Statement on the Legal Proposal on Information to Patients

Merz supports this important and necessary initiative organised by the EU with view to increasing the patient's access to information. We are therefore glad to offer to the EU Commission our experience and knowledge and to participate in the "Public Consultation".

In accordance with the structure in the paper *"Legal Proposal on Information to Patients"* we would like to express the following opinion:

2.1. What are the reasons for the proposal?

***We can only support an initiative of the Commission of the European Union which aims to provide high quality, sophisticated information to its European citizens*.**

With the extensive usage of the internet, medical knowledge in Germany has ceased to only be accessible to a select group of people. Now, internet-savy and English speaking patients can find information everywhere on the Net. International medical journals and scientific databases (mostly in English) have been made accessible online to everyone. US Websites of all sorts give detailed information on medical issues. Who is disadvantaged by the strict current regulations are people with little or no knowledge of English and little or no internet expertise. The "Digital Divide" in conjunction with the existing legislation excludes a whole section of the population from receiving important information. It is therefore only logical to change the legislation based on a ban of advertisements which dates back to a time of mass media without access to the internet.

Patient participation accounts for a considerable part of the success of a therapy. From the point of view of compliance it is desirable to keep patients well informed.

To provide patients with the information they need can improve the quality of the health care, particularly where compliance and drug safety are concerned. Well informed patients have a better understanding of the treatments and therapeutic decisions made for them and typically show a higher level of compliance.

In relation to health care based on personal patient responsibility it is important to support an approach which focuses on providing patients with more information.

In addition, governments are increasingly expecting their citizens to take responsibility for their own health care situation. However, if patients are to take more personal responsibility to make their own decisions, they need more information to correctly assess the risks and benefits involved in this process. Whilst patients are expected to competently make responsible decisions, they are at the same time prevented by our laws to receive high quality medical information which, in turn, is essential in the process of making well informed, responsible decisions. This includes the availability of up-to-date and easily comprehensible information on scientific studies and results.

***Extended medical circles like nurses and health care staff would also benefit from an improved and more extensive access to information for patients*.**

In Germany under the existing legislation, not only European citizens, but also "extended medical specialists" like nurses and carers – recognised service providers of the health care system – are excluded from receiving specialist information. It is these professional groups which will play a much more important role in tomorrow's health care system, considering the change in demographics, the looming shortage of medical professionals and the increasing numbers of chronically ill people. At the moment, it is made unnecessarily difficult for these very professional groups to independently source

information. Without changing national regulations on addressing expert circles these important professional groups would also benefit from an improved access to information for patients.

3.1 Provisions on advertisement

It should be ascertained which body should be responsible for assessing if a particular piece of information can be classified as an advertisement or as information. It is also important to clarify whether the establishment of a complaints centre would be advisable where market players and patients alike could make complaints on specific information offered.

3.2 Scope, content and general principles of the new legal provisions

It should also be ascertained as to who exactly is to define these “specific criteria”.

In this context, it should also be established that pharmaceutical companies would not be able to simply post package information leaflets on the internet or fax them to patients but that they would need to make patients understand how they are affected by the drug and what dosage they should use. Thus, it would be necessary to translate documents containing medical terminology and foreign words into a more easily understandable text.

3.3. Type of actions

No remarks.

3.3.1. Information passively received by citizens

In order to clarify this key point classical editorial online-media and factual online-media such as new and evolving editorial online-media (blogs, youtube) should be added to the scope of available channels.

3.3.2. Information searched by citizens

With reference to the position on “Announcing to national co-regulatory bodies” it should be noted that a formal registration without any approval procedures would, of course, be sustainable. However, this regulation should not be used for the purpose of censoring information. The registration process could be organised within the search engines, like the self registration of your own website. A voluntary registration of the published information on offer could even lead to the establishment of a public catalogue of quality-assured internet resources which, in turn, would be another step forward in the battle against untrustworthy websites. Equally, it would be worth examining whether other sender groups should equally volunteer their web offers.

So far the document has failed to clarify when new information should be registered and how the revising of information should be handled. Is it, for example, necessary to reregister, if a new column or page was to be added to an existing website?

Clarification is also needed on how to deal with the increasing convergence of the media.

3.3.3. Answering requests from citizens

The complaints procedure would need to be explained in more detail in this context in order to reach a conclusive assessment. In particular, the system would need to be protected from unmeritorious complaints.

4. Quality Criteria

There are already initiatives in place which are aiming to implement these high quality claims. The industry is actively participating in these initiatives; not only has Merz subjected the information that it offers to the HON-Code (Health On the Net Foundation) and has been accredited by the Foundation, but it is also following the AFGIS guidelines (aktionsforum gesundheits-informationssystem = action forum for a system on health information).

The standards developed for quality assessment must be transparent as well as accessible and easily understood by patients. This enables patients to adopt similar criteria for evaluation of information offers thus invalidated or not subject to EU law.

The main question in this context is who will establish the quality criteria on what basis and how will they be updated, should the need arise.

It also needs to be decided whether there should be an advisory board on a European level to supervise the development and updating of the criteria established.

5. Proposed structure for monitoring and sanctions

In this context, the establishment of national bodies responsible for quality assurance and modelled on the approach of an independent commission seems to be a feasible, fast and useful approach to help patients in Europe receive high-quality information.

Ideally, national associations of the pharmaceutical industry should take a lead in the establishment of such national bodies (alternative 2 in the proposal) as this would enable them to use structures already in existence.

Successful examples of a voluntary censorship are the “Freiwillige Selbstkontrolle” (FSK) of the German Media Association or the German Advertising Authority (Deutscher Werberat).

It should be decided whether the model of national co-regulatory bodies should be extended to the formation of the EU Advisory Committees. In case of having few or no representatives of the pharmaceutical industry in the EU Advisory Committee the favoured model would be that of an advisory council to the EU Advisory Committee.

It remains to be seen how to deal with untrustworthy information providers outside of the reach of EU legislation. Patients can access this information just as fast as they retrieve high quality and quality assured information offers from trustworthy providers within the EU. Patients in Europe have to suffer the consequences. This calls for a broadening of the proposal.

Conclusion

It is imperative to support regulations which enable responsible pharmaceutical companies to take a more active role in providing the population with information. It is self-evident that the information divulged must be of high quality, sophisticated and easily understandable. The contribution of the pharmaceutical industry is of particular importance because it is the pharmaceutical industry that has the most profound knowledge of the products in question.