Question for written answer E-008923/2015
to the Commission
Rule 130
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Subject: Regulation of human plasma-derived medicinal products

While the pharmaceutical industry is having increasing recourse to medicinal products derived from human blood or plasma as an effective treatment for a large variety of diseases, there is no specific Community legislation closely regulating such medicines.

Despite efforts by the WHO, the Council of Europe and the EU to promote self-sufficiency in every country, this has not been achieved in the EU with regard to human blood and plasma, which accordingly need to be imported from other countries such as the United States, where donations are remunerated.

In view of this and in the light of the objectives of ensuring a high level of human health protection (Directive 2002/98/EC), as well as self-sufficiency in human blood and plasma through voluntary donations (Directive 2001/83/EC):

1. Does the Commission consider it necessary to regulate specifically human plasma-derived medicinal products at all stages, in order to uphold bioethical standards and provide minimum guarantees?

2. What view does the Commission take of measures by the Member States to ensure self-sufficiency in human blood and plasma?

3. Does the Commission consider that deregulation of the sale of human blood and plasma will undermine quality and safety standards?