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STATEMENT

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European Commission

Statement regarding: Key ideas of a draft legal proposal on information to patients by the European Commission (DG Enterprise and Industry)

1. Background history, stakeholders and process

The issue was introduced in 2001-2004. At the time, there was to be a limited, 5-year trial project regarding three illnesses, after which the project was to be evaluated and its future decided upon. The Environment and Industry Committee abandoned the Commission's initiative. 494 MEPs voted against and 42 MEPs for the proposal. The idea was developed at the leading industrial countries' G10 group, of which the Commission subsequently established the Pharmaceutical Forum. After the 2004 European elections, the majority of its members had changed.

The Pharmaceutical Forum consists of representatives from Member States, three MEPs chosen for their personal merits, and a wide representation from the pharmaceutical industry. To represent patients' views, the Commission has chosen the European Patients' Forum (EPF), which is a "patient organisation" almost entirely financed by and with strong links to the pharmaceutical industry, and which has published a report in support of the project, which was also financed by the industry (EPF; see also BMJ 19 May 2007; HAI-Europe 2005). The Commission has replaced such members who have declined to collaborate with the industry. The Forum was set up without consultation from bodies representing a wider scope of healthcare professionals.

Comments on different statements regarding this issue have been invited, even if previous consultation rounds have not been completed. Currently we are at the fourth consultation on the same issue within ten months. Any comments arising from previous rounds have not been taken into account. **The Commission has yet again released a new document for public consultation, despite that the project evaluation has not been completed.**

2. Pharmaceutical companies' role as a source of information - conflict of interest

In its own statements, the Commission's idea of patient information is focused on prescription-only medicines and "high-quality medicinal information supplied by companies". When information is produced like this, however, **roles and responsibilities get mixed up. When the industry is made responsible for directly informing consumers on medicines, their marketing is brought in through the backdoor. Due to "refined" marketing strategies used, it is impossible for consumers to make a distinction between research-based, genuine information and information that is biased by market forces.**

Industry is not an unbiased and independent source and distributor of information and its distributor. Industry must be disqualified from disseminating information, because therein lies such a clear conflict of interest. The objective of pharmaceutical companies is to create as much profit as possible for themselves and investors. The Commission seems unable to face the fact that different players have different interests and come from different backgrounds. The Finnish Consumers' Association questions the Commission's proposition that there is a need for provision of information directly to consumers by the industry on prescription-only medicinal products. It is the job of healthcare professionals and authorities to provide information to people. In Finland, the professions of medical doctors and chemists were separated a long time ago, because the person who prescribes a medicine must not be able to sell it and profit from it financially. The current EU proposal regards a similar situation: **the commercial information source benefits financially from selling more and more of its product.**

3.The Commission's Communication to the European Parliament and the Council (COM (2007) 862 final, 20 December 2007)

Article 88a of Directive 2001/83/EC, introduced by Directive 2004/27/EC, called upon the Commission to present a report to the European Parliament and the Council in 2007 on current practices, in particular those found on the internet, with regard to information provision for patients. Further, after analysing the data, 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. **The Commission Report does not meet the above-mentioned requirements.**

The Commission does not mention that there are also independent sources of information on the internet. At no point has the Commission proposed to guarantee the functioning of such information sources, developing them and making them more prominent. The Commission is solely focused on the "informing" of citizens on the internet by pharmaceutical companies.

Unlike the Commission states, citizens should not make decisions on prescription-only medication based on the "information" they receive from pharmaceutical companies, and they should not be able to demand certain prescription-only medications from their doctor. Unlike the Commission states, it must not be the role of patients and consumers to "educate healthcare professionals".

According to the Commission, authorities in Member States are quite incapable of disseminating information, whereas the industry is very capable of doing this. This is an astonishing argument. The Commission also seems to think that the industry always disseminates information that is truthful and based on scientific facts. The Commission thinks that pharmaceutical companies also share information on all possible, adverse reactions of their medicines. However, companies have not disclosed all adverse effects caused by medicines, and furthermore, they have tried to hide and understate them for as long as possible. The Commission's suggestions that the **source of medicinal information is unimportant, and that it would avoid unnecessary bureaucracy, are completely groundless.**

4. Contents of the proposal

Focusing on medicinal information only distorts the general view towards all information and treatments being based on using medicines. In reality, patient information directed at

consumers is (mainly) health education and advice, as well as health-promotion and disease-prevention measures.

The information pharmaceutical companies direct at consumers does not fulfil the criteria set by the Commission itself: **the information is not of good-quality, objective and reliable,** etc, **but the efforts amount to sales promotion. The information is selective and vague. It is general practice that the companies employ an emotional approach, use scaremongering with illnesses and conditions, overdramatise them and their effects, make consumers unnecessarily worried about their health and coerce them into a vicious circle of endless self-testing, and unnecessarily encourage them to seek medical help.**

The Commission's own criteria on patient information would not be fulfilled as it would be more and more company-centred and individual companies would be able to:

- choose specific illnesses and conditions on which to disseminate information (i.e. illnesses and conditions for the treatment of which they offer medicines)
- choose specific medicines on which to disseminate information (see above)
- choose what information to disseminate for each medicine (presuming that the information is not misleading), enabling them to omit essential information leading to distorted information
- decide on the volume of marketing resources they use to produce information on different medicines.

In addition:

- weighting of patient information would become distorted, so that non-medicinal treatments and lifestyle changes would receive less attention
- weighting of patient information would be distorted in favour of certain medicines (in particular expensive, long-term medicines, designed to treat unclear conditions in the grey area between health and ill-health, as well as new medicines whose safe long-term use is still unknown)
- weighting of patient information would be distorted to medicalise different conditions (including normal everyday problems, risks and phenomena related to ageing, social problems, personality traits)
- patients and consumers would pressurise doctors for prescriptions for undiagnosed conditions
- patients and consumers would pressurise doctors to change their medicine based on a previous diagnosis into another medicine they have received information on from a pharmaceutical company
- expenses on medication and healthcare in general would rise in many different ways
- healthcare budgets would come under growing pressure
- any adverse reactions would be reported directly to pharmaceutical companies more often

Should patients and consumers require any additional information on prescription-only medicines, this information should be offered to them without any commercial interests. It is thoughtless of the Commission to justify cutting unnecessary bureaucracy (!) by combining commercial activity and medication. Individual patients' and consumers' health and public health issues must be at the heart of the matter, instead of priorities of individual pharmaceutical companies and putting the pharmaceutical industry before public health. The Commission's proposal is neither in line with patient security nor medical safety.

The Commission's legal proposal is not in the best interest of citizens, it does not prioritise patient and consumer interests, and it does not meet their needs or improve public health. The proposal and law amendment would not improve citizens' position as well-informed

consumers. The problems consumers may have in obtaining high-quality healthcare information will not be solved by this legal amendment. **If we want to be aiming at well-informed patients, we are far from the target and indeed heading in the wrong direction. The existing EU regulations must not be accessed and changed.**

5. Impacts on healthcare organisations

The legal proposal is part of the Commission's reforms, which aim at enforcing the competitiveness of the European pharmaceutical industry. The Commission has not stipulated that different interest groups have vastly different views on how they define patients' participation and proactiveness as service-users, and what they mean by consumerism in healthcare. Consumer associations have traditionally talked about patients' position and rights at a general level, and emphasised patient and consumer protection and safety issues. **The industry and the Commission's view on consumers emphasises consuming in the middle**.

The Commission uses a groundless argument that there would be some long-term social and financial benefits from pharmaceutical companies directly approaching consumers. In reality, **the financial benefits would fall on pharmaceutical companies, market research companies, PR agencies, advertising agencies and investors.**

The Commission is ignoring European national healthcare systems, which are mainly tax-funded and based on democracy. The Commission's proposal is not in the best interest of European healthcare systems.

6. Type of actions and monitoring

The proposal's starting point is trust in the industry's spontaneous ethics, which is insufficient. It is a fundamental problem also that any misgivings are only dealt with if somebody takes a proactive stance and makes a complaint.

National regulatory body: **There is no consumer representation, which is in contradiction with the (rhetoric) of health policy that emphasises participation by citizens.** Makeup of the body would include representation from the pharmaceutical industry **- if the partnership was employed in such a way that pharmaceutical companies would be allowed to "self-monitor", citizens' and consumers' interests would not be met.** At an EU level, the Commission would set up under its own leadership a Committee to be consulted before establishing national codes of conduct and to settle disputes. This appears to be relaxing regulation, codes and monitoring, rather than looking after national characteristics and conventions.

7. Action proposals

Patients must have the right to receive information that corresponds to their needs. This objective must be met within the current laws. It is possible to help consumers make well-informed choices by developing procedures within the boundaries of existing laws. In the EU as well as in Finland, there are independent information sources that must be developed, their financing secured and existence made more prominent to the general public by regularly guiding citizens to good sources of information.

8. Conclusion

This project has been underway since the beginning of the millennium in the Commission, Enterprise and Industry DG, and not in the Health and Consumer Protection DG (SANCO). Any issues relating to medicines should be considered as part of the EU's health policy, just as they are at national level, and not as part of industrial policy. All issues relating to medicines must be transferred from Enterprise and Industry DG to SANCO.

References

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