AstraZeneca Contribution to the European Commission public consultation on a legal proposal on information to patients

April 2008

Introduction

AstraZeneca is one of the world's leading pharmaceutical companies with a broad range of medicines designed to fight disease in important areas of healthcare. We have a substantial base within Europe including extensive research and development and manufacturing sites as well as affiliates in EU member states. We take seriously our responsibility for high standards of behaviour and compliance and we are pleased to have the opportunity to comment on proposed developments in European legislation.

We have summarised some of our key points at the end of the document and would welcome the opportunity to discuss our concerns and recommendations more fully if that would be helpful.

General Comments

AstraZeneca welcomes the Commission's 'Legal Proposal on Information to Patients' and supports the underlying policy objectives. We support the aim of providing good quality, objective, reliable and non-promotional information on prescription-only medicines to citizens and to harmonize the currently unequal access to such information. Citizens have a right to information on their medicines from multiple sources in their own language whether or not they have access to the Internet. Enabling pharmaceutical companies to provide more high quality, non-promotional information than is possible under current regulatory interpretations will undoubtedly be in the interests of patients.

It is the quality of the information that should be the primary determinant of what it is permitted and it is illogical to prohibit good information simply because it is produced by the manufacturer, while the same information from any other source would be acceptable. There is no reason to classify all information outputs from companies as promotional as appears to be the case in some countries. Many company outputs clearly do not have the intent or effect of advertising a particular medicine but provide good quality, non-promotional information on health and medicines.

We do not believe that Direct to Consumer Advertising (DTCA) of prescription-only medicines is appropriate in Europe and we support the Commission's desire to maintain the ban on DTCA. We firmly support the need to clearly differentiate advertising from information because currently some activities and materials are being prohibited in practice in the mistaken assumption that they are promotional. We expand below on how this distinction might be best achieved. It should also be remembered that the list of 'over the counter' products that may be promoted varies between Member States.

AstraZeneca supports harmonisation but this should be to current best practice and in no country should a change in legislation inadvertently result in a reduction in the availability of good quality information on health or medicines from pharmaceutical companies. The positive experiences of

pharmaceutical companies in countries such as Sweden and UK providing non-promotional information for citizens should be taken as an indication of the responsible way in which companies approach this activity in the interests of patients.

Even in countries where the possibilities for companies to provide non-promotional medicines information are severely restricted it is usually possible to provide health information, such as disease awareness communication, unconnected with specific medicines. Any legislation change should preserve this valuable service for citizens and should not encumber it with new, unnecessary bureaucracy.

It is important to recognise the high standards in countries where the local regulatory interpretations currently permit companies to provide various types of non-promotional information on prescription-only medicines. This is achieved through effective controls based on well-established industry 'Codes of Practice' with complaint resolution processes and also through companies' commitment to applying high standards. Any new European governance system should take as its basis the current national systems that have proved effective rather than creating a new untested system.

Where there are problems with misleading information on health and medicines this usually comes from dubious sources unconnected with the pharmaceutical industry eg on the Internet and through un-solicited e-mails. It is often connected with the offer for sale of products of doubtful efficacy or questionable safety or prescription products that could include counterfeit medicines. The Legal Proposal does not attempt to regulate those activities. It is entirely appropriate, and in patients interests, that when misleading or dangerous information concerning medicines is made available that companies should be able to provide good quality, factual information to counteract the danger.

AstraZeneca believes that a change in European legislation could allow us to make an increased and positive contribution to the wider availability of high quality medicines information accessible to European citizens. Currently we may undertake an information initiative in one country and find that it is well received and beneficial but that local regulatory interpretations in other countries prevent us from providing this benefit more widely. Pharmaceutical companies are in the unusual position of being able to develop high quality health and medicines information that could be made available through their national affiliates across many countries thereby reducing current inequalities in access.

While welcoming the legal proposal's objectives we have some doubts that the proposals, as set out, will overturn successfully the variable access to health and medicines information that currently exists. We therefore make some suggestions as to how the proposal might be amended so that this can be achieved.

Comments on the Legal Proposal text

2.2 Objectives and impact assessment

We support the policy objectives and look forward to the results of the impact assessment.

1. We fully support the stated objective for understandable, objective, high quality and non-promotional medicines information but wish to point out that the legal proposal addresses just one source i.e. pharmaceutical companies who are already associated with high quality information. Alternative higher risk sources that are associated with lower quality information (eg some Internet sites) and which, unlike pharmaceutical companies, have few or no internal quality control mechanisms are not covered.
2. Determining a clear distinction between advertising and non-promotional information that can be applied consistently across Europe is essential to achieving the legal proposal's aims. We comment further on this aspect below
3. In connection with the desire to avoid unnecessary bureaucracy it should be noted that currently pharmaceutical companies are free to provide non-promotional health information to citizens and that such communications are not subject to notification or external regulatory approval requirements. Any new bureaucracy must be able to demonstrate a clear benefit and its purpose must be clearly identified.

3. Key Ideas of the forthcoming proposal

We support the fundamental objective of the legal proposal to provide rules that harmonise practices on information provision to patients, remembering of course that this refers only to information from pharmaceutical companies in Europe. Information from many other sources including other information providers with a financial interest (eg payers that seek to minimise costs, providers of non prescription medicine healthcare solutions or Internet sites from US pharmaceutical companies) will not be subject to the continued advertising ban.

Provisions on advertisement: We agree that the ban on advertising prescription medicines to the public in Europe should continue. However in some countries this prohibition has been interpreted too widely in practice and citizens have been denied access to useful, high quality information from pharmaceutical companies that has been made available to the benefit of citizens of other countries.

Scope, Content and general principles of the new legal provisions: "Communication not covered by the definition of advertisement, should be regarded as information". We are concerned by the concept of an all-inclusive definition being used to define the scope of legislation on information on medicines and health. Firstly the current definition of 'advertisement' is vague and has been subject to multiple interpretations. Secondly companies produce a wide variety of information that may reach the public domain, and

which may or may not mention prescription medicines, including stock market announcements, business press releases, submissions to health technology assessment bodies, written and verbal scientific and business presentations etc. The scope of the legislative controls on 'information' must be very carefully drafted and we suggest that is best done by defining clearly the types of medicines and health information that are covered by the legislation. (See 3.3 below)

We agree with the general concept that the information provided by companies should be compatible with the summaries of product characteristics. However, when responding to a spontaneous request for information about a potential new medicine (e.g. from a patient group) or possible participation in clinical trials, it would be appropriate for companies' medical departments to be able answer such enquiries in a factual, non-promotional manner and to include references to their research activities.

We were pleased to support EFPIA in the development of Quality Criteria and also to the continuing work on a draft 'Health Information Code'. These documents should form the basis for the quality criteria mentioned in the legal proposal.

Types of actions, content and monitoring of information

We agree that a distinction between 'push' and pull' information is helpful. Additional definition of types of information on health and medicines that are permitted is needed and this would be best achieved by identifying the types of communication that are controlled. The draft EFPIA 'Health Information Code' would be a useful way to set out these types clearly and to associate with each type greater details of allowable activities.

The types of information set out in sections 3.3.1, 3.3.2 and 3.3.3 are useful.

3.3.1 **Information passively received by citizens.**

We do not believe that the active distribution of information on specific prescription-only medicines by TV and radio etc is appropriate in the EU. It is difficult to understand how this could not be considered as advertising a particular medicine if a company buys advertising space.

In situations when journalists, TV producers, patient groups or others produce programmes and communications on particular healthcare subjects, including specific medicines, if the quality of their outputs is to be optimised, companies should be free to respond, in a factual non-promotional way, to requests for information from journalists and others on their medicines as in 3.3.2.

AstraZeneca supports companies to distributing materials concerned with disease awareness. This is currently allowed in many countries and is a useful service in disease identification that can encourage citizens to seek help from their healthcare professional. Disease awareness information

by pharmaceutical companies can contribute significantly to prevention and/or early diagnosis of disease e.g. early recognition of diabetes.

We also support the continued, and more widespread, production of leaflets, electronic materials etc on specific medicines or on broader health topics directed to the patient (or their carer) for whom the medicine has been prescribed. This information supports health care professionals efforts and aids the safe and optimal use of prescribed medicines. Such information is provided in some Member States already and should be made available throughout Europe. It includes services to enhance concordance with therapy such as information on lifestyle choices (e.g. dietary advice to complement a statin prescription), more detailed information on the prescribed medicine (e.g. to help identify possible side effects) and motivational material (e.g. to encourage adherence with the prescribed regimen). It may be provided through the patient's healthcare professional or by companies directly if they have established that an individual is taking the medicine eg through the patient registering a request to receive the information. This type of information can have a significant and positive impact on the optimum and safe use of medicines.

The suggestion that **'information providers inform national co-regulatory bodies about their activities before action is taken'** requires significant clarification of the actions that a co-regulatory body is expected to take when it receives the material. The benefits that submission would bring should be clearly identified. An important requirement of an industry European 'Health Information Code' would be that a doctor or pharmacist must approve non-promotional information and activities before release. This is already in place in some countries and works well without the need for routine pre-approval submission to an external body. Further comments on the co-regulatory body are given below.

3.3.2 **Information searched by citizens**
As for 3.3.1 it is unclear to us what benefits are expected to arise from the suggested 'announcement' to the co-regulatory body. Also any code or other means that sets out detailed rules must accommodate the fact that information needs vary and flexibility in responding appropriately must be permitted. For example the information needs of a patient group are likely to be broader ranging than an individual patient.

3.3.3 **Answering requests from citizens**
It is entirely appropriate that companies be allowed to respond, in a balanced factual way, to requests for information from citizens. We understand that in some countries this is not currently permitted and find it difficult to understand how such a ban can be in patients' interests. A detailed Code of Conduct should make it clear that the healthcare professional – patient relationship should be supported by companies' responses. Company medical information professionals are in a good position to recommend that patients contact their health care professional when, for example, the query concerns personal medical advice.

The suggestion to monitor by complaints is appropriate. However, further details of the complaint mechanism are needed. We suggest that a structured complaints system modelled on that currently operated by ABPI / PMCPA in the UK should be followed. This involves a 2-stage adjudication process, including at stage 2 a committee chaired by a senior lawyer with lay and independent health professionals participation. This system has already ruled on a number of complaints concerning information to patients and is building an understanding of acceptability limits that goes beyond what is possible even with carefully drafted legislation and codes of conduct.

4. **Quality criteria**

Clear quality criteria as set out in EFPIA's 2005 'Principles and Guidance for high quality information' should form the basis for national Codes of Conduct. EFPIA is working on a European 'Health Information Code' that develops these 'Principles and Guidance' further into an operational code of practice. We believe that a single European industry code of practice on which all national codes must be closely based is an essential component of ensuring harmonisation and thereby ending the current unequal access of citizens to health and medicines information. The lack of a single code is likely to result in a continuation of the current situation where differing national interpretations of what constitutes advertising leads to some citizens being denied helpful medicines information.

It is stated that comparisons between products should not be allowed yet such comparisons are one of the main areas of information that citizens seek. We presume that a ban is suggested on the grounds that comparisons might be promotional. However a well-written code of practice that encompasses the criteria outlined in section 4 could ensure that comparisons emanating from companies, like other information, are fair, objective and non-promotional. It must be remembered that non-promotional comparisons are not currently prohibited in some EU countries and that comparisons from other sources, including ones that are driven by cost considerations, would not be regulated. It is in the interests of citizens if fair, objective comparisons from multiple sources are permitted.

5 **Proposed structure for monitoring and sanctions**

AstraZeneca supports elements of the proposed structure but we have serious concerns that without modification it will not enable the stated policy objectives to be fulfilled. We support 'co-regulation' but believe that changes are necessary from the model proposed by the Commission. We suggest that the structure is more closely based on the current European system relating to promotional communications to healthcare professionals that is tried and tested and known to work. In fact, in some countries such as the UK the 'co-regulatory body' and code of practice already cover information for patients from pharmaceutical companies and a number of cases have been adjudicated. The UK system includes oversight by the

national regulatory authority and involves a form of ‘co-regulatory body’ that includes independent healthcare and lay representatives.

We support a structure whereby:

- National codes of practice are closely based on a European template code produced by EFPIA.
- An EU advisory committee chaired by the Commission and involving multi-stakeholder involvement including several industry representatives could advise EFPIA on the European code and its operation. It could also advise when differences in national interpretations arise and inhibit consistent provision of information across Europe.
- Changes to the European directive should be limited to those necessary to ensure adoption of a ‘co-regulatory system’ (with national codes of practice based on a European template) and to ensure that the current unequal access to information does not continue. We see no benefit in introducing highly detailed requirements in legislation when high quality can be assured through less bureaucratic means.
- National ‘co-regulatory bodies’ should be chaired by an independent legally qualified person and have industry, healthcare professional and patient representation. In line with the best practice existing ‘co-regulatory bodies’ it is appropriate to have a majority of members that work within industry as medical directors and very senior executives. This not only provides for a body with the most relevant expertise but also serves to reinforce companies’ commitment to the applied standards. The ‘co-regulatory bodies’ should have power to adjudicate on complaints and impose sanctions. Submission of companies to the powers of the ‘co-regulatory body’ should be mandatory eg as a condition of the Marketing Authorisation.
- Co-regulatory bodies should not be expected to formally approve materials before or after distribution other than though their adjudication role (above). Companies should not be required to routinely notify the body about their non-promotional communications but rather, on request, the national body should have the power to request submission of specific items. This would be most appropriate when the activity or type of communication is novel and not previously undertaken in that country. It would be unnecessary, costly and bureaucratic to require the submission of every item or all updates to websites (which often happen daily). Any blanket submission requirement would be of very questionable benefit and would result in huge piles of materials that no one has the resource to review.
- National competent authorities should retain their current powers to take action in the event of an apparent breach of the law. They would also be consulted in the drawing up of national codes and could advise on matters of national peculiarity that were not adequately described in the European Code.

- All non-promotional information and materials on medicines and health produced by companies must be approved by medical doctors or pharmacists who are retained by companies for this purpose and who exercise their professional and ethical judgement in the interests of patients.

Executive Summary

- AstraZeneca supports the policy objectives of the legal proposal but there is as yet insufficient detail to judge whether the proposal will in practice lead to improved access for citizens across the EU to good quality, non-promotional information on prescription medicines.
- We advocate a move towards wide adoption of current best practices in information provision and controls but we are concerned that the proposals appear to be unclear on how the future systems might operate in practice.
- We support the adoption of clear and precise codes of conduct at a national level that are effectively implemented and suggest that these must be based on a single European code if current inequalities in access to information are to be resolved.
- Taking the Legal Proposal as a basis we have made suggestions for modifications that we believe will aid the achievement of the stated policy objectives.