

Regulations whose amendment is included in the updated form

Decision	1544	19.12.2022	22.12.2022	
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Government of Romania

DECISION No. 879*)
of 9 November 2018
on establishment of the National Committee for Limiting the Antimicrobial Resistance

***) Note:**

It includes all the amendments brought to the official regulation published in the Official Gazette, provided for in:

Government Decision no. 1544/19.12.2022 published in the Official Gazette of Romania no. 1241/22.12.2022.

Taking into account the provisions of Art. 5 point b), Art. 8 paragraph (1) point e) and Art. 10 paragraph (2) points b) and c) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, and Council Recommendation 2002/77/EC of 15 November 2001 on the prudent use of antimicrobial agents in human medicine,

pursuant to art. 108 of the Constitution of Romania, republished, and Art. 11 point c) of Law no. 95/2006 on the health reform, republished, with subsequent amendments and completions,

The Government of Romania hereby adopts the following Decision:

Art. 1 - (1) The National Committee for Limiting the Antimicrobial Resistance The establishment of the National Committee for Limiting Antimicrobial Resistance, hereinafter referred to as the CNLRA, is approved, a technical structure, without legal entity, led by a president and a vice-president, under the coordination of the Ministry of Health, whose aim is to develop and monitor the implementation of the National Strategy on the prudent use of antibiotics, limiting the increase in microbial resistance to antibiotics in the population and animals and preventing the spread of resistant microorganisms at national level.

(2) Within the meaning of this Decision, the terms and expressions below have the following meanings:

a) **antimicrobial** - any substance manufactured by synthetic or natural means with direct action on microorganisms, such as bacteria, viruses, fungi and parasites, particular protozoa, of the antibiotic, antiviral, antifungal and antiprotozoal type used for the treatment or prevention of infections or infectious diseases. Anthelmintics and substances classified as disinfectants or antiseptics are excluded from this definition;

b) **antimicrobial resistance** - the ability of pathogenic germs, microorganisms, to survive and multiply in the presence of antibiotics.

Art. 2 - The main duties of the CNLRA are:

a) *approving and monitoring the implementation of the National Strategy on the prudent use of antibiotics, limiting the increase in microbial resistance to antibiotics in the population and animals and preventing the spread of resistant microorganisms at national level and of the National Action Plan for achieving the objectives of this strategy;*

b) coordination of the activities that shall be carried out within the National Action Plan;

c) submits proposals to the authorities provided for in Art. 3 paragraph (5) regarding the adoption of new regulatory documents or the amendment of those in force, in particular regarding antibiotic susceptibility testing, antibiotic prescription and monitoring of antibiotic consumption, diagnostic, prevention and treatment guides for the main infectious syndromes.

Art. 3 - (1) The CNLRA is coordinated by the Ministry of Health and has the following structures:

a) Management Board;

b) Expert Group;

c) Technical Secretariat.

The Management Board represents the management and coordination body of the CNLRA members.

(2) *The expert group represents the technical body of the CNLRA and consists of 15 members, appointed by the public authorities referred to in paragraph (5) for a 3-year period. The members of the expert group are appointed by administrative act of the head of the institution they represent, in the specific field, common to that of the CNLRA. The expert group makes proposals and recommendations to the Management Board in order to elaborate decisions in its fields of intervention.*

(3) The technical secretariat is provided by the General Directorate for Medical Assistance and Public Health of the Ministry of Health, whose role is to coordinate, cooperate and communicate between the members of the CNLRA. The persons who make up the technical secretariat do not have the right to vote in CNLRA.

(4) *The CNLRA Management Board has two representatives, namely one full representative and one alternate member, from the following central public administration authorities and institutions:*

a) *the Ministry of Health;*

b) *the Ministry of Environment, Waters and Forests;*

c) *the Ministry of Labor and Social Solidarity;*

d) *the National Health Insurance House;*

e) *the National Authority of Quality Management in Health;*

f) *the National Sanitary, Veterinary and Food Safety Authority (ANSVSA);*

g) *the National Institute of Public Health;*

h) *the 'Prof. Dr. Matei Balș' National Institute of Infectious Diseases;*

i) *the 'Cantacuzino' National Institute for Medical-Military Research and Development;*

j) *the National Agency for Medicines and Medical Devices of Romania.*

(5) Representatives of the following organisations may participate in CNLRA meetings, with guest status:

a) The Romanian College of Pharmacists;

- b) The Romanian College of Physicians;
- c) The Romanian College of Veterinarians;
- d) The Romanian College of Dentists;
- e) other professional human and veterinary medical organisations;
- f) non-governmental organisations interested in the field;
- g) patient associations.

(6) Nomination of the members of the Management Board is made by order/decision/administrative act of the head of the institution they represent, within 15 days from entry into force of this decision.

(7) The President of the Management Board is a state secretary within the Ministry of Health, appointed through Order of the Minister of Health.

(8) *The Vice-President shall be appointed by joint order of the Minister of Health, the President of the National Sanitary, Veterinary and Food Safety Authority and the Minister of Environment, Water and Forests.*

(9) The CNLRA shall meet monthly or whenever necessary.

(10) The decisions of the CNLRA shall be taken in the presence of a simple majority of members, by consensus.

(11) The CNLRA Regulation on the organisation and operation of the CNLRA shall be approved within 60 days from the entry into force of this decision, through Order of the Minister of Health.

Art. 4 - The CNLRA prepares an annual report analysing the status of the implementation of the National Action Plan, the difficulties encountered in its implementation and the proposed solutions, which shall be presented by the Ministry of Health to the Government of Romania.

Art. 5 - In order to fulfil its duties, the Expert Group has access to the necessary information, provided by the institutions participating in the CNLRA, within the limits of legal provisions.

Art. 6 – In order to achieve the objectives of the National Strategy, the CNLRA:

1. submits measures and recommendations for:
 - a) preventing the spread of antimicrobial resistance of microorganisms, through rational use of antibiotics in order to limit the transmission of germs which are multi-resistant to antibiotics;
 - b) optimizing the use of antibiotics in human and veterinary medicine, also using local/national data on microbial resistance;
 - c) *disseminating information on the occurrence of variations in antimicrobial resistance notified by reference clinics and microbiology laboratories;*
 - d) issuing recommendations to specialised institutions on the topics required for training human and veterinary medical staff on the judicious use of antibiotics, antibiotic resistance testing and antibiotic resistance reporting, and communicating in the field of antimicrobial resistance of microorganisms;
 - e) informing the general public on the judicious use of antibiotics and the risks related to their inappropriate use;
 - f) developing medical research to solve public health issues related to antimicrobial resistance;
 - g) encouraging international cooperation in the field of antimicrobial resistance;
 - h) establishing a common method for collecting data resulting from surveillance of bacterial resistance in animals, including highlighting microbial circulation between animal species.
2. proposes to the Ministry of Health and the ANSVSA the regulation of data collection on

- the use of antibiotics for humans and animals;
3. defines the data necessary to be collected and supports the standardisation of the method of collecting data on microbial resistance in medical units and laboratories for human use;
 4. supports the creation and operationalisation of a network of microbiology laboratories that would allow the identification of the circulation of antibiotic-resistant germs and the issuance of alerts regarding the emergence of microorganisms with new resistance mechanisms.

PRIME-MINISTER,
VASILICA-VIORICA DĂNCILĂ

Countersigned:
On behalf of the Minister of Health,
Cristian-Vasile Grasu,
Secretary of state

Deputy prime minister, Minister of the environment,
Grația Leocadia Gavrilescu

Deputy Prime Minister and Minister of Regional Development,
Paul Stănescu

On behalf of the Minister of Research and Innovation,
Puiu-Lucian Georgescu,
Secretary of state

On behalf of the Minister of National Defence,
Nicolae Nasta,
Secretary of state

Minister of Waters and Forests,
Ioan Deneș

On behalf of the Minister of Labor and Social Justice,
Mergeani Nicea,
Secretary of state

Interim Minister of National Education,
Rovana Plumb

Minister of Agriculture and Rural Development,
Petre Daea