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 4

In order to adopt the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall perform a study assessing at least the following aspects:

(a) the technical options for the unique identifier of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC as inserted by this Directive;

(b) the options for the extent and the modalities of verification of the authenticity of the medicinal product bearing the safety features. This assessment shall take into account the particular characteristics of the supply chains in the Member States;

(c) the technical options for establishing and managing the repositories system, referred to in point (e) of Article 54a(2) of Directive 2001/83/EC as inserted by this Directive.

The study shall, for each of the options, assess benefits, costs and cost-effectiveness.