To: European Commission

Response to the EU's legal proposal on information to patients

General principles

Datapharm warmly welcomes the Commission's legal proposal on the provision of information to patients. Datapharm fully supports the main concepts for the revised legislation; to establish a legal framework for providing patients with access to good quality, objective information about their medicines across Europe, whilst maintaining a ban on pharmaceutical advertising.

The EU legal framework should reflect the increasing role that patients are taking in their health and treatment, as well as patients' entitlement to access information that meets their needs, from reliable sources, including pharmaceutical companies. We believe that only through access to good quality and reliable information about their medicines will patients have the tools to understand their treatment, make informed choices about medicine taking in partnership with their healthcare professional, and make best use of the medicines they are prescribed.

Datapharm has been directly involved with the development of a new, structured source of information for patients and the public about prescription medicines. This new resource is in the form of industry-funded on-line Medicines Guides, based on regulated product information and available at www.medicines.org.uk. The initiative is governed by a multi-disciplinary Board including patient groups, health professionals, the National Health Service, the Department of Health and the pharmaceutical industry. This project gives us a useful insight into the challenges of developing a non-promotional industry-funded medicines information resource with the support and guidance of all key stakeholders.

We strongly urge the Commission to protect the freedom already enjoyed by patients in the UK to access such reliable, user-friendly medicines information, and not to allow this legislative proposal to restrict current UK practice. The Commission should seek to encourage countries which lack established frameworks for information provision to bring their practices in line with those of the UK.

We believe that the quality standards applied to information about medicines produced by the pharmaceutical industry should, as a matter of principle, also apply to other information providers in all sectors including voluntary and statutory.

The areas of the current proposal where we believe further clarification is needed are summarized on the next page.

Limitation of regulated information
Whilst we agree that the regulated material (SPC and PIL), as legally approved documents, should be the basis for medicines information content (Medicine Guides are written based strictly upon the approved SPCs for medicines), we have however become increasingly aware that, particularly with medicines which have been in use for many years, the SPCs do not always include important information clearly accepted by clinicians and widely applied in clinical practice. We recognize that this has been a limitation in the usefulness of the patient information that we have produced and we consider that additional supplementary information which is not provided in the SPC or PIL would help patients in their understanding of their medicine and in their medicine taking. For example:
- Where the SPC/PIL does not include important information clearly accepted by clinicians and widely applied in clinical practice, as is the case for many older medicines
- Additional resources presented in ways that will help patients make best use of their medicines including e.g. videos on device technique, or materials which support compliance with therapy
- Presentation of medicines information in the broader context of information about the disease or condition.

The SPC and PIL are paper documents. The types of information they can carry is consequently limited by the static two-dimensional medium of paper. It is illogical, unnecessarily restrictive and counter to the interests of patients to confine all other non-promotional communication about prescribed medicines to that which can be represented on paper. We therefore propose that information for patients should be able to go beyond the key elements specified in the regulatory documents, as long as this is purely descriptive or reflects a clear clinical consensus, supported by advice from leading experts in the relevant specialty.

Distinction between 'pull' and 'push' information
We support the continuation of the ban on advertising and the principle of distinguishing between material that is actively sought as opposed to unsolicited. However, we believe that the examples provided require further clarification in the light of an expanding range of increasingly rich and interactive media and channels. We would welcome further definition of the term 'advertising' and greater clarity on the use of the channels available.

Governance
The UK's innovative medicine information resource, Medicine Guides, is governed by a multi-disciplinary stakeholder group, the Medicines Information Project Board, along the lines of the proposed co-regulatory authority. This has not only facilitated a positive partnership between key bodies within the UK health care sector, but provided an opportunity for interested parties to work together to address and meet the medicine information needs of UK patients and public. In the interests of minimising bureaucracy, we believe such mechanisms should be entirely voluntary and regarded as an optional enhancement to an underlying system of self-regulation backed up by the national regulator.

For further information, please contact:

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About Datapharm
Datapharm Communications is a not for profit organisation delivering electronic medicine information services to the public, patients and healthcare professionals. We derive our income from subscriptions from pharmaceutical companies, who provide regulated product information (SPCs and PILs). We collaborate with other organisations, for example the National Health Service (NHS), the Department of Health and patient groups such as the Royal National Institute for Blind People (RNIB) in the delivery of services.

Our core electronic medicine information services for the public, patients and healthcare professionals are:

- **Electronic Medicines Compendium (eMC)** – the largest, most-comprehensive, up-to-date and accurate repository of regulated medicines information (SPCs and PILs) for UK-licensed products
- **X-PIL** – Patient Information Leaflets (PILs) in formats suitable for blind people and those who are visually impaired, for example in large font, and with the use of screen readers. Through a collaboration with the RNIB PILs are available in Braille and large copy physical formats
- **Medicine Guides** – a new medicines information resource developed for patients, which maps individual medicines to information about conditions and treatments on the NHS' website (www.nhsdirect.nhs.uk). The NHS Direct website is the NHS' flagship web resource for health information. The medicines information component of that health information is provided by Medicine Guides.

All services can be accessed through www.medicines.org.uk