

Tout d'abord, je souhaitais vous remercier pour l'accueil que vous nous avez réservé au mois de février à M. Bordat et moi-même, et pour les intéressantes discussions que nous avons pu avoir.

En ce qui concerne la consultation, en lien avec la problématique de la mise à jour des annexes de la Directive , et plus précisément des listes positives , il y a , me semble t-il une problématique brevet . Lorsqu'une firme veut lancer un nouveau filtre solaire ou un nouveau conservateur elle doit au préalable réaliser de nombreuses études toxicologiques , puis transmettre le dossier au SCCP . Celui ci est débordé et les délais d'examen sont longs . Il peut y avoir demande de données complémentaires . Une fois l'avis du SCCP obtenu , si celui ci est favorable , il faut encore attendre sa traduction en Directive de la Commission puis la transposition de cette directive dans les réglementations nationales . Toutes ces étapes , qui se chiffrent en années , réduisent d'autant la durée réelle d'exploitation du brevet . Dans le domaine pharmaceutique , pour ne pas freiner la recherche , la durée d'exploitation réelle du brevet est améliorée avec un " bonus " qui démarre le jour de l'autorisation de mise sur le marché .

Il serait très intéressant de bénéficier d'une mesure similaire pour les substances soumises à listes positives .

Qu'en pensez-vous ?

A votre disposition pour en reparler

Cordialement

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## I. Pierre Fabre Facts

Company created in 1961 by Mr Pierre Fabre, PIERRE FABRE is a French private company with well-balanced activities from Healthcare to Beauty (Dermo-cosmetics & Dermatology).

Turnover 2005 : 1,486 million euros with a fast growing international presence.

Total employees (Dec. 2005) : 8 620

- France : 6 346

- International : 2 274

Total 2005 R & D budget : 182 million euros with a staff of 1 289 scientists from different nationalities.

A company with :

- wide R & D collaboration agreements with National and International Institutes and Universities,
- multiple partnerships with mid-size and multinational companies for co-development, licensing-In and Out agreements.
- a streamlined management structure enabling a quick decision process.

Pharmacy : 2nd independent French pharmaceutical Laboratory, Pierre Fabre Médicament directs its development towards targeted therapeutic axes. The commercial structures are turned towards the following therapeutic fields : Cancerology, Urology, Cardiology, Psychiatry, Phlebology, Pneumology, Infectiology, Gynaecology, Rheumatology

Dermo-Cosmetics : A rigorous approach based on our pharmaceutical culture. 1st European dermo-cosmetic laboratory in pharmacy, 4 % of our turnover is being dedicated to research and development

## II. PUBLIC CONSULTATION

The European Commission has raised questions in its public consultation on the simplification of the Cosmetics Directive. We were asked to take position on the 3 following issues:

- codifying and streamlining the legal provisions with a view to reducing administrative costs (items 1 to 7)
- introducing elements on the "new approach" where useful in order to simplify and improve operations of the legislation while maintaining a high level of safety in cosmetics (items 8 to 13)
- strengthening certain elements related to chemical safety, in particular with a view to innovative ingredients in cosmetics (items 14 to 18)

1- concerning the 1st issue, we are overall in line with the position taken by the European Cosmetics Industry. Since there are diverse interpretations by the Member States of the Directive, that means that the cost stemming of these interpretation divergences are carried out by the Industry. This is particularly true for the SME's. Considering this situation, we consider that the wish for a simplification is welcome, under the condition that this new clear regulation will be interpreted in the same way in all Member States. Guidelines and recommendations should complement this regulation

2- concerning the 2nd issue : the Pierre Fabre position is slightly different from most of the European Industry. We are in line with the wish of the European Commission to enhance the level of security for consumers and guaranty the freedom of movement. In this context, we are in favor of

the implementation on the European level of a cosmetovigilance system. This is coherent with the principle of liability of the manufacturer (as proposed by SLIM). A training system supported by Member States has to be set up in this context, in particular for SME's.

As a consequence, this is the reason why we are in favor of a notification system, Health Authorities need to be well informed before putting the product on the market. The existence of such a system cannot be sustained without creating a European Agency for the supervision of Cosmetics. Nevertheless, it seems to us that product categories should be classified according to a hierarchical system in relation with the product target. Considering the cosmetovigilance system, it seems to us that there is a strong need to clearly define side effects, according to the Council of Europe recommendations.

3- concerning the 3rd issue, we consider that the Cosmetics Directive should apply equally to all cosmetics, whether or not innovative. But, in this context, we would like to raise the question of the patent regulation. We consider that the delay for new substances to be registered should be added to the duration of the patent -as it is regulated in the pharmaceutical sector.

Best regards,  
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