



HELLENIC REPUBLIC
MINISTRY OF HEALTH
**NATIONAL ORGANIZATION
FOR MEDICINES**

Mesoghion 284, 155 62 Cholargus

www.eof.gr

Directorate: Control of Production and Marketing of Products

Department: PAKAEP

Information: M. Mothoneou

Cholargus 21/5/2013
Protocol No. EOF 39842

TABLE OF RECIPIENTS

Procedure for the correction of data on the Medicines Authenticity Sticker

Dear Sirs,

During the full operation of the New System of EOF for the on-line filing of the data recorded on the Medicines Authenticity Sticker, in direct connection with the Electronic Prescribing System, and during the preparation of Prescriptions by Private Pharmacies, the following categories of errors were discovered, which relate to the entry of the data of the Authenticity Sticker by the Medicines Marketing Authorisation Holders (MAH), thus excluding the product from being administered upon the preparation of the Prescription.

We point out that EOF granted to the MAH the ability to proceed with corrections and additions of the data on the Authenticity Sticker through the New System, from March 21 to April 20, 2013 and from May 8, to May 12, 2013.

In parallel, we point out that all MAHs, either they have been notified or not by EOF for the verified erroneous data of the Medicines Authenticity Sticker during the operation of the System, they must again inspect the correctness of the data of the Authenticity Sticker they have filed to EOF since February 2008.

Categories of errors discovered so far:

1. **Numbering of Authenticity Stickers not declared to EOF**, which have been attached to products already distributed in the market.
2. **Numbering of Authenticity Stickers which have been declared to EOF as defective**, while they concern Authenticity Stickers attached, without any problems, to products also distributed in the market.
3. **Numbering of Authenticity Stickers declared to EOF as having been attached to a different medicinal product (13-digid barcode) from the one already distributed in the market.** The error concerns the level of content and/or package and/or in whole the medicine's brand.
4. **Erroneous statement of the Year the Authenticity Stickers was printed.**

5. Numbering of Authenticity Stickers that have been declared for the correct medicine, but on an erroneous Batch Number.

Although, according to the applicable laws, the exclusive liability for the correct declaration of the data of the Authenticity Sticker to EOF lies with the MAH, with everything that such liability includes for the smooth operation of the supply chain until the end recipient of the medicine, EOF anew calls **until Saturday May 25 2013 at 11.30 p.m.** the Marketing Authorisation Holders **to send a Request for Correction – Approval to EOF for the categories of errors included only in cases 2, 3, 4 and 5** for the data of the Authenticity Sticker, quoting in parallel their views for the error, only at the e-mail: labels.correct@eof.gr (The emails: labels@eof.gr and support@eof.gr will not be used).

The Requests must be concise, completely explicit, specific and mention exactly all necessary data for the correction.

In addition, the full name and telephone number of the sender must be recorded.

EOF will examine the Requests on a case-to-case basis, and will proceed with the correction only of the data that concern apparent errors, always in accordance with the Requests.

As regards the Error Category No 1, the MAHs, after previously sending their views for this case to the above e-mail, they must make a declaration concerning the said Numberings, **not later than Saturday May 25, 2013 at 11.30 p.m.** through the New System of EOF, for on-line filing of the data of the Authenticity Sticker.

EOF reminds and **cautions the Marketing Authorisation Holders**, that the Electronic (on-line) Prescribing System will finally exclude from now on Medicines whose barcode of the S/N of the Authenticity Sticker has not been declared in the proper manner to EOF via the New System, and consequently the preparation of Prescriptions that contain medicinal products that fall into the scope of this case will not be possible.

We kindly thank you for your co-operation.

The Chairman of the BoD of EOF

Prof. I. Tountas

Table of Recipients (for information of their members):

1. *SFEE, Κηφισίας 280 & Agriniou 3, 15232
Chalandri, FAX: 2106891060*
2. *PEF, Kifissias 324, 15451 N. Psychiko, FAX:
2105247139*
3. *SAFE, T.Θ. 52894, 14610 N. Erythrea, FAX: 210 8071573*

6. *EFEX, FAX: 210 6197141*

NON-MEMBERS

IFET, FAX: 210 6039640
VIOFAR, FAX : 210 2461937
PHARMA CHEMIE, FAX: 2310 256057
LEOVAN, FAX : 210 9614945
ADH. ΦΑΡΜ, FAX : 210 5224184
IPSEN, FAX : 210 9887911
DOCTUM , FAX : 210 6643614
MEDICHROM, FAX : 210 6020118
MEDIPLANTS, FAX : 23210 97963
PHARMA CARE, FAX : 210 2887520
BIOSTAM FAX : 210 7790882
PROCTER & GAMBLE, FAX : 210 8764114
NI-THE, FAX : 210 6643895
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