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NOTE

from:	General Secretariat of the Council
to:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs** Council meeting on 20 and 21 June 2013 Provisions relating to the import of Active Pharmaceutical Ingredients in the Falsified Medicines Directive - *Information from the Commission* (Any Other Business item)

Delegations will find in the Annex an information note on the abovementioned subject.

ANNEX

The 'Falsified Medicines Directive' 2011/62/EU has been adopted in June 2011 and had to be implemented by Member States by 2 January 2013. It introduces for the first time EU-wide rules for the importation of active substances for medicines for human use. As of 2 July 2013 importations of API have to be accompanied by a "written confirmation" issued by the third country where the manufacturing site is established, confirming manufacturing standards at least equivalent to those in the EU.

This note provides a brief update on the Commission's work and the transposition status of the Directive.

To date, twenty infringement proceedings have been launched against those Member States which have not notified to the Commission the national transposition measures taken to comply with the Falsified Medicines Directive by the deadline. Since then, 9 Member States have notified transposition measures and the Commission is currently analysing these measures.
While waiting for the Member States to implement, the Commission has continued to work very actively to prepare stakeholders and third countries and to guarantee a smooth application of the new rules on importation of active substances.

The Commission has official information from all important active substance exporting countries that they have started issuing the "written confirmation", unless they have been "listed" by the Commission in accordance with Article 111b of Directive 2001/83/EC.
Commissioner Borg visited India and China in April and June 2013 to seek the cooperation of the local competent authorities on this file. The results are visible. India has issued over 110 written confirmations (out of 190 applications) and plans to process all the applications received by its authorities before 2 July. China started issuing written confirmations in mid-June.
Taiwan, South Korea, Israel, Ukraine, South Africa, Singapore and Argentina have also started issuing the "written confirmation", while Canada, Mexico, Russia, and Turkey will start shortly.

The Commission has intensified the "listing activities" under Article 111b of Directive 2001/83/EC. Switzerland, Australia, the Unites States and Japan are now listed. These countries will be able to export to the EU without written confirmation because they are "listed" as equivalent. In addition, for Brazil, the equivalence assessment is on-going. Israel and Singapore are modifying their legislation to be re-considered for listing. Argentina, Mexico and Malaysia will apply for listing later this year.

There is a certain risk that not all third countries will be fully ready in time (*i.e.* not all active substances manufacturing plants will receive a written confirmation by 2 July) but it is not to be expected that this translates in any critical shortages as a number of countries are already listed. In addition, industry is both (i) making plans to replace their uncertified suppliers with suppliers having obtained a written confirmation; and/or (ii) stock-piling so to be able to produce medicines while waiting for their usual supplies to obtain a written confirmation. Finally, to prevent shortage of medicines, Member States have the possibility to allow active substances to be imported from a third country if accompanied by an EU good manufacturing practice certificate. To date, Italy, Spain and the United Kingdom have communicated to the Commission their intention to use this possibility.

It is worth underlining that the European Medicines Agency is proactively coordinating the cooperation of Member State authorities as regards inspections of manufacturing plants in third countries, with a particular focus on priority plants and substances.
Considerable progress has been achieved in the preparation for the entry into application of the new rules.

Shortages of critical medicines caused by poor implementation in the first few months must be avoided.

The Commission and the European Medicines Agency are putting in place the necessary measures to ensure the early detection of potential difficulties, the rapid circulation of information between all the concerned players and swift and effective action if potential problems are detected.
An equal level of preparedness is expected of Member State authorities. Industry is expected to cooperate by providing authorities with early, complete and detailed information about sites and substances of potential concern.