EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 December 2022
EMA/869259/2022

Qualified Persons Responsible for Pharmacovigilance (QPPVs) of
marketing authorisation holders in the European Economic Area (EEA)

Dear Madam/Sir,

Subject: International transfer of personal (health) data in ICSRs originating from EudraVigilance

We are writing to you in the context of your global pharmacovigilance activities and the international transfer of personal (health) data contained in Individual Case Safety Reports (ICSRs), which originate from EudraVigilance. Earlier this year EMA was notified that case narratives retrieved and downloaded by certain marketing authorisation holders (MAHs) from EudraVigilance based on the Level 2B access of the EudraVigilance Access Policy[1], were transferred in full, without further redaction of personal data, to third countries. Reference is made in particular to submissions of ICSRs by these MAHs to the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research (FDA CBER)[2], which resulted in the publication of such unredacted case narratives on the U.S. Vaccine Adverse Event Reporting System (VAERS)[3] website and the U.S. Centers for Disease Control and Prevention (CDC) WONDER[4] website.

In this context, we would like to remind and inform you about the following:

1. Adherence to the principles set out in the EudraVigilance Access Policy

The EudraVigilance Access Policy provides two access levels for MAHs:

a. Level 2A – set of data elements to fulfil the MAHs' pharmacovigilance obligations;

b. Level 2B – Level 2A data elements plus case narratives to validate signals and to support the review of ICSR data warranted in the context of a pharmacovigilance assessment procedure (GVP Modules VII[5] and IX[6]) in the European Economic Area (EEA).
Access to case narratives is subject to a confidentiality undertaking (*Annex C of the Access Policy*), which sets out the data protection and confidentiality obligations of registered users of MAHs. Whilst it is recognised that MAHs may be subject to adverse reaction reporting

[1] Access to EudraVigilance data | European Medicines Agency (europa.eu)
[2] Center for Biologics Evaluation and Research (CBER) | FDA
[3] Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)
[4] CDC WONDER
[5] Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report
[6] Guideline on good pharmacovigilance practices (GVP) - Module IX – Signal management (Rev 1) (europa.eu)

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obligations outside the EEA, the confidentiality undertaking requires MAHs to "*ensure that personal data reported can no longer be attributed to a specific data subject*".
In this context, it is important to remember that in accordance with Recital 26 of Regulation (EU) 2016/679[7], the General Data Protection Regulation (GDPR), "[p]ersonal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person." Consequently, pseudonymised data is considered personal data, as detailed in Article 4(1) of the GDPR and is under the scope of the GDPR. This also applies to *the pseudonymised ICSR data held in EudraVigilance including case narratives, which are intended only for GVP signal and pharmacovigilance assessment procedures in the EEA* and *not for ICSR reporting to third countries*.

2. Transfer of personal (health) data to third countries - compliance with Union data protection legislation

As clarified by the European Data Protection Supervisor (EDPS), MAHs are controllers for the personal data processing activities carried out pursuant to the pharmacovigilance legislation[8] including the access and further processing of ICSR data originating from EudraVigilance.
MAHs are therefore accountable to comply with the rules set out in Union data protection legislation i.e., the GDPR and national data protection laws (where applicable). This includes adherence to the transfer requirements of personal data to third countries as set out in Chapter V of the GDPR and the confidentiality undertaking of the EudraVigilance Access Policy (as per point 1 above).
More specifically, as recently emphasised by the EDPS, we would like to raise awareness to the fact that the use of Standard Contractual Clauses (SCC) for international transfers[10] or Standard Data Protection Clauses (SDPC) by MAHs is not enough to guarantee compliance with the data protection rules, in particular, the provisions under Chapter V of the GDPR. As also confirmed by the Commission in its Questions and Answers[11] and in line with the Schrems II judgment (C-311/18), Clause 14 requires that prior to concluding the SCC, the parties assess (namely by carrying out a transfer impact assessment[12]) whether the laws and practices of the third country of destination applicable to the processing of the personal data by the data importer could prevent the latter from complying with the SCC, considering the specific circumstances of the transfer. Should the assessment be negative, the parties may only transfer data based on the SDPCs if they put in place additional ("supplementary") safeguards (e.g., technical measures to ensure data security, such as e.g., end-to-end encryption) that address the situation and thus ensure compliance with the SCC.

[7] REGULATION (EU) 2016/ 679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 27 April 2016 - on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/ 46/ EC (General Data Protection Regulation) (europa.eu)
[8] EudraLex - Volume 1 (europa.eu)
[10] Standard contractual clauses for international transfers | European Commission (europa.eu)
[11] questions_answers_on_sccs_en.pdf (europa.eu)
[12] Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data

3. Instructions for reporting of ICSRs originating from EudraVigilance to third countries

To ensure compliance with chapter V of the GDPR and national data protection laws as applicable including the requirements set out in the confidentiality undertaking of the EudraVigilance Access Policy, *MAHs are instructed to adhere to the following requirements* for reporting of ICSRs originating from EudraVigilance to third countries (including reporting to U.S. VAERS):

Reporting is to be based on the ICSR data elements as set out in the EudraVigilance Access Policy Level 2A including the following instructions		
ICH E2B(R3) Data Element	**ICH E2B(R3) Data Element Name**	**Reporting of EEA cases by MAHs to Third Countries**
C.1.1	Sender's (case) Safety Report Unique Identifier	Country code as part of the identifier must be provided as "EU" for all EEA countries[13].
C.1.8.1	Worldwide Unique Case Identification	Only to be reported if not publicly disclosed by the receiving party together with other ICSR data elements that could lead to the direct or indirect identification of a natural person (see Article 4(1) of the GDPR).
C.1.9.1.r.2	Case Identifier(s)	Only to be reported if not publicly disclosed by the receiving party together with other ICSR data elements that could lead to the direct or indirect identification of a natural person (see Article 4(1) of the GDPR).
C.1.10.r	Identification Number of the Report Which Is Linked to This Report	Only to be reported if not publicly disclosed by the receiving party together with other ICSR data elements that could lead to the direct or indirect identification of a natural person (see Article 4(1) of the GDPR).
C.2.r.3	Reporter's Country Code	Country code to be reported as "EU" for all EEA countries.
G.k.2.4	Identification of the Country Where the Drug Was Obtained	Country to be reported as "EU" for all EEA countries.
E.i.9	Identification of the Country Where the Reaction / Event Occurred	Country to be reported as "EU" for all EEA countries.

[13] Glossary:European Economic Area (EEA) - Statistics Explained (europa.eu)

Reporting is to be based on the ICSR data elements as set out in the EudraVigilance Access Policy Level 2A including the following instructions		
ICH E2B(R3) Data Element	**ICH E2B(R3) Data Element Name**	**Reporting of EEA cases by MAHs to Third Countries**
G.k.2.4	Identification of the Country Where the Drug Was Obtained	Country code to be reported as "EU" for all EEA countries.
D.7.1.r.5	Comments	Not to be reported.
D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	Not to be reported.
D.10.7.1.r.5	Comments	Not to be reported.
F.r.6	Comments (free text)	Not to be reported.
G.k.11	Additional Information on Drug (free text)	Not to be reported.
H.2	Reporter's Comments	Not to be reported.
H.4	Sender's Comments	Not to be reported.
D.7.3.	Concomitant Therapies	Not be reported if drug name may allow for the identification of the country of origin (e.g., nationally authorised medicinal product); instead, as active ingredients or the class of the concomitant therapies should be reported.
D.10.8.r.1	Name of Drug as Reported	Not be reported if drug name may allow for the identification of the country of origin (e.g., nationally authorised medicinal product); instead, active ingredient(s) of the drug should be reported.
G.k.2.2	Medicinal Product Name as Reported by the Primary Source	Not be reported if drug name may allow for the identification of the country of origin (e.g., nationally authorised medicinal product); instead, the active ingredient(s) of the drug should be reported.

Independent of these instructions, MAHs remain controllers for their personal data processing activities and are accountable to comply with the rules set out in Union data protection legislation (see point 2 above).

4. Update of the U.S. VAERS website

On 18 November 2022, FDA-CBER and CDC, who jointly administer U.S. VAERS, removed the content for the data fields set out in Annex 1 from the U.S. VAERS and CDC WONDER websites for individual cases originating from the EEA that were previously reported by MAHs. These measures were necessary to protect personal data of patients and healthcare professionals in the EEA.
Regarding ICSR submissions to U.S. VAERS, no changes apply to the remaining data fields as set out in FDA guidance ("Providing Submissions in Electronic Format — Postmarketing Safety Reports for Vaccines, Guidance for Industry, August 2015") and the corresponding Business Rules and Technical Specifications[14].

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In case you have any questions regarding your obligations concerning data protection and international data transfers to third countries, we advise you to contact the data protection authorities (DPAs) of Member States[15]. These authorities are competent for monitoring and enforcing the application of the GDPR as well as any national laws possibly applicable to a MAH in the relevant Member State. As a general rule, the main contact point for questions on data protection is the DPA in the EU Member State where your company is based.
As advised by the EDPS, EMA is also in consultation with the DPA in one EU Member State on the ICSR reporting to third countries based on the requirements set out in chapter V of the GDPR. We will inform you about the outcome of such consultation where these might impact current reporting practices.
We thank you for your cooperation in safeguarding personal data of patients and healthcare professionals in the context of the performance of your pharmacovigilance activities and in compliance with the legal provisions set out in Union data protection legislation.

Yours sincerely,

Dr Georgy Genov

Head, Pharmacovigilance Office
Head ad interim, Quality and Safety of Medicines Department

Dr Peter Arlett

Head, Data Analytics and Methods Task Force

CC: Heads of Medicines Agencies (Human Medicines), Members of the Pharmacovigilance Risk Assessment Committee (PRAC), Data Protection contact points for EudraVigilance

[14] https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation
[15] To find the national data protection authorities please see https://edpb.europa.eu/about-edpb/board/members_en

Annex 1

VAERS File	Data Field	Data Field Description	Type	Instructions
5.1. VAERSDATA.CSV	15. LAB_DATA	Diagnostic laboratory data contains narrative about any relevant diagnostic tests or laboratory results as recorded on the specified field of the form.	Free text	To be reported as MedDRA code; free text not to be reported
5.1. VAERSDATA.CSV	19. CUR_ILL	Illnesses at time of vaccination - contains narrative about any illnesses at the time of the vaccination as noted on the specified field of the form.	Free text	Not to be reported
5.1. VAERSDATA.CSV	20. HISTORY	Chronic or long-standing health conditions - contains narrative about any pre-existing physician-diagnosed birth defects or medical condition that existed at the time of vaccination as noted on the specified field of the form. For the VAERS 1 form, this field also includes pre-existing physician-diagnosed allergies.	Free text	Not to be reported
5.1. VAERSDATA.CSV	23. SPLTTYPE	Manufacturer/immunization project report number	Contains **country code***	Will not be published*
5.1. VAERSDATA.CSV	21. ALLERGIES	Allergies to medications, food, or other products - contains narrative about any pre-existing physician-diagnosed allergies that existed at the time of vaccination as noted in the specified field of the form. This is a VAERS 2 form field only.	Free text	Not to be reported
5.1. VAERSDATA.CSV	9. SYMPTOM_TEXT	Reported symptom text recorded in the form. MedDRA Terms are derived	Free text **Case narrative**	To be reported as MedDRA code; free text

VAERS File	Data Field	Data Field Description	Type	Instructions
		from this text and placed in the VAERSSYMPTOMS file.		not to be reported

* The plan is for the country code of EEA Member States to be replaced with the code denoting “EU”.