EMA
EUROPEAN MEDICINES AGENCY

EudraVigilance - *Masking Policy of Personal Data*

EDPS Audit Recommendation

19th Industry Stakeholders platform - operation of EU pharmacovigilance – 15 Nov 2024

Presented by Rodrigo Postigo

Recommendation

Following a EudraVigilance audit in 2023, the EDPS issued the following recommendation:

- Adopt - together with the joint controllers of the processing operations taking place in the context of the EudraVigilance database (European Commission and EEA Member States) - a common masking policy that should be complied with by all reporting entities.

- *The intention behind this is to determine which fields that contain personal data are not needed in EudraVigilance and therefore should be submitted as masked (MSK).*

How to identify the E2B fields that contain personal data?

Key definitions:

- **Personal Data:** Any information relating to an identified or identifiable natural person (‘data subject’).
- **Identifiers:** Identifiers can be used to uniquely identify an individual. For example, someone's full name or government ID number are considered identifiers.
- **Quasi-Identifiers:** Quasi-identifiers don't uniquely identify an individual, but, when combined and cross-referenced with other data they can increase the likelihood that an individual is able to be re-identified. For example, postal codes and ages are considered quasi-identifiers

EMA Risk Assessment

An assessment has been done initially by EMA to determine from the 282 E2B fields which ones are identifiers and quasi-identifiers

- 209 E2B considered potential personal data (based on identifiers or quasi-identifiers) - for instance country, patient age, sex, medical history, reaction, drug names are considered quasi-identifiers
- 73 fields not considered personal data
- From those 209 determined as identifiers or quasi-identifiers, it has been determined which ones are **NOT needed** for signal management, duplicate detection or case processing (and therefore can be masked or deleted)

Data elements to be masked

- **14** data elements for which the current guidance states that the sender should decide if the use of MSK is appropriate for the submission to EudraVigilance.
- These 14 data elements are not considered needed for signal management, duplicate detection or ICSR processing and it is proposed that these elements are set as MSK for the submission to EudraVigilance.
- For the data that has been submitted unmasked (including legacy data), EMA will MSK/erase the information provided in these data elements.

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide		
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**
ICH	C.2.r.1.1	Reporter's Title
ICH	C.2.r.1.2	Reporter's Given Name
ICH	C.2.r.1.3	Reporter's Middle Name
ICH	C.2.r.1.4	Reporter's Family Name
ICH	C.2.r.2.1	Reporter's Organisation
ICH	C.2.r.2.2	Reporter's Department
ICH	C.2.r.2.3	Reporter's Street
ICH	C.2.r.2.6	Reporter's Postcode
ICH	C.2.r.2.7	Reporter's Telephone
ICH	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)
ICH	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)
ICH	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)
ICH	D.1.1.4*	Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)
ICH	D.10.1	Parent Identification

Data elements to be left blank

- **12** further data elements are also not considered necessary for signal management, duplicate detection or ICSR processing.
- As nullflavours are not supported in the submission of these data elements, they should be left blank for the submission to EudraVigilance.
- When these data elements contain information (including legacy data), EMA will delete the information provided.

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide		
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**
ICH	C.3.3.2	Sender's Title
ICH	C.3.3.3	Sender's Given Name
ICH	C.3.3.4	Sender's Middle Name
ICH	C.3.3.5	Sender's Family Name
ICH	C.3.4.1	Sender's Street Address
ICH	C.3.4.2	Sender's City
ICH	C.3.4.3	Sender's State or Province
ICH	C.3.4.4	Sender's Postcode
ICH	C.3.4.5	Sender's Country Code
ICH	C.3.4.6	Sender's Telephone
ICH	C.3.4.7	Sender's Fax
ICH	C.3.4.8	Sender's E-mail Address

Senders feedback

The proposal has been circulated for consultation with the National Competent Authorities (via the Pharmacovigilance Business Team) and with Industry (via the EudraVigilance Expert Working Group and feedback has been received on the following topics

- Questions on the scope and the remit of the policy
- MAHs requested to have a transition period for the policy to come into effect
- Some data elements to be reconsidered
- EMA process to deletion of legacy data
- In general, there is support and no major comments or concerns have been raised

Process for consultation and approval

Agreement steps	Date
EMA proposal agreed by the EudraVigilance business coordination group	28 August 2024
EMA Data Protection Officer - consultation on the EMA proposal	03 September 2024
Internal controllers Agreement on the EMA proposal	26 September 2024
EMA proposal presented at the PhV Business Team for consultation	08 October 2024
EU-Network proposal presented at the EudraVigilance Expert Working Group for information and feedback	10 October 2024
EU-Network proposal presented to the Industry Stakeholders platform meeting	15 November 2024
EU-Network proposal adopted by PRAC	TBC

Any questions?

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