Working for people living with brain disorders

Response to Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use

Submitted by Mary G Baker on behalf of the European Federation of Neurological Associations (EFNA).

I welcome the opportunity to submit a response to the Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use. 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 wishes 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.

EFNA is concerned about the issue of counterfeit medicinal products for the reasons that are described in the consultation document:

- drugs for serious illnesses are now being targeted
- counterfeit medicines may contain no or very little active ingredient, leading to patients being under-treated or effectively taking placebo
- counterfeit medicines may be contaminated by toxic substances

In addition EFNA has a concern that counterfeit drugs may have misleading or missing patient information which might result in the drug being used

inappropriately, and possibly dangerously, with potentially serious and even fatal results.

We do not have the expertise as an organisation to comment in detail on any of the 'key ideas for change' that are outlined in the document. We welcome proposals that lead to the protection of the patient taking the medicinal product. We do have a concern, however, that any new processes should not lead to substantial increases in the price of medicines. Already many patients – even in Western European countries such as England – cannot afford their prescribed medication and we would not wish to see more patients disadvantaged as a result of increased legislation.

We would agree that any legislative measures need to be complemented by appropriate supervision and enforcement and we believe that patients should be involved in the surveillance for counterfeit medicines in Europe. We would be happy to discuss this with you further.

As an organisation with members whose constituencies covers member states with lower levels of protection of the legal distribution chain, we welcome that this issue is being addressed at European level. We would expect any changes to protect patients equally, wherever they happen to live in Europe and whatever their personal circumstances.

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