HELLENIC REPUBLIC **TO BE POSTED ON THE INTERNET**

MINISTRY OF HEALTH

NATIONAL ORGANISATION FOR MEDICINES Holargos, 14 August 2017

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ANNOUNCEMENT

SUBJECT: SAFETY FEATURES OF MEDICINAL PRODUCTS FOR HUMAN USE

Article 54a (2) of Directive 2001/83/EC authorised the European Commission to adopt measures with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54. In implementation of this authorisation, on 9 February 2016, the COMMISSION DELEGATED REGULATION (EU) 2016/161 (in short the DR) was adopted, stating, inter alia, the following:

The DR applies to:

(a) medicinal products subject to prescription which shall bear safety features on their packaging pursuant to Article 54a(1) of Directive 2001/83/EC, unless included in the list set out in Annex I to the DR;

(b) medicinal products not subject to prescription included in the list set out in Annex II to the DR;

(c) medicinal products to which Member States have extended the scope of application of the unique identifier or of the anti-tampering device in accordance with Article 54a(5) of Directive 2001/83/EC.

Where reference is made to the packaging in a provision of the DR, the provision shall apply to outer packaging or to the immediate packaging if the medicinal product has no outer packaging.

Clarifications:

The DR does not apply to:

(a) veterinary medicinal products;

(b) medicinal products for human use produced exclusively for export;

(c) medicinal products which are intended for clinical trials and have not been granted a marketing authorisation.

For authorised medicinal products to be used in clinical trials, the requirements of Directive 2001/83/EC and the DR apply. In this case, the unique identifiers of the authorised investigational medicinal products must be decommissioned in accordance with Articles 16 and 25(4) (c) of the DR. A batch of an authorised investigational medicinal product can be exempted from the rules on safety features if, at the time of manufacture, it is known that the entire batch is intended for use in clinical trials.

It should be pointed out that Greece is one of the few exceptions among EU Member States that already have a national system for the verification and authentication of medicines (authenticity tag), which has been proved to be effective and useful for controlling e-prescription and reimbursement of insured persons.

EOF has from the outset engaged in constant communication and cooperation with stakeholders to prepare our country for the transition to the new system. In this context, an inter-directorate committee has been established with a three-month mandate (ref. no. 9137/02.02.2017) in order to process and propose responses to the queries submitted by SFEE/PEF as well as by individual pharmaceutical companies.

The committee's proposals were approved by the Board of Directors of EOF (Decision No. O-217/8 / 22.06.2017) and included in the attached document (Committee's responses regarding the safety features of medicinal products).

Given that the discussion on the implementation of the DR is still ongoing at the European and the national level, EOF will issue announcements at regular intervals to ensure that all stakeholders are kept informed.

The Head of the Product Manufacture and Marketing Control Directorate

Pantelia Goura

Committee Coordinator

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