

# Pharmaceutical policy and the lay public\*

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## Abstract

Almost every national and supranational health policy document accords high importance to the need to listen to and 'empower' patients. The relationship between pharmaceutical policy and the lay public is not direct but mediated by several actors, including health care workers, patient organisations, industry and, most recently, the media. Although the overall aim of health and pharmaceutical policy is to address the needs of all citizens, there are only a few, well organised groups who are actually consulted and involved in the policymaking process, often with the support of the industry. The reasons for this lack of citizen involvement in health and pharmaceutical policymaking are many, for example: there is no consensus about what public involvement means; there is a predominance of special interest groups with narrow, specific agendas; not all decision makers welcome lay participation; patients and professionals have different rationalities with regard to their views on medicine. Because the lay public and medicine users are not one entity, one of the many challenges facing policy makers today is to identify, incorporate and prioritise the many diverse needs. The authors recommend research which includes studies that look at: lay attitudes towards pharmaceutical policy; lay experiences of drug therapy and how it affects their daily lives; the problem of identifying lay representatives; the relationship between industry and the consumers; the effect of the media on medicine users and on pharmaceutical policy itself. The authors acknowledge that although lay involvement in policy is still in its infancy, some patient organisations have been successful and there are developments towards increased lay involvement in pharmaceutical policymaking.

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## Introduction

In this article we look at the relationship between pharmaceutical policy and the lay public. As we will see, this relationship is not direct but mediated by several actors, including health care workers (physicians, nurses, and pharmacists), patient organisations, industry and, most recently, the media.

It is important to be aware that various terms are used in the literature to refer to medicine users and potential users. The term patients or medicine users refers to individuals with a particular diagnosis who belong to a particular group (for example people suffering from chronic illness such as asthma or HIV). However, in the context of pharmaceutical policy – the principles guiding decision making in this field – the broader terms laypersons, lay public and citizen are used.

Whereas the overall aim of health and pharmaceutical policy is to address the needs of all citizens, the fact is that only a very few, well organised groups are actually consulted and involved in the policymaking process, often with the support of the industry.

## The importance of pharmaceutical policy for the lay public

Whether decisions are made on the national, international, supranational or global level, the policies concerning pharmaceuticals – availability, access, and pricing – ultimately affect everyone. Policy decisions concerning the financing and priority setting of pharmaceutical R&D are also issues that affect us all. It is therefore important to ask – whom do decision makers have in mind when making decisions concerning health and pharmaceutical policy? According to one public watchdog organisation, Health Action International (HAI):

What policy-makers seem to have in mind when they talk of 'patients' is quite specific – people suffering from a chronic illness, whose contacts with the health care system are frequent and often serious<sup>1</sup>.

Few would argue that the problems of the chronically ill should not have high priority; however, herein lies the problem. Involvement in the policy consultative process appears to be both limited to and dominated by organisations articulating the concerns and needs of those with chronic illnesses. However, by and large the majority of users of the health care system and recipients of pharmaceutical services are the consumers of OTC painkillers, contraceptive products and occasional prescription drugs such as antibiotics<sup>2</sup>.

On close inspection, the majority of the lay public are not visibly organised, nor do they have advocates who specifically represent them in the policy arena. According to HAI, the result is a narrowing of the debate around the assumption that there is a permanent commonality of interest between patients' groups and the pharmaceutical industry in their common belief that medicines are the primary path to good health. The voices calling for greater focus and spending on prevention and primary health care are often drowned out by a call for policy to support the development of new, specific and (often expensive) medicines aimed at treating chronic disease.

It is therefore disconcerting to find that although health and pharmaceutical policy has a tremendous effect on the public at large, the public is neither particularly aware of nor involved in the policy process.

## The lay public's involvement in pharmaceutical policy

Whereas the lay public are still not visible as major actors in the policy arena concerning pharmaceuticals,

they are certainly interested in policy issues of health, illness and the price and quality of health care treatment. As individuals, the lay public accept personal responsibility for their health and undertake a range of self-directed and motivated health measures on their own.

Their contact is with health professionals directly, rarely with policymakers. It is when individuals (often patients with chronic diseases) join together in groups and networks to lobby both governments and the pharmaceutical industry that they become involved in pharmaceutical policy.

### ***Patient groups and networks***

The birth of lay public interest groups concerned with pharmaceuticals is relatively new, triggered by several examples of medicines 'gone wrong', such as thalidomide and early versions of birth control pills. However, lay involvement in health-related groups and networks has a long history and can be traced to occupational health issues that emerged during the industrial revolution and have continued to impact our health care systems<sup>3</sup>. The issues these groups address are concerned generally with disease or illness experience and the access to or provision of health services. Networks and groups range from small and informal to large, formal and politically active. Although similar in some ways, patient and lay groups differ significantly in others: their goals, how they organise themselves and manage their groups, their involvement in influencing policy, their means of funding, and their relationship to industry and health professionals, for example.

Societal shifts in values from paternalism to consumerism in the health care sector have occasioned an increase in the number and size of patient organisations. The advent of the Internet has been a major factor in increasing the influence of these organisations, making it easier for them to communicate with their members and giving them quick access to information. The role of patient organisations has changed over time from patient advocate to health provider, from giving advice to helping patients become their own advisers, and from a focus on individual experience to familiarisation with scientific knowledge.

The final decades of the 20th century witnessed an almost continuous flow of campaigns and court cases by patient groups and consumer organisations aimed at improving citizens' rights to health care and therapy via greater public access to medical science and information. No longer strictly voluntary, patient organisations and networks are now well funded, well organised and well connected. They have effectively targeted education and prevention, bringing political savvy to the policy arena, where they are important actors.

In the USA, the rise of activism in health care has proved that structural trends change when patient advocates become visible, often forging new types of clinical research and practice. For example, the breast cancer and AIDS movements have both been extremely critical, with large and ambitious followings and charismatic spokespersons who generated 'urgency and support' for their cause<sup>3</sup>. In the USA, activist pressure managed to shorten the Food and Drug Administration's (FDA) process of drug devel-

opment and testing for some types of drugs (called an expedited review), and gained early access to promising therapies before all the data were in (called a Treatment IND)<sup>4</sup>.

A recent study compared the approval times of the FDA and the European Medicines Agency (EMA) for new drugs and found the European agency to be much more reluctant to fast-track new drugs for cancer and HIV/AIDS<sup>5</sup>. One of the explanations offered by the authors is that European advocacy groups are smaller and weaker due to language barriers. However, this is gradually changing as evidenced by patient groups such as EURORDIS, a coalition of more than 200 European patient organisations representing 16 countries (13 EU members).

Another advocacy example is the pressure South Africa and other African nations put on the industry to allow the circumvention of patent protections for HIV/AIDS drugs, thus opening up a market for cheaper generic versions in these countries. Thirty-nine pharmaceutical manufacturers sued the government of South Africa in 1998 to prevent the implementation of a law designed to facilitate access to AIDS drugs at low cost. The pharmaceutical companies dropped their lawsuit in the spring of 2001 after an avalanche of negative publicity<sup>6</sup>.

### ***Industry ties to patient organisations***

It is important to ask: who belongs to the patient organisations? Who runs these organisations? Who funds these organisations?

First, in addition to patients or their close relatives, other people such as health care professionals and industry representatives populate patients' groups and organisations. In most cases, they do not hide their identity, although anecdotes in the international research community feature industry representatives who have begun infiltrating patient organisations – some even posing as patients – in order to use the organisation as a tool to promote their company's products.

A second problem is that it is extremely difficult to find 'purely' lay run and organised patients' groups. It is not unusual to find professional managers organising group activities and planning strategies, and while this need not be detrimental to the organisation, it does open the question of the mediator's role between the lay public and policy makers.

A third problem is that of funding. Patients' groups exist on a continuum running from those totally independent of funding from the pharmaceutical industry to the reluctantly industry-funded to the enthusiastically industry-funded and, ultimately, industry-founded organisations<sup>1</sup>. An example of the last on the list is the International Alliance of Patients' Organisations, which was founded in 1999 and funded by Pharmaceutical Partners for Better Health care, a consortium of 40 innovative pharmaceutical companies.

### ***Citizen involvement in health planning***

Citizen participation in health and health-system decision making has increased around the world for the last three decades. Almost every national and supranational health policy document accords high importance to the need to listen to and 'empower' patients. In some countries, citizens have become key

partners in contemporary public health, and their participation is expected at all levels of current public health activity<sup>7</sup>. Citizen involvement has been included as part of health reform, often in the form of lay health authorities, in Canada and Sweden<sup>8</sup>. The idea of involving citizens in the planning of health programmes is supported by various national and international documents. For example, the WHO Ljubljana Charter on Reforming Health Care of 1996 states that:

Health care reforms must address citizens' needs taking into account, through the democratic process, their expectations about health and health care. They should ensure that the citizen's voice and choice decisively influence the way in which health services are designed and operate<sup>9</sup>.

However, despite the call for increased participation, to date the input of service users into health services in developed countries has largely been limited to customer satisfaction surveys and complaint channels. As one researcher put it when commenting on consumer/citizen participation in health policy:

(The lay) voice has been restricted, while health care needs have been determined in a 'top-down' manner<sup>10</sup>.

According to HAI, involvement in the consultative process is generally limited to or dominated by organisations articulating the concerns and needs of people with chronic illness<sup>1</sup>.

A recent policy analysis of how consumerism manifested itself in pharmaceutical policy on the national level concluded that key actors were only interested in the benefits and limitations of free markets and the extent of public and political control of the pharmacy sector, and that consideration of the needs, interests and problems of medicine users was limited<sup>11</sup>.

### ***Problems with citizen involvement in policy***

There is no simple answer as to why there is a lack of citizen involvement in health and pharmaceutical policymaking. First, there is no consensus about what public involvement means. The lay public and medicine users are not one entity, and it is difficult to find people who are able to follow the technical aspects of policy debates and are also articulate in arguing for the desires and needs of society in general.

Second, as already pointed out, the predominance of special interest groups (with their own specific agendas) in influencing policy presents serious problems. Conversely, the typical users of the health care system (the general population) lack representation for their interests such as prevention, health promotion and improved primary health care.

Third, not all decision makers welcome lay participation in policymaking. The implications of citizen participation on health planning suggest a shift in the role of the traditional stakeholders and health professionals, often making the role(s) of health professionals less clear. Thus their resistance can be anticipated.

Next is the problem of communication between policy makers and the lay public. The scientific literature points out the problem of patients and professionals having different rationalities with regard to their views on medicines. The results of a British study

concerning medicine regulation<sup>12</sup> showed the key difference between experts (scientists) and non-experts (including patients) to be that the experts interpret patient exposure to new drugs as a necessary part of scientific progress for drug development, whereas the non-experts see it as being overly complacent about the risks to patients. Patients can be seen to have a subjective view based on their own experience as well as that of their social network, whereas professionals take a so-called objective view. The problem for policymakers is how to reconcile these differences.

Lastly, as already mentioned above, is the covert as well as explicit industry involvement in patient organisations.

### **Pharmaceutical industry's interest in the lay public**

The pharmaceutical industry is recognised the world over as a powerful and influential voice in policy-making. It is often criticised for its apparent lack of concern for public health issues and for bringing to market products predicted to sell in large volume for a profit, such as Viagra, while ignoring less lucrative drugs.

Until recently, the lay public was of minor importance to the pharmaceutical industry as a target group. Marketing efforts were directed at physicians as commonly holding the right to prescribe drugs to patients, as well as at policymakers in order to shape the regulatory environment. Two developments are changing the lay-industry relationship. First is the increasing tendency by policymakers to shift prescription drugs to over-the-counter (OTC) status. The main rationale here is that consumers choose and pay for OTCs, thus lessening the burden on the health care budget. The industry can market OTCs directly to consumers in most countries, and therefore has increased the emphasis on this target group.

The second development is the direct-to-consumer advertising of prescription drugs (DTCA) currently allowed only in the USA and New Zealand. The effect of such advertising is fiercely debated. One American study<sup>13</sup> showed that a large majority of patients who asked their doctor directly for a specific drug had seen it advertised either in a magazine or newspaper or on television. A study that compared behaviours of patients in the USA and Canada (where DTCA is not allowed) found that DTCA led to increased patient demand only for drugs that had been advertised<sup>14</sup>.

Critics point to the fine line between information and advertising, challenging what they consider to be inaccurate statements as well as the omission of possible side effects in current advertisements. Some patient advocates go so far as to say that consumers have been treated like children – talked down to and manipulated to buy products they don't need.

### **The media – new actors on the scene**

The media play many roles in society today, one of which is developing discourse and opinions about new medicines. Through their power to define and label medicines, the media have had an enormous influence on the lay public and the pharmaceutical

policy arena. For example, in the field of mental illness, the media are the source of the language, concepts and images of psychiatry for many people who have no direct experience with psychiatric illness<sup>15</sup>.

The media play an active role in creating as well as defining news. Media coverage of new medicines has shown the members of the press as willing collaborators in the indirect promotion of new medicines through what is referred to as 'planted publicity stories'<sup>16</sup>. While advertising prescription medicines is prohibited in most countries, the public hunger for news of wonder drugs that promise to save lives, curb disease and ease pain<sup>17</sup>. Conversely, the media are able to shape rather extreme opinions that can be detrimental to certain patient groups who need to take medicines. One author<sup>18</sup> traced the roots of the public image of 'an addicted America' back to the popular press and the widely publicised legislative hearings carried out in the USA between 1955 and 1980. The result was 'common wisdom' about tranquilisers that incorporates the ideas that drugs are invariably addictive; physicians prescribe them carelessly and irresponsibly; greedy pharmaceutical companies aggressively promote drugs despite evidence of risk; and people who use tranquilisers are self-indulgent seekers of fast relief<sup>18</sup>.

There are numerous examples of how the media's concepts and images influence patients' beliefs and attitudes about their medicines, which is likely to have a strong influence on their compliance and acceptance of treatment<sup>19-22</sup>.

A more recent example of the role of the media in the pharmaceutical arena is the recall of the COX 2 inhibitor Vioxx (rofecoxib) from the market. The media were very interested in this incident and critical of how administrative agencies and physicians handled it. Interestingly, little was heard from the public, but there is reason to believe that the Vioxx case will negatively affect the relationship of the lay public to the pharmaceutical industry.

Although research has shown that the mass media can play an important role in the dissemination of information about medicines, the effect of this information on medicine users is still not widely known<sup>19</sup>.

### **Why is lay involvement important?**

We have found very little evidence to dispute the fact that the lay public has little or no influence on pharmaceutical policymaking. This does not alter the fact that if the goal is a full and democratic debate on health and medicines policy, it requires wide public participation that can only be achieved by continually striving for public involvement. Pharmaceutical policy addresses issues relating to access, quality and cost of medicines. The user's experience and perspective is a crucial source of knowledge for decision makers and policymakers. As already mentioned, the WHO has made explicit the need to listen to the *vox populi* and give them a choice about shaping health care services. One means to this end is to support research that studies users' experiences with drug therapy and how it affects their daily lives. As the International Alliance of Patients' Organisations points out:

Patient involvement should not be dependent on the good will of individuals but institutionalised in

policy frameworks in order to become the rule, rather than the exception<sup>23</sup>.

### **Implications for research and practice**

Little research has been done to gauge lay attitudes about pharmaceutical policy. Incorporating the lay perspective into this arena is only possible if decision makers are aware of the needs and preferences of diverse and various segments of the population. For example, one recent study explored lay views of pharmaceutical research and development, specifically pharmacogenomics. The study concluded that the pharmaceutical industry and policymakers need not fear pressure from the lay public to develop new tailor-made drugs based on pharmacogenomics<sup>24</sup>; they are more interested in improvements in drug formulation and packaging.

Another important research topic concerns the increasing use of alternative medicines. There is a misconception among the general public that 'natural medicines' are safer than synthetic medicines. Their popularity continues to increase in many developed countries, and despite the shift towards Western medicines, herbal remedies remain the foundation of much therapy in developing countries. The global trade in herbal remedies is now worth USD 18 billion annually<sup>25</sup>. This issue urgently needs to be addressed on the policy level, especially regarding clinical efficacy and safety.

Despite widespread belief that patient and public involvement is a nice idea, albeit with little or no real justification, research findings on patient and public involvement in health policy show that lay involvement has many positive effects, such as increasing confidence and understanding between patients and professionals<sup>26</sup>. Studies are needed to look at lay attitudes towards pharmaceutical policy; lay experiences of drug therapy and how it affects their daily lives; the problem of identifying lay representatives; the relationship between industry and the consumers; the effect of the media on medicine users and on pharmaceutical policy itself.

There is wide consensus that the voice of the lay public is important and necessary in developing pharmaceutical policy. Because the lay public and medicine users are not one entity, the challenge facing policymakers is to identify and incorporate the many diverse voices.

In this article, we have discussed what we see as the dilemma concerning the enormous effects of pharmaceutical policy on the lay public contra their limited influence and involvement in the policy process. We acknowledge that although lay involvement in policy is still in its infancy, some patient organisations have been successful and there are developments towards increased lay involvement in pharmaceutical policymaking.

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