

The Ministry of Health

**ORDER No. 1.360
of 19 April 2023**

on approval of the Methodology for inclusion/exclusion of the immunological medicinal products mentioned in Art. 242 (3) of Law 95/2006 on healthcare reform in/from the list of medicinal products as provided to insurants, irrespective of personal contribution

Published in: the Official Gazette of Romania, no. 360 of 27 April 2023

On seeing Approval Report no. AR/7.325/2023 of the General direction of public health and health programmes of the Ministry of Health,

taking into account provisions of Art. 242 (3) and (4) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, and of Art. 7 (4) and Art. 11 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 - The Methodology for inclusion/exclusion of the immunological medicinal products mentioned in Art. 242 (3) of Law 95/2006 on healthcare reform in/from the list of medicinal products as provided to insurants, irrespective of personal contribution, mentioned in this Annex which is an integral part of this Order, is approved.

Art. 2 - The General direction of public health and health programmes of the Ministry of Health communicates this Order of the National Vaccinology Committee, whose duty is to carry out its provisions.

Art. 3 - This Order shall be published in the Official Gazette of Romania, Part I.

**Minister of Health,
Alexandru Rafila**

Annex

METHODOLOGY

for inclusion/exclusion of the immunological medicinal products mentioned in Art. 242 (3) of Law 95/2006 on healthcare reform in/from the list of medicinal products as provided to insurants, irrespective of personal contribution

Art. 1 – In view of inclusion of immunological medicinal products mentioned in Art. 242 (3) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, in the list of medicinal products as provided to insurants, irrespective of personal contribution, the National Vaccinology Committee performs the following activities:

a) performs an analysis of the types of vaccinations and of the age and risk groups to which they are recommended within the National Vaccination Programme provided for in Order of the Minister of Health no. 964/2022 on approval of the technical rules for the implementation of national public health programmes, as further amended and supplemented;

b) submits to the Ministry of Health, within a maximum of 10 working days from entry into force of this methodology, the list of types of immunological medicinal products to be included in the list of medicinal products as provided to insurants, irrespective of personal contribution, the population segments to which these are addressed and recommended degree of compensation.

Art. 2 - In order to establish the list provided for in Art. 1 b), the National Vaccinology Committee shall consider the following:

a) the proposed immunological medicinal products and age and risk groups are complementary to those recommended in the National Vaccination Programme;

b) the recommendations of European and international bodies regarding vaccination of the population and population groups exposed to risk;

c) data on the incidence and prevalence of vaccine-preventable disease, where available;

d) vaccine efficacy and safety data;

e) cost-effectiveness data, where available.

Art. 3 - Based on the list received from the National Vaccinology Committee, the Ministry of Health, after consulting the National Health Insurance House and the Romanian College of Pharmacists, initiates a Government Decision in order to supplement Government Decision no. 720/2008 for approval of the List of International Non-proprietary Names of on-prescription medicinal products as

provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national health insurance programmes, republished, as further amended and supplemented.

Art. 4 - (1) The update of the list provided for in Art. 3 is carried out periodically, depending on the proposals of the National Vaccinology Committee and the funds available to the Ministry of Health.

(2) If the funds allocated to the Ministry of Health for compensation of the immunological medicinal products provided for in Art. 1 are insufficient, the Ministry of Health requests the National Vaccinology Committee to elaborate a description of the types of vaccines and population segments to which they are addressed.