

# Medicinal products for human use: information on products subject to medical prescription

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The Committee on the Environment, Public Health and Food Safety adopted the report drafted by Christofer FJELLNER (EPP, SE) on the proposal for a regulation of the European Parliament and of the Council on amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The committee recommended that the European Parliament's position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

**Patients' rights:** Members consider that the Amending Directive has to focus on the patients and their interests and it has to be reflected in the Amending Regulation as well. The new provisions of the Amending Directive have to emphasise the right of patients for information instead of the right of the pharmaceutical companies to disseminate information.

**Information:** the report highlights the urgent need for a **more precise distinction between advertising and information**.

Non-promotional information on medicinal products must be made available to patients and to the general public by marketing authorisation holders according to the "pull principle" whereby patients/the public have access to information if they need it (contrary to the "push principle" whereby the marketing authorisation holders disseminate information among the patients and the general public).

In this context, Members propose an amendment relating to information not approved by competent authorities during the registration of medicinal products and is in fact hidden "push" information. Any relevant information relating to studies is included in the patient leaflet and the Summary of Product Characteristics (SmPC), which is part of the registration file for approval.

**Extending the time-limit for information:** Members propose extending the timeline for the tacit acceptance of the information from 60 to 120 days in order to meet the organisational needs of the Agency and to ensure that the companies remain fully liable for the information they provide to the general public. If the Agency asks for changes to a document submitted by the marketing authorisation holder, and if the latter resubmits an improved proposal within 30 working days, the Agency shall communicate its response to the new proposal within 60 working days.

**Database on medicinal products:** the report underlines that strengthening the EMEA's role with regard to information for the public on medicinal products for which a medical prescription is required is crucial in order to ensure that all citizens have equal access to high-quality information. The management of the database of information for the public should comply with exemption criteria for that information.

The database should be publicly accessible as a prime source of objective information. With this aim in mind, the Member States, the Commission and the Agency itself should make every effort to ensure that proper use is made of this database.

Members insist on promoting existing sources of independent reliable health information. There are many sources of independent and evidence-based information on treatment choices available within the European Union. These resources take into account cultural specificities and contexts for the population, including health determinants. They are developed by health authorities, medical products agencies, healthcare assessment bodies, healthcare providers, healthcare professionals, consumer organisations, and independent patients' organisations. These information sources should be actively promoted to the general public.

**Agency's budget:** the report requests that in the event that the additional costs incurred by the Agency as a result of its preliminary checking of certain types of information pursuant to this Regulation are not covered by the fees payable by the marketing authorisation holders for this purpose, the amount of the European Union's contribution to the Agency's budget should be reviewed. Accordingly, efforts should be initiated at Member State level with a view to the possible amendment of the European Union's contribution to the Agency.