MINISTRY OF HEALTH

ORDER
on approval of the Norms on classification for release of medicinal products for human use

On seeing the Approval Report Cs.A. 13.816/2010 of the Medicinal Product Policy Directorate,

Taking into account provisions of:

- Title XVII "The medicinal product" of Law 95/2006 on healthcare reform, as amended;

- Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices,

based on Government Decision No. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the minister of health hereby issues the following order:

Art. 1. – The Norms on the classification for release of medicinal products for human use are approved and included in the Annex which is integral part of this Order.

Art. 2. – The National Agency for Medicines and Medical Devices shall fulfil the provisions of this Order.

Art. 3. – On this Order coming into force, Order of the Minister of Health no. 679/2003 on approval of the Norms on classification for release of medicinal products for human use, published in the Official Gazette of Romania, Part I, no. 556 of 1 August 2003, is repealed.

Art. 4. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of health,

Cseke Attila

Bucharest, 31 December 2010.
No. 1.602.

ANNEX

NORMS
on classification for release of medicinal products for human use

Art. 1. - (1) These Norms regulate the manner of classification for release of medicinal products for human use.

(2) These Norms apply to medicinal products authorised for marketing in Romania through national, mutual recognition and decentralised procedure.

(3) These Norms are issued in accordance with provisions of Chapter VI "Classification of medicinal products" of Title XVII "The medicinal product" of Law 95/2006 on healthcare reform, as amended.

Art. 2. - (1) The subcategories of medicinal products released on medical prescription only are established by the National Medicines Agency in accordance with Art. 780 (2) of Law 95/2006, as amended.

(2) The terms used for the subcategories for classification for release of medicinal products for human use are as follows:

a) *PRF* - medicinal products subject to medical prescription withheld in the pharmacy (not renewed), in accordance with Art. 780 (2) a) of Law 95/2006, as amended;

b*) P6L* - medicinal products subject to medical prescription not withheld in the pharmacy (can be renewed), in accordance with Art. 780 (2) a) of Law 95/2006, as amended; the medical prescription can be used within 6 months as of release;

c) *PS* – medicinal products subject to medical prescription (drugs and psychotropes), in accordance with Art. 781 (2) first paragraph of Law 95/2006, as amended;

d) *PR* – medicinal products restricted to a medical prescription, to be used in certain specialised fields only, in accordance with Art. 780 (2) c) corroborated with Art. 781 (3) of Law 95/2006, as amended.

Art. 3. – Medicinal products not meeting the aforementioned criteria can be classified as over-the-counter medicinal products.

Art. 4. – The classification for release of medicinal products for human use shall be specified in the marketing authorisation, and the subcategory for classification shall be mentioned in Annex 3 to the marketing authorisation, "Information on labelling".

Art. 5. - (1) These Norms apply to all authorised medicinal products after their entry into force.

(2) For medicinal products authorised before this date, these Norms apply when the authorisation is renewed.

Art. 6. – For medicinal products authorised prior to these Norms entering into force, until authorisation renewal or within one year from these Norms entering into force (in case of medicinal products whose authorisation is available indefinitely), the terms used for classification subcategories shall be assimilated with the terms adopted throughout these Norms, as follows:

- P-RF with PRF;
- P-6L with P6L;
- P-TS with PS;
- S with PR.