A Contribution to the European Commission's legal proposal on information to patients

Introduction

The European Medicines Group (EMG) is the UK voice of research-driven pharmaceutical companies with headquarters in Continental Europe. It has 16 member companies. It was formed over six years ago to enable European companies to give their perspective on UK health policy, both directly to policy makers and influencers and as a constructive partner of the Association of the British Pharmaceutical Industry. The voice of the EMG is heard alongside those of the British, American and Japanese Pharmaceutical Groups; the European perspective is an important one, as European healthcare systems, which are generally based on a mixture of public and private provision, tend to be founded on social values that are closely aligned with those of the NHS. Since its launch in 2001, EMG has focused its activities on two main areas; improving access to medicines in the UK to the levels generally found elsewhere in Europe, and improving health outcomes by supporting better consumer access to medicines information.

This paper is a contribution to the emerging strategy for improving public access to medicines information in Europe in response to the legal proposal set out by the Commission.

The European Medicines Group supports the aims of the Commission's legal proposal, and broadly welcomes its content insofar that it:

- Establishes 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.

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

- Avoids unnecessary bureaucracy, in line with the principles of Better Regulation.

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Provisions on advertising

The EMG does not advocate the advertising of prescription medicines direct to the public in Europe (sometimes described as 'direct-to-consumer advertising') but it does support people's right to request and receive health and medicines information from any source, or sources, that they choose, including the pharmaceutical companies that research, develop, manufacture and supply the medicines that they take. Such information should be deemed "acceptable" depending on its quality rather than the source providing it.

We would however like to see more recognition that people's communication and learning styles vary as much as their information needs and wants. Information about prescription medicines should be presented in a variety of formats and through a variety of channels that are widely used by, and familiar to, the public as ways to retrieve, receive and understand information.

We believe that the effectiveness of the information provided will be compromised unless there is encouragement for information providers, including but not exclusively the pharmaceutical industry, to respond to what people want. Encouragement to provide such information should be given by national Member State authorities thereby allowing Member States with a more advanced medicines information culture to move ahead with guidance that supports their patient involvement policies.

In this context, the Internet is an abundant source of branded information about prescription-only medicines in a wide variety of formats and styles but it is mainly of US origin. As the Commission is specifically obliged to consider the risks and benefits of Internet access to medicines information, the EMG would put forward the view that the international nature of the web should be recognised. We propose that global websites providing factual, accurate and balanced information about prescription medicines from companies should be encouraged. They should accommodate country-specific links to national specific information available in the appropriate languages and including legal status and approved prescribing information and other reference information about a specific medicine.

EMG Proposals for an Approach to Change

In the EU, prescription only medicines (POM) may not be advertised directly to the public. The EU legislation that prohibits advertisements defines them broadly, as any "*activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products*"[1]. It gives examples of such activities, mainly activities constituting advertisements to healthcare professionals. It also includes four limited 'information' exemptions to the definition that are not advertisements and therefore fall outside the scope of the legislation. These exemptions from the definition of advertisement are:-

- labels and package leaflets (the content and form of which are separately regulated);
- correspondence (possibly accompanied by non-promotional information) needed to answer specific questions about particular medicines;
- factual announcements (provided that they contain no product claims e.g. pack changes and price lists);
- information on health and disease that makes no reference to medicines (even indirectly).

1 *Directive 2001/83/EC, Article 8*

Broadly speaking, the interpretation of this definition and its exemptions by most EU Member States has resulted in package leaflets (PILs) and regulatory documents such as Summaries of Product Characteristics and European Public Assessment Reports being the only recognised channel through which pharmaceutical companies may communicate information about the medicines they make directly to the public. Any other form of communication, however balanced, accurate and non-promotional is generally deemed to be an advertisement, particularly if benefits are discussed as well as risks because they are regarded as promotional claims.

Whilst PILs provide good basic instructions for use of a medicine at the time that it is prescribed they do not support treatment decision-making nor do they meet the needs of people with long-term medical conditions, whose information needs are known to change over the course of their disease. They, and the other recognised channels, cannot use the powerful potential of modern communications media, nor can they be targeted to communicate effectively with specific populations such as children or different ethnic groups. They are also regulatory documents with a product liability role that often reduces their power to communicate despite recent improvements as a consequence of user testing.

The European Medicines Group believe that the 'information' exemptions to the definition of advertising should be modified to allow for both today's communication technology and the public's right to seek and gain access to health and medicines information from whatever source they choose. The exemptions were originally drafted well over twenty years ago; a period in which there have been great changes in communications possibilities and practice, in freedom of information attitudes and legislation, and in relationships between healthcare professionals and the public. EMG believes that failure to update these exemptions is stifling interpretations that would allow pharmaceutical companies to respond to people's legitimate medicines information wants and needs.

Modification of the exemptions will clearly provide the distinction that the Commission is seeking to achieve between advertising and information provision on prescription medicines and enable EU citizens to get objective information from reliable sources in the format and via the channel they want to receive it.

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Appendix One – EMG Members

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Actelion Pharmaceuticals UK Ltd	BSI Building 13th Floor 389 Chiswick High Road London W4 4AL	www.actelion.com	020 8987 3333	020 8987 3322
Bayer Schering Pharma	Bayer plc Bayer House Strawberry Hill Newbury RG14 1JA	www.bayerscheringpharma.co.uk	01635 563 000	01635 563 393
Boehringer Ingelheim Ltd	Ellesfield Avenue Bracknell Berkshire RG12 8YS	www.boehringer-ingelheim.co.uk	01344 424 600	01344 741 444
Ferring Pharmaceuticals Ltd	The Courtyard Waterside Drive Langley Berkshire SL3 6EZ	www.ferring.co.uk	01753 214 800	01753 214 801
LEO Pharma	Longwick Road Princes Risborough Bucks HP27 9RR	www.leo-pharma.co.uk	01844 347 333	01844 342 278
Merck Serono	Bedfont Cross Stanwell Road Feltham Middlesex TW14 8NX	www.serono.co.uk	020 8818 7200	020 8818 7222
Norgine Pharmaceuticals Ltd	Chaplin House Widewater Place Moorhall Road Harefield Uxbridge Middlesex UB9 6NS	www.norgine.com	01895 826 600	01895 825 865
Novartis Pharmaceuticals UK Ltd	Frimley Business Park Frimley Camberley Surrey GU16 7SR	www.novartis.co.uk	01276 692 255	01276 692 508
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sanofi-aventis	One Onslow Street Guildford Surrey GU1 4YS	www.sanofi-aventis.co.uk	01483 505 515	01483 535 432
Servier Laboratories Ltd	Wexham Springs Framewood Road Wexham Slough Berkshire SL3 6RJ	www.servier.co.uk	01753 662 744	01753 663 456
Solvay Healthcare Limited	Mansbridge Road West End Southampton SO18 3JD	www.solvayhealthcare.co.uk	02380 467 000	02380 465 350
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