

Press release of the National Agency for Medicines and Medical Devices

To the attention of the Romanian Television Directorate, in response to the “RIALITI SOC” television show of 9 p.m., Saturday, 2 April 2011, run by the TVR3 Channel

The National Agency for Medicines and Medical Devices finds it necessary to use its entitlement to a response to the “RIALITI SOC” television show of 9 p.m., Saturday, 2 April 2011, run by the TVR3 Channel and hosted by Ms Camelia Robe, compelling to a firm stance.

We find it difficult to understand how a national television channel finds it fit to run a show promoting, as a "shock" (*it is not our desire to repeat the word "Rialiti" as well, fashioned, invented, in some twisted Anglo - Romanian, a sheer viewer insulting choice*), a misinformation of viewers in an area as sensitive as that of medicines.

It is unfortunate, in our view as experts in the field, that on a Saturday prime time, the public should be fed so much mistaken information, in part provided by former professionals not involved in the system for nearly 30 years, people who, we grudgingly have to admit, although at one time honourable representatives of the pharmacist profession, are not aware of the current legal framework, actually a faithful transposition of the European Directive on a Community Code in the field of medicinal products for human use (Law 95/2006 on healthcare reform, Title XVII – The Medicinal Product, as related to Directive 2001/83/EC).

We find it impossible not to share with you that we are usually approached by reporters who prepare their feature in a different manner, reading and acquiring information independently, following talks prior to the interview itself, touching on legal issues transposing European legislation. It is for the first time that we are involved with a reporter / TV producer that is so ill-informed that she actually fails to remember (or ... does not know ...) about Romania's Accession to the European Union and the implications thereof.

During her 2 hours plus interview with the Agency's spokesperson, the reporter/producer had been explained in detail that the National Agency for Medicines and Medical Devices is the national competent authority in the field of medicinal products for human use, organised as a replica to the European Agency Medicines, whose mission and activities are identical to any other drug agencies in the other 26 EU Member States, aiming to ensure quality, safety and efficacy of medicinal products for human use. The reporter/producer had been introduced to the manner in which scientific assessment is performed throughout the EU of scientific documentation for marketing authorisation, to related European guidelines, to Agency accredited control laboratories, to the European Network of Official Control Laboratory also including the Romanian Agency's control lab, working under direct supervision of the European Directorate for the Quality of Medicines (EDQM), to the role of pharmaceutical inspection performed by Agency specialists, to clinical trials conducted during pre-authorisation, unable however to fully report all possible adverse reactions to a medicine, adverse reactions also monitored later on, after marketing authorisation and many more.

We cannot help noting that rendering such a distorted view on the Agency's mission as warrant for the quality, safety and efficacy of medicines for human use within the legal system of distribution, actually casts a shadow upon that very TV channel, whose own mission we further take it to be proper information of the public.

"The SHOCK" the producer is after does not exist in today's real life of medicinal products provided in the legal, authorised medicines distribution network, which is strictly regulated by the European Union and rigorously inspected by the Romanian Agency's specialists.

All such aspects have been explained extensively during the interview.

We cannot accept the idea that, after all the information patiently provided in lavish detail and time, the conclusion of the show, stubbornly and by all means but, alas, with no justification, seeking to be a "SHOCK", should be the same personal idea-obsession of the producer, that it is better to throw medicines into the lake, as "nobody controls them, anyway".