Ministerial Decision No. ΓΥ 24α (3)

Authenticity tag of medicinal products

THE MINISTER OF HEALTH AND SOCIAL SOLIDARITY

Having regard to:

1. the provisions of:

a) Article 6 para 1 of Law 1316/1983 (Government Gazette A 3);

b) Article 3 para 13(c) of Law 1316/1983, as replaced by Article 71 para 7 of Law 3984/2011 (Government Gazette A 150);

c) Article 14 para 4 and Article 3 para 10 of Law 1316/1983;

d) Article 19 para 1 (2) and para 8 of Legislative Decree 96/1973, as amended and currently in force;

e) Joint Ministerial Decision ΔΥΓ3(α)/83657/2005 (Government Gazette 59/B/2006);

2. Decision/Recommendation No. 0−356/12/6.12.2011 of the Management Board of EOF;

3. the fact that this Decision shall entail no expenditure under the government budget;

We decide as follows:

Article 1

1. Every medicine in the Greek market shall bear an authenticity tag, mandatorily affixed to its outer package under the care and responsibility of the respective marketing authorisation holders (MAHs) or parallel export authorisation holders or emergency import authorisation holders under Article 29 of Law 1316/1983.

2. Authenticity tags shall be issued by the National Organisation for Medicines (EOF), which under its own care, responsibility and at its own cost shall supply them free of charge to the obligated companies or their duly authorised representatives.

3. The authenticity tag shall be manufactured from special paper with secure background watermarking and UV-visible features including the national emblem and the EOF acronym, and shall have the form of a double-layer self-adhesive tag, in a single piece or more pieces, sized 40mm x 24mm.

EOF shall ensure that a 12-digit Unique Serial Number as EAN-13 barcode and in numerals is indelibly printed on both layers of the tag so that it can remain on the package after the removal of the tag.

Article 2

1. Holders of marketing authorisation or parallel export authorisation or emergency import authorisation shall be required to communicate to EOF, within the first calendar days of November and May each year, a forecast of their tag requirements for the next year-half (January-June and July-December respectively).

2. EOF shall procure and supply to the interested parties the quantities of tags required on the basis of the above-mentioned forecast and to this end it shall establish

respective outlays in its budget for the costs involved by the issuance, distribution, storage, handling and, in general, any other expenditure related to the authenticity tags.

3. Holders of marketing authorisation or parallel export authorisation or emergency import authorisation shall be required to:

a) affix the authenticity tag on the outer package of their products and indicate on the tag in an abbreviated form and in legible lettering the marketing authorisation holder, as well as the name, pharmaceutical form and strength of each product. They shall also be required to print the code number assigned to the product by EOF in the form of an EAN-13 barcode and with the data other than the code number, as specified from time to time by EOF decisions. The affixation of the tag shall be carried out in series by lot. The affixation of the authenticity tag on manufactured or packed products shall be carried out after the packing of the entire lot has been completed and not on parts of the lot. The affixation of the tag shall be carried out in duly licenced facilities;

b) report to EOF, at the end of each calendar month, the number of authenticity tags they have used for their products, broken down by lot and EOF code, including a waste tolerance of no more than 3% of the total quantity of authenticity tags delivered;

c) to return any unused authenticity tags in the event of discontinuation of their business or whenever requested by EOF for replacement (change of colour) or in the event of a modification of the marketing authorisation in terms of prescription/OTC classification of individual products;

d) return forthwith to EOF any misprinted or faulty tags.

Article 3

1.a) Medicinal products supplied to hospitals, the central government and other legal persons in public law shall be stamped by the supplier with the indication “GOVERNMENT ARTICLE” in capital letters.

The authenticity tag shall not be removed from the package and shall not be reused.

b) Medicinal products supplied to private hospitals authorized to operate a pharmacy shall be stamped by the supplier with the indication “PHARMACY OF PRIVATE CLINIC” in capital letters before they enter the hospital.

The authenticity tag shall not be removed from the package and shall not be reused.

c) Medicinal products supplied to private hospitals not operating a pharmacy shall be stamped by the supplier, i.e. the pharmacy, the MAH or the MAH’s duly authorised representative, and before the delivery of the products the authenticity tag shall be cancelled with the stamp of the pharmacy or the company, respectively.

The authenticity tag shall not be removed from the package and shall not be reused.

d) For medicinal products dispensed by a pharmacy to private clients at their own cost, the authenticity tag shall be cancelled by the pharmacist with the stamp of the pharmacy.

The authenticity tag shall not be removed from the package and shall not be reused.

e) For medicinal products dispensed by pharmacies to the insured of the civil servants' healthcare scheme and other social security funds, the pharmacist shall remove the authenticity tag from the package and affix it on the respective prescription, which is the necessary supporting document for reimbursement. Authenticity tags affixed on prescriptions shall not have any erasures or overwriting.

2.a) The pharmacists, the persons responsible for taking delivery of medicines in private hospitals not operating a pharmacy and the holders of a wholesale licence shall be required to check the authenticity tags of the medicinal products supplied to them.

b) Pharmacies are prohibited from dispensing to private clients any medicines without the authenticity tag. Also, all parties involved in the pharmacaeutical supply chain (MAHs and other obligated persons, wholesalers, pharmacies, public and private hospitals, etc.) are prohibited from holding any removed authenticity tags or any medicinal products the authenticity tags of which have been removed or defaced in any manner other than as described hereinabove.

c) No medicinal products may circulate in the Greek market without an authenticity tag, excluding the medicines sold under the procedure of "individual order" following the approval of EOF.

d) The delivery and return of authenticity tags, the technical specifications as applicable from time to time, the manner and procedure for the submission to EOF of the data on the use of tags and any other technical modality or detail pertaining to the use of authenticity tags shall be specified by a decision of EOF published in the Government Gazette, in accordance with Article 3 para 10 of Law 1316/1983.

e) Large-volume medicinal products, as defined in the European Pharmacopoeia, shall be required to bear one authenticity tag affixed on each large-volume container.

f) Medicinal products in the form of multi-dose small ampoules shall bear one authenticity tag for every ten ampoules.

Article 4

1. The provisions of this Decision shall also apply to exported products, excluding those for which EOF has authorised production or packing exclusively for export.

2. In the event that any quantity of medicinal products authorised in Greece are exported by MAHs to EU or non-EU countries, MAHs shall indelibly cancel the authenticity tags in any appropriate method and, within the first ten calendar days of each month, shall forward to EOF a statement with their exports of such products during the preceding month, along with copies of the respective invoices.

3. For medicinal products with marketing authorisation in Greece which are exported from Greece by licenced wholesalers, the authenticity tag shall be mandatorily cancelled by being removed and affixed on a special EOF-supplied form and returned to EOF, under the exclusive responsibility of the licenced wholesaler-exporter. These forms shall be submitted to EOF, accompanied by relevant solemn declarations, within the first fifteen days of each calendar month and shall refer to exports during the preceding month.

4. After the completion of the system for the electronic real-time recording of authenticity tag data, the above procedure shall be revised by a new Ministerial Decision.

Article 5

Non-compliance with the provisions of this Decision shall incur a fine of up to €44,000, imposed by decision of the Minister of Health and Social Solidarity following a recommendation of the Board of Directors of EOF.

Any medicinal products marketed in infringement of these provisions shall be confiscated by the competent officers of the Ministry of Health and Social Solidarity or of EOF. Such confiscation shall be subject to the approval of the Management Board of EOF. The fate of confiscated products shall be determined by the Minister of Health and Social Solidarity -- with the concurrent opinion of the Management Board of EOF – who may order their destruction or donation to hospitals or other institutions.

Article 6

1. The provisions of this Decision shall enter into force as of the publication hereof in the Government Gazette.

2. As of the entry hereof into force, any earlier relevant provision shall be repealed.

We order that this Decision be published in the Government Gazette.

Athens, 22 February 2012

THE MINISTER

ANDREAS LOVERDOS