PHARMACOVIGILANCE AND THE CASE STUDY OF VIOXX®

Krancberg AN.[1], Chmielewska M.[1], Hermanowski TR.[1]
[1]Department of Pharmacoeconomics, *Medical University of Warsaw*, *Warsaw,* Poland

OBJECTIVES

Pharmacovigilance as a part of drug safety surveillance consists in collecting and analysing adverse effects reports and is intended to evaluate the safety of medicinal products and to eliminate drugs whose risks outweigh therapeutic benefits. The research aims were: to recognize the rules of current pharmacovigilance practices, to examine their capacity to effectively manage public health and to propose an improved pharmacovigilance model.

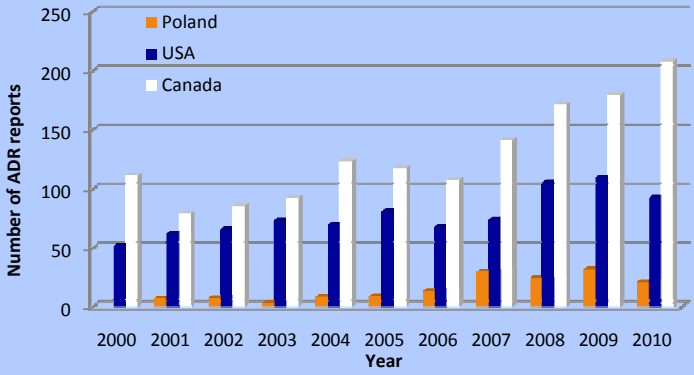
METHODS

The rules of drug safety monitoring in the United States, Canada, the UK and Poland have been presented, analysed and compared. In order to assess the effectiveness of the respective national practices, an additional analysis covered reports prepared by healthcare professionals, consumers and MAHs, submitted to the responsible healthcare agencies (FDA, Health Canada, MHRA and URPL, WMiPB) (Figure 1 and 2). Based on the results, an improved pharmacovigilance model was proposed. A case study of VIOXX® was used to review different pharmacovigilance practices by analysing reports on this recalled drug, including the incidence (Figure 3) and type of adverse effects reported (Figure 4), principles of pharmacovigilance signal detection and measures, taken by the agencies. The model was then subject to final evaluation.

RESULTS

The analysed pharmacovigilance practices allowed to collect sufficient data on adverse effects, but none of the agencies raised any alarm addressing safety issues before the product was recalled by the manufacturer.

Figure 1. The number of adverse drug reaction reports prepared by healthcare professionals and patients submitted directly to the competent national agencies in 2000 – 2010 for 1 mln of citizens* [1,2,4]



* In Poland patients and consumers did not have the entitlement to report adverse reactions to URPL by themselves till 21.07.2012

Figure 2. The number of adverse drug reaction reports submitted by MAHs to the competent national agencies in 2000 – 2010 [1,2,4]

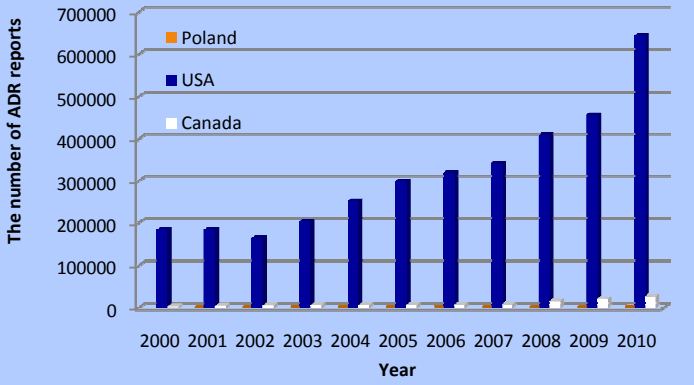


Figure 3. The total number of adverse drug reaction reports and number of death related to the medicinal product – VIOXX, noted in 1999 – 2011 in chosen countries [2,3,4]

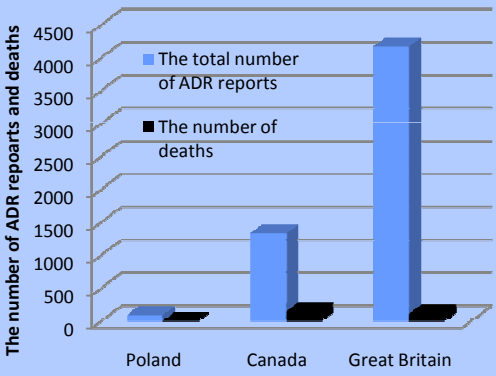
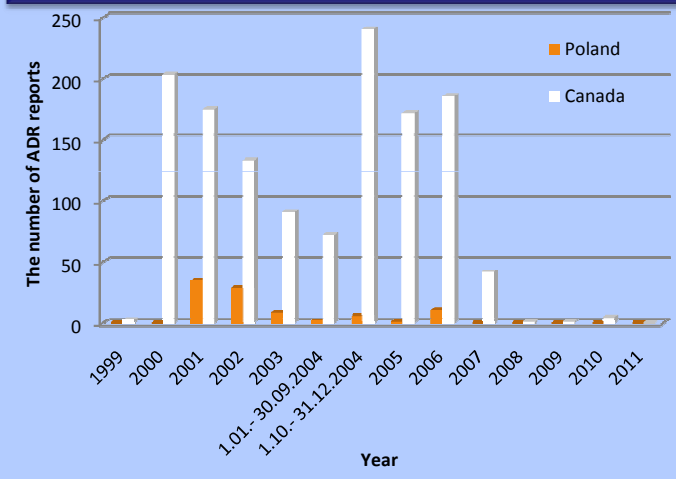


Figure 4. The number of adverse drug reaction reports related to medicinal product – VIOXX noted in 1999 – 2011 in Poland and Canada emphasizing the withdrawal date (30.09.2004) [2,4]



CONCLUSIONS

The procedures underlying pharmacovigilance practices need to be amended by adopting the ideas proposed in the model, especially in the area of data analysis and signal detection, for instance: rigorous five-year safety monitoring of new products, especially post-marketing surveillance; publicly available adverse effects reports collected by the agencies; publicly available standards of signal detection based on MAHs declarations in SPCs; and including clinical trials' analysis in standard drug safety monitoring.

References:

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Contact: Aleksandra Krancberg, Department of Pharmacoeconomics, *Medical University of Warsaw, Żwirki i Wigury 81,* 02-106 Warsaw
E-mail: a.krancberg@gmail.com