TRY OF SOCIAL AFFAIRS AND
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Ref. Public consultation, legal proposal on information to patients (the proposal document does not represent an official position of the European Commission)

Key messages by Finland to the public consultation

Summary

- Information produced by pharmaceutical industry is usually not objective and neutral. Therefore, even with the proposed quality criteria and supervision mechanisms it would be difficult to prevent advertising of prescription medicines to the public. This, in turn, will increase unnecessary consumption of prescription medicines, and hamper with drug cost containment efforts.
- Information given by the industry on basis of article 86(2) fourth indent, directive 2001/83/EC already often contains promotion of prescription medicines. It would be better to direct resources to better monitor this kind of subliminal advertising that to create new kinds of problematic information.
- The proposed supervision mechanism would create a significant amount of new regulatory work.
- Finland supports the view the information provided by the industry should not go beyond-the key elements in the Summaries of Product Characteristics (SPC) and Patient Information Leaflet (PIL). Information provided by the industry should be restricted to SPCs and PILs, and the industry should not give other medicine-related information. SPCs and PILs can and should, however, be further developed. In this context, EU wide internet portals should also be developed.
- If the proposal on pharmacovigilance is linked with this proposal allowing push information by the pharmaceutical industry, concerns about the protection of public health may arise.

Basic principles

Finland welcomes the opportunity to respond to the Commission's proposal for a legislative change in relation to patient information relating to medicines. Patients need good-quality, objective, complete, reliable and non-commercial information about the benefits and risks of medicines. To achieve good treatment concordance, proper knowledge about the positive effects as well as of risks of treatment is essential.

However, following the revision of pharmaceutical legislation in 2001-2004, the consultation processes undertaken during 2007, and the work in this area undertaken by the Pharmaceutical Forum Patients Working Group, Finland believes the proposals do not fully reflect the debate that has taken place or scientific evidence on information channels. It is also problematic that the Commission proposal has been put forward before the impact assessment has been finalized.

In 2001 the Commission proposed a five-year trial relating to article 88 of Directive 2001/83/EC during which the pharmaceutical industry could direct to a limited extent information to the general public about medicinal products used for the treatment of aids, asthma and diabetes. The European Parliament and Council rejected the proposal. In its report of 9 October 2002 the Parliament objected to direct-to-consumer advertising and considered that the Commission's proposal would lead to that. The Parliament was also worried about the circumstance that patients would obtain information about medicinal products but not about other treatments. Therefore, article 88a of Directive 2001/83/EC provided that "the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability."

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Despite the rejection mentioned above, the Commission is suggesting again a framework for the pharmaceutical industry to provide information on prescription medicines to the public. There is a real danger that this proposal would lead, in practice, to direct-to-consumer (DTC) advertising of prescription medicines.

The fact remains (as the consultation and numerous surveys also recognize) that health professionals such as doctors and pharmacists are the primary source of easily accessible and reliable information in relation to medicines. It is crucial that any legislative developments in this area support and sustain that role. Patient information should be based on evidence-based medicine, and therefore, on medicines that have proven cost-effectiveness. Any changes in the area of patient information can only be justified if they are to help patients, and unfortunately, the consultation gives the impression that that principle has been overlooked.

Basic problems of the proposal

Finland supports the Commission idea of creating quality criteria, which should be in line with those of the Pharmaceutical Forum. However, whatever quality criteria are being set, information produced by pharmaceutical industry cannot be considered totally objective and neutral. Within any set criteria, there is always room for different tones and options which may distort the message. By setting a legal framework for this, information carries a risk that in the minds of patients this industry-originating information is given an official label. If the industry is allowed to give information on their medicines, it is very difficult to keep the ban on DTC because in practice, advertising and non-promotional information cannot be distinguished clearly. Even if the distinction is clear in writing, it would not be so in practice but here also the proposed distinction is problematic. According to the proposal, 'Communication not covered by the definition of advertising should be regarded as information'. This principle should be turned around, and state that anything which does not comply with the quality criteria is advertising.

It should also be added that *the provisions already provided for in the directive 2001/83 are problematic.* For example, general information to human health or diseases without reference to a particular products given by the industry (article 86(2) fourth indent, directive 2001/83) often contains promotion of prescription medicines. *It would be better to direct resources to better monitor this kind of subliminal advertising that create new kinds of problematic information.*

Second, within the proposed framework it is *probable that the information provided will be focusing on areas with the most interesting commercial potential, and at the same time many areas for with remarkable public health interest would be left uncovered. This will increase unnecessary consumption of prescription medicines, and hamper with drug cost containment efforts.* The proposal is markedly that of the developed countries, and does not take into account undeveloped countries and their health problems. Further, when information is produced by actors with interests on particular products, the idea of problem-based information where medicines are seen only as one tool in the vast area of different problem-solving possibilities may be distorted.

The Commission has a good intention of keeping the new system within acceptable limits. However, even with the proposed monitoring system it would be very difficult to attain this goal. There is a real danger that the proposal would lead to DTC despite the new co-regulatory system, and even if there is a clear objective of avoiding unnecessary bureaucracy, *a significant amount of new regulatory work will be created by the proposed legislation.*

According to the proposal, the industry would need to inform national co-regulatory bodies about their activities before action is taken. The bodies should monitor the contents but there would not be a validation prior to dissemination of information (ex ante). This mechanism would not always be sufficient. If a company gives a general description of their activities to the co-regulatory body and then disseminates material of a forbidden nature, possible sanctions can only be applied after the damage has already taken place.

Finland is satisfied that in the Commission's view the information provided by the industry should not go beyond -the 'key elements' in the Summaries of Product Characteristics (SPC) and Patient Information Leaflet (PIL). SPCs and PILs are already required by the existing legislation, and their information is accu-

rate. Both PILs and SPCs can also be further developed in order to serve both professionals (especially SPCs) and the patients (especially PILs).

However, according to the proposal, the industry would also be allowed to give other medicines-related information on, e.g., about scientific studies and prices. Adding these categories creates possibilities for bias and skewed information and this could not be prevented or controlled by the proposed monitoring system.

Therefore, information provided by the industry should be restricted to SPCs and PILs, and the industry should not be allowed to give other medicine-related information. This is especially important when it comes to "push" information (TV and radio, printed material actively distributed to citizens, etc.). The Commission staff working document (20.12.2007, SEC(2007) 1740) states that there is little support for "push" mechanism even within patient organisations.

If information is restricted to SPCs and PILs, monitoring would not present a problem. Otherwise, ex ante validation by the proposed monitoring mechanism would in most cases be required. This would entail a lot of bureaucracy, financial investments, and it would still not satisfy the objective of good-quality, objective, reliable and non-commercial information about the benefits and risks of medicines.

In this context, Finland would also like to bring up the pharmacovigilance proposal. The EC legal proposal for a strategy to better protect public health by strengthening and rationalising EU pharmacovigilance will simplify existing requirements. The purpose is to shorten as much as possible the entry into the market of new medicines or medicines with new indications, trusting on the robustness of the post-authorisation pharmacovigilance. If this proposal is linked with the proposal to allow push information by the pharmaceutical industry, there are serious concerns about the protection of public health. The two proposals cannot prevent the marketing authorisation holder to refrain from pushing information to patients on newly authorised medicines, though they are included in a "list of intensively monitored medicines" due to the fact that their benefit-risk profiles have not been sufficiently tested. This should be considered carefully as it must be certain that if delays are removed there cannot be any extra risk for the patient.

The Internet

Article 88a requires that the Commission reports on the information on the Internet.

The Commission recommended in its Communication to the G10 Report (July 2003) that the quality and availability of information to patients is improved. The Council adopted a Resolution on "Pharmaceuticals and public health challenges – focusing on the patients" (2004) and invited the Commission to explore together with the Member States the possibility of setting up an European Information System, with the objective of providing information on medicines in a high quality, objective, transparent, comprehensive, reliable, and up-to-date manner.

The goals could best be attained by developing the databases that already exist, rather than creating new databases or other means. The Commission staff working document (20.12.2007, SEC(2007) 1740) gives a good description of these. EMEA is developing EudraPharm, which will include information on all medicines authorised in the community. This database will include SPCs and PILs, worded in an appropriate and comprehensible manner. The Commission document makes a rational suggestion that this database should seek synergies with other existing instruments, e.g. a link with the EU Health Portal.

According to the Commission proposal, when industry disseminates information on prescription medicines through Internet websites, it should announce such information activities to a national co-regulatory body which should monitor the contents without validating ex-post or ex-ante specific actions.

Finland reiterates that the information disseminated by the industry should be limited to SPCs and PILs. This information already fulfils the quality criteria because it must be readable, objective, reliable, and non-commercial. However, they can and should still be improved. The industry should be obligated to see to it that the information content of SPCs and PILs is updated on a regular basis and that it complies with the information about the benefits and risks of a medicinal product that is available at the time. In this context,

the new information produced by e.g. post-authorisation supervision (periodic safety update reports required by the Directive on medicinal products for human use) and by pharmaco-epidemiological research should be taken into account.

The SPC and PIL texts should be in as many ways as possible easily available to consumers and health care personnel.

A separate product-specific charge could be collected from the industry in the same context as the charge for marketing authorisation. The EU's joint portal for information on medicinal products, which would be based on the already existing portals, could be maintained by means of this charge. In the USA the FDA maintains a Healthfinder-type of a portal for dissemination of information on health and medicinal products. The industry should be obligated to submit SPCs and PILs on every product that has been granted marketing authorisation in all those languages of the EU countries in which the product has a valid marketing authorisation. For example in Finland the Pharma Industry already maintains an Internet site where PILs can be written or listened to (www.laakeinfo.fi). In addition to the SPC and PIL texts, also the portals for health and medicinal product information that fulfil the defined quality and neutrality criteria could be linked to it. Consumers would be informed in which ways they could comment on the quality of the medicinal products information available on the websites (e.g. the DARTS tool developed by the National Agency for Medicines).