Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Text with EEA relevance)

Article 3

At the latest 5 years after the date of application of the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall submit a report to the European Parliament and to the Council containing the following:

(a) a description, where possible including quantitative data, of the trends in the falsification of medicinal products in terms of: categories of medicinal products affected, distribution channels including sale at a distance to the public by means of information society services, the Member States concerned, the nature of the falsifications, and the regions of provenance of these products; and

(b) an evaluation of the contribution of the measures provided for in this Directive regarding the prevention of the entry of falsified medicinal products in the legal supply chain. That evaluation shall in particular assess point (o) of Article 54 and Article 54a of Directive 2001/83/EC as inserted by this Directive.