IPPOSI Consensus Response to the
EC PUBLIC CONSULTATION
“Legal Proposal on Information to Patients”

Submitted to the European Commission: Monday, 7 April 2008
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The Irish Platform for Patients’ Organisations, Science and Industry (IPPOSI) was established to provide a platform for discussion between patients’ organisations, scientists and industry (and where possible with State Agencies) in Ireland on policy, legislation and regulation around the development of new medicines, products, devices and diagnostics for unmet medical needs. As a unique partnership of patient groups/medical charities, science and industry our vision is one where state of the art innovations in health care are available to Irish patients at the earliest stages. Through expertise, dialogue, consensus building, networking and influencing we aim to smooth the path in Ireland for new medicines and therapies to move from basic science in laboratories to the patients who need them.

We are pleased to be in a position to submit the consensus view compiled by IPPOSI as a result of a consultation with key stakeholders on the EC Public Consultation “Legal Proposal on Information to Patients”.

Development of consensus response

On 11 March 2008, IPPOSI facilitated a meeting attended by patients’ organisations, science and industry to discuss the draft legislative proposal document put forward by the European Commission. A draft response was drawn up on the basis of the day’s discussions and was circulated for comment and endorsement. A final draft response was agreed and submitted to the European Commission in time for the consultation deadline.

Introduction

IPPOSI welcomes the opportunity to provide feedback on this important debate around the issue of information on prescription medicines. We see as a very positive development, attempts at EU level to simplify and improve access to medicines information by EU citizens. We agree that the best interests of the patient should be of primary concern and at the heart of the debate. It is, we believe, fundamental that patients have access to quality, non promotional information about their health/medical condition and about treatments/medicines.

IPPOSI welcomes the debate on the whole issue of suitable criteria for quality information and strongly supports the view that unnecessary bureaucracy at national and international levels would be unwelcome and agrees that this must be avoided.

Information vs Advertising on Prescription only Medicines
• In Ireland the ban on advertising of prescription medicines directly to the public is strictly enforced. IPPOSI supports this ban and does not advocate “direct to consumer” advertising for prescription-only medicines.

• The texts of the Patient Information Leaflets (PIL) and the Summary of Product Characteristics (SmPC) are independently reviewed and approved by the regulatory authority. In Ireland, these texts are not advertised directly to the public. A website (www.medicines.ie) made available by the Irish Pharmaceutical Healthcare Association (IPHA) does exist however which provides the regulatory approved texts of the PILs and SmPCs (for prescription and non prescription medicines) as an information source for healthcare professionals and members of the public alike. Members of the IPHA can place links to the SmPCs through their own company websites and on www.medicines.ie. IPHA actively promotes www.medicines.ie. Information to patients could include greater awareness of this resource.

• This approach does, however, have its limitations. IPPOSI agrees that current approved texts of SmPCs and PILs are not patient friendly. They are written in complex, technical language, not readily accessible to all patients or to the general public.

• IPPOSI would welcome more patient friendly materials, where simple language has been used. This would be in all actors’ interests.

• IPPOSI agrees that caution is required with regard to mass media use in the transmission of information on prescription medicines to the public. IPPOSI believes that the distinction between “advertising” and “information” as presented in the consultation document continues to remain somewhat confusing. Patient confidence is based on being able to clearly distinguish information from advertising. IPPOSI would welcome greater clarity with regard to the distinctions between “advertising” and “information”.

**Quality Criteria for Information on Prescription-only Medicines**

IPPOSI welcomes attempts by the European Commission to identify key criteria for quality information. IPPOSI agrees that quality information is that which is: objective and unbiased, patient oriented, evidence based, up to date, factually correct and not misleading, understandable, accessible, transparent, relevant, consistent with approved product-information and non promotional (focus on informing patients to correct and safe use of the medicine). IPPOSI would however like to add a couple of comments with regard to some of these headings to clarify our particular position.

*Patient oriented.* IPPOSI feels it important that patients’ needs and expectations are taken into account. Patients need to be empowered in the management of decision making around their own health/medical conditions. Patient-oriented information; material which is accessible to the entire patient audience will assist them to make informed decisions.
**Understandable.** We believe this to be key. Information must be easily read, understood and acted upon by the intended audience. A recognised, reputable, independent body which could assess information in these terms would be very valuable. An example of this is the UK “crystal mark”.

IPPOSI propose that information meeting the criteria which is both appropriate for the purpose and for the intended audience could receive a recognised “European Quality Information Mark”. This mark would be readily recognisable and would enhance patient confidence in the information material.

**Accessible** – via different mechanisms and in accessible formats. IPPOSI believes that this should also include requirements for visually impaired patients and other groups with specific needs.

**Information should not include any comparative sections between medicinal products.** Currently with regulatory approved PILs and SmPC materials there are no comparisons made. IPPOSI supports this situation.

**Means by which information is provided (Push vs Pull)**

**Pushed Passive**
With regard to pushed passive information, we reiterate our concern expressed above, namely that “IPPOSI agrees that caution is required with regard to mass media use in the transmission of information on prescription medicines to the public. IPPOSI believes that the distinction between “advertising” and “information” as presented in the consultation document continues to remain somewhat confusing” and requires further clarification.

Patient confidence is based on being able to clearly distinguish information from advertising. We acknowledge the positive aspects that accompany the wide reach of the mass media but caution additionally that with such a wide reach it can be difficult to repair damage if inappropriate, inaccurate information does reach a wide audience and retraction of same is difficult.

**Soft and Active Pull**
Information sought by citizens via registered internet sites, oral information (presentations, seminars) and answering on request (written solicited information including postings and emails).

IPPOSI feels that citizens should have the opportunity to access accurate, reliable, authorised, non promotional information on prescription medicine prior to actual purchase. At present citizens often only get to see the content of the PILs for a particular prescription medicine when they have actually been prescribed that medication and have purchased it. Opportunities do exist for current technology to be used to enable patients and citizens to
make informed choices about prescription medication prior to purchase and consumption. Computer information slots in pharmacies could offer patients the opportunity to key in the name of a prescription medication prior to purchase and to read an approved, regulated, patient friendly, non promotional text of a PIL or SmPC and to then engage with a pharmacist if any clarification was required. In the UK, NHS Direct webpages provide an extensive depository of information about licenced medications. This is a valuable service for patients, members of the public and health providers. Additional avenues where patients could access reliable, unbiased, up to date, non promotional information on prescription medications could be within the hospital environment, a designated information bearer – patient advocate, possibly within a multidisciplinary team could provide approved, regulated and patient friendly information on prescription medication.

Currently pharmaceutical companies are not in a position to answer patient queries about prescription medicines even if the patient is currently taking the prescribed medication in question.

There is an acknowledgement that the pharmaceutical industry is closely regulated with regard to the type of information they can provide and to whom, while other actors providing information however may not necessarily be subject to the same scrutiny eg. internet sites, patient groups. Regulation of information to patients by the proposed National Co-regulatory Body should apply to all information bearers to ensure accuracy and consistency.

With regard to Passive (pushed information), Soft Pull (information searched by citizens) and Active Pull (answering on request) proposals contained in the draft consultation table, IPPOSI would like to comment on the “Official EU language” issue. In Ireland there are two official languages where one of which is understood by all citizens. Information in that language is generally accepted by, and accessible to, all Irish citizens.

**Proposed Structure for Monitoring**

IPPOSI supports the establishment of a National Co-regulatory Body consisting of public authorities and a mix of stakeholders including healthcare professionals, patient organisations and the pharmaceutical industry. IPPOSI would suggest that a code of conduct be drawn up, perhaps something similar to that currently in use in Europe (EFPIA Code of Marketing Practice) and, in Ireland, (IPHA - Code of Marketing Practice).

At EU level, IPPOSI supports the establishment of an EU Advisory Committee which would deal with questions on information to patients with an EU community dimension and would suggest that the Committee consist of a mix of stakeholders similar to the National Co-Regulatory Bodies.

**In conclusion**, IPPOSI welcomes attempts at EU level to simplify and improve access to medicines information by EU citizens and is pleased to be in a position to submit our consensus response on this important issue.