

MINISTRY OF PUBLIC HEALTH

ORDER

on repeal of certain Orders of the Minister of Public Health

On seeing:

- Provisions of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended;

- Government Ordinance No. 125/1998 on the set up, organisation and operation of the National Medicines Agency, approved as amended through Law No. 594/2002, as amended,

Based on Government Decision No. 862/2006 on the organisation and operation of the Ministry of Public Health, as amended,

On seeing the Approval Report of the Pharmaceutical Directorate No. 8.502 of 29 December 2006,

the Minister of Public Health hereby issues the following Order:

Art. 1. - Order of the Minister of Health no. 1.629/2004 on approval of the Guideline on inspection procedures for assessment of compliance with Good Clinical Practice Rules, published in the Official Gazette of Romania, Part I, no. 79 and 79 bis of 24 January 2005, Order of the Minister of Health no. 1.630/2004 on approval of the Guideline on the training of inspectors assessing compliance with Good Clinical Practice Rules, published in the Official Gazette of Romania, Part I, no. 79 and 79 bis of 24 January 2005, Order of the Minister of Health no. 1.631/2004 on approval of Guidance on the content of the trials master file and archiving, published in the Official Gazette of Romania, Part I, no. 79 and 79 bis of 24 January 2005, Order of the Minister of Health no. 1.117/2004 for the approval of the Guidance for the request for authorisation of a clinical trial on a medicinal product for human use, submitted to the competent authority, approval of substantial amendments and declaration of the end of a clinical trial in Romania, published in the Official Gazette of Romania, Part I, no. 1.041 of 10 November 2004, Order of the Minister of Health no. 1.177/2004 for the approval of the Guidance on the investigation of bioavailability and bioequivalence, published in the Official Gazette of Romania, Part I, no. 1.042 of 11 November 2004, Order of the Minister of Health no. 1.179/2004 for the approval of regulations for NMA authorisation of clinical studies/NMA notification for non – interventional trials performed with medicinal products

for human use in Romania - published in the Official Gazette of Romania, Part 1, No. 1042/11.11.2004, Order of the Minister of Health no. 1.224/2004 for the approval of the Guidance on non-clinical safety studies necessary for the conduct of clinical trials for the evaluation of pharmaceuticals, published in the Official Gazette of Romania, Part I, no. 945 of 15 October 2004, Order of the Minister of Health no. 1.300/2004 regarding approval of Guidance on application form and documentation to be submitted in application for Ethics Committee opinion on clinical trial on medicinal products for human use in Romania - published in the Official Gazette of Romania, Part 1, No. 70/20.01.2005 are repealed.

Art. 2 – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Public Health,
Gheorghe Eugen Nicolăescu

Bucharest, 29 December 2006
Nr. 1.808.

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