PPTA
Plasma Protein Therapeutics Association

**6 May 2008** **BY E-MAIL**
**Reference: DGENT08005** entr-pharmaceuticals-counterfeit@ec.europa.eu

European Commission
DG Enterprise and Industry
Unit F2 Pharmaceuticals
BREY 10/106
B-1049 BRUSSELS

**Subject: Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use**

Dear Sir/Madame,

PPTA welcomes the Commission's initiative to prepare a legal proposal to combat counterfeit medicines for human use. We wholeheartedly agree that there is an imminent need to protect public health from counterfeit medicines and we appreciate the opportunity to contribute our views in consultation before the preparation of the proposal.

The factors facilitating the occurrence of counterfeit drugs may vary from country to country, however counterfeit medicines are a global problem and need to be counteracted on a global level. Vice-president Verheugen acknowledged the need for an internationally harmonised approach by his announcement that any anti-counterfeiting strategy of the European Commission will build on the results of the WHO International Medical Products Anti-Counterfeiting Task Force (IMPACT). Already, the Commission observed that there is evidence that EU Member States are starting to consider taking unilateral action to address the problem of counterfeit medicines and we, as the representation of the biggest supplier of plasma protein therapies to the global market are concerned that disharmonised individual approaches will lead to situations, where life-saving medicinal products, such as plasma protein therapies cannot be provided to patients because of logistical hurdles. In any case, disharmonised approaches will dramatically increase the costs of any pharmaceutical product and the Commission's commitment to specifically focus on impacts in terms of regulatory burden, including administrative costs for all actors in this sector is greatly appreciated.

We agree in principle with the Commission's key ideas for changes to EU legislation as outlined in the consultation documents, but we would like to share some thoughts with the Commission, based on previous discussions, particularly with the US authorities, since PPTA is already involved in the US authorities' efforts to introduce mass serilisation and pedigree.

We strongly support the implementation of pedigree, but we believe that the establishment of a central pedigree database is neither possible nor necessary. There are already other existing solutions based either on electronic documents or independent web enabled databases which would allow the creation of generic pedigrees in real time on demand (EPCIS).

An EU only solution for product identifiers is not sufficient because medicinal products are globally marketed and consequently there has to be a global standard. A unilateral European initiative would severely impact on patient access to medicinal products in other parts of the world.

When barcode technology is implemented as the only option inference is necessary Pedigrees have to take this into account. However, we strongly recommend defining and allowing at least two different data carriers (barcode and RFID)

A unique identifier for supply chain partners would be helpful as well, especially with regards to a database. We believe that such a number should be related to a specific role, but to a geographical site or eventually a company.

Serialization of the content in the original package should also be considered. PPTA would like to suggest applying the same number on the inner parts (blister, vials) as a reference.

In addition we would like to point out, that, once the legislation is adopted certain prerequisites for a successful implementation will need to be put in place. Particularly, the need for regular audits of GMP/GDP compliances of all involved parties in the manufacturing and distribution chain by qualified auditors would need to increase the inspectors' workforce significantly. Already today, there are availability issues due to the required inspection schedules. In addition, training programs need to be commenced as soon as possible to ensure that all inspectors are on the same level of knowledge and have a common agreement on the key principles of conducting the inspections.

Thank you very much again for the opportunity to contribute to this important initiative. We remain at your disposal for further discussions at any time of your convenience.

Sincerely Yours,

Dr. Ilka von Hoegen
Senior Director, Quality and Safety

Ms. Mary Gustafson
Vice President, PPTA Global
Regulatory Policy