



UPPSALA
UNIVERSITET

Kristina Johansson

Supervisor:

Ronald Meyboom

The Uppsala
Monitoring Centre

Examiner:

Björn Hellman

Department of
Pharmaceutical Biosciences,
Division of Toxicology,
Uppsala University

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www.who-umc.org

VIGIMED, an international drug safety e-mail discussion group



Pharmacovigilance

Pharmacovigilance is concerned with the monitoring of the quality, safety and efficacy of marketed medicines. This monitoring is necessary since by no means all of a medicine's effects are known at the time of its introduction. After being approved and marketed the medicine is going to be used in large groups of diverse patients, unlike the small and specifically selected groups of patients investigated in clinical trials. Therefore, hitherto unknown effects of the drug may be revealed.

The WHO Programme and the Uppsala Monitoring Centre

The WHO Programme for International Drug Monitoring started as a small project of 10 countries wishing to pool data regarding suspected adverse drug reactions. The Programme was established in 1968 in the aftermath of the thalidomide disaster and the intention was to develop international collaboration to make it easier to detect rare adverse drug reactions not revealed during clinical trials. Since 1978 the Programme has been maintained by the Uppsala Monitoring Centre (UMC).

Vigimed

'Vigimed' is the name of an e-mail discussion group that is maintained by the UMC. The Vigimed system allows, as the only e-mail group in the world, rapid exchange of information regarding drug-related problems between national pharmacovigilance centres around the world. At the moment 71 countries are represented on the Vigimed.

The Purpose of the Study

Thanks to the comprehensive documentation of all messages in Vigimed, the system can also be used as a unique source of information regarding to factual daily practice of governmental pharmacovigilance. We looked at the data in the Vigimed file, in an attempt to increase our understanding of what pharmacovigilance is about, which problems are encountered (the drugs, the adverse reactions or other experiences) and how they are solved. In addition we quantitatively evaluated how the Vigimed system is being used, the numbers and characteristics of the countries that ask questions, communicate problems and give answers.

Results

Some of the quantitative results of the study can be found in Table 1.

Table 1. Some of the quantitative results

Nr of countries on the Vigimed list	71	
Nr of active countries on the Vigimed	51	72 %
Nr of persons with access to the Vigimed (UMC staff excluded)	204	
Nr of active persons on the Vigimed	88	43 %
mean Nr of access persons/country	2,9	range: 1-13
mean Nr of active access person/country	1,6	range: 1-6
Nr of questions during study period	100	
Nr of answers during study period	576	
mean Nr of answers/question	5,8	range: 0-22
Nr of countries with at least one question	31	44 %
Nr of countries with at least one answer	51	72 %
Nr of countries with at least one question and one answer	27	38 %
mean Nr of questions/country	2	range: 0-17
mean Nr of answers/country	6	range: 0-66

For a country or a person to be classified as "active", it was required of them to at least had asked or answered 1 question

The results of the categorisation of the contents of questions put on Vigimed, which are a part of the qualitative results, can be found in Table 2. The most discussed subjects were safety problems like new adverse reactions and interactions and the regulatory status of different medical products in the countries represented on the Vigimed.

Table 2. Categorisation of the contents of the question

1 a	Safety problem – ADR	e.g. new adverse reaction, signal generation, evaluation, interactions	29 %
1 b	Safety problem	e.g. overdose problem, dependence	1 %
2 a	Use related problem	e.g. data sheet text, administration problem	6 %
2 b	Use related problem	e.g. inappropriate use, dependence	4 %
3	Regulatory status		38 %
4 a	Regulatory action under consideration	e.g. data sheet change	2 %
4 b	Regulatory action under consideration	e.g. suspension or withdrawal of licence	11 %
5	Other		10 %

Almost 90% of drugs that were discussed on Vigimed had been on the market for 7 or more years. This finding is of interest in the light of the relaxation of the legal obligations regarding pharmacovigilance to pharmaceutical companies, 5 years after the approval of a drug.