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To: 1. Marketing Authorization Holders
2. Clinical Trial/Study Sponsors

Subject: Amended process for electronic reporting of adverse reactions to the National Organization for Medicines (EOF).

Related Docs: 1. EOF Document Ref. Nr. 36043/29.5.2007, "Pharmacovigilance: Summary of Requirements for Marketing Authorization Holders and Sponsors of Clinical Studies"
2. EOF Document Ref. Nr. 89219/14.12.2009, "Parallel Submission of Individual Cases (ICSRs-SUSARs) to the Averse Drug Reactions Sector of EOF"

Until now, Marketing Authorization Holders and Clinical Trial/Study Sponsors were required to submit electronically to the National Organization for Medicines, within the Eudravigilance production environment (to the receiver ID "GREOF", in E2B format), all adverse reaction reports meeting submission criteria according to the abovementioned "Related Docs".
National Organization for Medicines' electronic reporting requirements are hereby amended as follows.

A. New electronic reporting requirements

From 27 September 2011, each individual case meeting the National Organisation for Medicines submission criteria in accordance with the provisions of the above "Related Docs", should be submitted in accordance with the procedures described below:

I. Management of Suspected Unexpected Serious Adverse Reactions (SUSAR) from interventional clinical trials

SUSARs occurring within the frame of interventional clinical trials are forwarded directly to Receiver ID **"EVCTMPROD"** in the production environment of Eudravigilance

II. Management of spontaneous reports, reports from non-interventional studies or others:

Spontaneous reports, reports from non-interventional studies or other organized data collection systems (including "individual or group early/expanded access programs", "compassionate use"), are forwarded directly to **"EVHUMAN"** in the production environment of Eudravigilance.

B. Transitional period

From 27 September 2011 until 14 November inclusive:
The National Organization for Medicines will continue to monitor the receiver ID "GREOF" and will send acknowledgments for cases that are transmitted to "GREOF". During this period Marketing Authorization Holders and Clinical Trial/Study Sponsors adjust their systems for direct transmission towards "EVHUMAN" or "EVCTMPROD" and inform the National Organization for Medicines regarding the completion of the transition via email at ev@eof.gr

From 15 November 2011 onwards:
All Marketing Authorization Holders and Clinical Trial/Study Sponsors submit cases only to "EVHUMAN" or "EVCTMPROD" as appropriate. Acknowledgments received from "EVHUMAN" or "EVCTMPROD" as appropriate, will be officially considered proof of successful electronic transmission of case reports to the National Organization for Medicines.
From 15 November 2011 the National Organization for Medicines will cease to monitor and send acknowledgments to cases transmitted to Receiver ID "GREOF".

C. Additional related amendments:

1. From the date of this announcement, electronic communication testing with the National Organization for Medicines is no longer required. Interested parties may proceed to the production phase when testing and registration with the European Medicines Agency (EMA) is completed and inform the National Organization for Medicines via email at ev@eof.gr
2. From the date of this announcement, the requirement for parallel paper submission of individual cases to the National Organization for Medicines no longer applies.
3. From 15 November 2011 onwards, with reference to literature reports submitted to the National Organization for Medicines as described in the abovementioned "Related Docs", the corresponding literature article (format and title according to Eudravigilance business rules) will be submitted via email to evlit@eof.gr

VICE PRESIDENT A',
NATIONAL ORGANIZATION
for MEDICINES

M. SKOUROLIAKOU