PHARMACOVIGILANCE IN FRANCE: A DECENTRALIZED APPROACH

Bernard Begaud, M.D.
Centre de Pharmacovigilance
Hôpital Carreire-Pellegrin
Bordeaux, France

SHORT HISTORY AND STRUCTURE

A decentralized pharmacosurveillance system has been set up in France since 1974. During the first years (1974 - 1976) reference centers (Centres de Pharmacovigilance) were created in five departments of pharmacology. The role of these centers was to: 1) answer inquiries about drug safety from practitioners, and 2) collect the cases of adverse drug reactions (ADRs) occurring in the area. These centers applied the same principle: a good information service is the best way of getting new information. The number of these "Centres de Pharmacovigilance" increased each year until 1982, date of the official recognition of pharmacovigilance in France by the Decree of July 30th, 1982.

This four page official text (in Journal Officiel de la République Française) summarizes the flow chart and the role of the French Pharmacovigilance as composed of 3 structures:

![Diagram of the French Pharmacovigilance System]

Figure 1. Structure of French Pharmacovigilance System.
The 30 Regional Centers (Centres Régionaux de Pharmacovigilance)

The geographical distribution of the regional centers (one center in each district capital) maintains an optimal link between the surveillance system and the prescribers. Each center is organized under supervision of a director appointed by the government. The centers have to:

1) collect and assess the ADR cases occurring in their reference area (including public and private practices)
2) answer inquiries (concerning ADRs, drug toxicity, interactions, drugs in pregnancy, etc.) from prescribers, pharmacists, nurses, etc.
3) carry out specific epidemiologic studies in the reference area
4) contribute to methodological research in the field of pharmacovigilance and ADR diagnosis.

The names of the regional directors and addresses and telephone numbers of the centers are published each year in the French Drug Formulary (Dictionnaire VIDAL des médicaments).

The Technical Committee (Comité Technique de Pharmacovigilance)

The Technical Committee is the bimonthly one day meeting of the 30 regional directors, at the French Health Ministry. The Committee is presided over by one of the 30 directors, chosen for three years by the French Health Minister. The Committee coordinates the work of the 30 regional centers, analyzes the case reports of the previous two month period, discusses the opportunities and methodology of surveys focused on a given drug-event association, and circulates foreign information about drug safety.

The National Advisory Board on Pharmacovigilance (Commission Nationale de Pharmacovigilance)

The National Advisory Board is composed of 27 members and 27 substitutes appointed by the Health Minister, as follows: 10 experts in pharmacology and/or toxicology, 11 physicians (including, at least, three general practitioners), three hospital pharmacists, one chemist, one representative for consumers and one representative for the pharmaceutical industry. The board meets six times per year, and more if necessary; it is presided over by the same person as the National Committee. The Board’s main role is to advise the Minister about administrative decisions concerning drug safety: whether to add a warning in the reference books and/or the package insert, to restrict the indications of an approved drug, and to maintain or to withdraw a drug from the market. With the exception of emergency problems, the Board’s decisions are based on inquiries prepared by the Technical Committee with the help of the manufacturer concerned.

The Decree of May 24th, 1984 completed the French pharmacovigilance organization by making the reporting of ADR cases mandatory. Prescribers have to report immediately to their regional center all the cases of unexpected adverse drug reactions they observe with drugs they have prescribed (it is not mandatory to report an ADR related to a drug prescribed by another physician). In addition, each year manufacturers have to send to the National Board all the reports they receive involving drugs they market in France (twice a year for recently marketed drugs).

DISTINCTIVE CHARACTERISTICS

Even if the basic scheme is the same as in other developed countries (to centralize reports for decision making), the system set up in France over the past 16 years greatly differs from those conducted by the main regulatory agencies elsewhere (CSM, FDA, BGA, etc.).

First, the regulatory agency is centralized for administrative and political decisions (National Board, Technical Committee), but decentralized for routine activities, especially for drug surveillance. This facilitates interface with prescribers: each center