
Oral Presentations

O.01 Surveillance of Adverse Events to Natural Products: The Italian Reporting System

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Introduction: Herbal medicine is becoming more and more popular worldwide to treat a large variety of conditions as well as for "maintenance of health". As with all medicines, herbal medicines are expected to have adverse side effects. The inclusion of herbal medicines in pharmacovigilance systems is becoming increasingly important. The Italian Pharmacovigilance System, in charge of the Italian Medicine Agency (AIFA), collects spontaneous reporting only for registered medicines, but the awareness of the need of a surveillance of natural products safety has stimulated the implementation of an adverse reaction reporting project in Italy by the National Institute of Health (Istituto Superiore di Sanità).

Methods: An ad hoc reporting form was defined. The form can be downloaded from different institutional web sites. Voluntary reports of suspected adverse reactions are sent by the reporters by fax to the National Institute of Health where the forms are collected and entered in an ad hoc database. All reports are evaluated by a multidisciplinary group of experts.

The most serious reactions are analyzed more in depth from the group and written reports are sent to the Italian Medicines Agency for possible regulatory actions.

Results: From April 2002 to March 2007, 234 spontaneous reports of Adverse Events (AEs) were collected. Sixty seven percent were related to women. The mean age was 42 years.

In 31% of AEs a concomitant use of conventional drugs was reported. A large proportion of adverse events were serious: hospitalisation was reported in 35% of forms; 6% reported life threatening events and two fatal events were signalled.

About 50% of AEs were related to gastrointestinal, skin, psychiatric and nervous system disorders. Mainly herbal products (66%) were reported. Seventy four percent of these products contained more than one plant (up to more than 60 components). Twenty one cases of hepatitis of various seriousness were reported, among these one liver transplantation and two deaths for fulminant hepatitis occurred.

Twenty one reports (9%) were associated with homeopathic preparations; 27 different products were involved (4 single-component homeopathic preparations and 23 preparations containing mixtures of substances and a variety of dilutions). Fourteen reports regarded reactions to products containing propolis, twelve of these concerned allergic reactions.

Conclusion: Safety and efficacy of "natural" medicine remain unknown. It is important to improve communication with the public on safety issues. Encouraging spontaneous reporting can contribute to improve awareness among health personnel and patients about the benefit/risk profile of these remedies.