## *To all Marketing Authorisation Holders (MAHs):*

In accordance with the entry into force of the new European legislation regarding pharmacovigilance of medicinal products for human use, notably Regulation (EC) 726/2004 as amended by Regulation (EU) 1235/2010 and Directive 2001/83/EC as amended by Directive 2010/84/EU, transposed as required in national legislation regulating medicinal products the Bulgarian Drug Agency (BDA) would like to notify Marketing Authorisation Holders (MAHs) for all medicinal products authorised/registered in Bulgaria, on the following **temporary*** requirements for ICSRs reporting.

- All **serious** ADRs from the territory of Bulgaria should be reported in E2B format within 15 days **simultaneously** to the BDA **(ID-BDA)** and to the EudraVigilance, Postauthorisation module **(ID-EVHUMAN)**.
- All **serious** ADRs outside the territory of the European Economic Area (EEA) should be reported in E2B within 15 days to the EudraVigilance, Postauthorisation module **(ID-EVHUMAN)** only.
- For all **non serious ADRs** from the territory of Bulgaria, other EEA or non EEA countries – reporting is still not required either to BDA, or to the EudraVigilance.

***** *until 6 months after the technical functionality of the database of the European Medicines Agency (EMA) - EudraVigilance is declared.*

MAHs are reminded that:

- BDA does not require performing testing or completing a pilot phase for MAHs, who are already in production with EMA, because BDA is an EV WEBTrader user. MAHs intending to start electronic transmission shall initially notify the BDA only by e-mail to bda@bda.bg
- In case of a system failure switch to alternative means of reporting (e.g. reporting *via* fax: +359 2 890 34 34 or e-mail: pharmacovig@bda.bg should be used and the BDA should be notified that there is a failure at the sender's site. The receipt of these reports will be acknowledged. If the problem is resolved and electronic reporting is restored, BDA should be informed and the E2B electronic version of the report should be submitted to **BDA**.

- The above mentioned requirements will be updated when the functionality of the database of the European Medicines Agency (EMA) - EudraVigilance is declared.

**Further information / Contact details**

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***Electronic Reporting of Suspected Unexpected Serious Adverse Reactions to the Bulgarian Drug Agency***

In accordance with Directive 2001/20/EC and the national Law on Medicinal Product for Human Use (as published in State Gazette 31/13.04.2007), sponsors of clinical trials are requested to submit all Suspected Serious Unexpected Adverse Reactions (SUSARs) in relation to clinical trials ongoing in Bulgaria to the Competent Authority in Bulgaria – the Bulgarian Drug Agency (BDA).

The BDA has implemented the European Union (EU) electronic data exchange system of adverse reactions through the web trader component of EVWEB.

The BDA requests all sponsors of clinical trials starting or ongoing to submit SUSARs electronically in the form of a report in full compliance with the E2B standards agreed at the level of ICH and Community guidelines.

**REPORTING RULES**

The following reporting rules apply to all clinical trials ongoing in Bulgaria:

- Sponsors of clinical trials should submit electronically SUSARs occurring **in Bulgaria** to both the EudraVigilance Clinical Trial Module with the message receiver identifier **EVCTMPROD** and to the BDA with the message receiver identifier **CTBDAP**.
- Sponsors of clinical trial conducted in Bulgaria should report SUSARs occurring **outside Bulgaria** directly to the EudraVigilance Clinical Trial Module with the message receiver identifier **EVCTMPROD**. The BDA **does not** wish to receive SUSARs of foreign origin even if the same study is conducted in Bulgaria and/or if a study with the same investigational medicinal product is conducted in Bulgaria. The

European Medicines Agency (EMA) has provided the BDA access to EudraVigilance where the BDA can retrieve these reports directly. Reporting obligations are considered already fulfilled when submitting to the EudraVigilance Clinical Trial Module the reports of SUSARs occurring outside Bulgaria.

Reports of SUSARs occurring in Bulgaria should be submitted to BDA (**CTBDAP**) as follows:

- any suspected unexpected serious adverse reaction that has occurred in the course of a clinical trial and has resulted in death or has proven to be life-threatening, within 7 days at the latest of receiving the information about it;
- additional information about the above mentioned cases within 8 days of the date on which a notification was sent;
- all other suspected unexpected serious adverse reactions other than those resulted in death or proven to be life-threatening that have occurred in the course of the clinical trial, 15 days at the latest from receiving the information about their occurrence.

For detailed reporting procedures, sponsors should follow the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (Eudravigilance – Clinical Trial Module), (2011/C 172/01).

The BDA does not require sponsors who are already in production with the EudraVigilance Clinical Trial Module to perform additional tests for the electronic transmission of SUSARs to the message receiver identifier **CTBDAP**.

Sponsors of clinical trials which are not yet starting electronic reporting should prepare for electronic submission following the rules and procedures for reporting to EudraVigilance, including testing with the EMA only.