

**Market Access  
& Health  
Technology  
Assessment**

**Romania**

# Romania

**The Market Access & Health Technology Assessments answers essential questions about this environment for pharmaceuticals in Romania.**

**It is a must have for any company operating in the country or looking to enter the market.**

**Prepared in association with Muşat & Asociații, a leading corporate law firm in Romania.**

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Muşat & Asociații is one of the first law firms established in Romania. For more than 30 years, the firm provides legal advisory services in all areas of business law, being an acknowledged market leader in Healthcare & Pharma, Mergers & Acquisitions, Corporate & Commercial, Competition & Antitrust, Intellectual Property, Public Procurement, Labor & Employee Benefits, Litigation & Arbitration, Criminal Law and Taxation.

Muşat & Asociații is recognized as one of the country's most knowledgeable law firms in the life sciences sector, having advised an impressive portfolio of international clients over the years, including 9 of the top 12 innovative pharmaceutical companies worldwide, leading medical devices companies, private healthcare providers, contract research organizations and industry associations.

Leading pharmaceutical companies rely on Muşat & Asociații for complex projects and day-to-day issues, including without limitation to the marketing authorisation, distribution and promotion of medicinal products, the pricing and the reimbursement of medicines, the supply of medicines and medical devices under public procurement proceedings, cost-volume agreements, the clawback tax, the EFPIA/ARPIM guidelines, competition, IP, corporate, employment, data protection, tax issues, FCPA and various other compliance matters.

In a unique position to provide expert advice in all legal matters concerning these highly regulated sectors, the firm has achieved constant success due to the strength and depth of its legal team, which encompasses regulatory, corporate, antitrust and intellectual property attorneys, as well as extensive litigation resources. This array of talent enables the firm to consolidate its undisputed top-tier position while developing further expertise in the most sensitive issues and conducting landmark cases.

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YEARS

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Muşat & Asociații is at the forefront of Romania's legal and business development, anticipating the evolving needs of its clients, thus acting as a pioneer in the field.

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# 01 HEALTHCARE SYSTEM AND FUNDING

1. Please make a general introduction to the public health sector in your country and its organization



## **1. Please make a general introduction to the public health sector in your country and its organization**

The Romanian social health insurance system is coordinated at a central level by the Ministry of Health, the National Health Insurance House and the National Agency of Medicines and Medical Devices. Each of these authorities have specific competences in connection with the marketing authorization, the pricing and the reimbursement of medicinal products, medical devices and healthcare services.

At the level of each county, the Ministry of Health is represented by a local public health department which supervises the activities carried out by the entities performing medical services and have other attribution in connection with the authorisation and coordination of the providers in the healthcare systems.

The National Health Insurance House set up a local county health insurance in each of the 41 counties of Romania, one local county health insurance for the Bucharest Municipality, as well as a separate insurance house for the insured individuals belonging to the military personnel, police and magistrates professions.

These local health insurance houses conclude agreements with the providers of medicinal products, of medical devices as well as with the providers of medical services (e.g. hospitals, medical centers and clinics). Based on these agreements, the providers will supply medicines or, as the case may be, medicinal products, or they may provide medical services to the insured individuals, free of charge or at a reduced price.

The value reimbursed by the Romanian state for the respective medicinal products, medical devices or medical services will be subsequently paid by the local Health Insurance House to the respective providers based on the supporting documentation submitted by these providers on a monthly basis.

In order to be reimbursed in the National Health Insurance System, a medicinal product needs to go through certain procedural steps, starting with the issuance of a marketing authorisation valid for Romania and ending with its inclusion in the list of reimbursement medicines.

The central authorities mentioned at the beginning of this section have specific attributions in connection with this proces. The marketing authorisation holder should appoint one or more local representatives, who will represent it before each competent authority.

As a rule, each procedure (e.g. marketing authorisation, price approval, HTA, reimbursement) is separate and should be handled by filing an application dossier with the competent authority. Certain steps can be performed only after the completion of other procedures (e.g., in order to apply for reimbursement, the medicines's price has to be approved by the Ministry of Health).

# 02 HEALTHCARE ACTORS AND PAYERS

1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?

2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?

3. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?

4. Which are the administrations, bodies and institutions that qualify as “payers” in your country and what are their respective responsibilities?

5. Which are the administrations, bodies and institutions in charge of pricing decisions in your country and what are their respective responsibilities?

6. Which are the administrations, bodies and institutions in charge of reimbursement decisions in your countries and what are their respective responsibilities?

7. Which are the administrations, bodies and institutions in charge of public procurement and tendering in your country and what are their respective responsibilities?

8. What are the other actors of significance with regards to market access in your country and what are their respective responsibilities?



**1. Which are the administrations, bodies and institutions in charge of public health in your country and what are their respective responsibilities?**

The main administrations, bodies and institutions in charge of public health in Romania are:

**(I) THE MINISTRY OF HEALTH**

The central authority in the health field, functioning under the subordination of the Romanian Government; the Ministry of Health has the following main competences in connection with the public health:

- (a) elaborates policies, strategies and action programs in connection with the population's health, in accordance with the Government's programs, coordinates and controls the implementation of policies, strategies and programs in the public health field, at national, regional and local level;
- (b) evaluates and monitors the health status of the population, takes measures to improve it and informs the Government on health indicators, evolution tendencies and necessary measures to improve them;
- (c) regulates the organization and functioning of the national health system;
- (d) elaborates, implements and coordinates national health programs, in order to achieve the objectives of the public health policy.

**(II) THE COUNTY PUBLIC HEALTH DEPARTMENTS**

Under the subordination of the Ministry of Health, these Public Health Departments:

- (a) operate at the level of the 41 counties of Romania and of the municipality of Bucharest;
- (b) have legal personality and function under the subordination of the Ministry of Health, in accordance with the applicable legislation;

The organization and functioning regulation of the public health departments, as well as the specific conditions for the public management functions in the public health departments are approved by order of the Ministry of Health.

**(III) THE NATIONAL INSTITUTE OF PUBLIC HEALTH**

A specialized body of the central public administration in the field of public health, subordinated to the Ministry of Health. The National Institute of Public Health has the following main attributions:

- (a) ensures the technical and methodological guidance of the public health network through its national and regional structures;
- (b) participates in the elaboration of strategies and policies in the field of public health;
- (c) drafts laws, norms, methodologies and instructions on specific topics related to the public health;
- (d) supervises the health of the population, the transmissible and non-transmissible diseases, to identify the common health issues;
- (e) provides the system of epidemiological supervision, as well as early alert and rapid response and participates in the exchange of information

within the European Epidemiological Supervisory Network in the field of transmissible diseases;

(f) elaborates the methodology, tools and indicators of monitoring and evaluation of services and programs of public health, health promotion and health education;

(g) carries out research and development activities in the field of public health and sanitary management.

#### **(IV) THE SPECIALIZED COMMISSIONS, SUB-COMMISSIONS AND MULTIDISCIPLINARY COMMISSIONS**

Within the Ministry of Health, which provide the necessary expertise on the basis of which the Ministry of Health coordinates, from a scientific, professional and methodological point of view, the medical assistance network. The specialized commissions of the Ministry of Health have a very important role in the issuance of the therapeutic protocols for the prescription of medicines.

### **2. Which are the administrations, bodies and institutions in charge of drug approvals in your country and what are their respective responsibilities?**

The National Agency for Medicines and Medical Devices (the “NAMMD”) is the main regulatory authority in Romania in the pharmaceutical field and it is in charge with medicinal products’ approvals. NAMMD is subordinated to the Ministry of Health.

Amongst the main competences of NAMMD, the following should be noted:

- (i) the drafting of various norms, guidelines and regulations in connection with medicinal products;
- (ii) the issuance of the marketing authorization for medicinal products, under the national procedure and under the mutual recognition/ decentralized procedure;
- (iii) the control of the quality of medicinal products as regards the manufacturing process, the import, the wholesale and retail distribution;
- (iv) the issuance of the wholesale distribution authorisation and manufacturing and import authorization;
- (v) the regulation and control of the pharmacovigilance activities.

### **3. Which are the administrations, bodies and institutions in charge of Health Technology Assessment in your countries and what are their respective responsibilities?**

NAMMD is the competent national authority in the health technology assessment (“HTA”) field and has the following main attributions:

- (i) elaborates and reviews the national methodology and the HTA criteria, as well as the form of the medical technologies evaluation HTA reports, in accordance with the international standards;
- (ii) analyzes and evaluates the reports drafted by authorized institutions, organizations, experts or external researchers, regarding the HTA, for objectivity, validity, compliance and scientific rigor;
- (iii) collaborates with professional bodies in the health system and academic institutions for HTA purposes;
- (iv) collects and analyzes the statistical data relevant for the HTA from all institutions of the health system;