December 25, 2011

Letter to the Editor in Chief, Pharmacologyonline Newsletter:

We refer to the IVth note of our cycle of papers published this year, celebrating the fourty years co-foundation of the WHO International Drug Monitoring Programme, and the WHO-Uppsala Collaborating Centre (UMC).

We write there, in Discussion, Part 3, at page 748 of [1] :

… This, we hope, will be yet another application of our method for highlighting the trends emerging from our post-hoc objective epidemiological analytical study. Which method might then be successively adopted by other national Authorities participating in the WHO programme and/or by the Organization itself ... . The starting basis was provided by the fundamental Venulet's studies and the development of new algorithms (some of which have been adopted) improving scientific acceptance and providing the broadest evaluation of adverse reactions since the inception of reporting activities to the Uppsala Centre (a topic that we shall not address here). All the consecutive efforts have, to our knowledge, been directed to enhancing the collection process through ADR reports and providing the results of the trends emerging from report analyses not only to the contributing governmental and political Organization but also to those sending the reports . It is a fundamental requirement for the optimization of any drug monitoring project, including ours, that feedback activities follow these guidelines.

In the same Volume 2, May-August 2011, as already announced in [1], we then presented the Vth and VIth [2,3] contributions of the series, which were then communicated to the WHO Pharmacovigilance Headquarters, the UMC Colleagues and the 141 Pharmacovigilance Officers in charge of the 137 present collaborating Countries. Although we did not explicitly ask so, we hoped to get a feedback which unfortunately did not come. Nevertheless, in our presentations [4] and [5] of the same Bulletin, the value of case series in adverse drug reaction assessment had been clearly stated and the used technique updated, which normally our French and Canadian Colleagues should appreciate, repeat and reinforce.

With best Seasonal Greetings, and an Happy New Year 2012!

Drs Dan Bradu & Luigi Rossini

[1] 064. Dan Bradu and Luigi Rossini - Contrast Agents - Full List Of The 30 Iodinated Products For Which Reports Have Been Sent Over The First 40 Years Of The Who Pharmacovigilance System, Subdivided Into Two 20-Year Periods. Fourth Who-Ita/Ita-Oms 2010-2011 Contribution On The 30 Basic Aggregated Who System-Organ Class Disorders (Socds), And Suspected+ Adverse Reactions And Event Preferred Names (SADRS+). Pharmacologyonline Newsletter 2: 701-836 (2011).

[2] 078. Dan Bradu and Luigi Rossini - Biosimilar Branded Iodinated Contrast Agents Related To The Largest Number Of Reports To The Who-Pharmacovigilance System Over The First 40 Years Of The Programme. Fifth Who-Ita/Ita-Oms 2010-2011 Contribution. Pharmacologyonline Newsletter 2: 929-962 (2011).

[3] 098. Dan Bradu and Luigi Rossini - 4,436 Reports from Italy, Accepted in the WHO UPM Collaborating Centre Thesaurus Vs 181,744 Globally Collected Reports from Other Participating Countries of Same 33 Monitored Contrast Agent-Products Over the First 40 Years of the Programme. Sixth WHO-ITA/ITA-OMS 2010-2011 Contribution. Pharmacologyonline Newsletter 2: 1140-1160 (2011).

[4] Antoine Pariente, C.N. Abou Chakrab, M. Pineta, L. Nkeng, N. Moorea & Y. Moride. Il valore delle casistiche nella valutazione delle reazioni indesiderate da farmaci. Adverse Drug Reaction Bulletin, Edito in Italia da CIS Editore S.r.l., Milano, sotto l' egida del Centro Nazionale di Farmacovigilanza ITA – OMS, Ancona 203, ottobre: 815-818 (2011).

[5] Antoine Pariente, C.N. Abou Chakra, M. Pinet, L. Nkeng, N. Moore & Y. Moride. The value of case series in adverse drug reaction assessment. Adverse Drug Reaction Bulletin 270, October: 1039-1042 (2011).