nefarma
vereniging innovatieve geneesmiddelen Nederland

Europese Commissie

Kenmerk: SC/BS/2008/02696
Betreft: Consultation legal proposal information to patients

The Hague, 7th of April 2008

Dear Sir, Madam,

In this letter Nefarma as the association of Dutch innovative pharmaceutical industry, would like to contribute to the consultation on the legal proposal on information to patients to ensure good-quality, objective, reliable and non promotional information on prescription-only medical products to citizens and to harmonize the existing situation in Member States.

Nefarma supports the EFPIA contribution on the European Commission Public Consultation on a legal proposal on information to patients. European citizens expect and deserve a modern and comprehensive EU information strategy that will truly benefit them and help to improve public health. Companies have not only unique product expertise but also considerable knowledge concerning diseases, and thus should be recognized as important contributors to health information alongside other key providers such as healthcare professionals, patient groups and regulatory agencies.

Nefarma fully supports the general objectives of the Commission consultation paper. However in order to meet these objectives, a number of clarifications are needed on three key points in order to be fully able to assess their potential impact, and value for EU citizens.

This applies firstly to the proposed governance model. In the legal proposal it remains unclear how such a system would operate in practice. Although being aware that legistive proposals will be presented in form of a EU Directive, Nefarma is concerned that such a model could potentially lead to a 'patchwork' of very different interpretations and implementations in national laws. Self regulation by pharmaceutical industry on European level could work alongside and complement any legislative change as envisaged by the European Commission. A Code would set out minimum

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standards which EFPIA and Nefarma considers must apply in order to make sure that in the member states same regulation is to be followed.

This applies secondly to the fact that EFPIA and Nefarma consider that neither TV and radio programmes nor print media would be appropriate ways to communicate information on specific prescription medicines to European citizens. Instead EFPIA and Nefarma propose a categorization of non-promotional information provision. Difference can be made in pro-active and reference information on diseases and medicines, reactive information on medicines and support information.

Thirdly Nefarma thinks that in the process to obtain reliable non-promotional information to patients, the information of the pharmaceutical industry is only one part of the issue. Nefarma recommends the European Commission to also consult other parties, such as physicians, in this process in order to create a cooperation in the Members States for all parties involved in this process.

Nefarma is prepared to discuss its ideas and different available options with policy makers and interested parties in more detail in order to contribute to the development of a modern European reform of health information provision in Europe.

If you have any questions, feel free to contact me on telephone number 0031-70 -3132291.

Yours sincerely,

Ir. Nellie Kraaijeveld
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