

Electronic Supplementary Material

Article title: *EudraVigilance Medicines Safety Database: Publicly Accessible Data for Research and Public Health Protection*

Journal: *Drug Safety*

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Introduction

To have an overview about how EudraVigilance (EV) data has been used in research and scientific publications, a search in Embase (1), Pubmed and Pubmed Central (2) was conducted using specific keywords¹. This provides an illustration of the use of the data with the aim of informing researchers how EV can be utilised. The limitation of this literature review was the fact that drug-related safety issues or other pharmacovigilance topics would have been the main subject of the publications rather than EV; for this reason, the search was performed in three different databases to retrieve as many publications as possible, considering that publications that did not include the search terms as keywords or mentioned them in the abstract, would not be retrieved.

The specific drug-related safety issues retrieved in the literature search are summarised table 1 of this electronic supplementary material including the drugs involved and the databases used for the analysis.

Table 1. Description of safety topics analysed in the publications that used EudraVigilance data up to 31 December 2016

Year	Drugs involved	Safety Issue	Databases
2009	Phosphodiesterase 5 inhibitors (3)	Pulmonary embolism	EV, Netherlands Pharmacovigilance Centre (Lareb), Vigibase
2010	Ranibizumab (4)	Thromboembolic events	EV, Italian Pharmacovigilance

¹ 'eudravigilance' OR 'ev database' OR 'ev data' OR 'ema database' OR 'ema data' OR 'emea database' OR 'emea data' OR 'european medicines agency database' OR 'european medicines agency data' OR 'adrreports' OR 'european database of suspected' OR 'adr database' OR 'adr data' OR 'adverse drug reaction database' OR 'adverse drug reaction data' OR 'adverse reaction database' OR 'adverse reaction data'

Year	Drugs involved	Safety Issue	Databases
			database of spontaneous reports of ADRs
2011/ 2012	Pandemic influenza A/H1N1 vaccines (5), (6)	Autoimmune disorders	EV
2012	Domperidone (7)	Cardiac events and potential interacting medications	EV, FAERS
2013/ 2014	Vaccines (8) (9)	Acute Disseminated Encephalomyelitis	EV, VAERS
2013	TNF-alpha inhibitors (10)□	Amyotrophic lateral sclerosis	EV
2013, 2015	Rituximab (11), (12)	Melanoma	EV, FAERS
2013	A/H1N1 2009 influenza vaccine (Pandemrix) (13)	Epileptic seizures	Swedish vaccination register, VAERS, EV
2013	Golimumab (14)	Myocardial infarction related events	EV and Vigibase
2013	Biotechnological drugs prescribed for rheumatoid arthritis (15)	Characterisation of safety profiles	EV
2014	Gadolinium-based contrast agents (16)	Nephrogenic systemic fibrosis	EV, FAERS, Danish Medicine Agency, ICNSFR registry, publicly available legal dataset
2014	Biologics/biosimilar epoetins (17)	Safety profile compared to the reference product	EV
2014	Inhaled colistimethate (18)	Thrombocytopenia	EV, Spanish PV system
2014, 2015, 2016	Bisphosphonates (19), (20), (21)	Cardiac valve disorders	Electronic healthcare databases (Italy , Netherlands, UK), EV, FAERS
2014	Non-insulin blood glucose lowering drugs (22)	Risks for selected cardiovascular, stroke, pancreatic and bladder outcomes	EV and FAERS
2014	Biologics approved for the treatment of ocular diseases (23), (24)	Characterisation of safety profiles	EV
2014	Naloxone (25)	Ventricular tachycardia	EV, Lareb

Year	Drugs involved	Safety Issue	Databases
2015	Antiepileptic drugs (26)	Drug reaction with eosinophilia and systemic symptoms	EV
2015	Carbapenems (27)	Seizures	EV, French PV database
2015	Set of drugs prescribed in geriatric settings (28)	Taste disorders	EV
2015	Trimebutide (29)	TdP (Prediction of proarrhythmia during drug development)	EV
2015	Everolimus (30)	Steatosis	EV, Italian National PV network database
2015	Nicardipine (31)	Acute pulmonary oedema	EV
2015	Medicines for rheumatoid arthritis (32)	Characterisation of the safety profile	EV
2015	Fingolimod (33)	Characterisation of safety profile	EV, Centre for multiple Sclerosis of AOUCity of health and science of Turin
2015	Monoclonal antibodies (34)	QT-prolonging effects	EV
2015	Levetiracetam (35)	Suicidal behaviour, ideation and attempt	EV
2015	Immunoglobulins (36)	Haemolytic reactions	EV
2015	Abiraterone and zoledronic acid (37)	Toxic epidermal necrolysis	EV, electronic medical records (Lanus), records of chemotherapy ordered and dispensed (Farmis and Silicon)
2016	Pregabalin and gabapentin (38)	Gabapentinoid misuse and dependence	EV
2016	Vemurafenib (39, 40)	Acute renal failure	French PV database, EV
2016	DPP-4 inhibitors (40)	Characterisation of safety profiles	EV
2016	Phenothiazine and antihistamine molecules (41)	Characterisation of safety profiles	EV
2016	Cabazitaxel (42)	Interstitial lung disease	EV
2016	Clindamycin (43)	Acute generalised exanthematous pustulosis	EV, Lareb, vigibase
2016	Clozapine (44)	Cardiomyopathy	EV

Year	Drugs involved	Safety Issue	Databases
2016	Dipeptidyl peptidase-IV inhibitors (45)	Bullous pemphigoid	EV
2016	All products in the database (46)	Interstitial Lung Disease	EV
2016	Incretin-based therapy (47)	Acute cholecystitis	EV, Antidiabetic monitoring registry (AIFA)
2016	Antibiotics (48)	Kounis Syndrome	EV and Vigilyze
2016	Influenza vaccines (49)	Narcolepsy	EV
2016	Statins (50)	Muscle rupture	EV, Lareb
2016	Pandemic influenza vaccines (51)	narcolepsy and/or cataplexy	EV
2016	Lamotrigine and valproate (52)	Characterisation of safety profiles	EV, Norwegian prescription database
2016	Oxaliplatin (53)	QT interval prolongation	EV, CredibleMeds
2016	Antiobesity medicines (ATC A08A) (54)	Characterisation of safety profiles	EV
2016	Vaccines (55)	Vasculitis	EV, VAERS, Vigibase

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