FEDERCHIMICA
ASCHIMFARMA
Associazione nazionale produttori principi attivi e intermedi per l'industria farmaceutica

EFCG
EUROPEAN FINE CHEMICALS GROUP

Enterprise and Industry
European Commission
200, Rue de la Loi
B-1049 Brussels
Belgium

17th December 2007

For the attention of: Mr. Nils Behrndt
Member of Cabinet of VP Verheugen

Dear Mr. Behrndt,

This is to thank you for the meeting at your office last week on 6th December.

Together with Aschimfarma, EFCG had the opportunity to enquire as to the follow-up that the Commission was providing to the Sartori sponsored Written Declaration. We understood that the matter of non-compliance with the law in relation to APIs, primarily the issues of imports from Asia and middlemen issues, is now being addressed in terms of studies leading to new legislation.

Our reaction was:

1. We are disappointed that after we have put 4 years of work on this issue, and have the EU Parliament majority aligned with us, the Commission is still at the data gathering stage.

2. We are not anti-Asia and we are not fighting for fortress Europe. Our members have plants in Asia and some of them are headquartered in Asia. Our objectives are: reducing risks to patients and removing the rogue players from the industry and from the market - these actions will also level the playing field.

3. We do not see the priority to be new legislation because in an EU context this takes many years. The escalating risk, driven by the combination of globalization and hyper-competition in off-patent medicines, makes decisive action imperative and urgent. We believe current legislation, though imperfect, is adequate, but what needs addressing is the intensity of enforcement and severeness of penalties - because in the EU at the moment there is little to no deterrent effect to help to ensure at least a reasonable level of average API compliance.

We were pleased to hear that your office was keen to hear constructive proposals from Industry. In the current letter you will find specific suggestions that we encourage you to consider including in the report on counterfeiting that will be ready soon.

By mid-January we commit to provide you with a list of proposals for the report on Supply Chain. These will be split into two classes: i) those that do not require legislation and could -subject to some catalyst effect by DG Enterprise- lead to a far better situation in Europe in terms of compliance with the law in the short term; and ii) those that would require new legislation that would bring the legal framework for the full length of the EU pharmaceutical supply chain into the 21st century. These shall specifically address issues related to the middlemen, transparency and traceability, consistency of action across the EU and at our borders, etc.

Our best wishes for Christmas and the New Year,
Yours Sincerely,

Guy Villax
Board Member

Gian Mario Baccalini
President

Aschimfarma
Via Giovanni da Procida 11 - 20149 Milano Italy
Tel. +39 02 34565 246 Fax +39 02 34565 364
aschimfarma@federchimica.it
http://aschimfarma.federchimica.it/

European Chemical Industry Council
Avenue E. van Nieuwenhuyse 4 B-1160 Brussels Belgium
Tel: +32 2 676 7211 Fax: +32 2 676 7301 mail@cefic.be

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Annex to
Letter to Enterprise and Industry
From EFCG/Aschimfarma
17th December 2007

Measures to consider in the Counterfeiting Report

Criticality of the API used in a medicine

It should be made crystal clear that the Active Pharmaceutical Ingredient in a medicine is the primary determining factor regarding safety and efficacy. It is the API that provides the therapeutic effect. Any serious API non-compliance issue of a GMP- or regulatory nature will result in a substandard, non-compliant medicine. A seriously non-compliant API (i.e. one that does not meet specification, or one that was not produced according to the process and the controls described in the registration dossier filed with the authorities or one that was not produced under GMP - in all cases the medicine will be non-compliant and therefore will not be within the law) forms a direct threat to the health of (many) patients: Even only one drum of API will normally form the basis for medicines for thousands of patients.

The quality of a medicine can never be better than the quality of the API that is used; it may be lower if poorly formulated - but it can never be higher than that which is built into the API (i.e. quality cannot ever be "corrected" by formulation).

Definition of a counterfeit API

The following definition of counterfeit APIs has been directly derived from EFPIA's definition of counterfeit medicines (EFPIA Position Paper on Counterfeit Medicines of June 2005): *Counterfeit APIs are active pharmaceutical ingredients for which source and / or quality are falsely represented on the label, on the Certificate of Analysis or otherwise. A medicine that contains a counterfeit API is a counterfeit medicine.*

EFCG recommends strongly that this definition will be included in the report.

Non-compliance of the API with GMP does not make the medicine a counterfeit it just makes it non-compliant. However a serious breakdown in regulatory compliance (break in traceability, mis-labeling, any kind of fraud or fabrication in related documentation used in a buy/sell/registration operation) will make the API a counterfeit API. Counterfeit APIs are normally also severely GMP non-compliant.
It is imperative that the definition of a counterfeit medicine will recognize that when a medicinal product contains a counterfeit API it is a counterfeit medicine.

Criticality to consider middlemen in the introduction of counterfeit APIs into the legal supply chain

The well documented human health catastrophes caused by sub-standard pharmaceutical ingredients (Gentamicin in the USA, glycerin contaminated with or replaced by the poisonous diethylene glycol in Haiti, Panama, India etc.) were effectively the result of unscrupulous middlemen altering quality, origin or even identity of active ingredients and excipients. Users of the materials were misled into thinking the materials were compliant APIs and pharma grade excipients, respectively. Thus these counterfeit materials entered into the official / legal supply chain and proved to be deadly. Everyone involved in the manufacture of pharmaceuticals or in the development of regulations for medicinal products should watch the video "The Vos Affair" on the Haiti tragedy: Parents with sick children buy cough syrup at the pharmacy and then unknowingly administer what turns out to be a lethal poison to their own children and then see them dying - 88 children.

Aschimfarma
Via Giovanni da Procida 11 - 20149 Milano Italy
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aschimfarma@federchimica.it
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Tel: +32 2 676 7211 Fax: +32 2 676 7301 mail@cefic.be