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Revision of EudraVigilance access policy for medicines for human use

Draft

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[1] In relation to the WHO-UMC specific arrangements

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Comments should be provided to EVAccess@ema.europa.eu

As part of the public consultation on the revision of the EudraVigilance Access Policy, we would also like to take the opportunity to obtain your feedback on the following two questions:

1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?

2. As regards stakeholder groups III. A "Marketing Authorisation Holders" do you consider the data set proposed in Annex 1 (Table column PV obligations – Level 2) as sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in Regulation (EC) 726/2004, Directive 2001/83/EC, the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practice Modules?

Current practices of Member States as regards the level of information provided to marketing authorisation holders for reports of suspected adverse reactions from patients and healthcare professionals, which have been received through national spontaneous reporting systems, are being assessed in parallel to this public consultation.

NOTE: Access to reports of suspected unexpected serious adverse reactions (SUSARs) based on the provisions set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC will be subject to a later consultation.

Table of Contents

EXECUTIVE SUMMARY 4

1. Background 6

2. Introduction 7

3. Objectives of the EudraVigilance Access Policy 7

4. EudraVigilance and Medicinal Products for Human Use 8

5. Access to data held in EudraVigilance 9

5.1. Stakeholder Groups 9

5.2. Overview 10

Table 1: Number of ICH E2B(R3) ICSR data elements 11

Table 2: Access to EudraVigilance data by the Commission and Medicines Regulatory Agencies in the EEA 12

Table 3: Access to EudraVigilance data by healthcare professionals and the public 13

Table 4: Access to EudraVigilance data by Marketing Authorisation Holders 14

Table 5: Access to EudraVigilance data by Research Organisations 15

Table 6: Access to EudraVigilance data by WHO-UMC 16

Table 7: Access to EudraVigilance data by international Medicines Regulatory Authorities 17

5.3. Access to EudraVigilance data and methods of access 18

5.4. Access by Stakeholder Group 18

5.4.1. Group I: Medicines Regulatory Authorities in the EEA, the European Commission and the Agency 18

5.4.2. Group II: Healthcare Professionals and the General Public 20

5.4.3. Group III: Marketing Authorisation Holders 20

5.4.4. Group IV: Research Organisations 22

5.4.5. Group V: World Health Organisation 24

5.4.6. Group VI: International Medicines Regulatory Authorities 24

6. Entry into force of the EudraVigilance Access Policy 25

Annex 1: Adverse reaction reporting and ICSR management principles 26

General Adverse Reaction Reporting Principles 26

Primary and Secondary Report Sources 27

Individual cases, ICSRs and classification rules 27

Annex 2: Accessible ICSR data elements for Stakeholder Groups I to VI 29

Annex 3: ACRONYMS 52

Annex 4: REFERENCES 53

EXECUTIVE SUMMARY

The European Medicines Agency (hereafter referred to as “the Agency”) and the Medicines Regulatory Authorities collectively comprise the European Union (EU) regulatory network. The network's responsibilities are the protection and promotion of public health through the evaluation and supervision of medicines and the continuous safety monitoring and benefit-risk assessment of medicines, including the collection, management and dissemination of information on suspected adverse reactions to medicines (pharmacovigilance). The key EU resource to support this activity is EudraVigilance, a centralised European database of suspected adverse reactions related to medicinal products authorised in the European Economic Area (EEA).

In December 2010, the EMA Management Board adopted a EudraVigilance Access Policy, which came in force in July 2011. This policy outlined the data elements for and the principles of providing access to Individual Case Safety Reports (ICSRs) held in EudraVigilance as regards Medicines Regulatory Authorities, healthcare professionals, patients and consumers, marketing authorisation holders (MAHs) in the EEA as well as research organisations.

In the context of the EudraVigilance Access Policy a proactive and reactive disclosure of information about ICSRs are considered as complementary. This is putting the principle of transparency into effect in the sense that maximum data are released proactively, that the needs of stakeholders are met and that the requirements of personal data protection pursuant to the provisions of Regulation (EC) No 45/2001 and Directive 95/46/EC are adhered to.

Since 2007, the Agency is granting Medicines Regulatory Authorities in the EEA with unrestricted access to all ICSRs held in EudraVigilance. Since May 2012, healthcare professionals, consumers and patients, MAHs and research organisations have certain levels of access to spontaneous reports held in the European pharmacovigilance database focusing on centrally authorised medicinal products. As of September 2014, this access will be gradually extended to active substances contained in all other medicinal products authorised in the EEA starting with substances included in the work sharing for signal management.

The 2010 pharmacovigilance legislation i.e. Regulation (EU) 1235/2010 and Directive 2010/84/EC as well as Commission Implementing Regulation (EU) 520/2012 introduced significant changes in the way adverse reactions are to be reported to and accessed in EudraVigilance. Those changes refer in particular to the:

- Empowerment of patients in all EEA countries to report ICSRs via national spontaneous reporting systems[2];
- Simplification of the reporting of adverse reaction reports, in particular for MAHs for which EudraVigilance will become a single reporting point in the EEA and the re-routing of ICSRs to the Member States where the adverse reaction occurred;
- Provision of EEA adverse reaction reports to the World Health Organisation (WHO);
- The extension of EudraVigilance access to MAHs to the extent necessary to fulfil their pharmacovigilance obligations through continuously monitoring of data in EudraVigilance to determine whether there are new risks or whether risks have changed and whether those risks have an impact on the risk-benefit balance of the medicinal product as well as to validate signals as appropriate based on an examination of ICSRs;

[2] Reporting in accordance with Article 107a of Directive 2001/83/EC

- Further increase of transparency such as the publication of agendas and meeting minutes of the Pharmacovigilance Risk Assessment Committee (PRAC) thus allowing stakeholders to follow the discussion and evaluation of safety issues by the PRAC;
- Enhancements to the EudraVigilance database, which is to be subject to an independent audit.

Taking into account these important developments, the EudraVigilance Access Policy as adopted in December 2010 has been updated whilst maintaining adherence to personal data protection requirements pursuant to the provisions of Regulation (EC) No 45/2001. The aim is to provide the access necessary for those with legal obligations in pharmacovigilance and the highest possible degree of transparency while minimising the necessity to engage in ad-hoc reactive disclosure of information based on individual requests. For this purpose access is being extended from spontaneous reports to reports from non-interventional studies. Country specific information including names of medicinal products authorised nationally are also other examples of the extended scope.

The mechanisms by which stakeholders are provided with access to EudraVigilance based on defined ICSR data elements and in accordance with EU data protection legislation have been further elaborated based on experience gained so far and taking into account the recent changes in legislation.

In summary:

- No changes in the EudraVigilance Access Policy have been introduced for the following stakeholders:
  - Medicines Regulatory Authorities, the Agency and the European Commission maintain access through the various EudraVigilance system components *(Section 5.4.1. and Table 2)*;
  - Healthcare professionals, consumers and patients maintain the possibility to search and screen ICSR data for all medicinal products authorised in the EU by means of easy to use retrieval functions provided through the Agency's European database of suspected adverse reaction reports *(Section 5.4.2. and Table 3)*.
- The main changes in the EudraVigilance Access Policy are:
  - MAHs will be provided with access through downloads of defined ICSR data element sets in support of their signal detection and other pharmacovigilance obligations *(Section 5.4.3. and Table 4)*;
  - Research organisations will gain access to ICSR data sets similar to those provided for MAHs in response to justified research requests *(Section 5.4.4. and Table 5)*;
  - WHO Uppsala Monitoring Centre (UMC) will receive weekly electronic data outputs for ICSRs originating from within the EEA *(Section 5.4.5. and Table 6)*;
  - International Medicines Regulatory Authorities will obtain data outputs on an ad-hoc basis, based on the same data elements as shared with the WHO-UMC *(Section 5.4.6. and Table 7)*;
  - The need to maintain the confidentiality of the identity of patients and reporters in accordance with EU data protection law is being further emphasised including the responsibility of concerned stakeholders to apply appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss *(text integrated in the description of access for each stakeholder);*
  - The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide *(Table 1 and Annex 2)*.

1. Background

In line with the 2010 pharmacovigilance legislation (i.e. Regulation (EC) No 726/2004[3] and Directive 2001/83/EC[4] as amended, Commission Implementing Regulation 520/2012[5]), the Agency is updating and further implementing the EudraVigilance Access Policy that defines the levels of stakeholder access to ICSRs reported to EudraVigilance, whilst fully respecting the need to protect personal data as defined by Regulation (EC) No 45/2001[6] and Directive 95/46/EC[7].

In 2008, a draft EudraVigilance Access Policy (hereafter referred to as 'Access Policy') was prepared by the EudraVigilance Expert Working Group (EV-EWG) in liaison with the EudraVigilance Steering Committee, Heads of Medicines Agencies and the Agency's Management Board.

The Agency released the draft Access Policy for a three months public consultation from December 2008 to March 2009 to provide interested parties the opportunity to comment. Twenty-two interested organisations and individuals provided feedback on the draft Access Policy.

All comments received were consolidated and reviewed by the Agency and the draft Access Policy was revised based on the feedback. An overview of the comments received and the outcome of the review of the comments by the Agency were presented in the document referenced as EMA/432253/2009.

Furthermore, on 7 September 2009, the Agency received the final Opinion[8] on "a Notification for Prior Checking regarding the data processing operations of EudraVigilance" from the European Data Protection Supervisor (EDPS). In its response dated 7 December 2009, the Agency has made proposals on how to address the recommendations of the EDPS, which have also been taken into account in the finalisation of this Access Policy.

Recommendations[9] of the European Ombudsman (EO) on transparency and openness as regards the Agency's activities for stakeholders to have appropriate levels of access to information, which is easily accessible and user-friendly, have also been considered and incorporated.

Taking into account the recent changes to the pharmacovigilance legislation, which are elaborated in chapter 2. , the Access Policy, which came into force in July 2011, has been updated. Furthermore, taking into account the technological progress, the data elements for ICSRs have been updated in line with the ISO ICSR[10] standard and the ICH E2B(R3)/EU ICSR Implementation Guide[11].

[3] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013).
[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version : 16/11/2012)
[5] Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council
[6] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data
[7] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
[8] Opinion on a Notification for Prior Checking Received from the Data Protection Officer of the European Medicines Agency regarding the EudraVigilance database, Brussels, 7 September 2009 (Case 2008-402)
[9] http://www.ombudsman.europa.eu/press/release.faces/en/4819/html.bookmark.
[10] EN ISO 27953-2:2011 Health Informatics, Individual case safety reports (ICSRs) in pharmacovigilance — Part 2: Human pharmaceutical reporting requirements for ICSR (ISO 27953-2:2011)
[11] Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs)
E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html); Draft EU Individual Case Safety Report (ICSR) Implementation Guide (EMA/51938/2013)

2. Introduction

The Access Policy defines the overall principles for the provision of access to EudraVigilance data in line with the EU legal framework and taking into account that the interest in and the use of the data may vary between stakeholders.

In addition, the requirement to protect personal data based on Regulation (EC) No 45/2001 and the recommendations of the EDPS and the EO were assessed and taken into account by the Agency.

As a general principle the Access Policy considers proactive and reactive information disclosure as complementary i.e. the maximum possible information is proactively made available sparing the need for additional requests for data by stakeholders. As part of its proactive information policy, the Agency is also providing additional explanations to facilitate the understanding of the data in the context of the mechanisms by which assess to EudraVigilance data is provided in accordance with this policy.

Taking into account recent legislative changes in the context of pharmacovigilance, the EudraVigilance Access Policy, which came into force in July 2011, has been updated.

According to Article 24(1) of Regulation (EC) No 726/2004, the EudraVigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

Article 24(2) defines the level of EudraVigilance access as follows:

- EudraVigilance shall be fully accessible to the competent authorities of the Member States and to the Agency and the Commission.
- It shall also be accessible to MAHs to the extent necessary for them to comply with their pharmacovigilance obligations.
- The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the EudraVigilance database, while guaranteeing personal data protection.

Article 28(c) of Regulation (EC) No 726/2004 further states that

- The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the World Health Organisation.

Detailed technical specifications related to the practical implementation of the Access Policy are being further elaborated taking into account the overall principles set out in this document.

3. Objectives of the EudraVigilance Access Policy

This Access Policy has been developed with the goal to facilitate the continuous monitoring of the safety of medicines and the evaluation of the benefits and risks of medicines authorised in the EU with the overall aim to promote and protect public health.

Furthermore, the Access Policy aims to meet the EU principles of transparency and openness and to ensure compliance with EU personal data protection legislation. As regards proactive and reactive information disclosure, the principles as outlined in the Access Policy apply accordingly as regards the data that are made accessible to stakeholders.

By providing proactive access to adverse reaction data collected in EudraVigilance, the following objectives should be met:

- Provide openness to citizens, who are directly affected by the EU Regulatory Network's decisions relating to the authorisation and supervision of medicinal products, including the monitoring and assessment of the safety of medicines;
- Facilitate the monitoring of the safety of medicines following their authorisation and marketing;
- Support signal detection and evaluation activities related to all authorised medicines in the EU;
- Allow for the use of adverse reaction data for research purposes to contribute to promoting and protecting public health and fostering the innovation capacity of European medical research;
- Provide promptly all suspected adverse reactions occurring in the Union to the WHO;
- Strengthen the collaboration with international Medicines Regulatory Authorities as regards the safety monitoring of medicines.

Whilst respecting the principles defined in this Access Policy, it should be noted that the level of disclosure of data held in EudraVigilance as part of documents such as Periodic Safety Update Reports and Risk Management Plans and the preparation of assessment reports triggered by regulatory procedures may vary from the data sets defined in this document. As a general principle, an adequate level of redaction of personal data included in the concerned assessment reports and other related documents must be ensured, taking into account the application of Regulation (EC) 1049/2001[12] concerning access to documents as well as applicable EMA/HMA transparency policies[13].

4. EudraVigilance and Medicinal Products for Human Use

EudraVigilance[14] serves multiple functions, which relate to the secure electronic transmission of ICSRs, the collection, administration and quality management of these reports in a centralised database, which serves the early detection of potential safety signals and the evaluation thereof. To support these functions, EudraVigilance is composed of the following main system components:

- **Data processing and management system components**
  - **EudraVigilance Gateway**, a data-processing network for the secure exchange of adverse reaction data.
  - **EudraVigilance Post-Authorisation Module (EVPM)** dedicated to the collection of ICSRs related to all medicinal products authorised in the EEA in line with Regulation (EC) No 726/2004 and Directive 2001/83/EC. The following ICSR types are collected in EVPM: "Spontaneous Report", Report from Study with study type "individual patient use" and "other studies", "Other" and "Not available to sender (unknown)".
  - **eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD),** dedicated to the coding of medicinal products as reported in ICSRs based on the information provided by marketing authorisation holders in line with Article 57(2), second subparagraph of Regulation (EC) No 726/2004.

[12] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents
[13] European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) POLICY/0043
[14] http://eudravigilance.ema.europa.eu

- **Data analysis and signal detection component**
  - **EudraVigilance Data Warehouse and Analysis System (EVDAS),** dedicated to support the EU pharmacovigilance safety monitoring activities with the main focus on signal detection and evaluation of ICSRs.

Adequate quality of ICSRs as reported to EudraVigilance is paramount in implementing this Access Policy. In accordance with Article 24(3) of Regulation (EC) 726/2004, the Agency is operating procedures that ensure the quality and integrity of the information reported in EudraVigilance.

This refers in particular to the responsibilities of stakeholders with EudraVigilance reporting obligations to:

- Adequately document individual cases and their follow-up in accordance with the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practices (GVP) module VI[15];
- MedDRA coding in line with the MedDRA Term Selection Points to Consider[16];
- Local detection and management of potentially duplicated individual cases;
- Adherence with the reporting timelines of suspected serious and non-serious adverse reactions;
- Compliance with personal data protection requirements as set out in Directive 95/46/EC;

and the responsibility of the Agency for the:

- Coding of medicinal product information reported in ICSRs against the XEVMPD and future ISO Identification of Medicinal Products (IDMP) standards as outlined in the Commission Implementing Regulation (EU) No 520/2012;
- Operation of procedures to ensure the quality and integrity of ICSRs reported in EudraVigilance including the detection and management of duplicated individual cases;
- Monitoring of the adherence with reporting timelines of ICSRs;
- Compliance with personal data protection requirements as set out in Regulation (EC) No 45/2001.

5. Access to data held in EudraVigilance

5.1. Stakeholder Groups

The stakeholders being granted access to EudraVigilance data can be grouped as follows:

- EEA Medicines Regulatory Authorities, the European Commission and the Agency (hereafter referred to as Stakeholder Group I)
- Healthcare Professionals and the Public (hereafter referred to as Stakeholder Group II)
- Marketing Authorisation Holders (hereafter referred to as Stakeholder Group III)
- Research Organisations (hereafter referred to as Stakeholder Group IV)
- WHO – Uppsala Monitoring Centre (hereafter referred to as Stakeholder Group V)

[15] Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products
[16] http://www.ich.org/products/meddra.html

- International Medicines Regulatory Authorities where confidentiality agreements are in place with the Agency (hereafter referred to as Stakeholder Group VI).

5.2. Overview

The ICSR data elements to be made available to stakeholders are defined in the "Implementation Guide for the Electronic Transmission of Individual Case Safety Reports (ICSRs) and E2B(R3) Data Elements and Message Specification" (Version 5.01, 12 April 2013) of the ICH E2B Expert Working Group and the corresponding EU ICSR Implementation Guide taking into account the need to comply with Regulation (EC) No 45/2001 and Directive 95/46/EC on personal data protection.

Differences in the number of data elements are based on the stakeholders' interests and needs as well as the requirement to comply with EU personal data protection.

A summary of the access provided to data elements of ICSRs held in EudraVigilance based on the six stakeholder groups and the principles outlined in this Access Policy is provided in table 1. Furthermore, an overview of the access for each stakeholder group is provided in tables 2 to 7.

The summary of all data elements and access provided for each stakeholder group is provided in Annex 2.

The ICH E2B(R3) ICSR Implementation Guide defines the "Type of Report" (Data element: C.1.3), which captures the type of report independently of its source (see also Annex 1) .

The reports of suspected adverse reactions collected in EudraVigilance as derived from legal obligations placed on Medicines Regulatory Authorities and MAHs in the EEA are further described in Annex 1 including different report types and the report classification in EudraVigilance. The Agency grants access to EudraVigilance by taking into account the different types of ICSRs independent of the primary and the secondary source(s).

Table 1: Number of ICH E2B(R3) ICSR data elements

ICH E2B(R3) ICSR Implementation Guide ICSR sections	Total	Group I EMA EC MSs	Group II HCPs Public[17]	Group III.A MAHs			Group IV Researchers		Group V WHO UMC	Group VI Int. Medicines Regulatory Authorities
				Level 1 Signal detection[18]	Level 2 Detailed PhV obligations	Level 3 Sender-based[19]	Level 1 Research proposal	Level 2 Research proposal		
Administrative data	41	41	4	3	19	41	3	19	37	37
Primary source	14	14	2	2	3	14	2	3	3	3
Literature & study information	7	7	6	0	6	7	0	6	6	6
Patient identifiers[20]	5	5	0	0	0	5	0	0	0	0
Patient characteristics[21]	10	10	3	3	9	10	3	9	5	5
Patient medical & drug history	33	33	0	0	33	33	0	33	0	0
Death	8	8	0	0	8	8	0	8	6	6
Parent information	8	8	1	0	6	8	0	6	4	4
Parent medical & drug history	31	31	0	0	31	31	0	31	0	0
Reaction	19	19	13	9	17	19	9	17	16	16
Tests	12	12	0	0	12	12	0	12	0	0
Drug	72	72	34	3	68	72	3	68	66	66
Narrative & related fields (not all free-text)	7	7	0	0	6	7	0	6	0	0
Grand Total	**267**	**267**	**63**	**20**	**218**	**267**	**20**	**218**	**143**	**143**

[17] Public includes MAHs and Researchers
[18] electronic Reaction Monitoring Reports (eRMRs) including a tabular presentation of related individual cases based on the defined data elements
[19] Sender based access is to all data fields
[20] Initials, record numbers
[21] Age, sex, weight, height, Last Menstrual Period date

Table 2: Access to EudraVigilance data by the Commission and Medicines Regulatory Agencies in the EEA

Table 2: Stakeholder Group I	EVPM		
	Disclosure	Provision of Access	Access Authorisation
• Medicines Regulatory Authorities (EEA) • Agency • Commission	• All data elements for ICSRs reported to EVPM	• EVDAS • EVWEB • Re-routing of ICSRs	• Authorised Personnel
Personal data protection requirements	In compliance with Directive 95/46/EC[22] and Regulation (EC) No 45/2001[23]: • Confidentiality of ICSRs and the personal data to remain protected in accordance with the applicable law on personal data protection. • Appropriate technical and organisational measures to be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.		

[22] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ L 281, 23.11.1995, p. 31.

[23] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (2) OJ L 8, 12.1.2001, p. 1.

Table 3: Access to EudraVigilance data by healthcare professionals and the public

Table 3: Stakeholder Group II	EVPM		
	Disclosure	Provision of Access	Access Authorisation
• Healthcare Professionals • General Public[24]	• Subset of ICSR data elements for substances/medicinal products authorised in the EEA	• European database of suspected adverse reaction reports (adrreports.eu)	• Not required
• Personal data protection requirements	• Data provision in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001		

[24] Includes also access to MAHs and Researchers

Table 4: Access to EudraVigilance data by Marketing Authorisation Holders

Table 4: Stakeholder Group III	EVPM		
	Disclosure	**Provision of Access**	**Access Authorisation**
Marketing Authorisation Holders	• Subset of ICSR data elements[25] defined for the purpose of signal detection • Extended subset of ICSR data elements restricted to substances for which a company holds a marketing authorisation in EEA • 'Sender-based' access to all ICSR data elements	• Restricted area of EV website: – e-Reaction Monitoring Reports (e-RMRs) and related ICSR data element subset – Download of extended subset of ICSR data elements in ICH E2B(R3) XML format for substances for which MAH holds marketing authorisation(s) in EEA • EVWEB (''Sender- based")	• Authorised Personnel designated by EU QPPV or appointed Deputy
Personal data protection requirements	In compliance with Directive 95/46/EC and Regulation (EC) No 45/2001: • Confidentiality of ICSRs and the personal data to remain protected in accordance with the applicable law on personal data protection. • Appropriate technical and organisational measures to be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.		

[25] This includes follow-up reports based on adverse reaction reports for which the Agency provides the medical literature monitoring and reporting services as outlined in Article 27 of Regulation (EC) No 726/2004

Table 5: Access to EudraVigilance data by Research Organisations

Table 5: Stakeholder Group IV	EVPM		
	Disclosure	Provision of Access	Access Authorisation
Research Organisations	• Subset of ICSR data elements[26] defined for the purpose of signal detection • Extended subset of ICSR data elements restricted to substances subject to the research	• e-Reaction Monitoring Reports (e-RMRs) and related ICSR data subset by means of secure data provision • Extended subset of ICSR data elements in ICH E2B(R3) XML format for substances subject to the research by means of secure data provision	• Nominated person by Research Organisation
Personal data protection requirements	In compliance with Directive 95/46/EC and Regulation (EC) No 45/2001: • Confidentiality of ICSRs and the personal data to remain protected in accordance with the applicable law on personal data protection. • Appropriate technical and organisational measures to be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.		
Pre-requisites for granting access	• Review research proposal for extended ICSR data set • Researches to sign confidentiality undertaking • Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients)		

[26] This includes follow-up reports based on adverse reaction reports for which the Agency provides the medical literature monitoring and reporting services as outlined in Article 27 of Regulation (EC) No 726/2004

Table 6: Access to EudraVigilance data by WHO-UMC

Table 6: Stakeholder Group V	EVPM		
	Disclosure	Provision of Access	Access Authorisation
World Health Organisation-Uppsala Monitoring Centre	• Subset of ICSR data elements as per agreement with WHO for EEA cases	• Subset of ICSR data elements in E2B(R3)XML format provided by secure means (on a weekly basis)	• WHO UMC authorised personnel
Personal data protection requirements	In compliance with Directive 95/46/EC and Regulation (EC) No 45/2001: • Confidentiality of ICSRs and the personal data to remain protected in accordance with the applicable law on personal data protection. • Appropriate technical and organisational measures to be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.		
Pre-requisites for granting access	• Agreement between the Agency and WHO-UMC on modalities for making available EU adverse reaction reports to VigiBase and arrangements for the data transfer and use, taking into account the principle of data quality, purpose limitation and adequate safeguards for the protection of personal data.		

Table 7: Access to EudraVigilance data by international Medicines Regulatory Authorities

Table 7: Stakeholder Group VI	EVPM		
	Disclosure	Provision of Access	Access Authorisation
International Medicines Regulatory Authorities	• Subset of ICSR data elements to facilitate safety monitoring	• Subset of ICSR data elements in Excel/E2B(R3) XML format provided ad-hoc by secure means	• Nominated contact International Medicines Regulatory Authorities
Personal data protection requirements	In compliance with Directive 95/46/EC and Regulation (EC) No 45/2001: • Confidentiality of records and the personal data of the subjects to remain protected in accordance with the applicable law on personal data protection. • Appropriate technical and organisational measures to be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.		
Pre-requisites for granting access	• Confidentiality Agreement between EMA and non-EEA Medicines Regulatory Authority		

5.3. Access to EudraVigilance data and methods of access

Proactive access to EudraVigilance data is provided through easy to use query and data retrieval functions at the Agency's or EudraVigilance restricted website or dedicated data sets by the following means:

- EVWEB
- EVDAS allowing for the use of integrated signal detection and analysis tools
- European database of suspected adverse reaction reports (adrreports.eu)
- Provision of e-RMRs and other statistical/analytical reports and downloadable files of ICSR data element subsets for the purpose of signal detection
- Provision of downloadable files of extended ICSR data element subsets by substances/substance classes in support of wider pharmacovigilance obligations besides signal detection or for the purpose of scientific research
- Re-routing of ICSRs from EudraVigilance to the national Medicines Regulatory Authorities' pharmacovigilance systems
- Provision of ISCR data subset for all reports from the Union to the WHO and other international Medicines Regulatory Authorities

Taking into account the various EudraVigilance system components as outlined in chapter 4. , EVDAS serves as the main data source for providing access to stakeholder groups.

EVDAS is updated daily with new information reported in ICSRs proceeded by a data management process. All EVDAS data are based on individual cases containing the most complete and most up to date information as reported electronically to EudraVigilance. Where a master case is generated due to confirmed duplicates, access is granted based on the consolidated information held in the master case and the associated ICSRs.

ICSRs classified as 'Error Reports' are excluded from the Access Policy, as they refer to incomplete or erroneous reports. If an ICSR is classified as 'Error Report', the sender is required to correct the ICSR and retransmit it before it will be further processed in EudraVigilance. The same applies to individual cases that have been nullified, as they no longer refer to a valid incident.

5.4. Access by Stakeholder Group

5.4.1. Group I: Medicines Regulatory Authorities in the EEA, the European Commission and the Agency

5.4.1.1. Reports of suspected adverse reactions in EVPM

In accordance with Article 24 of Regulation (EC) 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for all ICSR data elements for all medicinal products independent of the authorisation procedure or the source of the ICSR. This includes all ICSR types as outlined in chapter 4.

5.4.1.2. Methods of Access

The following mechanisms of access are provided:

- EVDAS including all available data analysis and signal detection tools
- e-RMRs and other analytical and statistical data outputs by means of secure data provision or download from restricted and access controlled EudraVigilance website
- EVWEB
- Re-routing of ICSRs to the Medicines Regulatory Authority of the Member State in line with legal provisions set out in Regulation (EC) 726/2004 and Regulation (EU) 534/2014

5.4.1.3. Access Authorisation

Access is granted to authorised personnel of the European Commission, the Agency and Medicines Regulatory Authorities in the EEA. The identification of 'authorised personnel' is based on the EudraVigilance registration process[27]. In Member States, where regional pharmacovigilance centres are established, the responsible Medicines Regulatory Authority determines the level of access, which should be granted to these centres.

5.4.1.4. Personal data protection requirements

The access provisions apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The fundamental right to protection of personal data has to be fully and effectively guaranteed in all pharmacovigilance activities. More specifically, taking into account the recommendations of the EDPS, stakeholder group I is responsible for ensuring that:

- Information is included on EudraVigilance in their privacy statements on their pharmacovigilance activities[28].
- Confidentiality of ICSRs and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- Appropriate technical and organisational measures are implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance.

In addition, the Agency is operating a procedure for access and rectification. In case the Agency is not able to identify the relevant ICSRs, it will refer to the NCA from which the reports likely originate.

[27] http://eudravigilance.ema.europa.eu/human/HowToRegister.asp
[28] An information notice for EMA's processing is available on the website www.adrreports.eu

5.4.2. Group II: Healthcare Professionals and the General Public

5.4.2.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 24 of Regulation (EC) 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for a defined set of data elements in compliance with Regulation (EC) No 45/2001. This applies to all ICSR types and all medicinal products independent of the authorisation procedure or the source of the ICSR.

General explanations and guidance on the nature and the interpretation of the data is provided on the dedicated website "EU database of suspected adverse reaction reports" (http://www.adrreports.eu).

5.4.2.2. Methods of Access

Access is provided by means of the European database of suspected adverse reaction reports (http://www.adrreports.eu).

5.4.2.3. Access Authorisation

No specific authorisation for accessing the data on the Agency's website is required i.e. all citizens can access adverse reaction data of interest.

5.4.2.4. Personal data protection requirements

Data access and provision through the European database of suspected adverse reaction reports is based on a defined data set in compliance with Regulation (EC) No 45/2001. A statement on data privacy is included under the section "Background" of the website www.adrreports.eu. The Agency is also operating a procedure for access and rectification in line with the personal data protection Regulation.

5.4.3. Group III: Marketing Authorisation Holders

5.4.3.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 24 of Regulation (EC) 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for a defined set of ICSR data elements in compliance with Regulation (EC) No 45/2001. This applies to all ICSR types and all medicinal products independent of the authorisation procedure or the source of the ICSR.

There are three levels of access, which are provided for the purpose of:

a) e-RMRs applied for signal detection and a related ICSR data element subset as used by EMA and EEA Medicines Regulatory Authorities for their signal detection and evaluation activities.

b) Fulfilling the MAHs' pharmacovigilance obligations based on an extended number of ICSR data elements but restricted to substances[29], for which a pharmaceutical company holds a marketing authorisation in the EEA.

c) Administrating and reviewing individual cases based on all data elements for ICSRs, which are submitted by the MAH to EVPM[30] ("Sender-based" access).

[29] This includes follow-up ICSRs that are generated as part of the medical literature monitoring and reporting services to be provided by the Agency in accordance with Article 27 of Regulation 726/2004.

As regards point b), the following applies:

- MAHs' pharmacovigilance obligations in the context of this Access Policy focus on signal validation and evaluation, benefit risk assessment in the context of Periodic Safety Update Reports and Risk Management Plans as well as meeting reporting obligations to non-EEA Medicines Regulatory Authorities.
- Medicinal product information as submitted and maintained by MAHs in accordance with Article 57(2), second subparagraph of Regulation 726/2004 is serving as a reference for granting access to the extended data set.

  In addition, MAHs have access to reports of suspected adverse reactions in line with the principles set out for stakeholder group I.

5.4.3.2. Methods of access

The following mechanisms of access are provided:

- EVWEB;
- e-RMRs applied for signal detection by means of secure data provision or the access controlled, restricted area of the EudraVigilance website;
- Download of ICSR data elements as defined for the purpose of signal detection in Excel format; the download is provided at the access controlled, restricted area and of the EudraVigilance website;
- Download of ICSR data elements as defined for the purpose of fulfilling the MAHs' pharmacovigilance obligations in ICH E2B(R3) XML format including applicable search and data retrieval functionalities; those search and download functionalities are provided at the access controlled, restricted area of the EudraVigilance website;

Data downloads specific to MAHs are logged by the Agency.

- European database of suspected adverse reaction reports (http://www.adrreports.eu).

5.4.3.3. Access Authorisation

Access is granted to authorised personnel of a MAH at headquarter level. The identification of 'authorised personnel' is based on the EudraVigilance registration process. The EU Qualified Person Responsible for Pharmacovigilance (QPPV) of the MAH or their registered Deputy nominates the authorised personnel in line with the EudraVigilance Registration Process and is responsible for updating the user registration for their organisation accordingly. Access to a maximum of five signal detection and data analysis experts will be granted as regards point ii, iii, and iv; these experts may reside within or outside the EEA.

5.4.3.4. Personal data protection requirements

The access provisions apply without prejudice to Directive 95/46/ and Regulation (EC) No 45/2001. The fundamental right to protection of personal data have to be fully and effectively guaranteed in all pharmacovigilance activities. More specifically, taking into account the recommendations of the EDPS, stakeholder group III is responsible for ensuring that:

[30] This includes initial ICSRs that are generated as part of the medical literature monitoring and reporting services to be provided by the Agency in accordance with Article 27 of Regulation 726/2004.

- Information is included on EudraVigilance in their privacy statements on their pharmacovigilance activities[31].
- Confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.
- Appropriate technical and organisational measures are implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss.
- The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance.

In addition, the Agency is operating a procedure for access and rectification. In case the Agency is not able to identify the relevant ICSRs, it will refer to the MAH from which the reports likely originate.

5.4.4. Group IV: Research Organisations

5.4.4.1. Reports of suspected adverse reports in EVPM

In accordance with the provisions of Article 24 of Regulation (EC) 726/2004, access to individual cases of suspected adverse reactions reported to EVPM is provided for a defined set of ICSR data elements in compliance with Regulation (EC) No 45/2001 and for substance(s)/class of substances subject to a research request. This applies to all ICSR types and any medicinal product independent of the authorisation procedure or the source of the ICSR.

Besides the data elements published at the European database of suspected adverse reactions, there are two levels of access that can be provided following receipt of a research request based on the principles outlined below:

Level 1: e-RMRs and a subset of ICSR data elements as provided to MAHs for signal detection purposes by means of secure data provision (see point ii and iii of chapter 5.4.3.1.). This applies to substances or substance classes which are subject to the research;

Level 2: An extended number of ICSR data elements but restricted to substances or substance classes which are subject to the research following the receipt of a research request[32]. This data set corresponds to the data set as provided to MAHs (see point iv of chapter 5.4.3.1.) and will be provided by means of secure data provision.

More specifically, access to data for research purposes is granted taking into account the following principles:

- The Agency supports in principle any efforts that aim to directly improve public health and work which is intended to improve procedures for protecting public health.
- The data access to be granted should be sufficient to carry out work aimed at either objective named above.
- Data access should observe EU legislation on protection of personal and commercially confidential data.

[31] An information notice for EMA's processing is available on the website www.adrreports.eu

- An ad-hoc EMA panel will review requests for research access to data based on a research request[33] The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.
- Those given access to EudraVigilance data should make appropriate efforts to publish their research.
- The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.
- A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.
- A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party.
- The Agency will have a standard timescale for response to requests for extended data.
- The data quality will be the best available to the Agency at the time of request. Issues of data quality may be raised with the Agency but no guaranteed timescale can be given for resolution of such issues.
- Meta data essential for interpretation of the EudraVigilance dataset will be made available.

5.4.4.2. Methods of access

The following mechanisms of access can be provided:

Level 1: e-RMRs and other analytical and statistical data outputs applied for signal detection by means of secure data provision;

Level 2: Extended subset of ICSR data elements in ICH E2B(R3) XML or Excel format via secure data provision.

5.4.4.3. Access Authorisation

Data will be provided to a person nominated by the research organisation to safeguard the EudraVigilance data for the research purpose.

5.4.4.4. Personal data protection requirements

The personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter 5.4.3.5.

[33] This research request should address as a minimum the following: the primary research question to be addressed, the methodology to be used, the way that the results of the study will impact on public health, the name and contact details of the person nominated to safeguard the EudraVigilance data for the research purpose; these details should not exceed 1500 words and should be in English.

5.4.5. Group V: World Health Organisation

5.4.5.1. Reports of suspected adverse reactions in EVPM

In accordance with the provisions of Article 28c of Regulation (EC) 726/2004, access to individual cases of suspected adverse reactions occurring in the EEA and reported to EVPM is provided for a defined set of ICSR data elements in compliance with Regulation (EC) No 45/2001. This applies to all ICSR types and all medicinal products independent of the authorisation procedure or the source of the ICSR.

5.4.5.2. Methods of access

The mechanism of providing access is based on the Agency making available electronically every week all ICSRs occurring in the Union based on a defined data element set to WHO UMC. The data will be provided in ICH E2B(R3) XML format by means of secure data provision.

5.4.5.3. Access Authorisation

Access for the purpose of the electronic submission of the defined data set is provided to authorised personnel of the WHO UMC. The identification of 'authorised personnel' is based on the EudraVigilance registration process.

5.4.5.4. Personal data protection requirements

The personal data protection requirements applicable to WHO are the same as for EU Regulatory Authorities as outlined in chapter 5.4.1.4.

5.4.5.5. Agreement between the Agency and the WHO UMC

An agreement between the Agency and WHO UMC further defines the modalities for making available EU adverse reaction reports to VigiBase and arrangements for the data transfer and use, taking into account the principle of data quality, purpose limitation and adequate safeguards for the protection of personal data.

5.4.6. Group VI: International Medicines Regulatory Authorities

5.4.6.1. Reports of suspected adverse reactions in EVPM

The set of ICSR data elements provided to international Medicines Regulatory Authorities corresponds to the data set provided to WHO UMC (see chapter 5.4.5.1.).

5.4.6.2. Methods of access

The mechanism of providing access is based on the Agency making available ICSRs based on a defined set of data elements in Excel or ICH E2B(R3) XML format.

5.4.6.3. Access authorisation

Access is provided to the nominated contact of the international Medicines Regulatory Authority.

5.4.6.4. Personal data protection requirements

The personal data protection requirements applicable to international Medicines Regulatory Authorities are the same as for EU Regulatory Authorities as outlined in chapter 5.4.1.4.

5.4.6.5. Agreement between the Agency and International Medicines Regulatory Authorities

Access is provided where a confidentiality agreement between the Agency and an international Medicines Regulatory Authority is established.

6. Entry into force of the EudraVigilance Access Policy

This Access Policy will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report, the EudraVigilance database has achieved full functionality.

Annex 1: Adverse reaction reporting and ICSR management principles

General Adverse Reaction Reporting Principles

Reports of suspected adverse reactions collected in EudraVigilance are derived from legal obligations placed on Medicines Regulatory Authorities, MAHs and Sponsors in the EEA.

In accordance with Regulation (EC) No 726/2004, simplified adverse reaction reporting rules will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report, the EudraVigilance database has achieved full functionality.

This implies the following as regards adverse reaction reporting and EudraVigilance:

- Each Member State shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients.
  - Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions, submit the reports electronically to the EudraVigilance database.
  - Member States shall, within 90 days from the receipt of reports, submit reports of non-serious suspected adverse reactions electronically to the EudraVigilance database.
  - Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the EudraVigilance database.
- Marketing authorisation holders shall access those reports of suspected adverse reactions through the EudraVigilance database.
- Marketing authorisation holders shall record all suspected adverse reactions in the Union or in third countries which are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study.
  - Marketing authorisation holders shall submit electronically to the EudraVigilance database information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
  - Marketing authorisation holders shall submit electronically to the EudraVigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
  - For medicinal products containing the active substances referred to in the list of publications monitored by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004, marketing authorisation holders shall not be required to report to the EudraVigilance database the suspected adverse reactions recorded in the listed medical literature, but they shall monitor all other medical literature and report any suspected adverse reactions.
- The Agency shall make available promptly all suspected adverse reaction reports occurring in the Union to the World Health Organisation.

Primary and Secondary Report Sources

The primary source of the information is a person who reports the facts. This should be distinguished from a sender (secondary source) who is transmitting the information (e.g., MAH sending a report on to EudraVigilance). Depending on the type of ICSR as outlined below, access is granted to all reports independent of the report source.

Individual cases, ICSRs and classification rules

An **Individual Case** is the information provided by a primary source to describe suspected adverse reaction(s) related to the administration of one or more medicinal products (including investigational medicinal products) to an individual patient at a particular point of time.

An **Individual Case Safety Report (ICSR)** provides the most complete information related to an individual case at a certain point of time. An individual case can be associated with one or more ICSRs.

A **Master Case** refers to a situation where information on the same individual case was reported by different primary and/or secondary sources, which has led to the creation of duplicates, which are subsequently consolidated to one single master case. In EudraVigilance all ICSRs related to the duplicates are associated with the master case, so the initial information can be traced back at all times.

The **ICSR types** refer to the following categories:

- Spontaneous report
- Report from study, further qualified by the differentiation between different types of studies (e.g. clinical trials or others)
- Other, where it is unclear from a literature report whether or not the case(s) cited are spontaneous observations or whether they arise from a study
- Not available to sender allowing for the transmission of information by a secondary sender (e.g. regulatory authority) where the initial sender did not specify the type of report
- Where "Report from study" is indicated, the data element (C.5.4) “Study Type Where Reaction(s)/Event(s) Were Observed”, can be used to distinguish the following:
  - Clinical trials (interventional studies)
  - Individual patient use (e.g. ‘compassionate use’ or ‘named patient basis’)
  - Other studies (e.g. pharmacoepidemiology, pharmacoeconomics, intensive monitoring)

Reports of suspected adverse reactions described in the world-wide literature are not captured as a separate type of report. If a case in the literature arises from spontaneous observations, the type of report is classified as ‘Spontaneous’. If the case arises from a study, the type of report is classified as ‘report from study’. If it is unclear from the literature report whether or not the case(s) cited are spontaneous observations or arise from a study, then it is classified as ‘Other’.

All **ICSRs and individual cases are classified** in EudraVigilance depending on their specific characteristics:

- Initial report
- Follow-up report
- Nullification report

- Error report
- Master report

Where a master case is prepared due to one or more confirmed duplicates, access is provided to the applicable ICSR data elements for the master case and all associated duplicated cases. It should be noted that whilst duplicate detection and management processes are in place, the existence of duplicates in EudraVigilance cannot be entirely excluded.

For ICSRs generated as part of the literature monitoring services in line with the provisions set out in Article 27 of Regulation (EC) 726/2004, access to the initial report is provided to concerned MAHs(s) for all ICSR data elements (same principle as “Sender-based” access) as information related to adverse reactions described in medical and scientific literature is already in the public domain. Access in relation to follow-up reports is granted based on the data element set defined for the purpose of complying with the MAHs’ pharmacovigilance obligations as outlined in chapter 5.4.3.1. taking into account the need to protect any potential new information on personal data obtained as a result of the follow-up.

Annex 2: Accessible ICSR data elements for Stakeholder Groups I to VI

ICH/EU E2B(R3) Data Elements in line with EU ISCR Implementation Guide			Stakeholder Group I	Stakeholder Group II	Stakeholder Groups III and IV MAHs and research organisations			Stakeholder Groups V and VI
ICH/EU	**ICSR ICH E2B(R3) Element Reference**	**DATA ELEMENT NAME**	Agency, Commission & Member States	HCPs & General public [34]	Signal detection eRMR[35] Level 1	PV obligations/Research Level 2	Sender-based Level 3	**WHO-UMC** **Int. Medicines Regulatory Authorities**
ICH	**N.1 ICH ICSR Transmission Identification (batch wrapper)**							
ICH	N.1.1	Types of Message in batch	Y	Y	N	Y	Y	Y
ICH	N.1.2	Batch Number	Y	N	N	N	Y	Y
ICH	N.1.3	Batch Sender Identifier	Y	N	N	N	Y	Y
ICH	N.1.4	Batch Receiver Identifier	Y	N	N	N	Y	Y
ICH	N.1.5	Date of Batch Transmission[36]	Y	N	N	N	Y	Y
ICH	**N.2.R ICH ICSR Message Header (message wrapper) (Repeat as necessary)**							
ICH	N.2.r.1	Message Identifier	Y	N	N	N	Y	Y
ICH	N.2.r.2	Message Sender Identifier	Y	N	N	Y	Y	Y
ICH	N.2.r.3	Message Receiver Identifier	Y	N	N	N	Y	Y
ICH	N.2.r.4	Date of Message Creation[37]	Y	N	Y	Y	Y	Y
ICH	**C.1 Identification of the Case Safety Report**							
ICH	C.1.1	Sender's (case) Safety Report Unique Identifier	Y	Y	N	Y	Y	Y
ICH	C.1.2	Date of Creation	Y	N	N	Y	Y	Y
ICH	C.1.3	Type of Report	Y	Y	Y	Y	Y	Y

[34] This includes also MAHs and Researchers
[35] Electronic Reaction Monitoring Reports (including tabular representation of key information of related individual cases)
[36] Displayed as EV Gateway Receipt Date
[37] Displayed as EV Gateway Receipt Date

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	C.1.4	Date Report Was First Received from Source	Y	N	N	Y	Y	Y
ICH	C.1.5	Date of Most Recent Information for This Report	Y	N	N	Y	Y	Y
ICH	C.1.6.1	Are Additional Documents Available?	Y	N	N	Y	Y	N
ICH	**C.1.6.1.r Identification of the Case Safety Report**							
ICH	C.1.6.1.r.1	Documents Held by Sender	Y	N	N	Y	Y	N
ICH	C.1.6.1.r.2	Included Documents	Y	N	N	N	Y	N
ICH	C.1.7	Does This Case Fulfil the Local Criteria for an Expedited Report?	Y	N	N	N	Y	N
ICH	C.1.8.1	Worldwide Unique Case Identification	Y	N	Y	Y	Y	Y
ICH	C.1.8.2	First Sender of This Case	Y	N	N	Y	Y	Y
ICH	**C.1.9.1.r Source(s) of the Case Identifier(s) (repeat as necessary)**							
ICH	C.1.9.1.r.1	Source(s) of the Case Identifier	Y	N	N	Y	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	C.1.9.1.r.2	Case Identifier(s)	Y	N	N	Y	Y	Y
ICH	**C.1.10.r Identification Number of the Report Which Is Linked to This Report (repeat as necessary)**							
ICH	C.1.10.r	Identification Number of the Report Which Is Linked to This Report	Y	N	N	Y	Y	Y
ICH	C.1 C.1.11.1	Report Nullification / Amendment	Y	N	N	Y	Y	Y
ICH	C.1 C.1.11.2	Reason for Nullification / Amendment	Y	N	N	Y	Y	Y
ICH	**C.2.r Primary Source(s) of Information (repeat as necessary)**							
ICH	C.2.r.1.1	Reporter's Title	Y	N	N	N	Y	N
ICH	C.2.r.1.2	Reporter's Given Name	Y	N	N	N	Y	N
ICH	C.2.r.1.3	Reporter's Middle Name	Y	N	N	N	Y	N
ICH	C.2.r.1.4	Reporter's Family Name	Y	N	N	N	Y	N
ICH	C.2.r.2.1	Reporter's Organisation	Y	N	N	N	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	C.2.r.2.2	Reporter's Department	Y	N	N	N	Y	N
ICH	C.2.r.2.3	Reporter's Street	Y	N	N	N	Y	N
ICH	C.2.r.2.5	Reporter's State or Province	Y	N	N	N	Y	N
ICH	C.2.r.2.6	Reporter's Postcode	Y	N	N	N	Y	N
ICH	C.2.r.2.7	Reporter's Telephone	Y	N	N	N	Y	N
ICH	C.2.r.3	Reporter's Country Code	Y	Y	N	Y	Y	Y
ICH	C.2.r.4	Qualification	Y	Y	Y	Y	Y	Y
ICH	C.2.r.5	Primary Source for Regulatory Purposes	Y	N	Y	Y	Y	Y
ICH	**C.3 Information on Sender of Case Safety Report**							
ICH	C.3.1	Sender Type	Y	Y	N	Y	Y	Y
ICH	C.3.3.1	Sender's Department	Y	N	N	N	Y	Y
ICH	C.3.3.2	Sender's Title	Y	N	N	N	Y	Y
ICH	C.3.3.3	Sender's Given Name	Y	N	N	N	Y	Y
ICH	C.3.3.4	Sender's Middle Name	Y	N	N	N	Y	Y
ICH	C.3.3.5	Sender's Family Name	Y	N	N	N	Y	Y
ICH	C.3.4.1	Sender's Street Address	Y	N	N	N	Y	Y
ICH	C.3.4.2	Sender's City	Y	N	N	N	Y	Y
ICH	C.3.4.3	Sender's State or Province	Y	N	N	N	Y	Y
ICH	C.3.4.4	Sender's Postcode	Y	N	N	N	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	C.3.4.5	Sender's Country Code	Y	N	N	N	Y	Y
ICH	C.3.4.6	Sender's Telephone	Y	N	N	N	Y	Y
ICH	C.3.4.7	Sender's Fax	Y	N	N	N	Y	Y
ICH	C.3.4.8	Sender's E-mail Address	Y	N	N	N	Y	Y
ICH	**C.4.r Literature Reference(s) (repeat as necessary)**							
ICH	C.4.r.1	Literature Reference(s)	Y	Y	N	Y	Y	Y
ICH	C.4.r.2	Included Documents	Y	N	N	N	Y	N
-	**C.5 Study Identification**							
ICH	**C.5.1.r Study Registration (repeat as necessary)**							
ICH	C.5.1.r.1	Study Registration Number	Y	Y	N	Y	Y	Y
-		-						
ICH	C.5.2	Study Name	Y	Y	N	Y	Y	Y
ICH	C.5.3	Sponsor Study Number	Y	Y	N	Y	Y	Y
ICH	C.5.4	Study Type Where Reaction(s) / Event(s) Were Observed	Y	Y	N	Y	Y	Y
ICH	**D. Patient Characteristics**							
ICH	D.1	Patient (name or initials)	Y	N	N	N	Y	N
ICH	D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)	Y	N	N	N	Y	N
ICH	D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)	Y	N	N	N	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	Y	N	N	N	Y	N
ICH	D.1.1.4	Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation Number)	Y	N	N	N	Y	N
ICH	**D.2 Age Information**							ICH
ICH	D.2.1	Date of Birth	Y	N[38]	N[33]	N[33]	Y	N[33]
ICH	D.2.2a	Age at Time of Onset of Reaction / Event (number)	Y[39]	Y[37]	Y[37]	Y[37]	Y[37]	Y[37]

[38] Age is calculated at time of onset of reaction (if available).
If several reactions/events are in the report, the age at the time of the first reaction/event is used.
For foetal reaction(s)/event(s) B.1.2.2.1 "Gestation period when reaction/event was observed in the fetus" is used (if available).
A validation is performed to ensure that all dates of onset of reactions –in case of multiple reactions- fall within a 12 months period.
If the dates are beyond a 12 months onset period, age is not calculated.
[39] Age and patient age group are mapped to a defined age grouping scheme applied in EudraVigilance

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	D.2.2b	Age at Time of Onset of Reaction / Event (unit)	Y	Y	Y	Y	Y	Y
ICH	D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (number)	Y	N	N	Y	Y	N
ICH	D.2.2.1b	Gestation Period When Reaction/Event Was Observed in the Foetus (unit)	Y	N	N	Y	Y	N
ICH	D.2.3	Patient Age Group (as per reporter)	Y	N	N	Y	Y	Y
ICH	D.3	Body Weight (kg)	Y	N	N	Y	Y	N
ICH	D.4	Height (cm)	Y	N	N	Y	Y	N
ICH	D.5	Sex	Y	Y	Y	Y	Y	Y
ICH	D.6	Last Menstrual Period Date	Y	N	N	Y	Y	Y
ICH	**D.7.1.r Structured Information on Relevant Medical History (repeat as necessary)**							
ICH	D.7.1.r.1a	MedDRA Version for Medical History	Y	N	N	Y	Y	N
ICH	D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)	Y	N	N	Y	Y	N
ICH	D.7.1.r.2	Start Date	Y	N	N	Y	Y	N
ICH	D.7.1.r.3	Continuing	Y	N	N	Y	Y	N
ICH	D.7.1.r.4	End Date	Y	N	N	Y	Y	N
ICH	D.7.1.r.5	Comments	Y	N	N	Y	Y	N
ICH	D.7.1.r.6	Family History	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	Y	N	N	Y	Y	N
ICH	D.7.3	Concomitant Therapies	Y	N	N	Y	Y	N
ICH	**D.8.r Relevant Past Drug History (repeat as necessary)**							
ICH	D.8.r.1	Name of Drug as Reported	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.1	Name part - Invented name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.2	Name part - Scientific name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.3	Name part - Trademark name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.4	Name part - Strength name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.5	Name part - Form name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.6	Name part - Container name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.7	Name part - Device name	Y	N	N	Y	Y	N
EU	D.8.r.1.EU.8	Name part - Intended use name	Y	N	N	Y	Y	N
ICH	D.8.r.2a	MPID Version Date/Number	Y	N	N	Y	Y	N
ICH	D.8.r.2b	Medicinal Product Identifier (MPID)	Y	N	N	Y	Y	N
ICH	D.8.r.3a	PhPID Version Date/Number	Y	N	N	Y	Y	N
ICH	D.8.r.3b	Pharmaceutical Product Identifier (PhPID)	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
EU	**D.8.r.EU.r Substance / Specified Substance Identifier and Strength (repeat as necessary)**							
EU	D.8.r.EU.r.1	Substance / Specified Substance Name	Y	N	N	Y	Y	N
EU	D.8.r.EU.r.2a	Substance/Specified Substance TermID Version Date/Number	Y	N	N	Y	Y	N
EU	D.8.r.EU.r.2b	Substance/Specified Substance TermID	Y	N	N	Y	Y	N
EU	D.8.r.EU.r.3a	Strength (number)	Y	N	N	Y	Y	N
EU	D.8.r.EU.r.3b	Strength (unit)	Y	N	N	Y	Y	N
-		-						
ICH	D.8.r.4	Start Date	Y	N	N	Y	Y	N
ICH	D.8.r.5	End Date	Y	N	N	Y	Y	N
ICH	D.8.r.6a	MedDRA Version for Indication	Y	N	N	Y	Y	N
ICH	D.8.r.6b	Indication (MedDRA code)	Y	N	N	Y	Y	N
ICH	D.8.r.7a	MedDRA Version for Reaction	Y	N	N	Y	Y	N
ICH	D.8.r.7b	Reaction (MedDRA code)	Y	N	N	Y	Y	N
-		-						
ICH	D.9.1	Date of Death	Y	N	N	Y	Y	Y
ICH	**D.9.2.r Reported Cause(s) of Death (repeat as necessary)**							
ICH	D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	Y	N	N	Y	Y	Y
ICH	D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)	Y	N	N	Y	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations	Sender-based	Stakeholder Group V and VI
ICH	D.9.2.r.2	Reported Cause(s) of Death (free text)	Y	N	N	Y	Y	N
-		-						
ICH	D.9.3	Was Autopsy Done?	Y	N	N	Y	Y	Y
ICH	**D.9.4.r Autopsy-determined Cause(s) of Death (repeat as necessary)**							
ICH	D.9.4.r.1a	MedDRA Version for Autopsy-determined Cause(s) of Death	Y	N	N	Y	Y	Y
ICH	D.9.4.r.1b	Autopsy-determined Cause(s) of Death (MedDRA code)	Y	N	N	Y	Y	Y
ICH	D.9.4.r.2	Autopsy-determined Cause(s) of Death (free text)	Y	N	N	Y	Y	N
ICH	**D.10 For a Parent-Child / Foetus Report, Information Concerning The Parent**							
ICH	D.10.1	Parent Identification	Y	N	N	N	Y	N
ICH	D.10.2.1	Date of Birth of Parent	Y	N[40]	N[43]	N[43]	Y	N[43]
ICH	D.10.2.2a	Age of Parent (number)	Y	N	N	Y	Y	Y
ICH	D.10.2.2b	Age of Parent (unit)	Y	N	N	Y	Y	Y
ICH	D.10.3	Last Menstrual Period Date of Parent	Y	N	N	Y	Y	Y
ICH	D.10.4	Body Weight (kg) of Parent	Y	N	N	Y	Y	N
ICH	D.10.5	Height (cm) of Parent	Y	N	N	Y	Y	N

[40] NO but Age is calculated (if birth date is available)

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	D.10.6	Sex of Parent	Y	Y	N	Y	Y	Y
ICH	**D.10.7 Relevant Medical History and Concurrent Conditions of Parent**							
ICH	**D.10.7.1.r Structured Information of Parent (repeat as necessary)**							
ICH	D.10.7.1.r.1a	MedDRA Version for Medical History	Y	N	N	Y	Y	N
ICH	D.10.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)	Y	N	N	Y	Y	N
ICH	D.10.7.1.r.2	Start Date	Y	N	N	Y	Y	N
ICH	D.10.7.1.r.3	Continuing	Y	N	N	Y	Y	N
ICH	D.10.7.1.r.4	End Date	Y	N	N	Y	Y	N
ICH	D.10.7.1.r.5	Comments	Y	N	N	Y	Y	N
-		-						
ICH	D.10.7 D.10.7.2	Text for Relevant Medical History and Concurrent Conditions of Parent	Y	N	N	Y	Y	N
ICH	**D.10.8.r Relevant Past Drug History of Parent (repeat as necessary)**							
ICH	D.10.8.r.1	Name of Drug as Reported	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.1	Name part - Invented name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.2	Name part - Scientific name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.3	Name part - Trademark name	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
EU	D.10.8.r.1.EU.4	Name part - Strength name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.5	Name part - Form name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.6	Name part - Container name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.7	Name part - Device name	Y	N	N	Y	Y	N
EU	D.10.8.r.1.EU.8	Name part - Intended use name	Y	N	N	Y	Y	N
ICH	D.10.8.r.2a	MPID Version Date/Number	Y	N	N	Y	Y	N
ICH	D.10.8.r.2b	Medicinal Product Identifier (MPID)	Y	N	N	Y	Y	N
ICH	D.10.8.r.3a	PhPID Version Date/Number	Y	N	N	Y	Y	N
ICH	D.10.8.r.3b	Pharmaceutical Product Identifier (PhPID)	Y	N	N	Y	Y	N
EU	**D.10.8.r.EU.r Substance / Specified Substance Identifier and Strength (repeat as necessary)**							
EU	D.10.8.r.EU.r.1	Substance / Specified Substance Name	Y	N	N	Y	Y	N
EU	D.10.8.r.EU.r.2a	Substance/Specified Substance TermID Version Date/Number	Y	N	N	Y	Y	N
EU	D.10.8.r.EU.r.2b	Substance/Specified Substance TermID	Y	N	N	Y	Y	N
EU	D.10.8.r.EU.r.3a	Strength (number)	Y	N	N	Y	Y	N
EU	D.10.8.r.EU.r.3b	Strength (unit)	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	D.10.8.r.4	Start Date	Y	N	N	Y	Y	N
ICH	D.10.8.r.5	End Date	Y	N	N	Y	Y	N
ICH	D.10.8.r.6a	MedDRA Version for Indication	Y	N	N	Y	Y	N
ICH	D.10.8.r.6b	Indication (MedDRA code)	Y	N	N	Y	Y	N
ICH	D.10.8.r.7a	MedDRA Version for Reaction	Y	N	N	Y	Y	N
ICH	D.10.8.r.7b	Reactions (MedDRA code)	Y	N	N	Y	Y	N
ICH	**E.i Reaction(s)/Event(s) (repeat as necessary)**							
ICH	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native Language	Y	N	N	Y	Y	N
ICH	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	Y	N	N	Y	Y	N
ICH	E.i.1.2	Reaction / Event as Reported by the Primary Source for Translation	Y	N	N	Y	Y	N
ICH	E.i.2.1a	MedDRA Version for Reaction / Event	Y	Y	N	Y	Y	Y
ICH	E.i.2.1b	Reaction / Event (MedDRA code)[41]	Y	Y	Y	Y	Y	Y
ICH	E.i.3.1	Term Highlighted by the Reporter	Y	N	N	Y	Y	Y

[41] Displayed as MedDRA Term

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	E.i.3.2a	Results in Death	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2b	Life Threatening	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2c	Caused / Prolonged Hospitalisation	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2d	Disabling / Incapacitating	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2e	Congenital Anomaly / Birth Defect	Y	Y	Y	Y	Y	Y
ICH	E.i.3.2f	Other Medically Important Condition	Y	Y	Y	Y	Y	Y
ICH	E.i.4	Date of Start of Reaction / Event	Y	N	N	Y	Y	Y
ICH	E.i.5	Date of End of Reaction / Event	Y	N	N	Y	Y	Y
ICH	E.i.6a	Duration of Reaction / Event (number)	Y	Y	N	Y	Y	Y
ICH	E.i.6b	Duration of Reaction / Event (unit)	Y	Y	N	Y	Y	Y
ICH	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	Y	Y	Y	Y	Y	Y
ICH	E.i.8	Medical Confirmation by Healthcare Professional	Y	Y	N	Y	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	E.i.9	Identification of the Country Where the Reaction / Event Occurred	Y	Y	Y	Y	Y	Y
ICH	**F.r Results of Tests and Procedures Relevant to the Investigation of the Patient (repeat as necessary)**							
ICH	F.r.1	Test Date	Y	N	N	Y	Y	N
ICH	F.r.2.1	Test Name (free text)	Y	N	N	Y	Y	N
ICH	F.r.2.2a	MedDRA Version for Test Name	Y	N	N	Y	Y	N
ICH	F.r.2.2b	Test Name (MedDRA code)	Y	N	N	Y	Y	N
ICH	F.r.3.1	Test Result (code)	Y	N	N	Y	Y	N
ICH	F.r.3.2	Test Result (value / qualifier)	Y	N	N	Y	Y	N
ICH	F.r.3.3	Test Result (unit)	Y	N	N	Y	Y	N
ICH	F.r.3.4	Result Unstructured Data (free text)	Y	N	N	Y	Y	N
ICH	F.r.4	Normal Low Value	Y	N	N	Y	Y	N
ICH	F.r.5	Normal High Value	Y	N	N	Y	Y	N
ICH	F.r.6	Comments (free text)	Y	N	N	Y	Y	N
ICH	F.r.7	More Information Available	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Stakeholder Group V and VI
ICH	**G.k Drug(s) Information (repeat as necessary)**							
ICH	G.k.1	Characterisation of Drug Role	Y	Y	Y	Y	Y	Y
ICH	G.k.2.1.1a	MPID Version Date / Number	Y	N	N	Y	Y	Y
ICH	G.k.2.1.1b	Medicinal Product Identifier (MPID)	Y	N	N	Y	Y	Y
ICH	G.k.2.1.2a	PhPID Version Date/Number	Y	Y	N	Y	Y	Y
ICH	G.k.2.1.2b	Pharmaceutical Product Identifier (PhPID)	Y	Y	N	Y	Y	Y
ICH	G.k.2.2	Medicinal Product Name as Reported by the Primary Source[42]	Y	Y	N	Y	Y	Y
EU	G.k.2.2.EU.2	Name part - Scientific name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.3	Name part - Trademark name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.4	Name part - Strength name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.5	Name part - Form name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.6	Name part - Container name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.7	Name part - Device name	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.8	Name part - Intended use name	Y	N	N	Y	Y	Y
EU	**G.k.2.2.EU.9 Device component (repeat as necessary)**							
EU	G.k.2.2.EU.9.r.1	Device Component name (free text)	Y	Y	N	Y	Y	Y
EU	G.k.2.2.EU.9.r.2	Device Component TermID version Date/Number	Y	N	N	Y	Y	Y

[42] Displayed as the medicinal product name after recoding

EU	G.k.2.2.EU.9.r.3	Device Component TermID	Y	N	N	Y	Y	Y
Field ICH or EU	**ICSR ICH E2B(R3) DATA ELEMENT**	**DATA EELEMENT NAME**	**Stakeholder Group I**	**Stakeholder Group II**	**Signal detection as in the eRMR**	**PV obligations/ Research**	**Sender-based**	**Stakeholder Group V and VI**
EU	G.k.2.2.EU.9.r.4	Device serial number	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.9.r.5	Device Batch Lot number	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.9.r.6	Device Model number	Y	N	N	Y	Y	Y
EU	G.k.2.2.EU.9.r.7	Device Software or firmware version	Y	N	N	Y	Y	Y
ICH	**G.k.2.3.r Substance / Specified Substance Identifier and Strength (repeat as necessary)**[43]							
ICH	G.k.2.3.r.1	Substance / Specified Substance[44] Name	Y	Y	Y	Y	Y	Y
ICH	G.k.2.3.r.2a	Substance/Specified Substance TermID Version Date/Number	Y	Y	N	Y	Y	Y
ICH	G.k.2.3.r.2b	Substance/Specified Substance TermID	Y	Y	N	Y	Y	Y
ICH	G.k.2.3.r.3a	Strength (number)	Y	Y	N	Y	Y	Y
ICH	G.k.2.3.r.3b	Strength (unit)	Y	Y	N	Y	Y	Y
-		-						
ICH	G.k.2.4	Identification of the Country Where the Drug Was Obtained	Y	Y	N	Y	Y	Y
ICH	G.k.2.5	Investigational Product Blinded	Y	N	N	N	Y	N

[44] As coded against the XEVMPD; where the reported substance (concomitant medication) cannot be recoded due to data quality issues, the information is not displayed in coded format

ICH	G.k.3.1	Authorisation / Application Number	Y	N	N	N	Y	Y
ICH	G.k.3.2	Country of Authorisation / Application	Y	N	N	N	Y	N
Field ICH or EU	**ICSR ICH E2B(R3) DATA ELEMENT**	**DATA EELEMENT NAME**	**Stakeholder Group I**	**Stakeholder Group II**	**Signal detection as in the eRMR**	**PV obligations/ Research**	**Sender-based**	**Stakeholder Group V and VI**
ICH	G.k.3.3	Name of Holder / Applicant	Y	N	N	N	Y	Y
ICH	**G.k.4.r Dosage and Relevant Information (repeat as necessary)**							
ICH	G.k.4.r.1a	Dose (number)	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.1b	Dose (unit)	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.2	Number of Units in the Interval	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.3	Definition of the Time Interval Unit	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.4	Date and Time of Start of Drug	Y	N	N	Y	Y	Y
ICH	G.k.4.r.5	Date and Time of Last Administration	Y	N	N	Y	Y	Y
ICH	G.k.4.r.6a	Duration of Drug Administration (number)	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.6b	Duration of Drug Administration (unit)	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.7	Batch / Lot Number	Y	N	N	Y	Y	N
ICH	G.k.4.r.8	Dosage Text	Y	N	N	Y	Y	Y
ICH	G.k.4.r.9.1	Pharmaceutical Dose Form (free text)	Y	N	N	Y	Y	Y
ICH	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date/Number	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.10.1	Route of Administration (free text)	Y	N	N	Y	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	G.k.4.r.10.2a	Route of Administration TermID Version Date / Number	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.10.2b	Route of Administration TermID	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.11.1	Parent Route of Administration (free text)	Y	N	N	Y	Y	Y
ICH	G.k.4.r.11.2a	Parent Route of Administration TermID Version Date / Number	Y	Y	N	Y	Y	Y
ICH	G.k.4.r.11.2b	Parent Route of Administration TermID	Y	Y	N	Y	Y	Y
ICH	G.k.5a	Cumulative Dose to First Reaction (number)	Y	Y	N	Y	Y	Y
ICH	G.k.5b	Cumulative Dose to First Reaction (unit)	Y	Y	N	Y	Y	Y
ICH	G.k.6a	Gestation Period at Time of Exposure (number)	Y	N	N	Y	Y	Y
ICH	G.k.6b	Gestation Period at Time of Exposure (unit)	Y	N	N	Y	Y	Y
ICH	**G.k.7.r Indication for Use in Case (repeat as necessary)**							
ICH	G.k.7.r.1	Indication as Reported by the Primary Source	Y	N	N	Y	Y	N
ICH	G.k.7.r.2a	MedDRA Version for Indication	Y	Y	N	Y	Y	Y
ICH	G.k.7.r.2b	Indication (MedDRA code)[45]	Y	Y	Y	Y	Y	Y

[45] Displayed as MedDRA term

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	G.k.8	Action(s) Taken with Drug	Y	Y	N	Y	Y	Y
ICH	**G.k.9.i Drug-reaction(s) / Event(s) Matrix (repeat as necessary)**							
ICH	G.k.9.i.1	Reaction(s) / Event(s) Assessed	Y	N	N	Y	Y	Y
ICH	G.k.9.i.2.r.1	Source of Assessment	Y	N	N	Y	Y	Y
EU	G.k.9.i.2.r.1. EU.1	EU Source of Assessment	Y	N	N	Y	Y	Y
ICH	G.k.9.i.2.r.2	Method of Assessment	Y	N	N	Y	Y	Y
EU	G.k.9.i.2.r.2. EU.1	EU Method of Assessment	Y	N	N	Y	Y	Y
ICH	G.k.9.i.2.r.3	Result of Assessment	Y	N	N	Y	Y	Y
EU	G.k.9.i.2.r.3. EU.1	EU Result of Assessment	Y	N	N	Y	Y	Y
ICH	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	Y	Y	N	Y	Y	Y
ICH	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	Y	Y	N	Y	Y	Y

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	Y	Y	N	Y	Y	Y
ICH	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	Y	Y	N	Y	Y	Y
ICH	G.k.9.i.4	Did Reaction Recur on Re-administration?	Y	Y	N	Y	Y	Y
ICH	G.k.10.r	Additional Information on Drug (coded) (repeat as necessary)	Y	Y	N	Y	Y	N
ICH	G.k.11	Additional Information on Drug (free text)	Y	N	N	Y	Y	N
ICH	**H Narrative Case Summary and Further Information**							
ICH	H.1	Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information	Y	N	N	N	Y	N
ICH	H.2	Reporter's Comments	Y	N	N	Y	Y	N
ICH	**H.3.r Sender's Diagnosis (repeat as necessary)**							
ICH	H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	Y	N	N	Y	Y	N

Field ICH or EU	ICSR ICH E2B(R3) DATA ELEMENT	DATA EELEMENT NAME	Stakeholder Group I	Stakeholder Group II	Signal detection as in the eRMR	PV obligations/ Research	Sender-based	Field ICH or EU
ICH	H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)	Y	N	N	Y	Y	N
-		-						
ICH	H.4	Sender's Comments	Y	N	N	Y	Y	N
ICH	**H.5.r Case Summary and Reporter's Comments in Native Language (repeat as necessary)**							
ICH	H.5.r.1a	Case Summary and Reporter's Comments Text	Y	N	N	N	Y	N
ICH	H.5.r.1b	Case Summary and Reporter's Comments Language	Y	N	N	N	Y	N

Annex 3: ACRONYMS

EEA	European Economic Area
EMA	European Medicines Agency
EVCTM	EudraVigilance Clinical Trial Module
EVDAS	EudraVigilance Data Warehouse and Analysis System
EV-EWG	EudraVigilance Expert Working Group
EVPM	EudraVigilance Post-Authorisation Module
EU	European Union
eXEVMPD	EudraVigilance Medicinal Product Dictionary
eRMR	Electronic Reaction Monitoring Report
HMA	Heads of Medicines Agencies
ICSR	Individual Case Safety Report
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
PRAC	Pharmacovigilance Risk Assessment Committee
QPPV	Qualified Person for Pharmacovigilance
WHO	World Health Organisation
WHO UMC	World Health Organisation Uppsala Monitoring Centre

Annex 4: REFERENCES

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013)
- Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ 12/1/2001, L 8 p. 1-22).
- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 31/5/2001 L 145/43-48).
- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145/43-48)
- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version:16/11/2012).
- European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/document_listing/document_listing_000312.jsp&
- Opinion on a Notification for Prior Checking Received from the Data Protection Officer of the European Medicines Agency regarding the EudraVigilance database, Brussels, 7 September 2009 (Case 2008-402).
- Draft EU Individual Case Safety Report (ICSR) Implementation Guide (EMA/51938/2013)
- CHMP Guideline on Detection and Management of Duplicate Individual Cases and Individual Case Safety Reports (ICSRs) (Doc. Ref. EMA/13432/2009)