References

Chapter 39

1 De Ponti F. Global perspectives in pharmacovigilance. *Journal of Pharmacovigilance.* 2013;**1**:e108.

2 European Parliament. Regulation (EU) 1235/2010 – 2010 Pharmacovigilance Legislation. Available from: http://eur-lex.europa.eu/homepage.html (last accessed 18 November 2015).

3 European Council. Directive 2010/84/EU – 2010 pharmacovigilance legislation. Available from: http://eur-lex.europa.eu/homepage.html?locale=it (last accessed 18 November 2015).

4 Bate A and Evans SJ. Quantitative signal detection using spontaneous ADR reporting, *Pharmacoepidemiology & Drug Safety.* 2009;**18**:427–36.

5 Harpaz R, DuMouchel W, Shah NH, Madigan D, Ryan P, Friedman C. Novel data-mining methodologies for adverse drug event discovery and analysis. *Clinical Pharmacology & Therapeutics.* 2012;**91**:1010–21.

6 Coloma PM, Trifiro G, Patadia V, Sturkenboom M. Postmarketing safety surveillance: where does signal detection using electronic healthcare records fit into the big picture? *Drug Safety.* 2013;**36**:183–97.

7 Moore N. The past, present and perhaps future of pharmacovigilance: homage to Folke Sjoqvist. *European Journal of Clinical Pharmacology.* 2013;**69**(Suppl. 1):33–41.

8 Hammond IW, Gibbs TG, Seifert HA, Rich DS. Database size and power to detect safety signals in pharmacovigilance. *Expert Opinions in Drug Safety.* 2007;**6**:713–21.

9 Poluzzi E, Raschi E, Piccinni C, De Ponti F. Data mining techniques in pharmacovigilance: analysis of the publicly accessible FDA Adverse Event Reporting System (AERS). In: Karahoca A, ed. *Data Mining Applications in Engineering and Medicine.* Croatia, InTech, 2012. Available from: http://www.intechopen.com/books/data-mining-applications-in-engineering-and-medicine/data-mining-techniques-in-pharmacovigilance-analysis-of-the-publicly-accessible-fda-adverse-event-re (last accessed 4 January 2016)

10 Bergvall T, Noren GN, Lindquist M. VigiGrade: a tool to identify well-documented individual case reports and highlight systematic data quality issues. *Drug Safety.* 2014;**37**:65–77.

11 Sabate M, Pacheco JF, Ballarin E, Ferrer P, Petri H, Hasford J, et al. A compilation of research working groups on drug utilisation across Europe. *BMC Research Notes.* 2014;**7**:143.

12 Sabate M, Ferrer P, Ballarin E, Rottenkolber M, Amelio J, Schmiedl S, et al. Inpatient drug utilization in Europe: nationwide data sources and a review of publications on a selected group of medicines (PROTECT project). *Basic & Clinical Pharmacology & Toxicology.* 2015;**116**:201–11.

13 Lindquist M, Sanderson J, Claesson C, Imbs J, Rohan A, Edwards I. New pharmacovigilance information on an old drug, *Drug Investigation.* 1994;**8**:73–80.

14 Lindquist M, Pettersson M, Edwards IR, Sanderson J, Taylor N, Fletcher P, et al. Omeprazole and visual disorders: seeing alternatives. *Pharmacoepidemiology & Drug Safety.* 1996;**5**:27–32.

15 Stahl MM, Lindquist M, Pettersson M, Edwards IR, Sanderson JH, Taylor NF, et al. Withdrawal reactions with selective serotonin re-uptake inhibitors as reported to the WHO system. *European Journal of Clinical Pharmacology.* 1997;**53**:163–9.

16 Lindquist M, Pettersson M, Edwards IR, Sanderson JH, Taylor NF, Fletcher AP, et al. How does cystitis affect a comparative risk profile of tiaprofenic acid with other non-steroidal antiinflammatory drugs? An international study based on spontaneous reports and drug usage data. ADR Signals Analysis Project (ASAP) Team. *Pharmacology & Toxicology.* 1997;**80**:211–17.

17 Lindquist M, Edwards IR. Risks of non-sedating antihistamines. *Lancet.* 1997;**349**:1322.

18 Anderson N, Borlak J. Correlation versus causation? Pharmacovigilance of the analgesic flupirtine exemplifies the need for refined spontaneous ADR reporting. *PLoS. ONE.* 2011;**6**:e25221.

19 Pierfitte C, Begaud B, Lagnaoui R, Moore ND. Is reporting rate a good predictor of risks associated with drugs? *British Journal of Clinical Pharmacology.* 1999;**47**:329–31.

20 Tavassoli N, Lapeyre-Mestre M, Sommet A, Montastruc JL. Reporting rate of adverse drug reactions to the French pharmacovigilance system with three step 2 analgesic drugs: dextropropoxyphene, tramadol and codeine (in combination with paracetamol). *British Journal of Clinical Pharmacology.* 2009;**68**:422–6.

21 Salvo F, Polimeni G, Moretti U, Conforti A, Leone R, Leoni O, et al. Adverse drug reactions related to amoxicillin alone and in association with clavulanic acid: data from spontaneous reporting in Italy. *Journal of Antimicrobial Chemotherapy.* 2007;**60**:121–6.

22 Goossens H, Ferech M, Vander SR, Elseviers M. Outpatient antibiotic use in Europe and association with resistance: a cross-national database study. *Lancet.* 2005;**365**:579–87.

23 Raschi E, Poluzzi E, Godman B, Koci A, Moretti U, Kalaba M, et al. Torsadogenic risk of antipsychotics: combining adverse event reports with drug utilization data across Europe. *PLoS ONE.* 2013;**8**:e81208.

24 Poluzzi E, Raschi E, Koci A, Moretti U, Spina E, Behr ER, et al. Antipsychotics and torsadogenic risk: signals emerging from the US FDA Adverse Event Reporting System database. *Drug Safety.* 2013;**36**:467–79.

25 Poluzzi E, Raschi E, Godman B, Koci A, Moretti U, Kalaba M, et al. Pro-arrhythmic potential of oral antihistamines (H1): combining adverse event reports with drug utilization data across Europe. *PLoS ONE.* 2015;**10**:e0119551.

26 Salvo F, Raschi E, Moretti U, Chiarolanza A, Fourrier-Reglat A, Moore N, et al. Pharmacological prioritisation of signals of disproportionate reporting: proposal of an algorithm and pilot evaluation. *European Journal of Clinical Pharmacology.* 2014;**70**:617–25.