From: Villier, Celine [CVillier@chu-grenoble.fr]
Sent: 31 January 2008 18:25
To: ARLETT Peter (ENTR)
Subject: public consultation

Dear Doctor Arlett,

I agree with what has been written by l_Association Fran_aise des Centres R_gionaux de Pharmacovigilance, but I would like to make more personal comments about the Section 3 of the document _Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance_.

I do agree that is necessary to simplify adverse drug reactions (ADRs) transmission within the EU. I also do agree that alert procedures must be uniformised.

But I strongly disagree with the first part of the title _strategy to better protect public health_, because I do not see within this document any concrete measure about public health. Numerous epidemiologic studies have measured importance of ADRs induced by anticoagulation drugs, NSAIDs, or anticancer chemotherapy. Most of them are old drugs, and suppressing periodic safety up-date reports for such drugs is frightening, unless they will be considered as drugs under intensive monitoring. The definition of an old drug is missing within the document.
This text only deals with data collection and handling. So maybe the right title should be _Strategy to strengthen and rationalise EU pharmacovigilance_.

Obviously, most of propositions are resulting of a strong lobby from the pharmaceutical industry, currently facing to a very deep innovation crisis and are trying to lighten regulatory constraints. The main are :

- reduce the time necessary to obtain a marketing authorisation to reduce the heaviness of investment
- lighten pharmacovigilance tasks focusing only the early signal detection to reassure shareholders
- allowing to patients to declare their ADRs can be of interest. Sharing this task between Marketing authorisation holders (MAHs) (for early signal detection of intensively monitored drugs) and national authority (for other _less interesting_ ADRs) is questionable. Making high quality patient reports requires to ask to the patient very precise data and by the way he expects precise information in return. But the directive does not deal with information or communication with patients. It can be deducted that this task will rest on national authorities and/or their regional network because MAHs acknowledge ADR reception and do not generally answer directly to patients from the scientific point of view to avoid judicial risk. Delegate time-costly, non cost effective, and risky tasks to national pharmacovigilance systems is cost saving_ only for MAHs.

In France, we have a funny expression to describe this. It could be traduced by _ to want the butter, to keep the money to buy the butter and to leave with the girl who sells the butter _.

Some measures could strengthen and rationalise pharmacovigilance within European Union without ambiguity:

- Transfer of EMEA from enterprise and industry directorate-general to public health directorate-general. It is currently the case at the French level and at the world level. Why Europe should be different ?
- Increase of taxes paid at the occasion of marketing authorisation submission to improve institutional pharmacovigilance. This could be easily done with the savings done.

From a more technical point of view, careful assessment of the following points has to be made before any decision :

- Changing definitions such as definition of ADR and suppression of the definition of abuse can have a strong impact on national networks (impact on the regional poison centers and pharmacodependance centers).
- Changing definition of post-authorisation safety study by suppressing _in accordance with the terms of the marketing authorisation_, that is allowing off label drug use, is potentially hazardous because this study can be used thereafter as a scientific reference to justify off

label use. At the same time it is useful to assess risks in real conditions of use. So what kind of funding is acceptable in such studies ?

- Direct patient reporting and patient information must considered together in tasks definition and means attribution

Thank you for your attention.
With kind regards,

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