BRITISH PHARMACOLOGICAL SOCIETY
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Dr. Ulla Närhi
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02 April 2008

Dear Dr. Närhi

Please find enclosed a response prepared on behalf of the British Pharmacological Society's clinical section to the EU public consultation on Legal proposal on Information for Patients.

We are happy for our response to be made public.
I can be contacted for further information via Karen Schlaegel at the BPS office (ks@bps.ac.uk; 0044 20 7417 0110).

Yours sincerely

Professor Robin E Ferner
Chair of the Clinical Pharmacology Section of the British Pharmacological Society

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EU Public Consultation on Legal proposal on Information to Patients

Response of the British Pharmacological Society

1. The British Pharmacological Society

The Clinical Section of the British Pharmacological Society represents Clinical Pharmacologists – doctors who specialize in the effects of medicines in humans – and those interested in human pharmacology. A principal aim of the Society is to ensure safe, effective, rational, and appropriate prescribing of medicines. We therefore wish to state our views in the furtherance of this aim for the citizens of the EU.

2. The need for patient information on medicinal products

We agree strongly that patients require objective, understandable, and non-promotional information (paragraph 2.2) on medicinal products, in order to participate in discussion and make informed and rational decisions about their own treatment and the treatment of those they care for.

We also endorse the view that such information should, as far as possible, be objective and unbiased, evidence-based, current, relevant, and non-promotional if it is to be of acceptable quality (paragraph 4).

However, treatment choices can only be made when there is objective information on the following:

- the nature and prognosis of the condition being treated;
- the probability, nature, and extent of benefit from treatment;
- the probability, nature, and severity of adverse effects and other harms;
- the direct financial costs (whether borne by the individual or a private or state insurer); and
- the existence of other options for treatment, including non-pharmacological methods.

It will be necessary to ensure that passively disseminated information (termed 'push' information in the Consultation Document) provides or refers to these key elements, if patients are to make rational and informed choices.

3. The difficulties with information provided by the pharmaceutical industry

We endorse the continued ban on advertising to the public (paragraph 3.3.1) and recall that studies suggest that such advertising increases the consumption of pharmaceuticals without corresponding health benefits.

We believe that the conscious and unconscious interests of commerce make it impossible for pharmaceutical companies by themselves to provide information that fulfils the requirements of being objective and non-promotional. While there may be ethical and public-spirited attempts by pharmaceutical companies to improve the public health, there is also evidence or suspicion of unethical or dishonest practices that are counter to the desire for rational, effective, and cost-effective use of medicines for the benefit of the community. These include: exaggerated claims [1]; biased studies and partial analyses [2,3,4]; covert promotion of unlicensed uses [5]; the re-designation of social or cosmetic problems as medical problems capable of pharmaceutical solution [6,7]; and prolongation of drug profitability by minor changes in composition [8] or inhibition of generic competition [9].

We therefore consider that strong safeguards are necessary, and that those safeguards should be independent of pharmaceutical companies.

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4. The necessary safeguards

Given the serious concerns over the ability of pharmaceutical companies to deliver objective, understandable, and non-promotional information, we strongly support the system referred to in the EU report regarding Article 88a. From this we note that in some Member States, provision of information is mainly ensured by public authorities, and includes predominantly product related information they have approved. Many such authorities go further and cover other types of information, such as guidelines on treatments, or comparative information on the value of medicines. This system balances the needs and rights of patients and consumers to have reliable and comprehensible information against the needs of companies to promote the use of medicinal products.

The EU may decide that it is impossible or undesirable to restrict the provision of unsolicited information to public authorities. In that case, we would urge that – given the well-documented difficulties with data from the industry – information put into the public domain should first be seen by the competent authorities and checked against a series of criteria for accuracy, balance, and comprehensiveness. We do not support the notion of a 'co-regulatory body' that included representatives of pharmaceutical companies, since this would be analogous to the accused sitting on the jury.

While we do not wish to set out detailed criteria here, necessary standards for information should at least include the following provisions:

1. when evidence of benefit is claimed, the claims should be put in terms of absolute benefit, not relative benefit, accompanied by information on the baseline effect (measures such as the number-needed-to-treat may also be helpful);
2. when evidence of benefit is claimed, it should be supported by references to material in the public domain;
3. all discussions of benefit should be accompanied by evidence of any frequent or serious adverse drug reactions, with an indication of the likely reliability of this information (for example, the upper 95% confidence limit for the likely incidence of a fatal adverse drug reaction);
4. discussions of safety should be supported by references to material in the public domain;
5. all discussions of a specific medicinal product should indicate the likely cost of a standard course of treatment (for an average patient of the specified age-group) or, when the product is intended for use for periods longer than one year, the annual treatment cost.

It may be that some assurance that information is consistent across the EU, and that the disseminated information is comprehensible to the average school leaver, should also be sought.

5. Secondary sources of pharmaceutical information

Pharmaceutical companies have considerable influence on academic doctors and pharmacists, patient support groups, and expert committees. When a pharmaceutical company helps any of these groups to produce pharmaceutical information for the public, we urge that the same rules should apply as if the information came directly from pharmaceutical company.

6. Information solicited by the public

The public can solicit information on drugs and medicines from many sources, including pharmaceutical companies. Private enquiries and enquiries on behalf of others should be answered honestly and in accordance with the spirit of the regulations suggested. We accept that a regulator could not examine all such information before it is disseminated, although standard information might best be agreed before it is used. We also support the view (paragraph 3.3.3) that complaints should be monitored. We believe that they should also be investigated by the regulator or by an

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independent body; who should have the power to undertake random checks of information supplied by pharmaceutical companies to members of the public.

7. Conclusions

The Society welcomes the opportunity to comment on proposals for the regulation of information from pharmaceutical companies. We argue that such information is not guaranteed to be objective, balanced, and accurate unless it comes from public authorities. At the least, information offered to the public by pharmaceutical companies should meet strict criteria, and should be examined to ensure that it does so before it is disseminated.

8. References

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