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9. Adverse Drug Reaction Reporting at the Belgian Centre for Pharmacovigilance for Medicinal Products for Human Use of the Directorate General for Medicinalproducts (DGMP)

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Introduction: The reporting of adverse drug reactions (ADRs) in Belgium has been in effect since the start of the activities of the Belgian Centre for Pharmacovigilance for Medicinal Products for human use (BCPH), 30 years ago. A continuous increase in the number of adverse drug reaction was noticed, but crucial years were 1995 and 2004.

Methods: ADR-reports were collected from healthcare professionals (HPs), by use of yellow cards, and from marketing authorisation holders (MAHs) or sponsors from clinical trials first on paper (CIOMS) and since 2005 electronically (E2B).

Results: Until now, the BCPH received more than 32.000 reports. 15% of those reports are received by HP on a voluntary basis. The other ADRs were reported by MAHs or sponsors of clinical trials on an obligatory basis. Of all European countries, the highest reporting rates in 2004 were noticed in Sweden and Ireland; Belgium follows at the 8th place with a reporting rate per million capita of 283,27 which is far above the average value (152,93) in Europe.[1]

After 1995[2] and after 2004[3], there was a marked increase in the number of reports of ADRs, due to new obligations of the MAHs and sponsors of clinical trials, i.e. their obligation to systematically forward serious suspected ADRs (table I). The most often reported ADRs in Belgium were body as a whole and gastro-intestinal disorders (each +/-11%); however, skin, psychiatric and nervous system disorders were also frequent (+/-6%). The highest reporting rate in Belgium is for patients older than 40 years, possibly related to the higher use of medicinal products (table II).

Table I. Number of reports (n) in Belgium per year

2005	3442	2000	1881	1995	442
2004	2895	1999	1327	1994	450
2003	2211	1998	1304	1993	448
2002	2144	1997	869	1992	347
2001	2153	1996	623	1991	336

Conclusions: The study illustrates the usefulness of the BCPH in collecting safety data in Belgium and it's contribution to the European pharmacovigilance system. Based on the data available in the Belgian reporting system, some patterns of ADRs could be detected. Other approaches should be applied to enhance reporting on voluntary basis, especially by HPs. Projects for electronic reporting by this group are running at the BCPH.

Table II. Reporting rate (%) by age group

0-20Y	8.8%
21-40Y	16.6%
41-60Y	28.5%
61-80Y	32.6%
81 and older	5.3%

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