



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Key principles

17th Industry Stakeholder Platform – Operation of EU Pharmacovigilance

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An agency of the European Union





Key principles

- The EudraVigilance Access Policy provides two access levels for MAHs
 - Level 2A - to fulfil their pharmacovigilance obligations
 - Level 2B – including case narratives - to validate signals and to support a review of ICSR data warranted in the context of a pharmacovigilance assessment procedure (GVP Modules VII and IX) – subject to a confidentiality undertaking
- International transfer of personal data in the context of pharmacovigilance

MAHs are data controllers and responsible/accountable to adhere to the

 - confidentiality undertaking of the EV Access Policy (annex C) – *“ensure that personal data reported can no longer be attributed to a specific data subject”*
 - requirements for the transfers of personal data to third countries as set out in CHAPTER V of Regulation (EU) 2016/679 (GDPR)



Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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