ORDER No. 420
of 3 April 2018

on the repeal of Orders of the Minister of Health containing regulations in the field of pharmacovigilance

Published in: the Official Gazette no. 335 of 17 April 2018

On seeing the report for approval No. SP 3.169/2014 of 2.04.2018 of the Medicinal Product and Medical Device Policy Directorate and Notification no. 49.076E, 50.304E of 15.12.2017 of the National Agency for Medicines and Medical Devices, registered at the Ministry of Health with no. 49.088, 55.767 of 15.12.2017,

taking into account the provisions of:

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products;
- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council;
- art. 827 - 854 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

taking into account the provisions of Art. 4 (2) a) and of Art. 12 (9) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as further amended and supplemented,

pursuant to Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Art. 1 – On entry into force of this Order, the following shall be repealed:

a) Order of the Minister of Health no. 179/2004 regarding the Pharmacovigilance Inspection at the Marketing Authorization Holder, published in the Official Gazette of Romania, Part I, no. 198 of 5 March 2004;

b) Order of the Minister of Health no. 410/2005 on approval of the Guideline on clinical safety data management/the Periodic Safety Update Reports for marketed medicinal products, published in the Official Gazette of Romania, Part I, no. 461 and 461 bis of 31 May 2005;

c) Order of the Minister of Health no. 411/2005 on approval of Regulations on pharmacovigilance activities, published in the Official Gazette of Romania, Part I, no. 461 and 461 bis of 31 May 2005.

Art. 2 - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Sorina Pintea
