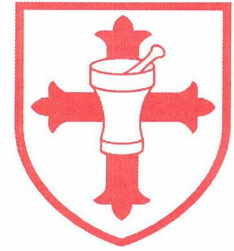

GHP

*Guild of
Healthcare
Pharmacists*



7th April 2008

Ulla Närhi
European Commission

Dear Sir/Madam

European Commission Public Consultation: “Legal Proposals on Information to Patients”

Response from the Guild of Healthcare Pharmacists UK

Thank you for the opportunity to comment on this draft document. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by Primary Care Trusts (PCTs) and pharmacists employed by other public bodies such as the Commission for Social Care Inspection and the Healthcare Commission. The Guild is part of the health sector of the union Unite-Amicus section.

Summary of our views.

We agree with the proposal that EU citizens should have available to them understandable, objective, high quality and non-promotional information about risks and benefits of their POMs and other medicines which healthcare professionals, regulators and others feel meet appropriate standards. The current situation where members of the public search the internet but do not know which information sites are trustworthy is unsatisfactory. The difficulty is, how to achieve this in practice, without allowing the pharmaceutical industry effectively to advertise.

We have concerns that, from the way the consultation document is worded, that the proposal will open the market for advertising. We totally oppose this.

The prime objective should be provision of unbiased information for patients of a suitable quality, and which patients can recognise as such. As written we do not think the proposal will achieve this. The fundamental objective of the pharmaceutical industry is to make a profit, not to safeguard the health of

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the population, so cannot be relied on to produce unbiased information without considerable input from others.

Comments on the detail of the proposal

The legal proposal includes “to provide rules that harmonise practices on information provisions to patients”. If practices are to be harmonised the process must be to raise standards towards the best practice available, NOT to reduce standards to the lowest common denominator.

We agree that the current rules which ban advertising of prescription only medicines (POMs) to the public, but allow advertisement of over the counter medicines, should remain as they are.

We agree that “clear criteria should distinguish information that is allowed and information that is not allowed”.

However, we disagree with the proposal for clarifying “information” and “advertising” such that “communication not covered by the definition of advertisement should be regarded as information”. This is far too big a loophole to leave and will lead to legal uncertainty and unnecessary costs of legal challenges in the courts.

We agree that it should be possible for a pharmaceuticals firm to send information to a patient on a prescription only medicine (POM) which has been prescribed for them, provided the information has been requested by the patient or by a health professional on their behalf, that it is only about that drug, does not compare the drug with any other drug and contains only such information as is allowed in the Summary of Product Characteristics (SPC) or Patient Information Leaflet (PIL) or possibly included in national expert authoritative works such as the British National Formulary (BNF).

We strongly disagree with the proposal as written, which implies that the pharmaceutical industry should be able to disseminate information actively in any on POMs directly through TV and radio programmes, and through printed material actively distributed. This is advertising, even if technically in law it is not, and will have the same effect as advertising eg requests to clinicians to prescribe particular drugs even though this may not be the best drug for them. Health professionals already get enough actively distributed material on drugs and can ask for what they need.

However, there is also the issue in the UK that there are no proper standards for any information on POMs given out on media such as radio and television. If the information on POMs allowed was only the proposed “approved” information this would be a significant improvement on the current situation.

The UK has a “Medicines Information Project” running which allows manufacturers to work together rather than individually under the guidance and governance of a multi-sector stakeholder group, including patient groups, government, the National Health Service, health professionals, regulators and the industry. The group produces “Medicines Guides” from the SPCs and PILs but does find that on occasions this does not include other authoritative nationally recognised information such as in the BNF. The aim is to provide unbiased consistent information of a good standard.

Information produced in this way or in a similar manner should meet specified quality criteria and could be “accredited” and marked so as to show the public it is of an approved standard, along with other material of a non-promotional nature for example a video on how to use inhalers, even if produced by pharmaceutical industry. We commend this model for providing patients with “accredited” non-promotional information, rather than letting the industry have a free hand. Dissemination of the accredited information should still remain in the control of health professionals, not the industry.

Patients also want information on comparative treatments, whether drug treatments or non-drug treatments. The proposal does not seem to address this issue.

The proposal to set up “co-regulatory bodies” in each country to “police” the system could be very expensive and if this proposal is agreed it is imperative that a fair proportion of the cost is met by the pharmaceutical industry.

Our reply may be made freely available.

Yours sincerely

Jean Curtis

Jean Curtis
Professional Secretary