COMMENTS ON

EUROPEAN COMMISSION

PUBLIC CONSULTATION: LEGAL PROPOSAL ON INFORMATION TO PATIENTS

The Royal College of Physicians of Edinburgh is pleased to respond to the European Commission on its public consultation on *Legal Proposals on Information to Patients*.

The College supports the main policy objectives, namely:

1 Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.

2 Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non-promotional information.

3 Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

In addition to the product characteristics and patient information leaflets, the consultation document seems to envisage the production of non-advertising material by the pharmaceutical industry on prescription-only medicines which would be disseminated through television 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. Indeed, there is also the beginnings of pharmaceutical companies supporting patient support groups, with the real risk of active product promotion through presentations at meetings etc.

This seems to go beyond what the companies themselves are seeking (the European industry association makes it clear on its website - www.efpia.eu - that proactive information provided to the public by companies should be limited to general information but not mention specific medicines). Improved information for the public on specific medicines should not come directly from the manufacturers. In addition, there is general concern that information provided in this way should be unbiased and be clearly 'non-advertising'. One other concern is that product related information provided in this way would necessarily be single-product related and not comparative. It would, therefore, be impossible to provide an authoritative overview which might properly inform the patient.

The alternative would seem to be the provision of information by approved organisations such as NICE in England, SIGN in Scotland and the equivalent of these organisations in other European countries.

Whatever the mechanism for providing such information, it would obviously be important that there is also a mechanism for monitoring the content and the quality of that information through some form of accreditation or regulation. In addition, it would be necessary to ensure that the quality of information being provided in each European country was of a comparable standard.

Against this background, there is also the problem of how to control and regulate the information which patients may receive either from direct approach to a pharmaceutical company or via internet websites.

Although this document does not represent an official position by the European Commission, the College wishes to emphasise its concern about the clear proposition that the pharmaceutical industry would play a major role in the provision of objective and unbiased, patient-orientated, evidence-based, up-to-date, accessible, transparent, relevant and consistent information. There are too many current examples of how companies have allowed their commercial interests to influence them into seeking to circumvent their interaction with existing regulations and responsibilities.

The College therefore supports the principles most strongly but call for a major re-think about how these aspirations might be realised.

All College responses are published on the College website www.rcpe.ac.uk.

Further copies of this response are available from Lesley Lockhart (tel: 0131 225 7324 ext 608 or email: l.lockhart@rcpe.ac.uk)

4 April 2008