

Brussels, 28. 06. 2011
CAB D (2011) Ares

694681

Dear Mrs Alves,

Subject: your joint open letter on information to patients

Thank you for your letter of 20 May regarding the Commission amended proposals on information to patients.

Although it is correct that under the current Directive, some information can be disclosed by the marketing authorisation holder, Member States have different views in applying these provisions. This has led to a significant disharmony throughout the Union, which leaves patients with a very different level of access to available medicines.

Furthermore, the European Court of Justice recently ruled that the dissemination of information relating to a medicinal product under prescription which has been selected or rewritten by the manufacturer, is to be considered as prohibited.

In view of these elements, I would consider that the adoption of the amended proposals is still necessary in order to clarify what information marketing authorisation holders *can* make available, but also to *oblige* them to make available some information. This is also the approach taken in the resolution adopted by the European Parliament.

I share many of your views. Indeed, any change to the product information leaflet should be introduced only when the report on the readability of the package leaflets and their value to healthcare professionals and the general public will be available. However, I would not want to further delay the adoption of amended proposals and I consider that such improvement of EU legislation could be introduced at a later stage.

Like you, I believe that existing tools should be further used in order to improve the access to information on medicinal products but also to answer to the need for broader information not limited to medicinal products. I am reflecting in particular on the European medicines web-portal recently established by Regulation (EU) No 1235/2010 as a central point of access to information about medicinal products, but also to other databases such as the EU Health Portal.

Lastly, on the issue of comparative information, as I expressed at the European Parliament in November 2010, I generally agree that information should not cover comparisons between medicinal products, as this could be seen as having a promotional effect. Of course this information is highly relevant for patients and healthcare professionals but, due to its potential abuse for promotion, it requires a strict framework. We are cooperating with Member States on such a framework in the area of health technology assessments.

Yours sincerely,



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