REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 NICOSIA

Our Ref.: Ph.S 21.6.21

April 4, 2012

Tel. No: + 357-22407179
Fax No: + 357-22407149
E-mail: cpetrou@phs.moh.gov.cy

To all Marketing Authorization Holders

c/o Pharmacovigilance Qualified Person

Dear Sir/Madam

Re: Amended procedure for the electronic reporting of adverse reactions (ICSRs and SUSARS) to the Cyprus Competent Authority (Drugs Council, Pharmaceutical Services)

I wish to refer to the above subject and to inform you about the amended process for electronic reporting of adverse reactions to the Cyprus Competent Authority (Drugs Council, Pharmaceutical Services).

2. Until now, Marketing Authorization Holders and Clinical Trial/Study Sponsors were required to submit all Serious ICSRs occurring in Cyprus electronically to both the Pharmaceutical Services and to the European Medicines Agency within the Eudravigilance production environment (with message receiver identifier CYPPVPR and EVHUMAN respectively, in E2B format).

3. From 16 April 2012, each individual case 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.

4. Transitional period: From 16 April 2012 until 30 April inclusive: Pharmaceutical Services will continue to monitor the receiver ID "CYPPVPR" and will send acknowledgments for cases that are transmitted to "CYPPVPR". During this period Marketing Authorization Holders and Clinical Trial/Study Sponsors should adjust their systems for direct transmission towards "EVHUMAN" or "EVCTMPROD".

From 01 May 2012 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 Pharmaceutical Services.

From 01 May 2012 Pharmaceutical Services will cease to monitor and send acknowledgments to cases transmitted to Receiver ID "CYPPVPR".

5. Should you need any clarification don't hesitate to contact us through the E-mail address: cpetrou@phs.moh.gov.cy .

Registrar Drugs Council