

DIRECT TO CONSUMER INFORMATION

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Incoherent policy making for medicines and health policies

At national level pharmaceutical policies are integral part of the health policies. This is not the case at EU level where DG ENTERISE, the Directorate General responsible for the competitiveness of the industry and not DG SANCO, the Directorate General responsible for public health policy is in charge of pharmaceutical policy. As a consequence, **EU priorities and policies for medicines reflect both the uncoordinated nature and inherent industrial policy leanings of the decision making structure.** Even the EMEA is seen more as a licensing office than a patient protection agency. Within the Commission, responsibility for health policy is divided between DG Enterprise (dealing with medicines) and DG Sanco, dealing with health policy more generally. We oppose this allocation of responsibilities. We do not do so out of some simplistic opposition to the pharmaceutical industry but because we think it leads to a "disconnect" between important aspects of health policy, and acts as a barrier to coherent policy making. An example of this disconnect is that the issue of "Consumer access to information about Legal Pharmaceuticals" has been put high on the agenda in the discussions between the EU and US for the meeting of the Transatlantic Economic Council (TEC) on 9th November. This is an altogether inappropriate forum for discussion of such an important health policy issue. It seems also that this item is placed on the TEC agenda as part of an effort to reduce regulatory barriers rather than as a means of improving health outcomes on both sides of the Atlantic. (It seems also that this item has been placed on the agenda ultimately at the behest of the US pharmaceutical manufacturers, and not at the behest of any public health authority on either side of the Atlantic.)

We do not suggest that the Commission or DG Enterprise do not care about health, the problem is a different one. **Rather, the fact that medicines are approached as part of industry policy means that health policy, health interests, health professionals, independent health economists and health users have less input into policy making than they should have, and industrial interests more influence than they should have. The effect (but not the intention) is that we get a less coherent health policy.**

We all know that this inconsistency is linked to the provisions of the Treaty (according to which the EU deals with medicines on the basis of its general power under Article 95 of the Treaty to promote the internal market, considering them as any other products) as well as to the subsidiarity principle and to the limited extent of EU competences in health care but this does not justify ignoring the problem, that is the lack of coherence that hinder health policies at EU level. We therefore argue to unify health policies competences within the Commission and for a more concerted action in health.

BEUC position on information to patients

To be effectively engaged and actively participate in their health care consumers need more and better information about health, diseases, treatments and medicines. This information should be independent, accessible, reliable, accurate, appropriate, consistent, evidence based, unbiased, updated, comparative, transparent and understandable. Information needs are very complex and highly individual and it is essential both for policy makers and for health professionals to identify these specific needs and respond accordingly.

There is room for improvement and need to empower consumers who are confronted with a growing amount of information. But stating that there is a "patient information syndrome" and that pharmaceutical company can solve this problem is not true¹: readily accessible sources, adapted to the different national or regional context are available,

¹ BEUC response to the Pharmaceutical Forum consultation, May 2007.

offering patients relevant information to make informed choices. BEUC has already suggested the following policy options outlined below to improve information to patients within the existing legal framework:

- Implementing health education programmes to empower patients
- **Fostering the role of the EMEA as a central and impartial source of information about medicines**
- Making statutory information equally available and accessible in all Member States
- Ensuring transparency of medicine regulatory agencies to guarantee access to drug evaluation data and pharmacovigilance data
- Making pharmaceutical companies fulfil their obligations concerning packaging
- **Including consumers as actors in the pharmacovigilance system**
- Ensuring the existing European regulation on drug promotion is enforced
- Improving package information leaflet content and relevance as a information tool (see also EMEA patients and consumers working party recommendation , March 2005)
- Speeding up the process of the inclusion of information on all the medicines authorised via the different authorization procedures in the Eudrapharm database (at the moment it includes only some drugs authorised by the EMEA)
- Improving the visibility of some trusted websites such as the EMEA and the EU health portal web sites (which, at the moment, are very difficult to find through a normal web search) and exploit synergies between them.
- Fostering national platforms for health information
- Developing networks of libraries for health
- Investigating the possibility of having an EU logo that identifies reliable sources of information that comply with the core principles for high quality information
- **Developing and reinforcing good sources of health information;**
- Giving financial support to initiatives that consider social and cultural aspects
- Supporting information initiatives at national, regional and local level(ex. EU wide campaigns for prevention and promotion, EU health Portal, Public health programme funded projects

BEUC also called the European Commission to conduct a comprehensive study to identify and quantify patients and consumers needs for information on medicines and health related information. We also urged the European Commission to follow the European Union Health policy Forum recommendations to carry on a mapping exercise to identify all initiatives and policies addressing the different aspects of health information.

We strongly oppose any amendment in the current EU legal restrictions on what pharmaceutical companies can do in relation to advertising/information to patients. Any change in current EU law on this point would create insurmountable conflicts of interest. The danger of conflicts of interest cannot be resolved merely by new forms of regulation on what industry can and cannot.

The Pharmaceutical Forum

On the occasion of its last plenary meeting we expressed our grave concerns regarding the High Level Pharmaceutical Forum, notably but not only in relation to its work on information to patients.

In brief **we believe that the Forum has little credibility, both in its composition and methods of working – and this despite the undoubted personal integrity of each of the individual members.**

Furthermore the consultation process in and around the issues discussed in the Forum have been confusing, burdensome and very far from best practice.

As to the composition of the Forum the representatives of patient groups, the representatives of the European Parliament, are overwhelmingly on record as being in favour, in the interests of providing more information to patients, of amending the current provisions of the directive on the advertising of prescription medicines. This view is also apparently shared by DG Enterprise. Representatives the health professions are also present and they could not be excluded but other wise it seems to us that the members of the Forum were chosen on a selective basis. These members are of course sincere and entitled to their view but the Commission should have selected a more representative group.

The selection process for the Working Group on Patient Information and the actual composition of the Group both reflect the wider problem of the composition of the Forum as a whole. Furthermore the Group was given a wide mix of tasks, political, scientific, and advisory that is altogether inappropriate for such a body.

We also questioned the process by which the fact sheet on diabetes was developed. This was a task that should be given to independent experts, working like a scientific advisory committee and not to a sub-group of a working group of the Pharmaceutical Forum. The process of preparing the fact sheet was politicised by the context in which it was developed. The role of the pharmaceutical industry in the sub-group was particularly questionable, especially given the opposition of the industry to the used of the term "unbiased" as one of the quality criteria for information to patients. The industry prefer the term "objective" but objective information can be partial, incomplete and biased by omission, especially in the context of trying to provide full health information to patients – and not just some information on specific medicines.

In general the composition of the Forum and the working procedures give the pharmaceutical industry a disproportionate influence (we do not say control) over the outcome.

Because of the flaws outlined above **we regret to say that the outcome of the Pharmaceutical Forum cannot and should not form a firm basis for future policy** in this area.