



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Legal proposal on information to patients

Response by the Royal Pharmaceutical Society of Great Britain to the Directorate-General for Enterprise and Industry

1. Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of regulatory functions within the three Countries of Great Britain that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

2. RPSGB policy on information about medicines for patients

The RPSGB supports the provision of balanced, evidence-based, accurate and accessible information to patients and the public on, for instance:

- a medical condition
- the range of treatment and care options available
- comparison of medicines of a similar type, or for the same condition
- specific medicines.

3. Summary of comments

Based on our policy in this area and the pharmacy profession's experience of providing information to patients and the public, the RPSGB makes the following comments on the EC's proposals:

- We support the Commission's proposal to establish a framework that helps provide citizens of EU member states with understandable, objective, high quality and non-promotional information about the benefits and risks of their medicines and which maintains the confidence of citizens, regulators and healthcare professionals.
- We consider that the main sources of information for patients should be health professionals and other accredited and objective sources which do not have a financial interest in the products themselves. We support continuation of the ban on direct-to-consumer-advertising of prescription medicines (DTCA) (Objective 2).
- We agree with the need for specific quality criteria for patient information. We consider that patients and the public would benefit from the introduction of an accreditation scheme for **all** providers of information so that patients and members of the public can have confidence in the sources they access.
- We accept the case for harmonising practices on information provision to patients and think the EU has a role in promoting these, primarily through the exchange of good practice.
- We oppose the proposal put forward in this consultation to allow the pharmaceutical industry to use TV, radio and other media to disseminate what it considers to be information on prescription medicines to patients. We do not consider that the industry can be regarded as an objective source of information given the nature of its financial interest in prescription medicines and hence we consider that this proposal is not consistent with the broad objectives set out in the consultation document.
- We believe that current EC proposals for a new regulatory framework are essentially premature. Before such a framework can be developed, more work is needed to define what constitutes reliable and objective information, how it is most efficiently produced and delivered and by whom, and what standards should be the basis for quality assurance and, in due course, regulation. We contend that this 'preparatory' work would be a better use of regulatory resources than a new organisational structure for the regulation of information from industry.

We elaborate on these comments in subsequent sections.

4. Provision of information

We agree that patients should have access to high-quality information about prescription medicines but we do not consider that the proposals set out in the consultation document represent a satisfactory way of achieving this. This objective should **not** be linked as it is in the consultation document to the provision of a framework for the industry to provide information on medicines to the public. What is needed is a framework which covers **all** current and potential providers of information and which therefore guarantees good quality 'across the board', including in particular internet sites which are now, together with health professionals, a major source of medicines information for the public.

5. The role of professionals

We welcome the consultation document's assertion that trained health professionals should remain the primary source of health information for the public. We support and promote concordance - an approach to the prescribing and taking of medicines involving negotiation between a patient and a healthcare professional, resulting in an agreement that accords primacy to the beliefs and wishes of the patient. Balanced, evidence-based, accurate and accessible information, provided in conjunction with advice from a trained health professional, supports concordance in medicine taking: it empowers patients, enabling them to take an active role in the management of their medical condition.

Pharmacists are an important source of unbiased, high quality advice about medicines and their use for other health professionals and the public. Pharmacists rely on information resources such as the British National Formulary (BNF) which is published twice a year, jointly by the British Medical Association and the RPSGB. The BNF provides sound, up-to-date information about the prescribing and use of medicines. It evaluates a range of information sources including the manufacturers' product literature, medical and pharmaceutical literature, UK health departments, regulatory authorities, and professional bodies. The BNF also takes account of authoritative national guidelines and emerging safety concerns. In addition, the editorial team receives advice on all therapeutic areas from expert clinicians; this ensures that the BNF's recommendations are relevant to practice. The BNF can be accessed via the internet by anyone, including the public.¹ We would be very concerned if unbalanced information on medicines became readily available to the public, for example through the media.

6. Quality criteria

We agree that quality criteria are needed and that the information provided should be objective, evidence based, up to date, accessible, transparent, relevant and consistent with approved information. In addition we believe there is a need for accreditation of providers of information so that patients and the public can have confidence in the information sources they access.

In October 2007, the Department of Health in England initiated work to develop the Information Accreditation Scheme, which will deliver a nationally recognised programme to reassure citizens that the health and social care information they access is from a reliable source.² It is also the stated aim of the Scheme to raise the overall quality of health and social care information by establishing a clear, accessible standard and providing support for organisations to improve their information production processes. The United Kingdom Accreditation Service has been established as the sole national accreditation body recognised by government to assess organisations that provide certification, testing, inspection, and calibration services against agreed standards. The Scheme is voluntary and funded through application fees. Early experiences from the Information Accreditation Scheme may prove useful to the future development of the European Commission's proposals.

Another initiative from the Department of Health in England will see information prescriptions given to everyone with a long-term condition or social-care need by the end of 2008. Information prescriptions will be given in consultations with a health or social care professional and will guide patients to relevant and reliable sources of information. They will contain a

¹ <http://www.bnf.org/bnf/bnf/current/104945.htm> [accessed 8 April 2008]

² <http://www.dh.gov.uk/en/Healthcare/PatientChoice/Choice/BetterInformationChoicesHealth/Informationaccreditation/index.htm> [accessed 7 April 2008]

series of links or signposts to guide people to sources of information about their health and care, where to get advice, how to get support and where to network with others with a similar condition. In 2007, a pilot project was carried out nationally across 20 sites to provide evidence of effectiveness and impact on the public, professionals and organisations.

7. Ban on direct to consumer advertising (DTCA)

We support a continuation of the EU ban on DTCA. Although the demand for information about prescription medicines from patients and the public is likely to increase, we do not think advertising is the best way of providing it. The aim of advertising is to persuade, rather than to give balanced information about benefits, risks and options. We think prescription-medicines advertising would expose more patients to the potential adverse effects of new drugs than would otherwise be the case. DTCA could adversely affect the relationship between patients and health professionals, distort health-system priorities, disrupt the cost controls operated by the British NHS and other healthcare systems, and would not address the specific information requirements of individual patients.

8. The proposal to allow the pharmaceutical industry to disseminate information

The consultation document suggests that it should be possible for the pharmaceutical industry to disseminate information on prescription medicines through TV, radio and other media. We do not support this proposal.

The consultation document states that the aim of the proposal is to 'enable citizens to get objective information from reliable sources'. The pharmaceutical industry cannot be regarded as an objective source of information because it has a conflict of interest relating to the need to maximise profits. As we argue below we believe that the way forward is to develop a system of accreditation covering all potential providers of information including in particular internet sites.

In its present form the proposal rests on the assumption that communication not covered by the definition of an advertisement should be regarded as information and that clear criteria should distinguish between the information that is allowed from the information that is not allowed. We believe that this distinction is much harder to make in practice than the consultation document suggests.

The exact nature of information that is thought to be "non-promotional" is of key importance. The consultation document goes on to define such information as that which would "focus on informing and guiding patients to correct and safe use of the medicine" and states that this kind of "information should not include any comparative sections between medicinal products".

The de facto distinction between promotional information (which supposedly would include DTCA) and non-promotional information thus depends on a difference in "focus" and a ban on direct comparisons of products. From the perspective of patients and professionals, this is clearly insufficient. Most patients and members of the public would understand non-promotional information as information that does not make a case for a particular medicine or brand of medicine. According to the proposed definition, there is nothing to prevent marketing authorisation holders from advertising the benefits of their particular brand of product as long as their focus is on guiding patient to the correct and safe use of that medicine. It will be practically impossible to sensibly enforce the regulation of the "focus" of information but, more importantly, it also will be completely impossible to tell the difference between "pushed" patient information and commercial advertising.

The consultation paper distinguishes between patients passively receiving information (push) and actively seeking it out (pull) and suggests different regulatory mechanisms for each. In practice there clearly will be grey areas between them. Marketing authorisation holders (and

other information providers under their influence) may, for example, choose to interlink information strategies. A TV programme (pushed information) could be used to invite citizens to request further information about a product (active pulled). To accommodate this, it would be necessary for the monitoring authority or body to include within the quality criteria a requirement that information strategies are not interlinked in this fashion. However, it would be simpler, as we suggest here, that all sources of information were treated in the same way and subject to the same criteria.

If this proposal were introduced it would have to be effectively monitored. We have some concerns about the ability of the regulatory authority or body to monitor a potentially very significant information flow and the costs of doing so. It would be crucial for the success of the scheme that national bodies or authorities have the necessary resources to carry out this task in a consistent manner.

9. EU Role in promoting and maintaining standards

The consultation document proposes that practices relating to the provision of information to patients should be harmonised across member states. We agree that citizens of all member states should have access to good quality information from reliable sources about prescription medicines. We believe however that the main EU role should lie in the sharing of good practice and the promotion of quality standards and that it should be left to each member state to determine the appropriate mechanisms, in the light of their different healthcare systems.

10. Conclusion

We support the provision of balanced, evidence-based, accurate and accessible patient information and thus a continuation of the ban on DTCA and maintain the view that trained health professionals should be the main source of information for patients.

We also consider that the need now is for the development of quality criteria covering all sources of information that patients may wish to access. The EU should not be putting forward proposals which aim to provide a framework for the pharmaceutical industry alone. We therefore do not support the proposal to allow the pharmaceutical industry access to TV, radio media and other media.

At the heart of this proposal is a poorly defined distinction between non-promotional and promotional (DTCA) information which renders the proposal unachievable and unsuitable. As it currently stands, we are not convinced that the Commission's proposal would deliver the level of regulatory oversight that is required to protect patients against the harmful effects of DTCA. We are, moreover, concerned that even a regulatory regimen that provides adequate oversight will fail in the attempt to provide quality information to patients, because the industry in the past has shown very limited inclination to provide information that is genuinely non-promotional.

The proposals put forward in this consultation for a regulatory framework are premature. Before a regulatory framework can be developed, more work is needed to define what constitutes quality information, how it is most efficiently produced and delivered, and what standards should be the basis for quality assurance and, in due course, regulation. We contend that this 'preparatory' work would be a much better use of regulatory resources than an organisational structure for the regulation of information from industry.

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