

Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most frequently prescribed drugs in the Western world. During the past decade a large number of new compounds were marketed, some of which had to be withdrawn after a short while because of adverse drug reactions. These experiences led to an understanding that a complete picture of the safety of these drugs can only be obtained after their introduction into the marketplace.

Different methods of post-marketing surveillance (PMS) serve as important tools for monitoring the frequency of adverse reactions and for generating and corroborating hypotheses. Experience with PMS has thus far been quite limited in Germany. In 1987 a non-profit organization, Verein zur Langzeituntersuchung von Arzneimittelwirkungen auf dem Gebiet der Rheumatologie e. V. (VLAR) was founded by interested physicians and pharmacologists to raise funds and perform investigations on the safety of NSAIDs. The first project by the VLAR, SPALA (Safety Profile of Antirheumatics in Long-Term Administration), was sponsored by F. Hoffmann-La Roche AG (Basel, Switzerland). In July 1990, when the project was successfully terminated, almost 30,000 patients had been completely documented and their medical records entered into a computer for subsequent review by a select panel of experts with experience in monitoring adverse reactions to NSAIDs. The comments, criticisms, and ideas of these experts were brought together at a symposium organized by the VLAR at the Klinikum Steglitz (Berlin, Germany) on 12 October 1990.

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