Question for written answer E-001188/2017
to the Commission
Rule 130
Renaud Muselier (PPE)

Subject: Misapplication by France of Directive 2011/62/EU on Falsified Medicinal Products

Directive 2011/62/EU on Falsified Medicinal Products introduces the requirement to establish a system of serial numbers for medicinal products manufactured in the EU so as to make these easier to trace and prevent counterfeiting. This mechanism ensures there can be no tampering with the packaging of any prescription medicines.

The EU Directive only requires that the mechanism be established for prescription medicines. However, France has chosen to apply the rules more strictly by requiring that it apply to all medicines reimbursed through the social security system. This means that rather than applying to a minority (around 20%) of medicines, it should apply to almost 80% of all medicines produced in France.

While the aim of protecting the public against counterfeiting is laudable, the misapplication of the directive is particularly disadvantageous to the French pharmaceutical industry. It clearly clashes with the fair competition that the EU wishes to establish across all Member States.

Given these circumstances, does the Commission plan to:

1. Remind the French authorities of the compelling obligation to apply the letter of EU law?

2. Review its criteria in respect of control requirements so as to bring these into line with those applied by the French authorities and hence maintain fair competition between all EU operators, while also protecting the European public against counterfeit medicines?