REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
1475 NICOSIA

Our Ref.: Ph.S 21.6.21

September 1, 2008

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To all the Marketing Authorization Holders

c/o Pharmacovigilance Qualified Person

Dear Sir/Madam

Re: Pharmacovigilance: a) Reporting & Submission requirements to the Cyprus Competent Authority of ICSRs and PSURs, b) QPPV and product's list and electronic product's list

I wish to refer to the above subject and to inform about the amended reporting requirements for ICSRs and PSURs to the Cyprus Competent Authority, the Drugs Council.

2. Until further notice, please be advised that ICSRs have to be transmitted electronically in the timeframe of 15 days as follows:

- **All Serious ICSRs occurring in Cyprus should be transmitted electronically to both the Cyprus Competent Authority with message receiver identifier CYPPVPR and to the EMEA Eudravigilance post authorization module with message receiver identifier EV-HUMAN.**
- **All Serious ICSRs occurring in the territory of another Member State should be transmitted electronically to the EMEA Eudravigilance post authorization module only with message receiver identifier EV-HUMAN.**
- **All Serious ICSRs occurring in the territory of a third country should be transmitted electronically to the EMEA Eudravigilance post authorization module only with message receiver identifier EV-HUMAN.**

3. Until further notice, please be advised that PSURs should be submitted as indicated in the following table (CD-ROM means PDF + WORD format i.e. two formats should be submitted).

PSUR submission requirements					Address
CAP		MRP/DCP and NAP in PSUR work sharing		NAP outside PSUR work sharing	
Always	In addition if Rapporteur	(P-)RMS	CMS		
CD-ROM No of copies:1 PAPER No of copies:0	CD-ROM No of copies: 0 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 1	CD-ROM No of copies: 1 PAPER No of copies: 0	CD-ROM No of copies: 1 PAPER No of copies: 0	Registrar Drugs Council Pharmaceutical Services Ministry of Health 1475 NICOSIA CYPRUS

4. You are kindly requested to submit electronically at the E-mail address: cpetrou@phs.moh.gov.cy an EXCELL spreadsheet that includes the name and the contact details of the QPPV, his/her deputy and the names of the products for which he/she is responsible. In the same spreadsheet please include the name and the contact details of your local Pharmacovigilance contact person (in case you are QPPV is not located in Cyprus). Please submit the requested information as soon as possible.

5. Should you need any clarification don't hesitate to contact us.

Registrar Drugs' Council