HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Electronic Transmission of SUSARs Associated with the Use of Human Medicines

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

This document provides guidance to sponsors on electronic submission of Suspected Unexpected Serious Adverse Reactions (SUSARs) associated with use of human medicines to the Health Products Regulatory Authority (HPRA).

Background information on relevant legislation and guidance documents governing these activities is also provided using hyperlinks throughout this document.

Only SUSARs occurring within Ireland should be reported directly to the HPRA on an expedited basis, in parallel with reporting to EudraVigilance.

2 INTRODUCTION

All sponsors in the European Economic Area (EEA) are responsible for implementing standards that ensure electronic communication with regulatory authorities in compliance with the standards agreed at ICH level and in accordance with Community legislation and guidance described in the Clinical Trial Directive (Directive 2001/20/EC), the 'Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use (CT-3)' and in national legislation as described in S.I. No. 190 of 2004, which outlines the requirements for sponsors to report to the HPRA and the Eudravigilance Clinical Trial Module (EVCTM) in parallel.

The ICH guidelines describing the requirements for electronic transmission of ICSRs are available from the ICH website (http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html). Currently, reports may be submitted to the HPRA in either ICH E2B(R2) or ICH E2B(R3) format.

Information regarding the required standards formats and guidelines are also available from the EMA website (http://www.ema.europa.eu/ema/).

3 REQUIREMENTS TO ESTABLISH E2B REPORTING WITH THE HPRA

In order to facilitate implementation of electronic transmission of SUSARs by sponsors in Ireland, a phased approach has been adopted. This approach is described below and is relevant for sponsors using a local pharmacovigilance system compliant with the ESTRI gateway standards Sponsors using the EVWEB interface need only provide the relevant contact details as specified in section 3.1 below, no testing is required, The HPRA does not have any additional requirements other than those defined by the EMA.

As mentioned above, sponsors must first be registered with the EMA to allow messages to be transmitted via the EudraVigilance gateway. Full details on how to register are available from the EMA website (http://www.ema.europa.eu/ema/).

3.1 Phase one: registration and testing

On successful registration with the EMA, the organisation should then make contact with the EudraVigilance co-ordinator at the HPRA using the following e-mail address: eudravigilance-test@hpra.ie. The following information should be provided within the initial contact e-mail and the test report should also be submitted at the time of registration.

Sponsor name:
Contact Name:
Address:
E-mail:
Phone:
Fax:

Primary contact for all future correspondence in relation to the implementation of electronic transmission of SUSARs
Name:
Title:
Address:
Phone:
Fax:
E-mail:
Sponsor name and sponsor profile(s) on the EMA gateway (both test and production).

Sponsor in production with the EMA [Yes] , [No]

Test report ID submitted:

In order to complete testing, sponsors should submit one Irish (IE) SUSAR to the IMBCTT test environment. This report may contain fictitious data. Sample test cases are available on the EMA website (www.ema.europa.eu). For technical requirements and validation rules implemented in the EudraVigilance system, please refer to the following document 'Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs)', available on the EMA website (www.ema.europa.eu).

Test reports will be evaluated and ongoing feedback provided. On successful completion of this phase, sponsors may then begin the production phase.

3.2 Phase two: production

On completion of the above test phase, sponsors may proceed with regular electronic transmissions to the HPRA. To facilitate this, the identifier 'IMBCTT' (test clinical trial system) needs to be updated to 'IMBCT'. All correspondence s should be e-mailed to medsafety@hpra.ie. The EudraVigilance case reference number or XML file number to which the correspondence relates must be clearly stated in each e-mail.

4 TRANSMISSION USING EVWEB

For sponsors who do not have a local pharmacovigilance system with an operational gateway meeting the ESTRI standards, the EMA has developed EVWEB, a web-based application which allows sponsors to report electronically to the agreed ICH standards.

Access to EVWEB will be granted following completion of a training programme, to ensure that individuals are familiar with the concepts of electronic reporting requirements and the web application.

Further information about EVWEB and the training programme can be found on the EMA website (http://www.ema.europa.eu/ema/). Sponsors using the EVWEB application do not need to carry out the testing procedure.

5 TECHNICAL ISSUES

In the event of unavailability of the EudraVigilance gateway or EVWEB, sponsors may send SUSARs to the HPRA within two business days of the system becoming available again.

In the event of a technical failure at the sender's side, the sponsor should contact eudravigilance@hpra.ie to outline the issue and discuss alternative submission options. If the sponsor is able to generate valid safety message(s) these can be submitted via a Eudralink account.

APPENDIX 1 LEGISLATION

A1.1 EU Directives

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

A1.2 National Legislation

S.I. No. 190 of 2004 (Clinical Trials on Medicinal Products for Human Use Regulations 2004)

A1.3 Additional Guidelines

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')

Note for Guidance on the Electronic Data Interchange (EDI) of Individual Case Safety Reports (ICSRS) and Medicinal Product Reports (MPRS) in Pharmacovigilance during the Pre- and Post- Authorisation Phase in the European Economic Area (EEA)

ICH E2B package of specifications and guidance documents

Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs)

Implementation plan for the 'Note for guidance – EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs)' 15 October 2010 (EMA/H/20665/04/Final Rev. 2)

HPRA Guide to Clinical Trial Applications