Irish Pharmaceutical Healthcare Association response to the European Commission Public Consultation on a Legal Proposal on Information to Patients

General Comments

The Irish Pharmaceutical Healthcare Association (IPHA), which represents the interests of the international research-based prescription medicines and consumer healthcare industries in Ireland and abroad, welcomes the European Commission’s legal proposal on information to patients. The Association believes that patients have a legitimate need for, and right to, quality information about diseases, therapeutic strategies and medicinal products. It views the legal proposal as an important step in delivering reliable, quality information which meets public demand.

Patients are increasingly seeking enhanced information about diseases and the treatment options available to them. The development of the internet means that the question is no longer one of whether or not patients should have access to more information but rather the quality and the reliability of the information to which they have access. Additionally, information should be assessed on its quality not necessarily on its source.

Pharmaceutical manufacturers are an excellent source of medicines information, having researched and developed their medicines over 10-12 years and therefore having unique product expertise and disease knowledge. However, current legal restrictions in many Member States prevent pharmaceutical companies – legally liable for their products – from communicating even basic and legally authorised information about their medicines to the public, ironically while allowing anyone else to do so in a completely unregulated way.
However, Industry has the ability to be an important contributor to health information alongside other key providers such as healthcare professionals, patient groups and regulatory agencies.

The Irish experience\(^1\) has been that the industry, working in partnership with other stakeholders – healthcare professionals, patient groups and the State – and within a clear regulatory framework, can help to meet the need for enhanced non-promotional information about diseases and about the medicines it spends years developing and about which it has an expert knowledge. We propose that the effective, well coordinated and quality information provision practices currently occurring in Member States such as Ireland, the UK and Sweden are considered in the development of any legal proposal and that European standard should not be less than the standards occurring in these countries.

Finally, rather than the proposed three tier structure for monitoring and sanctions, and in line with the principles of Better Regulation, we propose that a simple yet highly effective two tier system building on a proven track record of efficient self-regulation, be adopted. The two tier system would include a new European Standing Advisory Panel overseeing the work of national self-regulatory bodies which have efficient governance and enforcement procedures (like those in Ireland, the UK and Sweden).

### Comments on the key ideas in the forthcoming proposal

#### 3.1 Provisions on advertising

The current rules prohibit the advertising of prescription medicines to the general public. At the same time they allow the advertising of over the counter medicines. We agree that those rules should not be changed. However, EU citizens and patients should have the possibility to access high quality, non promotional information from multiple sources, including pharmaceutical companies that are legally liable for their product.

#### 3.2 Scope, content and general principles of the new legal provisions

IPHA agrees that under revised legal framework information and advertising should be clearly defined. Assuming that the current definition of advertising in Article 86(1) is maintained the revised Directive should clarify the rules around the provision of information on prescription-

\(^1\) Irish Pharmaceutical Healthcare Association (IPHA) response to the ‘European Commission draft report on current practice with regard to the provision of information to patients on medicinal products’ (June 2007)
only medicines by pharmaceutical companies (e.g. it should continue to permit information made available by companies to inform stakeholders, stock exchanges and the like by way of annual reports and announcements etc as well as business-orientated medicines information provided to current or prospective employees).

Pharmaceutical companies should be allowed to provide patients with the approved Summary of Product Characteristics (SmPC), package leaflet (PIL) and other quality medicine-related information such as information about scientific studies, disease prevention (e.g. vaccines), medical treatments and prices, provided that it is compatible with the approved SmPC and PIL.

3.3 Type of actions, content and monitoring of information

The proposed distinction of ‘push versus pull’ is a workable categorisation.

3.3.1 Information passively received by citizens

IPHA does not support prescription-only medicine information dissemination through television and radio programmes. Instead we propose the following categorisation of non-promotional information provision:

1. “Pro-active information” (“Push”), which is provided unsolicited to the public, should be limited to general information on diseases, e.g. covering awareness, prevention etc. but not mentioning specific medicines.

2. “Reference information” on diseases and medicines (“Pull”), which is sought by patients and citizens as in a library, e.g. through the Internet.

3. “Reactive Information” on medicines, which is supplied in response to spontaneous enquiries received from patients and citizens.

4. “Support information”, which is supplied with or subsequent to a prescription for a specific medicine, e.g. to support concordance with the prescribed medicine.

The information provided should be based on authorised information (e.g. PIL, SmPC etc) and comply with clearly defined standards for high-quality information (“quality principles”).
Consistent application of the aforementioned quality principles could be ensured through a European wide industry “health information” code of conduct, including effective quality assessment procedures for the information and ex-post control mechanisms (with involvement of third/independent parties), as well as robust enforcement procedures in case of breaches (sanctions, fines).

While we agree that the information provided should be monitored such monitoring is best achieved through the existing pharmaceutical industry self-regulatory bodies. Currently, both regulatory authorities and member states endorse the use of self-regulation where it is performed with efficient governance and enforcement procedures. Self regulation works well and should be continued: it can quickly adapt to changing needs in a non-bureaucratic manner. We believe that a system with a strong self-regulatory element would be best suited to meet the original Commission’s objectives and achieve the greatest benefit for public health.

### 3.3.2 Information searched by citizens

We are concerned that the proposal to announce certain information activities to a national co-regulatory body, if implemented, will add an unnecessary administrative step; given that such information must already adhere to quality standards outlined in Section 3.4 of this document. As noted by the Commission in setting out the main policy objectives to be pursued in this area unnecessary bureaucracy and delays should be avoided in line with the principles of Better Regulation.

### 3.3.3 Answering requests from citizens

We agree that replies by industry to written enquiries by citizens should be monitored based on complaints. Phone or other verbal enquiries should also be monitored and this would require the maintenance of appropriate records. Any complaints would be most appropriately and effectively handled by a self-regulatory system as described under point 5.

### 3.4 Quality criteria
Access to high quality medicines information from multiple sources, including from the pharmaceutical industry, is needed. Criteria for high-quality information are an essential element of any future proposals. The quality criteria of provided information must be objective and unbiased, patient oriented, evidence-based, up-to-date, understandable, accessible, transparent, relevant, consistent with approved product information and non-promotional. Additionally, any comparative information on prescription medicines should only be in the context of a balanced and objective overview of the therapeutic options.

A key element is that information should be deemed ‘acceptable’ depending on its quality rather than its source.

3.5 Proposed structure for monitoring and sanctions

While we agree with the principle of multi-stakeholder involvement in future governance models, we are concerned that the commission proposed model for monitoring could become bureaucratic, lead to a variance in interpretation in different countries and does not embrace ‘Better Regulation’ principles. Self-regulation with efficient governance and enforcement procedures would be the most effective and beneficial monitoring structure, provided that an adequate European legislative framework is created.

For example, existing pharmaceutical industry self regulation works well and can quickly adapt to changing needs in a non-bureaucratic manner. The pharmaceutical industry has a long experience with self-regulation (e.g. the IPHA Code of Marketing Practice for the Pharmaceutical Industry). In Ireland IPHA assists its members to achieve the highest level of compliance with the regulations through the provision of regular training classes for industry employees and the operation of a voluntary system of pre-vetting of proposed non-prescription advertising. It also runs regular training courses for the medical media, advertising agency personnel and public relations personnel on the IPHA Codes of Practice. This model has worked well in ensuring a wide knowledge of the Codes and in ensuring the highest possible compliance. IPHA also operates procedures under which complaints about possible breaches of the Codes from whatever source can be made and dealt with by a Code Council and Appeals Board chaired by independent persons from outside the industry.

2 Irish Pharmaceutical Healthcare Association (IPHA) response to the ‘European Commission draft report on current practice with regard to the provision of information to patients on medicinal products’ (June 2007): Section 5 The framework within which pharmaceutical companies provide information to patients
From a European perspective, a European Standing Advisory Panel could oversee the national self regulatory bodies, advise on the content of and interpret a European ‘Minimum Standards for a Health Information Code’. This Advisory Panel could include healthcare professionals, patient groups and representatives from the pharmaceutical industry. The proposed Health Information Code would work alongside and complement any legislative changes as envisaged by the Commission.

**Conclusion**

Better informed patients will lead to safer and more successful health outcomes, a more efficient use of healthcare resources and ultimately, to healthier societies.

The pharmaceutical industry working in partnership with other stakeholders, healthcare professionals, patient groups and the State, and within a clear regulatory framework, can help meet the need for enhanced non-promotional information about diseases and about the medicines it spends years developing and about which it has an expert knowledge.

As pointed out by the Commission, one of the objectives of the future legal proposal should be “to avoid any unnecessary bureaucracy, in line with the principles of Better Regulation”.