

**Order no. 561**  
**of 3 April 2020**

**on amendment and supplementation of Annex to Order of the Minister of Health no. 85/2013 on approval of the Rules for implementation of provisions of Article 703 (1) and (2) of Law 95/2006 on healthcare reform on medicinal products for special needs**

**Published in: The Official Gazette no. 286 of 6 April 2020**

On seeing the Approval report of the Medicinal Product Policy and Medical Devices Directorate No. NT 472 of 3 April 2020 and NAMMDR notification no. 53.611E of 25 March 2020, registered at the Ministry of Health with no. 15.966 of 25 March 2020,

taking into account provisions of:

- Article 703 (2) of Law 95/2006 on healthcare reform, republished, as further amended;

- Decree no. 195/2020 regarding the state of emergency established in Romania;

- Article 4 (3) point 1 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

based on Article 7 (4) of 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:

**Article I** – Annex to Order of the Minister of Health no. 85/07.02.2013 on approval of the Norms for implementation of provisions of Article 703 (1) and (2) of Law No. 95/2006 on healthcare reform concerning medicinal products for special needs, published in the Official Gazette of Romania, Part I, no. 93 of 14 February 2013, as further amended and supplemented, is amended and shall read as follows:

**1. A new Article, namely Article 11<sup>1</sup> is introduced after Article 11, as follows:**

"Article 11<sup>1</sup> - (1) By waiver from the provisions of Article 10 (2), during the pandemic, the National Agency for Medicines and Medical Devices of Romania may issue an authorisation regarding the supply of medicines for special needs only for the medicinal products provided in the Protocol for the treatment of the SARS-Cov-2 virus infection, as approved through Order of the Minister of Health no. 487/2020, as amended, at the initiative of the Ministry of Health, through specialised commissions or directorates, pursuant to Article 703 (2) of Law 95/2006 on healthcare reform, as further amended and supplemented, for medicinal products both authorised and unauthorised for marketing in Romania.

(2) The National Agency for Medicines and Medical Devices of Romania issues the authorisation regarding the supply of medicinal products for special needs, in Romanian and English, based on the medical justification report issued by the specialised commissions within the Ministry of Health, within maximum 72 hours from the date of registration of the request sent by the Ministry of Health.

(3) The authorisation for supply of medicinal products for special needs shall be valid until the stock for which it was issued is exhausted, but no later than the expiry date of the authorisation.

(4) The medicinal products authorised in line with this Article shall be exempted from the legal provisions in force concerning the packaging / labelling of medicinal products authorised for placement on the market. "

**2. Throughout the entire regulatory act, phrase "The National Agency for Medicines and Medical Devices" shall be replaced with "The National Agency for Medicines and Medical Devices of Romania".**

**Article II** - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,

**Nelu Tătaru**

---