Question for written answer E-004021/2013
to the Commission
Rule 117
Rebecca Taylor (ALDE)

Subject: The Falsified Medicines Directive and potential future shortages of medicines in the EU

Given that Directive 2011/62/EU is due to come into force in July 2013, does the Commission think that, in order to avoid shortages of some medicines, it will be necessary to exempt further third countries from rules governing importation if:

– the country's regulatory framework for active substances is equivalent to that of the EU?

– an exporting plant has been inspected by a Member State and found to be compliant?

What measures, if any, is the Commission taking to encourage third countries to apply for exemptions under these criteria?