

Public Consultation on Information to Patients Comments of the Austrian Medical Chamber

Introduction

The Austrian Medical Chamber is the statutory professional organization of all doctors practising in Austria. We represent approximately 37 000 doctors - working either in a self-employed, or in an employed capacity. On the one hand, the Austrian Medical Chamber represents their professional, social and economic interests, on the other it constitutes the competent national authority for Austrian doctors. The responsibilities of the Chamber comprise, besides others, the following areas: involvement in medical training, continuing medical education and professional development, quality assurance in continuing medical education and medical practice, the conclusion of contracts with social insurance institutions and of collective agreements, admission to and administration of the Medical Register, recognition of foreign medical diplomas, execution of disciplinary legislation and arbitration.

Comments on the consultation

The Austrian Medical Chamber welcomes the initiative launched by the Commission, and in particular the form of opinion making procedure. A broad public debate guarantees that the problems in this field are dealt with from different perspectives and that all stakeholders are given the opportunity to comment.

Comments on the key ideas of the forthcoming proposal

1. Provisions on advertisement

The Austrian Medical Chamber strongly **supports** the Commission's intention to **retain the present rules which ban advertisement of prescription medicines to the general public.**

2. Scope, content and general principles of the new legal provisions

We disagree with the view according to which any communication not covered by the definition of "advertisement" should be regarded as sheer "information". In order to distinguish the kinds of communication which should fall under the legal provisions regulating advertisement, the following shall be considered

- who is the author of the respective communication and
- how does the addressee understand this communication

The fact of **who is the author of a communication**, that is to say, on whose initiative, for whose expenses and under whose responsibility a communication is directed to citizens, gives information about the underlying motives of this communication. Communication directed to citizens on the initiative, for the expenses and under the responsibility of pharmaceutical companies, is naturally motivated by **the intention to promote the sales of the respective products**. The Austrian Medical Chamber holds the view that any communication motivated by sales promotion has to be classified as advertisement.

Furthermore, the **effects of a communication on its addressee are of vital importance** for its classification as information or advertisement. Patients receiving positive or neutral information on medicines (as it seems clear that pharmaceutical companies will not publish negative information on their products), will tend to use these products. As a matter of fact, communication **stimulates the selling of the concerned product**, which is why we **classify** communication **as advertisement**.

Therefore, we advocate that any communication not clearly covered by the definition (which needs to be clarified) of “information”, shall be qualified as advertisement.

We take a differentiated view on the proposals to make medicine-related information supplementary to the information contained in the summary of product characteristics available to patients. The Austrian Medical Chamber holds the opinion that **information about ongoing scientific studies shall by no means be communicated to the public**, as they are likely to create massive **uncertainty in patients**.

The same applies to **information on prices** of medicinal products, which we consider absolutely **irrelevant**, as it might lead the patient to urge his or her doctor for economic reasons to prescribe a particular product, which – from the medical point of view – is not necessarily ideal for the treatment of this patient.

Type of actions, content and monitoring of information

We share the opinion that, in principle, a distinction should be made between the cases where the patient passively receives information and those where he actively searches for information. In many cases, however, it will be **hard to distinguish** between those two groups.

We would like to outline the following situation in support of our view: A patient visits a website which contains a banner leading to product information. It is true that, by following this link, the patient actively retrieves the information. Therefore, one might argue that the patient has actively searched for it. On the other hand, it was only **on the active initiative of a third party** (using the means of a banner) that the patient was **induced to engage in further activities**. Therefore, one might argue that the patient was **“pushed to pull”**. We hold the opinion that more liberal provisions that might be put in place for situations where patients take the initiative themselves are **not** suitable for cases where patients are “pushed to pull” as described above.

Information passively received by citizens

The Austrian Medical Chamber strongly rejects that information on prescription-only medicines are disseminated through TV and radio programmes, through printed material actively distributed to the public and through information in printed media.

As already mentioned before and as experience has shown, information of this kind creates the wish in the patient to obtain the product in question. Consequently, patients urge their doctor to prescribe a certain product, which – from the medical point of view - might not be the best for the treatment of the individual patient. With regards to the doctors, this situation constitutes an irresolvable dilemma: doctors, who for medical reasons do not comply with their patients' demand for a certain product, disappoint and frustrate their patients. In such cases, patients often get the impression that they are not taken seriously, or they doubt whether they receive best care, even after the doctor has given an explanation of his point of view. Doctors, on the other hand, who fulfil their patients' wish for a certain product, offend against their professional obligations and their self-conception which consists in rendering best care to every patient.

We have a more differentiated view regarding the situation where the **doctor makes audiovisual and written material available to the patient**. In this case, the personal doctor-patient contact allows the doctor to take a certain corrective action. The doctor is in the position to explain the information provided and to give the patients additional advice, tailored to their specific situation.

As far as **prescription-only medicines** are concerned, we hold the opinion, however, that this form of dissemination of information should be **restricted to doctors**, as it is them, in the end, who take the therapeutic decision together with the patient and who bear the responsibility for prescribing a certain product to a certain patient or not. The dissemination of information to patients by other healthcare professionals could cause wishes in the patients which the attending doctor, for medical reasons, might be unable to fulfil.

Information searched by citizens

We have **no objection against the publication** of objective and factual information, such as the **summary of product characteristics, on websites of pharmaceutical companies, however, on the condition of ex-ante validation by a national authority** (and not by a body which also represents interest groups). In the same way, **lectures on prescription-only medicines should be announced beforehand, in order to allow adequate monitoring.**

As outlined before, **a clear distinction should be made between cases where patients search information on their own initiative, and those where they are induced to search information.** From our point of view, measures inducing the patient to “actively” search for information (“push the patient to pull”) fall under the ban of advertisement of prescription-only medicines.

Answering requests from citizens

We share the opinion that, in general, it will be sufficient that **individual replies by pharmaceutical companies to enquiries from individual citizens** by letter or email **should be reviewed only in the case of complaints.**

3. Quality criteria

We support the details set out in this point.

4. Proposed structure for monitoring and sanctions

The Austrian Medical Chamber holds the view that **each Member State is competent to nominate the national authority** responsible for monitoring information to patients on medicines. It is not the responsibility of the EU to instruct the Member States on national authorities to be established and their composition.

In our view, it is advisable to assign a **state authority** with the **exclusive competence** to monitor information to patients on medicines and execute the relevant legal provisions. This authority would be in the position to call in experts from patients' and

doctors' representatives groups, but would take its **decisions independently from these interest groups.**

We consider voluntary codes of conduct on information to patients on medicines as reasonable and worth supporting. Nevertheless, they cannot replace relevant legal provisions, and their monitoring and execution by a state authority.

Proposal of the Austrian Medical Chamber

The Austrian Medical Chamber, in order to give consideration to the justified need of patients for objective and complete information on medicines, advocates the following initiative: The EU Commission should publish the summaries of product characteristics of all medicines which are authorised in at least one Member State, on a website, which is administered and monitored by the EU Commission (for example within the framework of the Community register of medicinal products on the website of the DG Enterprise and Industry). Preferably this information should be available in all official languages of the European Union.



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