Contribution of Deutsche Rheuma-Liga Bundesverband to the Public Consultation of the EU Commission regarding the Legal Proposal on Information to Patients

Deutsche Rheuma-Liga Bundesverband is the patient organization of people with different forms of arthritis in Germany. Deutsche Rheuma-Liga has 250,000 members who suffer from some kind of arthritis and speaks for about 9 million people with arthritis in Germany. It is the biggest diagnosis oriented patient organization in Germany. The provision of reliable and understandable information to arthritis patients is one of the main tasks of Deutsche Rheuma-Liga.

The EU Commission, Directorate-General Enterprise and Industry, has published a public consultation about a proposal on Information to Patients. Deutsche Rheuma-Liga very much supports the objectives which are laid out in the proposal, namely to ensure patients receive understandable, objective, high-quality and non-promotional information to patients, to maintain the ban on direct-to-consumer advertising of prescription medicines and to avoid unnecessary bureaucracy.

However, Deutsche Rheuma-Liga has strong doubts whether the measures proposed in the document will be able to ensure that these objectives are achieved. Opening the possibilities for industry to provide information to patients will definitely not lead to objective and reliable information to patients and the proposed control measures will lead to an unnecessary need for bureaucracy. We therefore advise the EU commission to change their plans for the legal proposal.

Our concerns in detail:

Objectives and impact assessment, no. 2.2:

The Proposal of the EU-Commission focuses exclusively on the provision of information about medicines. Experiences with the provision of information to patients show that patients are in need of a range of information. They need information about the condition, the different treatment options including medicines, physiotherapy, rehabilitation and self-help possibilities. Patients with chronic conditions, which like arthritis lead to functional impairments also need information about ways how to cope with the changes in their lives and about living and working with the condition. The provision of information about medicines must be seen in this context.
Regarding the key ideas of the proposal, no. 3:

The proposed harmonization of practices of the provision of information to patients in all member states does not take into account that the provision of health care has so far not been harmonized in all member states and that very different frameworks for health insurance/health care provision exist throughout Europe. To harmonize only one aspect of the health care provision system, namely the provision of information to patients, without allowing member states to find appropriate ways of providing information which take the context of the health care system into consideration does not seem feasible.

The proposal states that a clear distinction has to be made between information and advertising. It further states that all communication that is not an advertisement should be regarded as information. In Germany, pharmaceutical industry is so far not allowed to provide information about medicines to patients. There exist, however, a number of internet websites and information leaflets of industry which already give information about the condition and the treatment. These websites are not classified as advertisement, but they mostly do not provide unbiased information. They show that the distinction between advertisement and information is not easy to make and that a lot of information is given with the intent of furthering product marketing. Deutsche Rheuma-Liga is therefore of the opinion that opening information possibilities to the industry will only lead to even more biased and misleading information without real benefit to the patients.

To effectively monitor the information provided by industry in order to ensure that the information is unbiased would necessitate a huge amount of controlling. The European Commission proposes to give this task to a national co-regulatory body. Regarding information which is actively sought out by patients a monitoring is proposed only in cases of complaints. The forming of a national co-regulatory body with an extremely busy agenda is no way to avoid unnecessary bureaucracy.

Deutsche Rheuma-Liga holds the opinion that instead of providing industry with further marketing possibilities the European Commission should strengthen the available providers of good quality information. In order to do this, a first step would be to ensure that the summary of the product information which should be available to the public according to current regulations are in fact made available to all European citizens in their respective languages. The central databases for these summaries should be supported and linkage from all relevant information sites on the internet to this validated information of the relevant medicines regulatory authorities should be encouraged. Additionally printed handouts of this information should be available as not all European citizens have access to the internet.

Regarding the Quality criteria, no. 4:

The quality criteria mentioned would ensure a benefit for patients.
Regarding the proposed structure for monitoring and sanctions, no. 5:

The EU-Commission proposes that national co-regulatory bodies are formed out of public authorities and a mix of stakeholders including healthcare professionals, patient organizations and the pharmaceutical industry. In order to monitor all information provided by industry such a body would have to have considerable resources to be able to monitor all activities of the industry. Even in order to monitor the existing information material in Germany huge amounts of work would be necessary. If information possibilities for the industry were expanded, even further materials/websites would be developed, resulting in even more work. It is unclear why EMEA is seen as having no role in the monitoring process as the validation of the information according to the quality standards including evidence basis will be crucial.

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