AIM
ASSOCIATION INTERNATIONALE DE LA MUTUALITE

AIM Response to Public Consultation on a "Legal proposal on information to patients"

4 April 2008

Summary of AIM response

- AIM is very much concerned by the Commissions legal proposal. It gives priority to industrial commercial interests rather than to public health concerns and consumer protection interests.
- AIM strongly rejects any direct or indirect processes aimed at relaxing the existing ban on information provided by pharmaceutical companies on prescription drugs to the patients/consumers (equivalent to DTCA). We therefore call on the Commission not to change the current EU-legislation on advertising as proposed in the consultation paper.
- DTCA has an adverse impact on public health especially on perceptions, requests for specific drugs, medication prescribing and compliance, as well as on healthcare expenditure and drug prices.
- Pharmaceutical companies have a vital role in information for patients, especially in producing package labelling and the patient information leaflet. Key information on drugs needs to be included in the patient leaflets. Improvements to patient leaflets are still necessary and should be the first priority of the pharmaceutical industry and the European Commission.
- Pharmaceutical companies are required to provide all necessary information on clinical trials (positive and negative ones) and pharmacovigilance data to relevant public authorities. But practice has shown that sometimes key information is not disclosed if this might hurt sales. Improvements in respecting legal requirements are absolutely necessary and should urgently be considered by the pharmaceutical industry, the Commission and the Member States. AIM emphasises the need for a public register for all clinical trials.
- AIM fully agrees with the Commission that health professionals are a key source of information to patients.
- The Commission does not provide any definition or distinction between advertising and information in its proposal.
- The differences between proposed monitoring systems for "push" and "pull" situations are very confusing and lead in our opinion to unequal protection levels. The proposed monitoring system does not focus on the validation of the content of information which is vital to guarantee patient confidence, maintain a high level of consumer protection and safeguard public health. The way the monitoring system is conceived cannot avoid abuses and represents therefore unnecessary bureaucracy.
- AIM invites the Commission instead to support the empowerment of EU-citizens and patients through better access to comparative, unbiased high-quality information generated by official independent bodies within a validated process. Many examples of such information and good practice exist already and should be benchmarked throughout the Member States. We are convinced that high added value for all Member States, EU citizens and patients is best achieved by developing synergies at EU-level and reinforcing collaboration among existing national bodies involved in issuing independent patient information.

General remarks

The consultation paper is based on the Commission's report[1] on current practice with regard to provision of information to patients on medicinal products published on 20 December 2007. In this report, the Commission concluded that the rules and practices on available information vary significantly among Member States, which results in unequal access of patients and the public to information on medicinal products. The Commission further concluded that "*Member States' authorities may not be in a position to*

[1] Commission communication on information to patients, COM(2007)862 published on 20 December 2007

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fully address patients' needs in terms of the substance of information and the access via different means. In turn, the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals throughout the EU".

AIM is much concerned by these very strong Commission conclusions. Within the framework of the Pharmaceutical Forum, AIM repeatedly requested the Commission to conduct a detailed stock-taking analysis of the availability of information for the general public on diseases and pharmaceuticals. The Commission's ten page report (even if complemented by the staff working document) cannot be considered as an in-depth overview of the availability of information to patients in the EU. The analyses of provision of information by sources other than public authorities (including via internet), and related benefits and risks, is evidently incomplete.

AIM strongly rejects any direct or indirect processes aimed at relaxing the existing ban on DTCA. We therefore call on the Commission not to change the current EU-legislation on advertising as proposed in the consultation paper. Instead, AIM invites the Commission to support the empowerment of EU-citizens and patients through better access to comparative, unbiased high-quality information generated by official independent bodies within a validated process. Many examples of such information and good practice exist already and should be benchmarked throughout the Member States. We are convinced that high added value for all Member States, EU citizens and patients is best achieved by developing synergies at EU-level and reinforcing collaboration among existing national bodies involved in issuing independent patient information.

DTCA effects on public health and sustainability of public health systems

As the Commission proposal is silent on the effects of DTCA on public health we would like to raise some key issues of DTCA's effects on public health.

Almost all government, health professional and consumer inquiries into DTCA have concluded that it causes net public harm. Currently, only the USA and New Zealand authorise DTCA for prescription-only products. Between 2002 and 2004, almost all health professional groups in New Zealand called for a ban on DTCA and the provision of centrally funded independent consumer health information. In the US too, surveys show that consumers prefer to get information from health professionals and that they dislike being misled. What is even more worrying is that citizens assume that information in advertisements is balanced, accurate and truthful and that only medicines that are safe are permitted to be advertised.

Experience from New Zealand and the US shows that DTCA can give rise to unreasonable patient expectations. These expectations can lead to inappropriate and excessive prescribing. **DTCA has an impact on perceptions, requests for specific drugs, medication prescribing and compliance**.

According to several analyses[2] of prescribing decisions in the US setting with legal DTCA, more advertising leads to more requests for advertised medicines, and more prescriptions. If DTCA opens a conversation between patients and physicians, that conversation is highly likely to end with a prescription, often despite physician ambivalence about treatment choice[3]. According a French study (July 2006)[4] the evolution of prescription volume is essentially linked to promotion by pharmaceutical firms. By comparison, a drop in pricing has no similar impact on prescription volume.

DTCA is mainly limited to drugs that are profitable to advertise: mostly expensive, new drugs for long-term use. Such advertising increases premature rapid uptake and overuse of new drugs before having a clear view on possible safety problems. DTCA rarely focuses on high-priority public health messages. Content analyses of DTCA have found that the information provided is usually flawed and incomplete. A study of US television advertisements for prescription drugs found that the majority gave more time to benefits than to risks. DTCA is often ambiguous and widens the indications beyond those for which the promoted drugs are worthwhile.

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[2] ***UNITED STATES – GAO (United States Government Accountability Office),*** *"Prescription drugs: Improvements needed in FDA's Oversight of Direct to Consumer Advertising"* ***Report to Congressional Requesters November 2006***
http://www.gao.gov/new.items/d0754.pdf

[3] **CANADA – B. Mintzes et al., "**How does direct-to-consumer advertising affect prescribing ? A survey in primary care environments with and without legal DTCA"**, CMAJ, 2003 http://www.cmaj.ca/cgi/reprint/169/5/405.pdf**

[4] ***FRANCE - François Pesty,*** *« Impact de la visite médicale sur la prescription du médicament – étude inédite des données MEDIC'AM 2006 »****, juillet 2006. Etude réalisée dans le cadre du projet Puppem (Pour une prescription plus efficiente du médicament : puppem.com).***
http://puppem.com/Documents/Etude_in%E9dite_MEDICAM_2006_FP_07-2007.pdf

Advertising drugs might create high expectation of benefit from those drugs and can cause severe distress when a drug is unaffordable or when its effects are disappointing.
Heavy costs of DTCA contribute to higher drug prices. DTCA may lead to promotion of 'medicalisation' of conditions that are in fact within the spectrum of normality.

Based on the above mentioned arguments, AIM calls strongly for the European Commission to consider and maintain the allegations of Directive 2001/83/EC which are still valid today. **Recital 40** states that "*the provisions governing the **information supplied to users** should provide a **high degree of consumer protection**, in order that medicinal products may be used correctly on the basis of full and comprehensible information*". **Recital 47** mentions that "*The advertising of medicinal products to **persons qualified** to prescribe or supply them contributes to the information available to such persons. Nevertheless, this **advertising should be subject to strict conditions and effective monitoring**".* Further in **recital 52**, it is stated that "***Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market**. Whereas it is nevertheless for the **Member States to take all measures necessary to this end, in the light of their own particular situation***."

Role of pharmaceutical industry on information to patients: in case of conflict of interests, the source of information is a main issue of trust and reliability

A first aspect to clarify is the current role of the pharmaceutical industry as regards information to the general public for medicines, in particular prescription-only products. A second aspect is to scrutinise open or unmet needs and requests of the patients/citizens.

At a the Pharma 2008 conference in Frankfurt on 21 February 2008[5], the German MEP Jorgo Chatzimarkakis, who sits on the EU Pharmaceutical forum said "*The biggest problem we have is that people do not want information from the industry about the medications that they produce. This kind of prejudice is very deeply ingrained but we have to get rid of it somehow*." The request for more "information from industry about their medications" is however not shared by many European patients and citizens.

At the consultation on the current practice with regard to provision of information to patients on medicinal products (April-June 2007), a large number of respondents questioned both the Commission report's assumption that the answer to patients' information needs lies with industry, and its conclusion that the pharmaceutical industry should be allowed a greater role in the provision of information to patients. Many responses recommended that the Commission should pay particular attention to issues of trust and reliability of information. According to a study from the Picker Institute "the first and most trusted source of information for the patients is their doctor"[6]. Pharmaceutical industry is usually ranked as having low trustworthiness compared to doctors.

According to the "Delfi-Studie" concerning patient information in Germany (2006)[7], 74% of patients wanted information in addition to the doctors' information. Most of them preferred information from pharmacists (62,2%), from consumer organisations (44,2%) and from health insurers (44%). Only 18,9% wanted it from pharmaceutical companies. Within the nine categories of possible sources, the association of pharmaceutical industry was the last one mentioned with only 6,5%.

Considering the submitted legal proposal, and considering the above mentioned statements, we have the strong conviction that the Commission's initiative is based much more on industrial interests than on patient/user needs. Currently, the Commission has not conducted an analysis of patients' – unmet – needs for information. Those who have conducted such an analysis have noted that following questions are important for the patients:

- What information do patients need?
- Symptoms and course of illness
- Will the condition spontaneously resolve or need for treatment?
- Treatments necessary and suggested
- Comparisons of different treatments

[5] Article published by APM on 21 February 2008 "Pharma must polish reputation and work with EU on unified laws".
[6] http://www.pickereurope.org/Filestore/News/Picker_Institute_response_to_EC_patient_information_report.pdf
[7] GERMANY – S.Greß, S. Maas, V. Ulrich, U. Schneider, M. Koch, K. Grabein, J. Wasem, „Direkte Patienteninformationen für verschreibungspflichtige Arzneimittel – Internationale Erfahrungen und Optionen für Deutschland"**, Januar 2007, 63p.** **http://www.uni-due.de/wiwi-essen/pdf/155.pdf**

The Commission proposal does not respond in any way to these questions.

What is the current role of the pharmaceutical industry as regards information to the general public for medicines, in particular for prescription-only products?

Today, DTCA is only forbidden for 'prescription-only' drugs. Advertising for OTC products is allowed. Communication of information on prescription-only products to the general public by the pharmaceutical industry is strictly limited by law for reasons of public health, consumer protection and sustainability of health insurance systems. The existing limitations are necessary to maintain the DTCA ban on prescription-only medicines.

Pharmaceutical companies nevertheless have a key role in providing information to patients, especially in producing package labelling and the patient information leaflet. The patient leaflet is the main official product information document for the patient/citizen available in the different EU languages. These leaflets should include all necessary information the patient/user needs to know about the product. **Improvements of the patient leaflets are still necessary and should be the first priority of the pharmaceutical industry and the European Commission**. On the example of EMEA, Member States should be requested to make available patient leaflets in the respective official national languages to guarantee equal access to official product information.

Furthermore, the pharmaceutical industry is required to provide all necessary **information on clinical trials (positive and negative ones) and pharmacovigilance data** to relevant public authorities. Despite such legal requirements, several experiences have shown that pharmaceutical companies keep from relevant public authorities and doctors important findings about clinical trials and reports of adverse events which might hurt sales. **More transparency on clinical trials and pharmacovigilance data as well as improvements in the respect of legal requirements are absolutely necessary and should urgently be considered by the pharmaceutical industry, the Commission and the Member States.** In line with this, AIM emphasises the need for a **public register for all** (positive, negative and interrupted) **clinical trials.**

Contrary to the conclusion of the Commission's 2007 December report, we would like to stress that there exists no ban for the provision of information to healthcare professionals. We **fully agree with the Commission's declared 'intention' that healthcare professionals should remain, as they are today, the primary source of health information, including for prescription-only medicines.**

As the legal proposal only concerns 'prescription-only' medicines the question has to be raised: 'what can the industry add, that the health professional cannot already do?'.

The Commission seems to be convinced that a legal framework can ensure the provision, by the pharmaceutical industry to the general public, of good-quality, objective, reliable and non promotional information on prescription-only medicines. We wonder how the Commission can possibly expect that for-profit business companies whose main interest lies in maximising product revenue can be considered as completely neutral and impartial when addressing reliable non-promotional information about its own products through mass media to the general public. With the underlying conflict of interest this seems impossible.

According to the Commission, the intended legal framework should contribute to harmonise the scope and the practice of pharmaceutical industry activities regarding information to patients on prescription-only medicines in the different Member States: this should also aim at reducing difference in access to information. We consider however that the submitted proposal goes extensively beyond that intention by broadening the current authorised activities and practice of pharmaceutical industry, especially by allowing direct-to-consumer information through mass media. We could not find in the submitted text any proposal for guaranteed equal access to such information.

Distinction between information and advertising

The Commission intends to build up a legal framework based on **a clear distinction between advertising and information**. A definition of both aspects is thus fundamental. **But the Commission does not provide any proposal for a definition in the consultation paper**.

The Commission intends to allow the marketing authorisation holder to disseminate information on his prescription-only products directly to the general public through TV, radio programmes, printed material

actively distributed, printed media, audiovisual and written material provided to patients by healthcare professionals, and internet Websites.

Taking into account the underlying conflict of commercial interest, the dissemination of information on prescription products by the pharmaceutical industry through TV and radio is in our opinion identical with DTCA. The fact that a supplier of a product speaks through mass media on its products offered for sale - even with quality criteria requirements - cannot realistically be considered as non-promotional. **This will also lead to obscuring of the public's perception of who is considered as "supplier" and who should be considered as "adviser"**.

Information on scientific studies

The legal proposal also allows information on scientific studies. This is a further possibility to introduce, under the label of 'scientific studies', advertising for specific products. The editorial in JAMA in February 2008[8] draws attention to misleading information resulting from the availability of "fragmented information" (selected individual studies).

Quality criteria

The Commission proposes that the information provided by the pharmaceutical industry has to fulfil a series of quality criteria. Information should be objective and unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information. But the **Commission does not propose to allow information on comparisons between pharmaceuticals**.

The improvement of the quality of available information is an objective shared by all actors.
However, information can be entirely 'objective' and yet still mislead through incompleteness or lack of balance and context[9]. Exactly this could happen if companies are permitted to communicate about their respective products through mass media like websites, TV and radio.

The evidence-base of information provided by the industry to health professionals is already open to question. A June 2007 Belgian study on the quality of written information provided by the industry to doctors indicated that only one in six messages (17%) was evidence-based or referred to the patient leaflet[10]. Most messages contained vague or non-scientifically proven evidence. We are therefore very sceptical that information addressed directly to patients would be more reliable and evidence-based than the information submitted to health professionals.

The Commission proposal does not outline 'how and who' will analyse respect for communication quality criteria; in actual practice this must mean that there would be no effective process for validation of the content of the information.

Monitoring

The proposed monitoring system, differing for "push" and "pull" situations, is very confusing and leads in our opinion to unequal protection levels. Citizens and users who are actively looking for information need in our opinion an even higher level of consumer protection as they are much more exposed to possible harm from misleading information.

For a **push situation** (user is passive) the proposed monitoring system "tell and do" is based on the communication by the information providers to the national co-regulatory body about its information activities before action. The consultation paper only mentions that the information provider has an obligation to inform 'a priori' about its planned activity. It is not mentioned if this implies an official approval "a priori" before launching the activity.

In case of **pull situation** (user is active) the information provider should announce the information activity to a national co-regulatory body which monitors the content without a validating process.

The proposed three level structure (national co-regulatory body, national competent authorities, EU advisory committee) for monitoring and sanctions does not respect the announced main policy objectives.

[8] JAMA. 2008;299(8):953-955.
[9] BMJ, 6 Octobre 2007, vol 335, 694-695
[10] http://www.kce.fgov.be/index_en.aspx?SGREF=9152&CREF=9431

Firstly, we are astonished that for a legal framework which aims to provide high-quality and non-promotional information and to maintain the confidence of citizens, regulators and healthcare professionals, a monitoring system at three levels is needed.

Secondly, we also wonder how the Commission intends to maintain the confidence of citizens, regulators and healthcare professionals in a legal framework which is monitored by a co-regulatory body in which the pharmaceutical industry plays itself an active role.

Thirdly, without a validation process for the content of information, the respect of quality criteria cannot be assured as would be necessary to give confidence to citizens, regulators and healthcare professionals.

Commission officials have resisted AIM's proposal for 'quality marks', arguing that there can be possible abuse of such labels. We would like to return the same remark to the Commission's proposed legal framework – there could be possible abuse. The Commission proposal intends only to act and apply sanctions in case of repeated and severe cases of non-compliance.

We would also like to understand better the logic of putting an 'EU advisory committee' at the top of a monitoring system, taking into account that the decision level to impose penalties remains with the national competent authorities.

Experience has shown that self-regulation and 'code of conduct' are insufficient guarantee for avoiding abuse. According to that experience in New Zealand and the USA, neither does a control system based on patient complaints work: there are only few complaints because most consumers do not have enough technical knowledge to know that they are being misled, and the process of making a complaint is time consuming. The advertising 'run' is often finished before decisions on complaints are made and there are no effective deterrent penalties.

Following our observations above we conclude that the whole system proposed by the European Commission is not balanced. It gives priority to industrial commercial interests rather than to public health concerns and consumer protection interests. The way the monitoring system is conceived cannot avoid abuses and represents therefore unnecessary bureaucracy. Member States would be requested to focus their limited resources on monitoring and control of the information provided by pharmaceutical industry. Instead, they should be responding to patient needs by financing independent bodies able to provide impartial, evidence-based, comparative information in a validated process on diseases and treatment.

About AIM

The *'Association Internationale de la Mutualité'* (International Association of Mutual benefit societies) (AIM), created in 1950, brings together 45 national federations of autonomous health insurance and social protection bodies in 28 countries, all operating according to the principles of solidarity and not-for-profit orientation. They provide coverage against sickness and other social welfare risks to more than 170 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; finally, autonomous management and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

AIM endeavours to voice concerns and ideas raised within the sphere of non-profit health insurance institutions in the EU. AIM positions, requiring validation through its own statutory decision-making process, do not commit its individual member organisations. Therefore, AIM involvement does not detract from its member organisations taking dissentient views.