Working for people living with brain disorders

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DG Enterprise & Industry
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Dear Ms Närhi

I welcome the opportunity to submit a response to the public consultation on the *Legal Proposal on Information to Patients* as President of the European Federation of Neurological Associations (EFNA). EFNA engages in activities which contribute to the advancement of neurology and related areas with a view to improving the quality of life of people living with neurological conditions, their families and carers. EFNA wants to promote a meaningful dialogue between science and society. It wants to widen the understanding of research from merely being a search for cures to become the provision of information about quality of life and health economics - to provide evidence which will enable policy makers to effect positive change.

EFNA's aims are:

- To improve the quality of life of people with neurological disorders, their families and carers
- To promote rapid and accurate diagnosis, appropriate treatment, rehabilitation and care for people with neurological illnesses
- To promote better access to information which is accurate and easy to understand
- To promote public awareness and understanding of neurological conditions
- To eliminate prejudice and stigma associated with neurological disorders
- To increase priority given to neurology by policy and decision makers and by health care providers.

I would wish to preface my remarks by emphasising that patient information is a vital support for patients facing neurological and other illnesses. At EFNA we believe that information should be widely and readily available to patients and their carergivers but would emphasize that it should supplement and not replace information provided by the health professionals. EFNA also believes that the company which manufactures a treatment is an excellent information resource about the treatment that currently is not accessible directly by patients. There is no legitimate reason that the information they hold should not be available to the people using their products. For this reason we are pleased that information to patients is being given priority. In light of the activity on patient information elsewhere in the EU, the legislation should be drawn up with input from DG Sanco as well as DG Enterprise and Industry.

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The stated intention of the legal proposal on information to patients is to ensure good-quality, objective, reliable and non-promotional information on prescription-only medicinal products to citizens. This is an objective which we support. However, we note that although the consultation is about information to patients, it is stated that the legislation should *'create a framework for the industry to provide certain information on their medicines to the **public'***. The proposal further states that it relates to making information widely available *'through TV and radio programmes, through printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals'*. It is difficult to see how TV and radio programmes can target patients rather than the public and we hold the view that this differentiation must lie at the heart of any legislation if we are to avoid direct to consumer advertising.

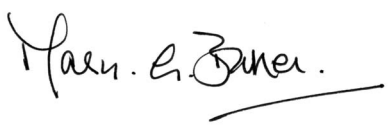
The proposal that a distinction should be made between the cases where the patient is passively receiving or actively searching for the information is appropriate. Any information provided to patients should be compatible with approved summaries of product characteristics but, where specifically requested by patients, the information provided should respond to the request even if this is broader than the approved summary of product characteristics. Appropriate criteria should be in place to ensure the quality of any information provided and it is important that the same quality criteria are consistently applied in patient information initiatives within Europe to avoid confusion.

The proposal states that comparisons between medicinal products should not be allowed, and this is problematic. Patients need to be able to compare the available options and this is made complicated if they must make the comparisons themselves from a range of materials that provide information on one option only. While difficulties may arise if a company is to provide information on the product of another company as part of comparative information this possibility should not be excluded from the legislation.

While the consultation includes proposals for monitoring the legislation more emphasis should be made on making it very easy for *patients and caregivers* to complain. A scheme similar to the Yellow Card patient reporting scheme in the UK would be one way to achieve this. The proposal suggests that the competent authority in member states should *act in the case of repeated and severe cases of non-compliance* but any inappropriate activity may be damaging to patients and therefore any non-compliant activity should be dealt with. Where there is either repeated and/or severe non-compliance, the sanction should be meaningful.

Finally, I would wish that patients as the recipients of information – in addition to patient organisations - are actively involved in contributing to the legislation that is being developed and to overseeing its implementation and monitoring by involvement in both national regulatory and European monitoring committees.

Yours sincerely



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