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Submission of comments on 'Concept Paper Submitted for Public Consultation on the Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and Its Verification' (Ref: Sanco.ddg1.d.3(2011)1342823)

Comments from:

Name of organisation or individual
IPFA, International Plasma Fractionation Association, our ref. IP-12-143a

1. General comments

General comment (if any)
IPFA appreciates the reinforcement of requirements regarding the prevention of the entry into the legal supply chain of falsified medicinal products. This Concept Paper proposes to identify main requirements of the unique identifier and safety features, two important tools in limiting the spread of falsified and/or counterfeit medicinal products. Nevertheless, we would like to emphasise that these tools are going to have only a limited impact because they will be efficient within the European Union only, where the counterfeiting/falsified medicines phenomenon, even if increasing, is still limited compared to some other regions of the world. Consequently, those tools will have very limited impact on protection of: - European patients shopping their medicines through illegal online pharmacies; - European marketing authorisation holders and European manufacturers, suffering from the counterfeiting/falsification of their medicinal products outside of the European Union, in those countries where falsification occurs the most and less equipped for robust controlled distribution systems. Therefore this is like playing tennis with a hole in the racket.