
EXPANDING THE BOUNDARIES OF SELF-MEDICATION IN A GLOBAL CONTEXT

Consumers: ignore them at your peril

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Although I am a guest and it may be considered rude to be critical, I need to say that I have become increasingly concerned as this conference has proceeded. I think it is time to engage in the debates which you need to have. The issues are there. They have been raised explicitly or implicitly by many speakers but the questions which arise from them have not been asked. Let me comment on four.

There is a constant tension between a free market philosophy, which as manufacturers you tend to favour and the appropriateness of regulation for the public good. On what bases do those tensions get resolved? One answer given through the papers presented has been to put strong pressure on regulators to regulate less. Or it has been suggested that as manufacturers you should think outside the box whereas it seems to me that you would be jumping out of one box and into another – with the regulators. As consumers where the boundaries are drawn affect us intimately. Let us have this debate and engage us in it.

A barrier to the appropriate level of regulation has been said in some countries to be the self-interest of professional groups. Mr Danjoh has made that point quite eloquently. There is a real need to engage professional groups in the issue. If the consumers are also represented, there is a greater possibility of shifting the debate more productively onto what is the appropriate level of regulation or access for the appropriate use of particular products. Consumers may often be your allies in these debates.

A theme throughout has been that self-medication saves government money and that this argument can be used in influencing government towards favourable treatment, in “switching” decisions, for example. Whilst there is no doubt that there are community interests in containing government cost what you have failed to address is where do the costs shift to. They shift to the consumer. From our point of view, there is a question of appropriateness of medication so that costs, for whoever pays, are justified.

Two contradictory positions have been put about the consumer role in medication. The argument for self-medication has been the one that consumers are better educated, better informed and make responsible decisions about their medications. At the same time, some papers have been arguing that consumers need to be more socially responsible. Andrew Herxheimer has argued from the floor for better education for consumers. What is the real position? The fact is that for better or worse most people manage their health most of the time as best they can with the resources available to them. The barriers are largely structural, as Nadine Gasman, for instance, has shown. People will make decisions for themselves, which may be rational for them given all their circumstances, but may not lead to appropriate use of medicines. As an example your agreement with WHO to work on smoking cessation is notable, but where is smoking uptake increasing most rapidly? In poorest communities. What choice will these people make between spending on 10 cigarettes a day or ten times as much on a medication assisted quitting programme?

Introduction

In the changing environment in which pharmaceuticals are being marketed consumers must become not only your market target but your partners in the development and maintenance of health in our communities. You, knowing your own cultures and particular segments of the industry are best able to judge the risks in not taking account of consumers.

Let me offer a few confessions. In my paid working life, which was cut short by illness and disability, I had several interesting jobs with policy development at their core. I had been a child welfare worker and an adult parole officer when I was thrust into the task of modernising our child welfare legislation. I took the initial steps in this task in total isolation, drawing only on my own experience of what worked and didn't work for me as an officer using the legislation. My work was highly commended and approved by the hierarchy within which I served. I was pleased with myself. It was another ten years before the legislation was in fact changed and then thankfully it was changed after extensive consultation and with very little of my work intact. My proposals were inappropriate and so unacceptable to other parties with an interest in child welfare that they were unimplementable. It had not dawned on me then that the subjects of the legislation should have a voice. Indeed, I did not even have the wit or wisdom to consult other interested parties. Since my work was approved I assume that in the 1960s this was a common failing in government.

Later, and indeed wiser, I was employed as a social planner in Australia's National Capital planning authority. The city had a growth rate of 7% per annum, unprecedented in Australia. New precincts were being built almost as soon as they were on the drawing board. The haste resulted in roads, housing and offices but little in the way of social infra-structure. This time it was obvious to me that residents needed to be consulted though it was clearly a novel idea to my superiors. How to consult with residents who hadn't yet moved in and weren't yet known? We overcame that challenge with a mixture of consultations with people from previous new towns and gathering of potential residents. A highly participative local forum developed where competing interests were declared and discussed. There was no lack of information on which to base policy and planning decisions. What resulted was a very active lobby group that put pressure on planners and government for more services, sooner. When limited budgets were used as a reason for delays the group began to uncover inefficiencies in the planning authority and to make life very uncomfortable for it. Changes had to be made inside the organisation and its processes had to become more transparent.

There are other stories but I am loathe to expose myself more. Suffice it to say that I learned a lot about consultation, participation and the power of the consumer voice. I learned that policy made without users was bad policy. It was often ineffective. It sometimes made life easier for those with the power, those in the know, but it rarely changed things for the better.

Then I became ill and an unwilling consumer of health services and products. I had a wealth of experience about how policy is often made(and should not be), as well as a

few clues about the validity of the consumer perspective and how essential it was in the development of good policy. I have spent the better part of my life (and I mean better in every sense of the word) working with other consumers so that we could establish our own policy agenda and contribute effectively and accountably to the policy of others.

Who are consumers?

As manufacturers, you have no difficulty in recognising consumers as the purchasers and users of your products. In English, at least, this is the true and original use of the word. In many countries we have also taken over the word and given it a new "political" meaning. We have used it to counter the concept of the passive "patient" of the western medicine tradition. We have used it to organise ourselves, to share our stories, to do our own research and to develop our own policies. In Australia, we guard jealously our right to speak for ourselves. In some countries, I know that those who speak for us are themselves health workers, particularly in the field of public health. When others speak for us it is important to determine which role they are truly representing. It is human nature to easily confound the assumed interests of others with our own.

When consumers organise there is a tendency for other interests to dismiss their voice as "merely" ideological or political. Generally, this is a mistake, though it is always legitimate to question the credentials of those seeking to represent others. At an assembly such as this where you come together because of your own similar interests and where you seek to identify your commonalities and learn about differences it should not be difficult to acknowledge that this is also a legitimate approach for users of your products.

I may seem to be labouring this point. I wish to identify it at the beginning for two reasons. Firstly, it deals with the questions of legitimacy and accountability of the consumer perspective. Secondly, recognising the organised consumer voice also helps to consider ways in which consumers may be involved in policy beyond traditional market research and clinical trials.

What is policy?

This is the simplest and most difficult question to address. For my purposes in this discussion, there are two important elements to good health policy. It should be based on principles which can be made explicit. The Guiding Principles released during this conference are an excellent example of this. Outcomes can be tested against these principles. For example, a policy to extend market share might have principles related to health outcomes for particular populations, or principles related to quality use of medicine. The principle may simply be to grow returns to shareholders or to force another company out of business. These principles can then be examined. Are they compatible? Are they mutually exclusive? Do they really match our objectives?

The strategies and tactics for implementing policies are the areas where most attention is focussed. To be able to implement policies the legitimate interests of other sectors will need to be identified and acknowledged. This is often the area in health policy formulation where con-

sumers become invisible. *I spent about five years in a wheelchair and that contraption had a remarkable capacity to make me invisible. Shop keepers used to ask my carer if the clothes I was trying on fitted; doctors asked my husband if I was feeling pain; waiters asked my companions if I was satisfied with the meal.* Policy making seems to have the same magical effect. It makes consumers invisible.

Why involve consumers?

I wish to suggest three of the many arguments there are for involving consumers in your policy making.

1. Consumers are necessary informants.

This is not an argument in much contention in your industry. As marketers you know the value of market research, of testing your market and targeting your product and promotion. You do this by finding out what consumers do, and what they say they do or would do. You analyse which people do what I wish to suggest that there is more to be known. The why, the what else? In other words something more about the broader context in which people make their choices and behave in the way they do. Dr Gasman has made some of these issues clear in her paper.

While your marketing arm will be primarily interested in consumers in the traditional sense, as users of a product, your company as a whole will be interested in the appropriate and safe use of your products. You will in fact be interested in the medication process as much as the medicinal product. Is your product being used in a way that optimises its effectiveness and minimises risk. Appropriate use, that is, quality use, is your aim. For your product to be used appropriately you may need to be sure that other products, used in conjunction are taken into account. At the individual level you will need to know a lot more about why your consumers behave in the ways they do and how, if necessary to influence that behaviour. At the general community level there will be good reason for you to consult with consumer groups and your competitors and regulators to develop ways to encourage the most appropriate use of all the products. Strategies and campaigns for behaviour change which do not include information and ideas from consumer are likely to fall far short of their target.

2. Consumers can define the real problem.

Choice and access are the two consumer needs which providers of products and services readily quote as the consumer justification for expanding their market or for seeking to switch products. The right to choice and affordable access are indeed two important rights in the consumer charter of rights. Information and redress are two others which seem to be less often quoted by those who are not in the position of being a consumer.

My own experience in consultation with groups of consumers around primary health care and pharmaceutical services is that the most frequently raised problem is that of the limited information available on which consumers can base decisions about their health care. This is as true for over the counter medicines as for prescription products, even though it is generally recognised that the risk of inappropriate choice may not be as great. This is why we

are pleased that the consumer initiative which has led to the work of the Labelling Dialogue is making progress during this week.

Redress is not a comfortable topic but it is a concern. We need well structured post market surveillance programmes which are transparent in the community. Ideally we want an adverse event reporting system which caters directly for consumers and is not dependent on mediation by health professionals.

Of course there are concerns from time to time about availability of particular products and genuine concerns about the cost of medicines. In Australia where many prescription drugs are subsidised by government there is still a concern about over-all costs particularly for individuals and families experiencing chronic conditions. The switch of stronger anti-fungals in Australia improved access but indirectly created a new problem of cost, particularly for consumers with chronic conditions who are regular users of these products. After the switch the government removed its subsidy adding significantly to the cost burden of many people who are already disadvantaged with high, unsubsidised health costs.

Identifying what the particular concerns in any community are in relation to specific conditions and the availability of treatment can lead to policy making which genuinely addresses the community's need. I have not heard consumers express the need for ten products with the one formulation, for instance, yet it would seem that a lot of "research" and promotional money is expended in such products to the health benefit of not one additional person. If you are working in partnership with local consumers you will not talk so glibly about information or education; you will not focus on growing the market share without addressing efficacy. You will ask questions about quality use when you talk about more sales.

3. Involving consumers is ethical

We all deserve respect for our experience, our priorities and our capacity to contribute. The self-medication industry puts a high value on individuals' capacity to choose and to make appropriate decisions about their health care. It is a natural extension of these principles to involve consumers and their representatives in policy making and planning. In fact the question arises: is it ethical in the health industry not to model healthy behaviours?

The Australian experience

In Australia consumers have had a unique opportunity to demonstrate that their involvement in policy and planning can make a difference. In 1988 a national organisation was formed by community groups with an interest in health and health based consumer groups. This organisation, Consumers' Health Forum (CHF), which I had the privilege to chair for four years and from whose Board I have just retired, has been able to focus the voice of health care consumers on national health issues. It does this in several ways. It consults with its members and consumers more widely on particular issues, identifying consumer needs, priorities and ideas, uses this work to develop policies and then lobbies on these matters. Alongside this it runs a programme of identifying consumers with particular interests to represent consumers on

national government, professional and industry committees. Sometimes these representatives have a brief to carry the policy of the organisation into the committee but mainly consumer representatives are simply carrying their own experience and the shared experience of others into forums where this knowledge can inform discussions. It is here that the value of the consumer as informant and as one who can articulate the real problem can be invaluable.

It was through Consumers' Health Forum in the late 80's that consumers were able to raise concerns about the lack of a rational medicine policy in the country. Consumers developed a discussion paper identifying their issues and concerns and tentatively proposing some solutions. This paper was distributed for comment to industry, professional groups and to relevant sections of government. I have to say that it was not well received by industry at that time. Your own fledgling organisation reacted as business often did in those days to consumer critiques. It was defensive and negative and dismissive of the relevance of the consumer view. You were not alone. The regulatory authority, the Australian Medical Association and Pharmacist organisations were equally uncomfortable with the proposals. It didn't matter how long clearance of drugs took: safety was paramount. Consumers didn't need direct information about medicines: just trust the doctors. Consumers didn't need to worry: pharmacists only interest was in caring for them. Yet from within each sector there were individuals saying, yes you are right about this issue or that. There are problems. With an understanding government and a consortium of other individuals we were able to have a National Rational Medicines Policy, consistent with WHO guidelines, adopted. Many of our specific recommendations for moving the policy forward were immediately implemented. Consumers had focussed on the three arms of the policy addressing safety, access and quality. In adopting a policy acceptable to all parties we recognised that a viable industry was a necessary fourth arm for a balanced policy.

One such proposal was for a round table of representatives from all sectors with an interest in pharmaceuticals to meet from time to time to work through issues of concern to each. This became the Australian Pharmaceutical Advisory Council (APAC) which meets at least twice a year and reports to the Health Ministry. It has exposed the leaders of each sector to the issues and concerns of the other and has forged some remarkable alliances. Consumers and industry have, for instance, been working together to make the product information, which industry is required to produce for consumers, into an effective tool to promote the quality use of medicines. We are less strident in our criticism of self-regulation of industry because we have been able to come to some agreement about a co-regulatory system, that is, a largely self-regulatory system underpinned by legislative sanctions. Consumer representatives sit on the advertising code councils of the prescription and over the counter industry organisations, initially because government required it. Now I think industry associations have come to see us as an ally in their efforts to establish good practice across their industry.

Following our recommended review of the government regulator consumers and industry alike achieved

what was wanted in a more timely approval process but one that did not jeopardise safety. Consumer representatives now sit on most of the technical advisory committees which consider the safety of medicine and recommend on their approval for distribution and sale. Our views are sought on other policy issues by the regulator from time to time. A consumer representative also sits on the committee that makes recommendations about the classification of medicines. Should they remain on prescription? What criteria should be used to allow a product to switch. At times the consumer representative has had more in common with the industry representative on this committee than with the various regulators and medical specialists. They still have a tendency to say "No" in an attempt to protect against all risk rather than look at the balance between access and safety as the consumer representing competing consumer interests is bound to do. I certainly am not easily convinced by the argument of medical specialists that control of access must stay in their hands. Our experience has been that they often do not share the amount of information we seek and that their continuing paternalism works against our capacity to play a part in our own health management. Your industry representative and I as consumer representative worked in concert to force the committee to be more transparent and consultative. It was tough but the committee now operates within agreed guidelines and has criteria against which it makes its decisions. The affected bureaucrats found our alliance surprising.

Although change comes slowly and consumers remain frustrated that some of their policies have still not resulted yet in tangible outcomes we are convinced that our presence has made a positive difference. I take the invitation of consumer representatives to speak at industry conferences such as this that we are in a new era and have discovered the value of cooperation. I have been told that a senior regulator recently commented that Australia would not be where it is now (in good standing internationally) in relation to medicines if it weren't for Consumers' Health Forum.

Can the experience be applied elsewhere?

Consumers' Health Forum is unique and it came about through a unique set of circumstances. However, the need to involve consumers for better policy and better outcomes remains everywhere. In some of your countries the consumer voices may be muted, silent or even silenced. In some places public health workers will speak, or purport to speak for us. In many places elected politicians will claim their ability to speak for consumers on all issues. But where you have a market you have consumers. The challenge is to listen to their experiences, their issues and concerns and where possible to engage them in discussions about what you want to do and how you plan to do it. Perhaps the most important contribution you can make is to continue to value our voices even if you cannot yet hear them clearly.

In other places, you will be well aware of organised groups of consumers. You may find them critical and their voice strident and not at all to your liking. We can get very angry when we are not heard. Conversely, we can be constructive partners when you pay us attention. *I am reminded of my grandson, who when young spent*

much time in the garden and in the shed “working” with his grandfather. At night he would tell his parents about all the work he had done. “But if you are doing all this work” his father asked “what are you being paid?”. He answered quite confidently “I’m being paid attention.”

In some cases, you will be ready to engage with consumers regarding policy and practices but not have an obvious way of starting the process. This is a problem our general practitioners (family doctors) found when they first tried. “We don’t know any consumers,” they said. Start with your patients, we suggested, but in different settings and based on a different relationship. Perhaps a questionnaire asking them for ideas to improve the practice or what their main health concerns are. Bring a group of them together to share their experiences and to bounce ideas off each other. If they are valued for themselves and not simply as patients, you may be surprised at what you hear. The same may apply to your market research focus groups and panels.

In Australia, we are still on a journey of discovery with each other and about each other. Consulting takes time. The agenda of a company or an industry body may not fit with a consumer agenda. Individuals still make a difference. There is conflict and misunderstanding. The journey itself can feel perilous. For consumers, for example, there are the risks of being co-opted, for industry there are risks associated with shifting direction. For all of us, however, there are the delights of new learning and understanding.

Conclusion

I have not said “ignore consumers at your peril” because I have learned in the past ten years that working in partnership is more constructive. Partnerships are not forged under threat but arise from respect and trust. I have put to you that consumers are not simply users of your products but they are people with experiences and views which can be shared and contributed. There are at least three reasons for involving consumers:

- we have information ,
- we can identify the real problem,
- it is ethical to take account of us.

The Australian experience demonstrates that consumers add value. There is potential for productive partnerships. In the short term, finding the methods and mechanism may be difficult. Convincing yourselves of the need to pay attention to consumers first will enable you to find the means. A new way of working may at first seem, in itself perilous. The risks are worth taking. The journey itself is a healthy one. The destination is better, more effective policy which produces improved health outcomes.

