



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections and Human Medicines Pharmacovigilance Division

European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use

Annex C – Confidentiality undertaking for marketing authorisation holders

Introduction

This Confidentiality Undertaking is aimed principally at ensuring the protection of personal data. It governs the access and use by marketing authorisation holders in the European Economic Area (EEA) of the ICSR data set Level 2B as defined in chapter 5.2.5.3 of the European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (Doc. Ref. EMA/759287/2009 Revision 2) (“Policy”). By signing the Confidentiality Undertaking, access to ICSR data set Level 2B will be granted to the marketing authorisation holder by the Agency.

Access to the ICSR data set Level 2B under the policy

The marketing authorisation holder acknowledges that the ICSR data set level 2B will be made available in electronic format. Before being granted access to the ICSR data set level 2B, the marketing authorisation holder shall provide the EMA with:

- A confirmation that either:
 - The initial signal management steps as outlined in the Good Pharmacovigilance Practice Guide Module IX “Signal Management” have been performed, including a reference to the corresponding e-RMR if applicable;
 - A review of ICSR data is warranted in the context of a pharmacovigilance assessment procedure such as the PSUR as outlined in GVP Module VII or when required by the PRAC in a referral or signal assessment procedure;
- Elements concerning the identity of the marketing authorisation holder (Organisation ID Headquarter level, name and contact details in accordance with the EudraVigilance Registration details);
- A copy of the Confidentiality Undertaking signed by the EU QPPV and where different, by the Deputy appointed by the EU QPPV or any other personnel, under the strict responsibility of the EU QPPV, who is registered with EudraVigilance and holds a valid user ID and password and obtains access to the ICSR data set Level 2B, which includes a case narrative.



Confidentiality Undertaking

As a condition of my access to the EudraVigilance database, for the purpose of ensuring the protection of personal data therein, I agree to the following terms:

- I agree at all times to treat as confidential all information related to the ICSR data set Level 2B and to use it for the purpose of signal management as outlined in GVP Module IX or in the context of a pharmacovigilance assessment procedure such as the Periodic Safety Update Report as outlined in GVP Module VII or when required by the PRAC in a referral or signal assessment procedure according to the conditions set in this Undertaking and in compliance with applicable data protection legislation. In particular, I agree not to seek to identify, profile, contact or target the data subjects from the ICSR data set Level 2B.
- I agree not to transfer or dispose of the ICSR data set Level 2B for which access is provided under the condition of this Confidentiality Undertaking to any third party, where there are no legal obligations for the marketing authorisation holder to do so. I shall not permit any third party to access, study, analyse, refer to or otherwise use the data or permit any party to reproduce any ICSR data.
- I agree to access and use only the minimal amount of personal data that is necessary for the performance of my pharmacovigilance activities pursuant to the applicable laws and I agree to acknowledge that the source of the data is the EudraVigilance database.
- I shall ensure that any personal information is anonymised when there is a legal requirement for the marketing authorisation holder to report suspected adverse reactions for the medicinal products for which they hold a marketing authorisation in the EEA to a medicines regulatory authority in a third country. Personal information mean any recorded information that could, either by itself or in combination with other information, be used to link or associate the information to a particular individual.
- I agree to maintain adequate technical and security measures to prevent unauthorised or unlawful access, disclosure, dissemination, alteration, destruction, accidental loss or copying of the ICSR data set Level 2B, in accordance with applicable data protection legislation, and to immediately notify the Agency of a breach of security leading to any thereof.
- I acknowledge that this Undertaking will be in effect from the date of my signature and that the terms of this Undertaking will apply to any secondary analysis of the ICSR data set Level 2B I perform using the EudraVigilance data.
- I understand that compliance with this Confidentiality Undertaking is a condition of my access to the EudraVigilance database and that failure to comply may result in immediate termination of my right of access and use of the data.

I have read, understood and I agree to comply with the terms stated above at all times.

Name: _____ Title: _____

Signature: _____ Date: _____