Open Access Pharmacovigilance Databases: Analysis of 11 Databases

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Abstract (300 word limit)

The concept of transparency regarding scientific data is more and more obvious, this work aims at describing and analysing what kind of safety data can be obtained from pharmacovigilance (PV) databases that offer public access. Nine national pharmacovigilance databases (Australia, Canada, Denmark, Germany, Netherlands, New-Zealand, Japan, United Kingdom, USA) plus the World Health Organization (Vigibase) and the European pharmacovigilance databases were compared according to the type of data provided, the possible requests (by drug, by adverse reaction) and the format of the safety data. Public access to PV databases was thus classified as high, medium or low. The results show that six databases grant case-level access, the others only provide aggregated data. In terms of general case information, the USA and Canada come first by sharing case ID, the type of report, the reporter and their qualification, whereas Vigibase does not provide any general information. The other databases mostly provide only one of these three items: source, case ID, or type of report. Overall, the databases from Denmark, Japan, the Netherlands, UK and VigiBase were classified as providing a low level of access to available safety information; those from Australia, EudraVigilance, Germany and New Zealand as providing a medium level of access; and those from the USA and Canada, as providing a high level of access.

The 11 PV databases analysed, except for those in North America, provide limited information. This may be acceptable for patient use but not for research purposes.

Image

Country	Website name	Items to complete in online patient reporting form available on NCA website (*n*)	Open access items in the pharmacovigilance database (*n*)	No. of items displayed in the pharmacovigilance database/total no. of items in patient reporting form ratio (%)	Pharmacovigilance database access classification
WHO[a]	VigiAccess	25	5	20	Low
USA	FDA	39	21	54	High
EU[a]	ADRREPORTS	25	6	24	Medium
UK	MHRA	53	5	9	Low
Australia	TGA	34	7	39	Medium
Canada	MedEffect	39	20	51	High
Germany	BfArM	37	15	41	Medium
Netherlands	Lareb	41	6	15	Low
NZ	Medsafe	38	8	21	Medium
Denmark	Sundhedsstyrelsen	44	5	11	Low
Japan	PMDA	45	6	13	Low
Mean	NA	40	9	25	NA

ADR adverse drug reaction, *BfArM* Bundesinstitut für arzneimittel und medizinprodukte, *CIOMS* Council for International Organizations of Medical Sciences, *FDA* US Food and Drug Administration, *MHRA* Medicines and Healthcare Products Regulatory Agency, *NA* not applicable, *NCA* National Competent Authority, *NZ* New Zealand, *PMDA* Pharmaceuticals and Medical Devices Agency, *PV* pharmacovigilance, *TGA* Therapeutic Goods Administration, *UK* United Kingdom, *WHO* World Health Organization

[a] CIOMS was used instead for item counting

Pharmacovigilance databases comparison regarding public access information and case report information

Recent publications (minimum 5)

1. A Fouretier, A Malriq, D Bertram. Open Access Pharmacovigilance Databases: Analysis of 11 Databases. Pharmaceutical Medicine Volume 30, Issue 4, 221–231. 2016
2. F Margraff, D Bertram. Adverse drug reaction reporting by patients: an overview of fifty countries. Drug Safety 37 (6), 409-419. 2014
3. A Fouretier, D Bertram. New regulations on medical devices in Europe: what to expect? Expert review of medical devices 11 (4), 351-359. 2014
4. M. Pflieger, D. Bertram. Pediatric drug development: ICH harmonized tripartite guideline E11 within the United States of America, the European Union, and Japan. Arch Pediatr. 21, 1129-1138. 2014
5. E Hoffmann, A Fouretier, C Vergne, D Bertram. Pharmacovigilance regulatory requirements in Latin America. Pharmaceutical Medicine 26 (3), 153-164. 2012

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Biography (150 word limit)



Delphine Bertram, PharmD, PhD has more than 12 years' experience in managing the safety of clinical trials. She built and managed the Vigilance Unit of the second public French Hospital. She has hosted and managed European and French Health Authorities inspections (preparation, conduct and CAPA management), planned and executed Internal/external audits. She has extensive knowledge of the international regulatory (ICH, FDA guidance's, GVP, MEDDEV) environment for both pre- and post-marketing product, e-Health and social media monitoring. She co-developed a free application to allow patients and healthcare professional to report drug adverse effect to the health authority. I have a particular interested in e-health precisely in the use of social data to improve drug surveillance

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Notes/Comments: