# DECISION OF THE GOVERNMENT No. 315/2014
# on amendment of Decision of the Government no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices

In force as of 24.04.2014

Based on provisions of article 108 of the Constitution of Romania, republished, The Government of Romania hereby adopts this Decision.

**Single article.**

Decision of the Government no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, published in the Official Gazette of Romania, Part I, no. 531 of 30 July 2010, as amended, is hereby amended and supplemented, as follows:

1. Article 1(4) is repealed.

2. Three new paragraphs (3) - (5) are introduced under Article 2(2), as follows:
"(3) The NAMMD is the competent national authority in the field of health technology assessment.
(4) Health Technology Assessment is equally applicable to human medicines, medical devices and high performance MEDICAL equipment.
(5) The criteria and methodology for assessment of medical technologies are approved by order of the Minister of Health."

3. Letter c) of Article 3, is amended and shall read as follows:
"c) control, ensuring the monitoring and verification of compliance with regulations specific to its field;".

4. Article 4 (2) is amended and shall read as follows:
"2) In accordance with the legal provisions, the NAMMD has the following main responsibilities in the medicinal product field:
a) development of rules, instructions and other binding regulations on human medicinal products, submitted for approval to the Ministry of Health;
b) grant of marketing authorisation for medicinal products for human use; monthly notification to the Ministry of Health on marketing authorisations granted;
c) surveillance and control of the quality of medicinal products in manufacture, import, wholesale and retail, through regular inspections and planned audit activities, as well as in all cases of complaint and/or alerts on medicinal product quality and efficacy and responds to requests of the Ministry of Health for inspection and activities in its area of competence;

d) authorisation and control of clinical trials conducted with human medicines as well as their sites, in accordance with good clinical practice guidelines;
e) performance of laboratory tests on the quality of medicinal products in the frame of the authorisation process, quality surveillance and official batch release for immunological products or medicines derived from human blood or human plasma;
f) organisation, provision of guidance and control of pharmacovigilance activities, conduct of studies on use of human medicinal products, development of information on pharmacovigilance;
g) assessment and approval of advertising of human medicinal products in accordance with regulations in force;
h) development and maintenance of the human medicinal product Index, for each product stating the category to which it belongs, according to classification for, with or without prescription;
i) cooperation with national and international bodies on development of the European Pharmacopoeia;
j) ensuring operation of a service for information on medicinal products for human use; develops and publishes the NAMMD Newsletter in electronic format as well as specialist publications and specific information;
k) cooperation with the Ministry of Health and the National Health Insurance House in compiling the list of medicines for human use in the Index of medicinal products for human use provided to insured persons based on prescription, with or without personal contribution;
l) decision, as appropriate, on suspension, withdrawal or amendment of marketing authorisations for medicinal products for human use; notifies its decision on suspension or withdrawal of marketing authorisations for medicinal products for human use to the Ministry of Health and the National Health Insurance House within 48 hours;
m) provision of various services and activities specific to its departments, except for those required by legal entities, for preparation of the dossier for authorisation of medicinal products, organises training;
n) initiation, negotiation, and conclusion of international agreements and cooperation documents in the area of medicinal products, within the powers conferred by the law, organises involving international relations and cooperation in its field;
a) organising of work meetings, training courses and scientific events in the field of medicinal products for human use;
p) ascertaining violations of the law in its own field and applies appropriate penalties in accordance with the law;
q) performance of other specific activities in the field of medicinal products for human and specific activities required by the Ministry of Health;
r) grant of the certificate attesting compliance with good manufacturing practice to manufacturers of active substances or manufacturers of medicines for human

use in third countries, based on a favourable inspection report prepared by NAMMD inspectors;
s) grant of the wholesale distribution authorisation or wholesale authorisation in the warehousing/custody system to wholesalers of medicines for human based on a favourable inspection report prepared by NAMMD inspectors and the certificate of compliance with good wholesale distribution practice;
t) identification of other areas for action in line with its duties and objectives;
t) grant of the manufacturing /import authorisation to Romanian manufacturers/importers of human medicinal products/ human investigational medicinal products, based on a favourable inspection report prepared by NAMMD inspector and the certificate of compliance with good manufacturing practice;
ț) issuance of authorisation for independent control laboratories performing medicinal product quality control under contract between manufacturer and control laboratory;
u) issuance of the Good Laboratory Practice certificate for sites involved in conduct of non-clinical studies or clinical bioequivalence studies, respectively, provided for by legislation related to authorisation of medicinal products for human use;
v) conduct of inspections to marketing authorisation holders for check of compliance with specific pharmacovigilance obligations and other obligations arising under the law for medicinal products for human use;
x) issuance of the certificate attesting Qualified Person status to applicants meeting conditions provided for by law;
y) approval of export declarations for medicinal products for human use;
z) issuance of authorisations for the supply of special needs medicines;
aa) conduct of activities to prevent the entry into the legal supply chain of falsified medicinal products in accordance with legal provisions;
ab) conduct of activities related to record and supervision of brokers of medicinal products for human use;
ac) conduct of and participation in assessment of the quality, effectiveness and safety of medicines for human use conducted/initiated at European level (CAT, PRAC, PDCO, CHMP), through its own or external experts."
5. A new letter, q) is introduced, under Article 4 (3) p), as follows:
"q) issuance of the scientific opinion on the quality and safety of ancillary active substance incorporated as integral part in medical devices."

6. A new paragraph, (31), is inserted under Article4(3), as follows:
"31) In accordance with the law, the NAMMD has the following main responsibilities in the area of health technology assessment:
a) development and periodical review of national methodological guidelines for assessment of health technologies and formats of health technology assessment

reports, in accordance with international standards, approved by order of the Minister of Health;
b) review and assessment of reports drawn up by relevant institutions, organisations, experts or external researchers, on assessment of medical technologies for objectivity, validity, compliance and scientific rigour, or upon the order of the Ministry of Health;
c) collaboration with professional bodies in the healthcare system and the academia for assessment of health technologies;
d) participation in the development of clinical guidelines through coordination, development of methodologies, collection and analysis of critical studies and monitoring;
e) collection and analysis of statistical data from all healthcare services, relevant to health technology assessment;
f) development and implementation of priority-setting mechanisms for health technology assessment, with approval of the Ministry of Health;
g) ensuring transparency of the process for substantiation of decisions on health technology assessment;
h) implementation of a mechanism for rapid assessment of health technologies, undertaken by approved research institutions and authorities based on analysis and evaluation reports from Member States of the European Union, for the decision, with the approval of the Ministry of Health;
i) continuous development of institutional capacity in the field of health technology assessment, including training activities;
j) participation in exchange of scientific information, development of models and assessment tools, as well as in studies and development of material in cooperation with Member States of the European network for Health Technology Assessment;
k) participation together with the Ministry of Health in international projects with similar institutions;
l) requirement from specialised commissions of the Ministry of Health to develop therapeutic protocols;
m) critical examination and approval of therapeutic protocols developed and/or revised by the specialised committees of the Ministry of Health."

7. Letter d) of Article10 shall be amended and shall read as follows:
"d) endorsement of proposals for NAMMD fees, approved by the Minister of Health."

Bucharest, April 23, 2014.
Nr. 315.