

To: see list page 4/4

Your date	Your reference	Our date	Our reference	Office/officer
		2003-02-03	200301783	LB/OV/Harald Lislevand

CIRCULAR 4/2003

Requirement of electronic transmission of adverse drug reaction reports (ICSR) for marketing authorization holders in Norway

As from 31 January 2003 all reporting of Adverse Drug Reactions (ADR) involving medicinal products for human use should be transmitted electronically according to the guidelines given by the EMEA¹ and ICH². The requirements are, in Norwegian legislation, founded on *Forskrift om legemidler (legemiddelforskriften) §11-2 b*)³.

As part of an extended EEA-agreement, Norway takes part in the common European medicinal product regulation and is thereby covered by the same legislation and guidelines as the European Union (EU) Member States in this area. The guidelines describing the requirements for electronic transmission of ICSRs are given in Volume 9 of *The rules governing medicinal products in the European Community*⁴. Information regarding the required standards, formats and guidelines are also available on the EudraVigilance website (the European data-processing network and database management system for the exchange, processing and evaluation of Individual Case Safety Reports related to medicinal products authorised in the Community)⁵.

The requirements of electronic reporting of ICSRs in compliance with the standards agreed at the level of the ICH/EMEA apply for all Marketing Authorisation Holders (MAH) in the EU including Iceland, Liechtenstein and Norway.

¹ The European Agency for the Evaluation of Medicinal Products

² The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

³ <http://www.lovdata.no/for/sf/hd/td-19991222-1559-035.html>

⁴ <http://pharmacos.eudra.org/F2/eudralex/index.htm>

⁵ <http://www.eudravigilance.org/>

Letters should be addressed to the Norwegian Medicines Agency. Please state our reference.

How to start electronic transmission of adverse drug reaction reports (ICSR) with the Norwegian Medicines Agency

- Obtain ESTRI/EudraVigilance Gateway certification
- Contact EMEA Electronic Transmission CO-ordinator (eudravigilance@emea.eu.int) to inform that you wish to start electronic transmission with the Norwegian Medicines Agency
- Contact the Norwegian Medicines Agency Electronic Transmission CO-ordinator (harald.lislevand@noma.no) to inform that you want to start electronic transmission
- Send a Letter of Intent for the Electronic transmission of ICSRs together with an implementation plan to the EMEA Electronic Transmission CO-ordinator and with a copy to the Norwegian Medicines Agency Electronic Transmission CO-ordinator
- The date for initiation of the test phase (see below) of electronic transmission of ICSRs and a plan stating the criteria's for Regulatory transmission must be agreed upon with the Norwegian Medicines Agency Electronic Transmission CO-ordinator
- Information about the responsible person(s) for pharmacovigilance and/or technical matters regarding ICSRs, including those responsible for maintaining the timeframes for expedited reporting given in Volume 9 of *The rules governing medicinal products in the European Community*, must be exchanged before initiation of electronic transmission.
- The profile ID for the Norwegian Medicines Agency is "NOMAADVRE"

Test phase

Before transmission of ICSRs fully can replace paper reports a test phase needs to be performed. During this test phase the currently established regulatory reporting mechanism (paper reporting) will be further maintained for 3 months (or a minimum of 20 safety messages) whereby the Norwegian Medicines Agency may decide to shorten this period or extend it. This will allow comparison of the submitted data and ensure quality assurance and data consistency. During the test phase, the MAH will, in the same manner, receive reports from the Norwegian Medicines Agency both electronically and in paper.

It should be stated in the cover letters for the paper reports that they have also been sent electronically. Paper reports regarding ADRs originating from Norway should also be clearly separated from reports from non-EEA countries.

The paper reporting will represent the legal regulatory reporting mechanism until agreement on fully electronic transmission is achieved by the end of the test phase.

As the electronic transmission of ICSRs presents practical arrangements to achieve more consistent and efficient reporting, it needs to be stressed that the requirements for what and when to report adverse drug reactions as presented in Norwegian legislation and Volume 9 of *The rules governing medicinal products in the European Community* remain unaffected.

Transitional solution for MAHs who have not implemented a ICH/EMEA system for electronic exchange of ICSRs

For those holders of a marketing authorization in Norway who have not implemented an ICH/EMEA system for electronic exchange of ICSRs, the Norwegian Medicines Agency are willing to accept, as an interim solution, reports in paper or electronic reports not transmitted through the ESTRI/EudraVigilance Gateway, but by regular e-mail or floppy disk/CD. Reports are accepted in XML (E2B)-, word-, pdf- or similar formats. Please see Circular 7/2001 (Reporting of CIOMS-I to the Norwegian Medicines Agency by e-mail)⁶ for more information regarding reporting of CIOMS-I.

It is important to emphasize that this interim solution must not result in any delay of the implementation of an ICH/EMEA compliant pharmacovigilance system for electronic transmission of ICSRs. It is expected that a plan for the implementation of/access to such a system with timeframes given will be submitted to the Norwegian Medicines Agency and the EMEA. Any changes to this plan should be communicated immediately to all parties.

The Norwegian Medicines Agency Electronic Transmission CO-ordinator details:

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NORWEGIAN MEDICINES AGENCY

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⁶ <http://www.legemiddelverket.no/eng/reg/circular7-2001-CIOMS-I-reporting.htm>

Legemiddelfabrikanter og representanter
Statens helsetilsyn
Norges Apotekerforening
Norges Farmaceutiske Forening
Legemiddelindustriforeningen
Norsk Industriforening for Generiske Legemidler
Legemiddelparallelimportørforeningen
Legemiddelgrossistforeningen (LGF)
Nasjonalt folkehelseinstitutt
Nasjonalbibliotekavd. i Rana
Norsk Medisinaldepot ASa
NMD avd. Trondheim
Tamro Distribution AS
Holtung AS
VESO AS
Europharma AS
Institutt for farmakoterapi
Felleskatalogens redaksjon
Bransjerådet for Naturmidler