STATE INSTITUTE FOR DRUG CONTROL

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YOUR LETTER R.N./DATED	OUR R.N.	ATTENDS/EXTENSION	DATE
		Novotná/885	17 May 2006

Dear doctor,

we wish to inform you about registration requirements applicable to your company and about the procedure for reaching ICSRs standard electronic exchange with SUKL (post marketing and also related to clinical trials). This procedure was prepared in connection with SUKL transition to a new system of processing electronic ICSRs.

1. Implementation schedule and conditions for electronic communication

I. Registration of partner for ICSRs electronic exchange with SUKL

- **Beginning of registration with SUKL is subject to completing registration with the EMEA and fully operational production ID**
- Interested company should send registration form both in electronic format (using Reg-company.xls form) and its paper version (signed xls or rtf form)
- Interested company should send (by e-mail) a declaration about sending electronic ICSRs from third countries to the EMEA database electronically

II. Test phase for checking technical compatibility of systems

- Commencement of test operation (SUKL will inform registered partner electronically)
- Sending of test ICSRs and receiving of ACK messages (acknowledging receipt of ICSRs)
- Receiving of test ICSRs and sending of ACK messages

III. Pilot operation for content validity check

- Commencement of pilot operation (SUKL will inform registered partner electronically)
- Sending of testing ICSRs (also in paper form) and receiving of ACK messages
- Receiving of testing ICSRs and sending of ACK messages
- Backlog management (partner should provide necessary administrative details before sending XML)

IV. Production operation

- Commencement of production operation (SUKL will inform registered partner electronically)

If production operation conditions are not met during the production operation SUKL reserves the right to interrupt the production operation and send the partner back to pilot operation.

Proceeding into the next phase shall be subject to fulfillment of the previous phase conditions. With regard to limited personal capacity of PHV unit SUKL reserves the right to include interested companies (wishing to proceed to the next phase) piecemeal depending on date of fulfillment of relevant conditions.

IDs used for el. communication via Eudravigilance system are as follows:

CZSUKLT – testing ID
CZSUKL – pilot and production ID

Companies which are already in pilot operation and send reports to old IDs (CZSUKLWEB and CZSUKLCT) can use their IDs until they commence sending of reports to ID CZSUKL. Currently there is no point in testing with CZSUKLTWEB AND CZSUKLCTT IDs (testing will proceed only with CZSUKLT ID).

2. Explanation of steps needed for correct partner registration

The basic prerequisite for starting communication with SUKL is a successful registration with the EudraVigilance system in the EMEA. You will find detailed information on web page http://eudravigilance.emea.eu.int (Registration with EV - see middle part of blue column on the left, titled EudraVigilance, please note that the EMEA can change appearance of its web pages).

Partner registration form

This form serves for machine processing of data, it means that filled data will be automatically loaded into our database. This form is available as annex to this e-mail, or on http://www.sukl.cz, division Léčiva-EudraVigilance. Guide to fill individual entries is accessible in heading through comments. To view a comment please move the mouse pointer over the red corner, or use MS Excel menu function "Display comments",.

If you represent more MAHs (or sponsors of ongoing clinical trials), it is necessary to send a separate registration form for each partner. Data stated in marketing authorization (clinical trial protocol) are crucial for individual company distinction.
Please state amount of entries for backlog (tens, hundreds, etc.) in the registration form.

Kindly send the correctly filled-in form Reg-Company.xls by e-mail back to **el.icsr@sukl.cz**. Instead of the word "Company" fill in the name of your company with underscores (_) instead of blank spaces in compound name, please do not fill dots.

Example:

Original filename: Reg-Company-C01.xls

Partner: Farm Firma s. r. o.

Renamed file: Reg-Farm_Firma_sro-C01.xls

If the registration form is not filled in correctly, it will be sent back to you by return email with request for filling in missing entries. If you are not sure about validity of form entries you sent, first send the form as a version 00 electronically and when its final version is agreed please send also the signed paper form.

The registered partner is obliged to re-send his registration form in case of any changes made. In that case please number individual versions in ascending order (last 2 digits in form name)

How to communicate with us?

There is a communication focal point el.icsr@sukl.cz established only for communication needs between you (partners) and SUKL. By this way we will keep in touch with you. Always use this e-mail address for your answers and relevant questions. For other communication purposes with the pharmacovigilance unit (including sending of ICSRs "paper form") please use e-mail address farmakovigilance@sukl.cz. Any communication relating specifically to

reports from clinical trials should continue to be held with responsible persons of the clinical trials unit (at present viktor.vlcek@sukl.cz and lucie.kravackova@sukl.cz).

According to guideline PHV-4 (Chapter 3.3) it is necessary to send "Registration EV partner" application also in paper form (signed document). This obligation is considered fulfilled if the partner has already sent application by mail in format according to PHV-4 guideline (rtf version). Nevertheless, every partner has to send Reg-Company.xls in current version and simultaneously store a copy for the purpose of reporting changes.

Address for registration in paper form:

State institute for Drug Control
Sekce klinického hodnocení léčiv a farmakovigilance
Srobarova 48
100 41 Prague 10
fax: 272 185 222

We hope that this letter will contribute to early achievement of standard ICSRs electronic exchange.

Yours sincerely

MUDr. Ivana Koblihová
Head of Branch of Clinical Trials
and Pharmacovigilance