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For everyone concerned with the issues of pharmacovigilance

New directions in pharmacovigilance

October 2008 - a major week in Uppsala

A fresh start in Italy

MedDRA in the WHO ADR database

Visitors at the new UMC office



The Italian system of Pharmacovigilance

Characteristics and perspectives



Mauro Venegoni

In 2001 the Italian national pharmacovigilance system was restructured following the cerivastatine crisis which had shown some difficulties in the management of a pharmacovigilance problem. As a result, a National Pharmacovigilance Network (Rete Nazionale di Farmacovigilanza – RNF) was set up to collect, analyse, elaborate and share data on adverse drug and vaccine reports. Dr Mauro Venegoni, formerly a hospital physician in Milan, with experience of working with his local pharmacovigilance centre in that region, took charge of the RNF two years ago, and has recently given us a report on the latest situation with pharmacovigilance in Italy.

between local and regional centres and the national unit has helped to strongly reinforce the Italian system of pharmacovigilance.

The large number of local pharmacovigilance settings, while a valuable means of disseminating information and contacting physicians and pharmacists, may at the same time cause difficulties in reproducing standard coding and in the training and updating of so many users. According to Italian law reporting is mandatory for physicians.

Reaching out to health professionals

The pharmacovigilance bulletin *Reazioni* was first published in 2007 with six editions in the paper version and 22 on-line versions. *Reazioni* was successful: the paper version went up from 15,000 to 25,000 copies, and each on-line version was consulted by more than 10,000 readers including physicians, pharmacists and nurses. (The agency's website is www.agenziafarmaco.it/ then go to Registrazione e Farmacovigilanza.)

Activities over the last two years have obtained good results: during 2007 spontaneous reports increased by 50% (from 6,600 to 9,400), and the overall reporting rate increased from 108 to 165 reports per million inhabitants (although in two regions with 14.5 million inhabitants the reporting rate is more than 350/million).

National office in Rome

The RNF offices in Rome are beautifully located on the outskirts of the Italian capital. RNF links the national unit with more than 350 peripheral structures (in teaching hospitals and local health service units), regions and pharmaceutical companies.

Health care professionals have to report observed suspected adverse reactions to the local person responsible for pharmacovigilance (LRP) of the health peripheral structure to which they belong. ADR reports are coded (according to the MedDRA dictionary) and then entered in the national database by the LRP. Each night, reports included daily in the RNF database are electronically transferred into the Eudravigilance database according to the standard ICH E2B.

The RNF includes a dedicated, closed e-mail system, only accessible by authorised users, by which every input or update of reports generates an automatic message to inform the marketing authorization holders and regions about new information. This mail system is also used to send urgent information to all local health units or to hospitals and to share important information concerning drugs and vaccines safety.

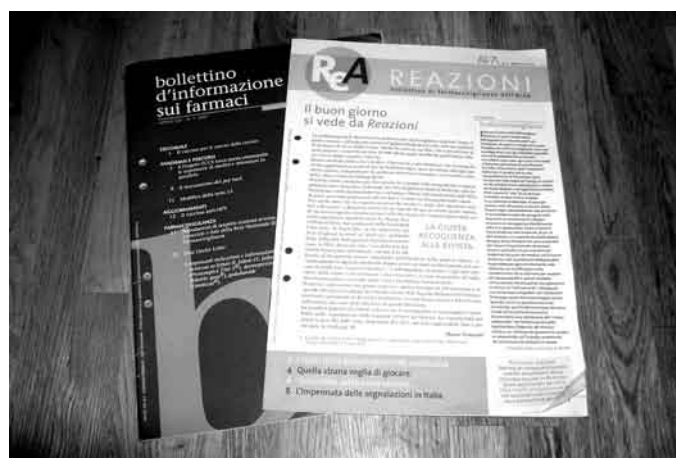
Reporting trends

In 2006 the Centre received around 6,000 case reports of suspect adverse drug reactions, mainly from health care practitioners, and a large number of them through one of the regional pharmacovigilance centres or health agencies.

Over the last two years, the Regional Centres have begun to work closely with the National Unit, with the aim of managing the MedDRA coding and performing causality assessment. This co-operation

Local and regional activity

The aims of the local centres are to collect the spontaneous reports and to put them into the RNF, to give answers and information to reporters, and to disseminate pharmacovigilance information ('Dear Doctor' letters and other safety information). For this reason, the regional centres aim to control coding quality, perform the causality assessment for serious reactions, plan continuous medical education in pharmacovigilance, and, together with the national centre, to perform data-mining and contribute to the newsletter *Reazioni*.



Italian drug safety journals

The activities of the National Centre consist of the regulatory activity of safety monitoring of the nationally- authorized drugs, and to co-operate with the other national agencies and the European Agency (EMA) for centralized authorized drugs with PSUR analysis, data-mining, etc.

Intensive monitoring

In Italy some new drugs, such as new antidiabetic or innovative drugs, are submitted to intensive monitoring, to collect early the adverse reactions and to evaluate the appropriateness of prescribing them. These drugs are prescribed within a national register, which is monitored by the Agency. At present there are active registers for new antidiabetic drugs, dotrecogin, natalizumab, psoriasis drugs (with a programme called 'Psocare'), ivabradine and new antidiabetic drugs (incretines).

For data-mining, data from National network are examined twice a year at a meeting with regional centres: for vaccines also, meetings are planned twice a year, with those responsible for immunisation.

Collaboration with WHO is very important, in particular with the UMC; since 2006 the submission of Italian spontaneous reports, which was interrupted for some time has been restarted from the RNF.

UMC visitor in Rome

Ronald Meyboom from the UMC visited the Italian national centre on 29 September last year and met the eleven staff members, mainly young, dedicated and well-trained doctors and pharmacists. With a very positive impression of activities in Rome, he is keen for Dr Venegoni to make a visit to Uppsala in the near future to exchange ideas and discuss future plans.



A bright future

For the future the RNF is implementing patient reporting, which until now has not been developed, and reports from nurses. Furthermore, a 2007 financial regulation which gives 25 million per year to the regions, will help to fund the regions for pharmacovigilance activities, based on achieving active pharmacovigilance projects approved by Agenzia Italiana del Farmaco (AIFA), and other relevant areas in pharmacovigilance. These projects will start during 2008.

Our thanks to Dr Maura Venegoni for providing much information for this article.

ISoP news

Mexico has recently been accepted as a National Chapter within ISoP. Dr Alejandra Rosete of the Pharmacovigilance Institutional Centre at Medica Sur Hospital was the promoter in the country, and is hoping that membership will help to reinforce continuous education to healthcare professionals and also to motivate the health authorities to support and increase their interest in the field.

Dr Rosete is preparing a national pharmacovigilance meeting in November at Acapulco Beach, details of which will be announced soon.