EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance – new functionalities and EudraVigilance access policy (patient access)

Eleventh Stakeholder forum on the Pharmacovigilance legislation

21 September 2017

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Project overview

- EudraVigilance auditable requirements project started in October 2013
- Independent audit completed in February/April 2017
- Favourable PRAC recommendation in May 2017
- Confirmation and announcement by the EMA Management Board that full functionality of the new EudraVigilance database has been achieved on 22 May 2017
- **Go-live of the new EV system: 22 November 2017**

Expected benefits

New Features	Benefits
Enhanced signal-detection and data-analysis tools for safety monitoring by NCAs and MAHs	Better detection of new or changing safety issues, enabling rapid action to protect public health
Improved quality and completeness of ICSR data	Better searchability and more efficient data analysis
Enhanced scalability of the EudraVigilance system	Capability to manage an increased number of ICSRs

Expected benefits

New Features	Benefits
Simplified reporting of ICSRs to EudraVigilance and the rerouting of ICSRs to Member States	Reduced duplication of efforts MAHs no longer have to report ICSRs to NCAs, they submit these to EudraVigilance only
EMA will provide data to the World Health Organization (WHO) Uppsala Monitoring Centre directly from EudraVigilance	Enhanced collaboration between EMA and WHO Member States will no longer need to carry out this task

Expected benefits

New Features	Benefits
Extended access to EudraVigilance to MAHs to fulfil their pharmacovigilance obligations	Strengthened safety monitoring of medicines
Enhanced access features for patients and healthcare professionals	Greater transparency in compliance with data protection legislation

Access to patients and healthcare professionals

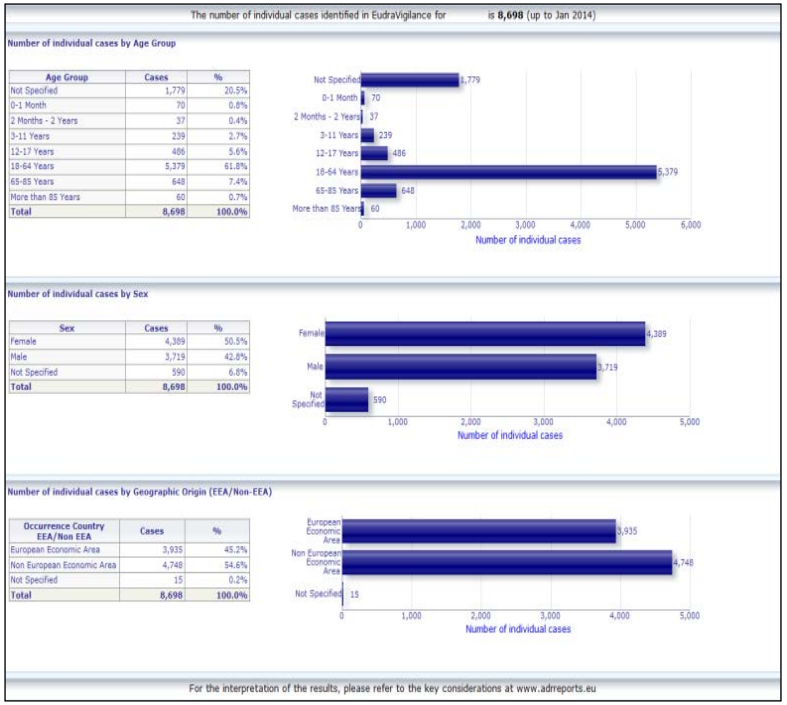
- Access is defined in the EudraVigilance Access Policy (rev 3 adopted by EMA MB in Dec 2016 – applicable as of 22 Nov 2017)
- An extended subset set of data elements for spontaneous reports is made available including new data outputs with detailed guidance on the nature and interpretation of the data and advice to patients not to change their medication without consulting a healthcare professional
- Publicly accessible European database of suspected adverse drug reaction reports: http://www.adrreports.eu/

Access to patients and healthcare professionals

- Current web-reports focus on aggregated data representation
- Search function by medicinal product (centrally authorised medicinal products) or active substance

Example:

- ***Number of individual cases*** by
  - Age Group, Sex and Geographic Origin

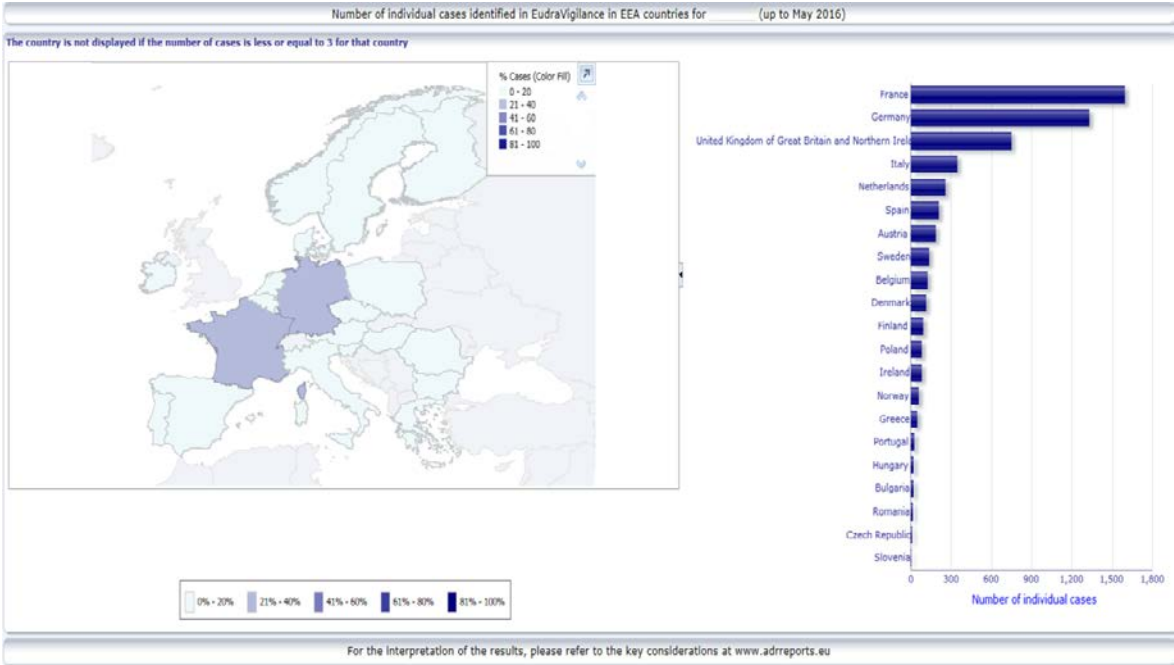


Access to patients and healthcare professionals

new

Aggregated data - dashboard reports

- ❑ **Number of individual cases in EEA for selected medicinal product/substance**
  - – Map view displays the percentage of total EEA cases in each country.
  - – Graph view displays the total number of individual cases in each country.



Access to patients and healthcare professionals

- **Line listing of individual cases reported to EudraVigilance for a specified product or substance**

- The data elements listed below can be used to filter the line listing:
  - Seriousness
  - Geographic Origin
  - Reporter Group
  - Sex
  - Age Group
  - Reaction Groups
  - Reporter Suspected Reaction
  - Gateway Date

Access to patients and healthcare professionals

new

- **Line listing of individual cases reported to EudraVigilance for a specified product or substance**

Line Listing Report
Time run: 18/09/2017 14:10:06

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10143972	31/12/2015	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Diabetic ketoacidosis (n/a - Unknown - Other Medically Important Condition), Ketoacidosis (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition)	INVOKANA (S - Diabetes mellitus - Unknown - [n/a - n/a - Oral]), [CANAGLIFLOZIN, METFORMIN] (S - Diabetes mellitus - Unknown - [n/a - n/a - Oral]), [DAPAGLIFLOZIN] (S - Diabetes mellitus - Unknown - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10144168	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Cerebral haemorrhage (n/a - Fatal - Results in Death)	[CANAGLIFLOZIN] (S - Type 2 diabetes mellitus - Not applicable - [n/a - 100mg - Oral])	[AMLODIPINE BESILATE, IRBESARTAN] (C - n/a - Not applicable - [n/a - 1(DF) - Oral]), [FEBUXOSTAT] (C - n/a - Not applicable - [n/a - 40(DF) - Unknown])	ICSR
EU-EC-10144242	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Bladder neoplasm (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	[CANAGLIFLOZIN] (S - Type 2 diabetes mellitus - Dose not changed - [n/a - 100mg - Oral])	[ALOGLIPTIN BENZOATE] (C - Type 2 diabetes mellitus - Not applicable - [n/a - 25mg - Oral]), [CHLORPHENAMINE MALEATE, DIHYDROCODEINE PHOSPHATE, METHYLEPHEDRINE HYDROCHLORIDE-OL] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), [GLIMEPIRIDE] (C - Type 2 diabetes mellitus - Not applicable - [518d - ..9mg - Oral])	ICSR
EU-EC-10144306	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Mycobacterium avium complex infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal tubular necrosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	INVOKANA (S - Type 2 diabetes mellitus - Drug withdrawn - [n/a - 300mg - Oral])	[GLIPIZIDE] (C - Type 2 diabetes mellitus - Not applicable - [n/a - 10mg - Oral])	ICSR
EU-EC-10144346	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Sepsis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	INVOKANA (S - Product used for unknown indication - Unknown - [n/a - n/a - Oral])	Not reported	ICSR
EU-EC-10144348	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Acute kidney injury (n/a - Recovered/Resolved - Other Medically Important Condition)	INVOKANA (S - Type 2 diabetes mellitus - Drug withdrawn - [n/a - 300mg - Oral])	Not reported	ICSR
EU-EC-10144354	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Rectal cancer (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	CANAGLIFLOZIN (S - Type 2 diabetes mellitus - Dose not changed - [n/a - 100mg - Oral]), [TENELIGLIPTIN] (S - Type 2 diabetes mellitus - Dose not changed - [n/a - 20mg - Oral])	Not reported	ICSR
EU-EC-10144355	31/12/2015	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Gastric cancer (n/a - Recovering/Resolving - Life Threatening), Incorrect dose administered (n/a - Unknown - Life Threatening)	[CANAGLIFLOZIN] (S - Type 2 diabetes mellitus - Dose not changed - [n/a - 50mg - Oral])	VILDAGLIPTIN (C - Type 2 diabetes mellitus - Not applicable - [n/a - 100mg - Oral]), [AMLODIPINE BESILATE] (C - Product used for unknown indication - Not applicable - [n/a - 5mg - Oral]), [DEXCHLORPHENIRAMINE MALEATE] (C - Product used for unknown indication - Not applicable - [n/a - 12mg - Oral]),	ICSR

Access to patients and healthcare professionals

Data element	Description	Example
EV local number	Unique report identifier	EU-EC-12345
Receipt date	Date the report was received by the EV gateway	01/01/2014
Report type	Type of report	Spontaneous
Primary source qualification	Grouped as grouped as HP or non-HP	Healthcare professional
Primary source country	Defines reporting country from a regulatory perspective displayed as EEA/non-EEA	EEA

Access to patients and healthcare professionals

Data element	Description	Example
Literature reference	The reference for a case described in the literature	Biopsychosoc Med. 2015 Feb
Patient age group	Based on reported patient age or calculated difference between 'Date of Birth' and 'First Reaction Start Date' where reported	18-64 Years
Patient Age Group (as per reporter)	Age group as per reporter	Adult
Patient sex	Gender	Female
Parent/Child	If a report relates to a parent and a child	Yes

Access to patients and healthcare professionals

Data element	Description	Example
Reaction List PT (Duration – Outcome - seriousness criteria)	Reaction as reported with information on the reaction duration and outcome as well as the seriousness criteria as applicable	Rash (3d – Resolved - Life Threatening, Caused / Prolonged Hospitalisation) Nausea (1d - Resolved) Headache (3d – Not resolved)
Drug List (Drug Char - Indication PT – Action taken – [Duration - Dose - Route])	Description of the medicine, the indication, action taken with the medicine route of the administration and duration	PRODUCT [Substance] (S -Dental pain, Headache – Drug withdrawn – [1d – 0.5mg – oral])

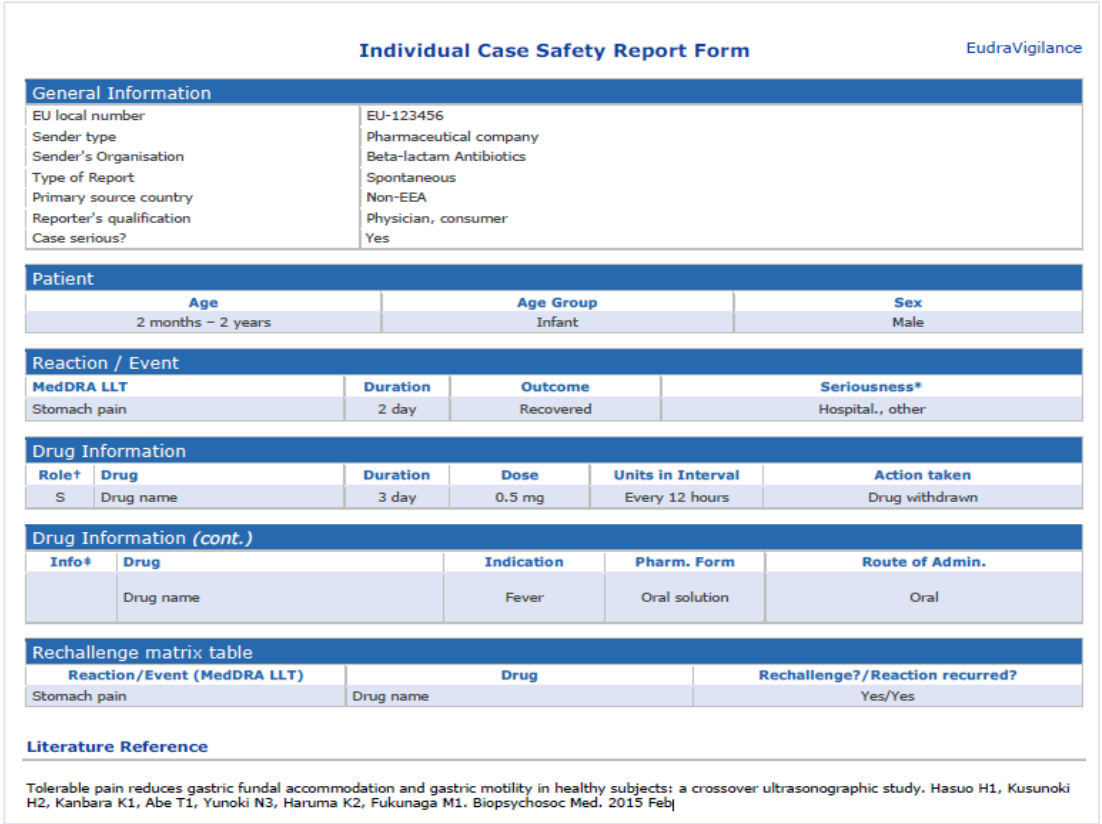
Access to patients and healthcare professionals

❑ Individual Case Safety Report (ICSR) form

- As it is not possible to include all data elements for an ICSR in the line listing, an ICSR form is also available for further review
- The ICSR form presents the data elements for an individual case as per the EudraVigilance Access Policy (public access)
- Data elements in the form are grouped into logical sections (e.g. drug, reaction, medical history) so that the user can easily visualise the available information

Access to patients and healthcare professionals

- **Individual Case Safety Report (ICSR) form**



Individual Case Safety Report Form EudraVigilance

General Information	
EU local number	EU-123456
Sender type	Pharmaceutical company
Sender's Organisation	Beta-lactam Antibiotics
Type of Report	Spontaneous
Primary source country	Non-EEA
Reporter's qualification	Physician, consumer
Case serious?	Yes

Patient

Age	Age Group	Sex
2 months – 2 years	Infant	Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness*
Stomach pain	2 day	Recovered	Hospital., other

Drug Information

Role†	Drug	Duration	Dose	Units in Interval	Action taken
S	Drug name	3 day	0.5 mg	Every 12 hours	Drug withdrawn

Drug Information *(cont.)*

Info‡	Drug	Indication	Pharm. Form	Route of Admin.
	Drug name	Fever	Oral solution	Oral

Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	Rechallenge?/Reaction recurred?
Stomach pain	Drug name	Yes/Yes

Literature Reference

Tolerable pain reduces gastric fundal accommodation and gastric motility in healthy subjects: a crossover ultrasonographic study. Hasuo H1, Kusunoki H2, Kanbara K1, Abe T1, Yunoki N3, Haruma K2, Fukunaga M1. Biopsychosoc Med. 2015 Feb

Conclusion

- With the launch of the new EudraVigilance system a major milestone in supporting the protection of public health will be achieved by
  - Implementing the simplified reporting process as set out in the 2010 phv legislation
  - Strengthening the monitoring of the safety of medicines by means of improved signal detection and management functionalities
  - Enhancing data quality by implementing the new ISO/ICH E2B(R3) ICSR standard
  - Providing access to MAHs to EudraVigilance to the extent necessary for them to meet their pharmacovigilance obligations
  - Strengthening the collaboration with WHO related to the safety of medicines
  - Increasing transparency and better access to information on suspected adverse reactions related to medicines to patients and healthcare professionals

Thank you for your attention

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