European Commission
DG Enterprise and Industry – Unit F2 "Pharmaceuticals"
By email: ulla.narhi@ec.europa.eu

**Comments on document entitled "*Legal proposal on information to patients*"**

Amgen is a pioneer in the development of biotechnology-derived proteins, with experience covering the fields of molecular and cellular biology, target discovery, safety assessment, therapeutic delivery, biotechnology process development and personalized medicines. Amgen has discovered, developed and/or manufactures many of the leading products derived from biotechnology. It is from this perspective that Amgen would like to comment on the above-mentioned document.

Amgen would like to thank the European Commission's services for giving us the opportunity to comment before embarking into the drafting of a legal proposal aiming at enabling biopharmaceutical companies to provide information to patients under certain conditions.

Amgen believes that biopharmaceutical companies have a role to play when it comes to information provision to patients and fully supports such an initiative and encourages the European Commission to adopt a legal proposal amending Directive 2001/83/EC before the end of this year. We hope that such a proposal will be adopted by the Council and the European Parliament with a sense of urgency.

Our specific comments on the document under consultation are as follows:

## 1. Reasons for, and objectives of, the proposal

Amgen fully supports the proposal to reduce differences in access to information and clarify and harmonize current practices, with the objective of ensuring that European patients, their family members and stakeholders become empowered and proactive regarding the prevention and treatment of their diseases and illnesses.

As already mentioned in our June 2007 comment on the draft Commission's report, Amgen endorses the current prohibition of advertising of prescription medicines to the general public. However, this makes it even more important to have a clear distinction between advertising and other forms of communication.

Amgen believes that the legal proposal should pursue the policy objective of introducing a complete (i.e. not a partial or optional) harmonization of the national rules on the provision of health-related information. Amgen is concerned that less ambitious approaches, such as merely introducing a clarification of the distinction between advertising and non-promotional information, will not have any "enabling effect" by lifting current restrictions and would thus fail to reduce the current information gap. We therefore suggest to set out in the legal proposal that, if health-related information complies with certain criteria, then Member States must allow such information to be provided and are not entitled to adopt different or stricter rules than those set

out in the proposal, without prejudice to their competence to regulate matters relating to public health.[1] Also, in order to avoid that the proposal could have the effect of preventing information providers to carry out certain activities that are allowed under the current regulatory framework, we recommend including in the legal proposal a so-called "grandfather clause".

## 2. Scope and general principles

Amgen supports limiting the scope of the legal proposal to information provided by biopharmaceutical companies on prescription-only medicines, without changing the current situation whereby healthcare professionals are the primary source of health information. We are nevertheless deeply concerned about the fact that the consultation document seems to focus on setting rules on the provision of information by "*marketing authorization holders*".[2] This seems to imply that the proposal does not envisage enabling the provision of health information prior to the grant of the marketing authorizations.

We are opposed to such a narrow approach and/or the introduction of artificial limits as to the point in time when health-related information can be provided. We note that Directive 2001/83/EC includes within its scope medicinal products that are intended to be placed on the market[3] or the situation where marketing authorizations are lacking or applications are pending.[4]

We are convinced that innovative biopharmaceutical companies such as Amgen can be a useful and reliable source of information on the development of new medicines and in a large number of other "pre-approval" circumstances, including: (i) disease awareness campaigns; (ii) general information on treatment options; (iii) compliance information; and (vi) information relating to human health or diseases, continuous innovations and trends in the healthcare sector. We firmly believe that an appropriate information strategy should ensure that patients and citizens have access to such information and we would therefore recommend including this possibility within the scope of the legal proposal.

According to our experience, patients and their families are interested to receive comprehensive information about medicinal products in all settings (development/clinical and commercial product), including full disclosure of all risks and benefits, compliance schemes, side effects and how to manage side effects, but most importantly to receive this in a patient-friendly format and with an appropriate level of readability. They are also interested in receiving verbal and/or written approved materials about use of products that are permissible and those that are regulated and the terms relating to failure to comply with regulation. Finally, they are interested to be involved in the development of appropriate information by other information providers, including biopharmaceutical companies.

Amgen supports the proposed principle that any communication not covered by the prohibition of advertising, should be regarded as allowed information, if it complies with certain fair, balanced and science-based criteria. Such an approach is appropriate in light of the fundamental principle of the freedom of expression and information.[5]

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[1] Consideration should be given to list in the proposal the cases where the Member States are allowed to adopt provisions departing from the rules laid down in the proposal.
[2] Refer to point 2.1 of the consultation document.
[3] Article 2.1 of Directive 2001/83/EC, as amended.
[4] Article 126a of Directive 2001/83/EC, as amended.
[5] Refer, for instance, to Article 11 of the Charter of Fundamental Rights of the European Union.

Whilst we support the proposal that information should be compatible with, and should not contradict, approved Summaries of Product Characteristic (SmPC) and Patient Information Leaflet (PIL), we wonder whether it is proportionate, or indeed even necessary, to seek preventing the provision of information that "*goes beyond the key elements specified in* (the SmPC and PIL)".[6] On the contrary, it seems that patients often need to be provided with information that is not included or goes beyond what is specified in the SmPC and the PIL, which relates to issues such as compliance and other relevant elements related to the products. For instance, certain biological medicines (e.g., vaccines, monoclonal antibodies) must be administered at regular, but some times large, time intervals in order to remain efficacious. It is essential that biopharmaceutical companies are empowered to provide to patients the information necessary (and are able to use appropriate technological tolls and mechanisms) to ensure adherence to the treatments, using modern technologies (e.g., text messaging, e-mails, etc). In addition, for more chronic conditions that have a broad (high) incidence and are treated by a significant number of physicians (for instance, asthmas, diabetes, osteoporosis), whereby customary channels of information to the patient (company representative-physician-patient) may be limited or inconsistent, information should be provided about disease state, product, compliance as it relates to efficacy and management of adverse effects (where evidence exists).

## 3. Type of actions, monitoring and quality criteria

We fully support the proposal to distinguish between "push" and "pull" in terms of the type of actions by information providers and to allow the biopharmaceutical industry to disseminate (non-promotional) information by the various means listed in the consultation document. We do not support introducing restrictions concerning the type of health-related information or the means that can be used to disseminate such information. Such restrictions run the risk to conflict with fundamental principles such as freedom of expression and technology neutrality.

We support the proposal to require information providers to inform regulatory bodies about their "push" activities in advance.[7] We suggest clarifying that such an information obligation would correspond to a notification procedure and introducing into the legal proposal a principle excluding prior authorization for such activities.[8]

As far as "pull" activities are concerned (e.g., Internet websites), we are not opposed to a reasonable monitoring system, whereby a regulatory body, made up of scientific experts, would validate the information, including by way of proportionate ex-ante or ex-post specific actions. We believe that innovative biopharmaceutical companies such as Amgen are well placed to collaborate with regulators on information provision, in local languages and in strict compliance with the quality criteria listed in the consultation document.[9]

By contrast, we do not see any need to regulate under the legal proposal the activity consisting in answering requests from patients or citizens. Most of such activities, if not all, would most likely be considered as private communications and subject to the rules on privacy.

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[6] Refer to point 3.2 of the consultation document.
[7] For instance, TV, radio programmes, printed materials, written and electronic communications.
[8] Refer, for instance, to Article 4 of Electronic Commerce Directive (Directive 2000/31/EC).
[9] Including the need for any information to be objective, unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent, refer to point 4 of the consultation document.

Finally, whilst we agree that comparative statements about medicinal products may not in most cases not be appropriate,[10] we believe that biopharmaceutical companies should be allowed to provide healthcare professionals with (non-promotional) information about different products/treatment options within a particular therapeutic class or new treatment options (including medicines) that are being developed, as the result of the innovative efforts of companies. We feel it is important that patients are aware of the latest advances in their respective disease area and the impact this has on treatment options, standards and new medicines.

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We look forward to working further with the Commission's services on the development of a new Community legislative framework for the provision of health-related information in Europe.

Yours sincerely,

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Thomas Bols
Director Government Affairs

[10] Refer to point 4 of the consultation document.