be reduced or compromised by consideration of industry or other interests.

2. There should be a consistent approach to the regulation of the production and marketing of therapeutic goods, food, chemicals and gene technology, so far as they affect human health and well-being.

3. Where there is uncertainty, public health and safety should be protected by using an approach based on the precautionary principle.

4. There should be transparency and accountability of all decision making.

5. Decisions about the regulatory system and the products it regulates should be made in partnership with consumers.

6. There should be comprehensive and readily available information for the community at all stages of the regulatory and marketing process, including consumer information about safety, quality, and efficacy of the products and in food, the nutritional value and content of the product.

7. The regulatory system should be, and be seen to be, independent of industry and political influence. While industry should be asked to bear some of the costs involved in assessing products, government funding must also be provided to enable independent assessment and monitoring and to enhance the confidence of consumers.

8. Regulators should oversee the entire process of the production and distribution of food, therapeutic goods, chemicals and gene technology

9. The regulatory system (including administrative arrangements) should be simple, easy to understand and be accessible to consumers. A single point of entry to the regulatory regime is required.

10. The regulatory system should be efficient and effective to ensure that the community has timely access to safe products and the system is affordable for the community.

11. The efficacy and safety of all products should be demonstrated to an acceptable standard and any potential limitations on either efficacy or safety must be recorded and publicly available as part of the regulatory regime. Any such limits must be monitored and reported on as part of the assessment or registration process.

12. There must be adequate posting-marketing surveillance, enforcement and appropriate remedies for breaches of legislation to ensure compliance.

Conclusion

CHF recommends that wherever regulatory agencies adopt cost recovery, the focus and accountability of the regulatory agency remains the protection of public health and safety, including protection of the environment, which must not be reduced or compromised by consideration of industry or other interests. Further, the regulatory agency should include in its stated objectives, meeting the community expectations of the regulator, based on the principles outlined above. As such, the regulator should be accountable to the community in transparently reporting on its achievements against these goals.

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[1] **References**

[i] *Developing a Rational Drug Policy for Australia – What Does it Mean?* CHF, Canberra, 1988
[2] *Towards a National Medicinal Drug Policy for Australia.* CHF, Canberra, 1989.
[3] *National Medicines Policy 2000.* Commonwealth Department of Health and Aged Care, Canberra, 1999.
[4] *Community Service Obligations: Identifying and Preserving the Public Interest Role of the Therapeutic Goods Administration.* CHF, Canberra, 1997.
[5] *Submission to the Regulatory Reform Taskforce from the Australian Consumers' Association and the Consumers' Health Forum of Australia. October 2000.* Available on CHF's website: www. chf.org.au
[6] *Consumers' Health Forum Submission to the Labelling Project 99/00 Discussion Paper,* Effective by Design. *June 2000.* Available on CHF's website: www.chf.org.au