HELLENIC DEMOCRACY
MINISTRY OF HEALTH
NATIONAL ORGANIZATION FOR MEDICINES
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Athens, 29th November 2012
Protocol number: 76485

Division: **Manufacturing & Marketing Control**
Section: **Inspection**
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Subject: Directive 2011/62/EU 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

Directive 2011/62/EE (http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf) defines specific conditions, within the framework of preventing the entry of falsified medicinal products into the nominal supply chain, regarding the import of active ingredients from Third Countries (article 1, paragraph 6). Among those, it is required that active substances should be accompanied by a written confirmation from the competent authority of the exporting third country (relevant template has been issued by EU: http://ec.europa.eu/health/files/eudralex/vol-4/2012_06_19_template.pdf)unless one of the following cases is valid:

- If the exporting country is included in the list referred to in Article 1, paragraph 25. In order for a country to be included in the relevant list, the exporting country should submit an application, which will be assessed by the EU.
- When, und3er exceptional circumstances and where necessary to ensure the availability of medicinal products, a manufacturing facility for an active substance for export has been inspected by a Member State and was found to comply with the principles and guidelines of good manufacturing practice (article 1, paragraph 6);.

To clarify the above, EU have uploaded to its website the relevant documentation (http://ec.europa.eu/health/human-use/quality/index_en.htm and http://ec.europa.eu/health/files/documents/active_pharmaceutical_ingredients_leaflet_en.pdf)

It is noted that above requirements are not applied to active ingredients used in medicinal products for veterinary use.

The above requirements of directive 2011/06/EU will become effective on 2nd July 2013. In order to ensure public health and the availability of medicinal products, the Marketing Authorization Holders should take all necessary measures.
In addition, Marketing Authorization Holders or their Local Representatives, in collaboration with the manufacturing plants of the medicinal products, should notify EOF until 30th November 2012, for authorized products that are marketed in the Greek market and contain active ingredients imported from Third Countries. More specifically, Marketing Authorization Holders or Local Representatives should send to the Division of Manufacturing & Marketing Control a table containing the following data:

- The name of medicinal product, the pharmaceutical form, the name (and the country) of the manufacturing site of the product and the active ingredient's strength.

- The name of active ingredient, the name of its manufacturing plant, located in the Third Country, (please note that only the sites that actually manufacture the API should be included) and the source country of the active ingredient
- The Competent Authority from EU/EEA or a country under mutual recognition agreement with EU (MRA Agreement), that has inspected the API manufacturer site as well as the inspection date.

Data can be submitted to the following e-mail address: bstamati@eof.gr

THE DEPUTY
DIRECTOR OF DIVISION

B.STAMATI

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