Warsaw, 14th September 2012

European Commission
DG Health and Consumers
Unit D5 'Medicinal products – authorisations, EMA'
E-mail: SANCO-FEES-PHARMACOVIGILANCE@ec.europa.eu

On behalf of the Polish Chamber of Pharmaceutical Industry and Medical Devices POLFARMED, we hereby submit remarks to the draft document **"INTRODUCTION OF FEES TO BE CHARGED BY THE EMA FOR PHARMACOVIGILANCE"**

(PChPIMD POLFARMED is an association of Polish pharmaceuticals and medical devices producers.)

Notes:

Regarding section 3.3 Assessment of Pharmacovigilance Referrals:

1. Does the proposed fee for the procedure *Assessment of Pharmacovigilance Referrals* regard the medicinal products included in the Annexe to the European Commission decision, which were included in the assessment process and the scientific procedure?

2. We hereby apply for a definition of the fee incurred by the entities responsible (when forming a group) for the procedure *Assessment Pharmacovigilance Referrals* applying the market share proportion principle and considering the information connected with the quantity of medicinal products packagings marketed by each entity.

3. Specifying the method for the procedure of distributing the costs between the responsible entities, which declare their intention to join the group in order to pay one common fee.

Regarding section 3.4 Pharmacovigilance Service Fee:

1. Specifying the method of fee calculation for PV services for the medicinal products, which contain the same active substance or a mixture of substances: whether the strength, form or various indications for the same substance or a mixture of substances influence the fees amount for a single active substance or a mixture.

2. Taking into consideration that the draft submitted for consultations contained only the maximum annual fee amount for PV services, we would like you to specify in detail the fees amounts for the generic status products, the established application products, homoeopathic products, traditional herbal and hybrid medicinal products for which the fees should be considerably lower, in our opinion.

3. Considering the average price amount index for a unit packaging of a medicinal product in a given market during preparation of unambiguous principles of calculation of the annual fee.

4. We also apply for stopping the proposed annual PV services fee until EMA has undertaken all the declared activities in this area and ensuring the offered IT tools, including the full and correct operation of the EV base.

Additionally:

- Considering the possibility to pay one joint fee for the activities proposed by EMA (described in sections: 3.1, 3.2, 3.3: *Grouping*), we hereby apply to receive detailed conditions for joining a given group by the responsible entities as well as the principles and methods for costs distribution among the entities, which declare their intention of joining a group, having in mind protection of small and medium-sized companies.

- We would like you to declare the final (estimated) date for introduction of the fees, resulting from the submitted document *Introduction of fees to be charged by EMA for Pharmacovigilance*.

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