The Pharma Legal Handbook

Romania

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

Romania

The Pharma Legal Handbook 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 Mușat & Asociații, one of the leading law firms in Romania, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN APRIL 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: APRIL 2020**

MUȘAT & ASOCIAȚII
Attorneys at Law

Mușat & 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.

Mușat & 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 Mușat & 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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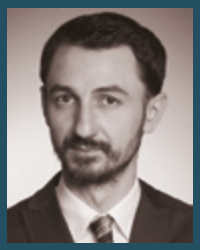

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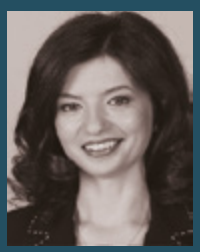
Paul Buta is the Deputy Managing Partner of Mușat & Asociații and the Head of the Intellectual Property, Competition and Life Sciences Department, having advised and represented for more than 16 years some of the world's leading pharmaceutical and medical devices companies.

Paul advised clients on transactions, mergers & acquisitions, restructurings and reorganizations in the life sciences and healthcare sectors and on a wide range of regulatory and competition matters, including merger control, restrictive practices, dominance, cartel investigations, dawn-raids and sector inquiries. Paul has successfully represented numerous clients before the regulatory and the competition authorities and before the competent courts.

Paul regularly advises high-profile corporations on international and domestic patent, trademark and copyright matters, including on the acquisition, development, implementation, enforcement, licensing and other exploitation of IP rights, on IP litigations concerning patent protection, trademark infringement, counterfeiting, copyright, domain name disputes, as well on the enforcement of other various IP rights against third parties.



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Manuela advised leading pharmaceutical clients on competition law matters related to investigations of the antitrust authorities, merger control notifications, the structuring of distribution systems, contractual and promotional activities, and performed numerous trainings on antitrust and compliance matters. Manuela has a master degree in European Union Law from the University of Strasbourg 3 Robert Schuman (2006) and graduated from the University of Paris 1 Pantheon – Sorbonne and the University of Bucharest (2005).

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Dan Minoiu (Partner) has more than 12 years of experience in regulatory, mergers & acquisitions, corporate, commercial and compliance matters in the pharmaceutical, medical devices and healthcare sectors.

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Julieta Sfeclă (Managing Associate) has an extensive expertise in the pharmaceutical field, particularly in intellectual property and dispute resolution matters.

Julieta advised leading companies in pharmaceutical and healthcare fields on intellectual property matters related to business transfers, technology transfers, promotional and advertising campaigns, as well as on the conclusion of copyright and services agreements with healthcare professionals and healthcare organizations. She represented innovative pharmaceutical companies before the competent IP, regulatory and customs authorities, as well as before the courts of law, in landmark cases concerning the protection and enforcement of patents, trademarks and other intellectual property rights.

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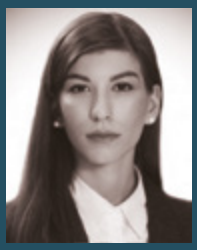
Mateea Predescu (Senior Associate) has more than 6 years of experience on life sciences regulatory matters, corporate & commercial, consumer protection and dispute resolution.

Mateea has a wealth of expertise in the market access, pricing & reimbursement, promotion and labelling of medicinal products, medical devices, cosmetics and food supplements, having advised some of the leading international pharmaceutical companies acting in Romania on numerous regulatory matters. Mateea regularly advises clients in complex litigations concerning the clawback tax applicable to medicines.



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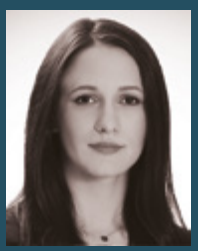
Carmen Turcu (Associate) focuses on intellectual property and life sciences regulatory matters, advising international clients acting in the pharmaceutical, medical devices, cosmetics and healthcare sectors.

Carmen has acquired a significant expertise in the protection and enforcement of IP rights, particularly in cases of trademark and copyright infringements. She represented clients in complex product liability cases concerning medicinal products, cosmetics, biocides and food products, and provides legal assistance on labelling, consumer protection and specific compliance issues in the life sciences field.



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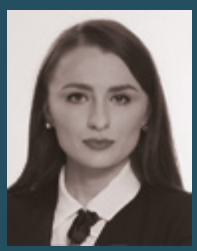
Diana Gruiescu (Associate) focuses on competition and compliance matters, having advised international and local players in the healthcare & pharmaceuticals sectors on the implementation of complex life sciences projects.

Clients rely on Diana especially for sensitive competition issues arising from all types of antitrust matters, such as merger control, restrictive practices, dominance, cartel investigations, dawn-raids and sector inquiries. Diana represented leading pharmaceutical companies in administrative proceedings before the Romanian Competition Council.



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Ioana Câdă (Associate) advises international and domestic clients acting in the pharmaceutical, medical devices, cosmetics and food supplements business.

Ioana is regularly assisting clients on the marketing authorisation, advertising, distribution, promotion and supply of such products, on the implementation of complex life sciences projects designed for improving the patients' access to treatment, on compliance matters and other day-to-day issues.

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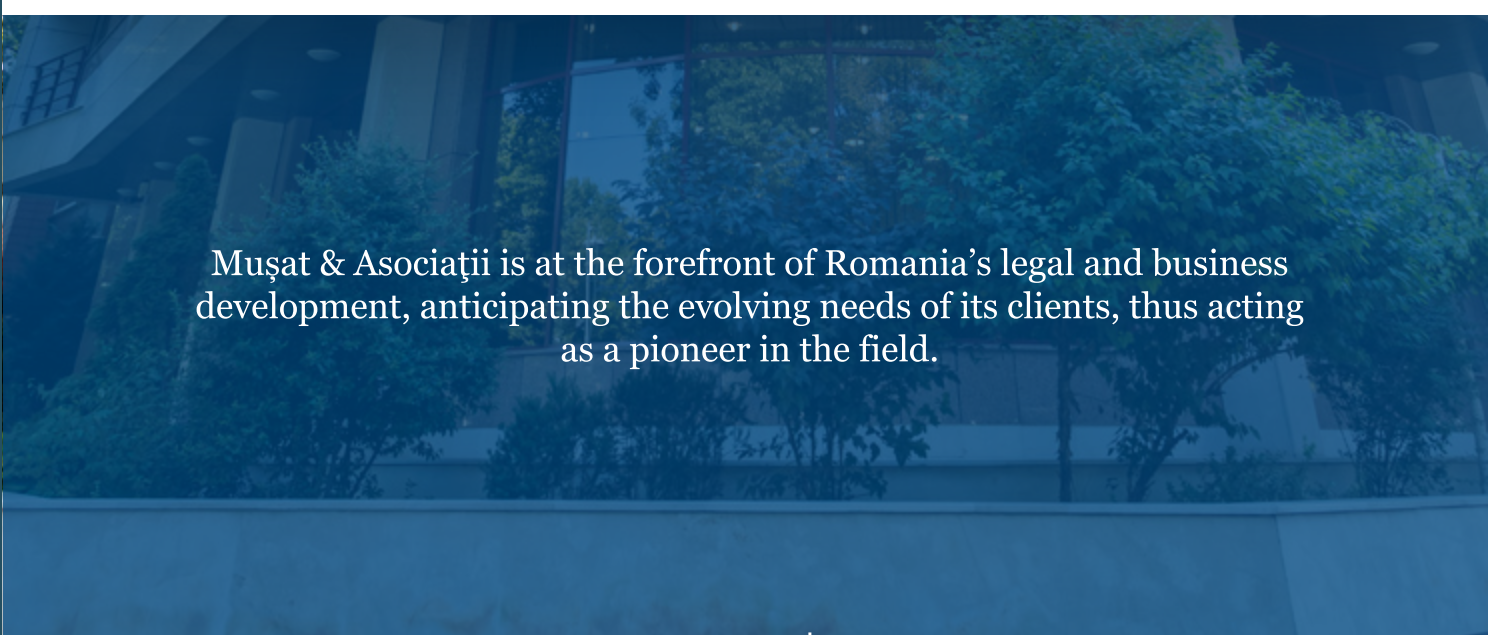

Mușat & Asociaţii is at the forefront of Romania's legal and business development, anticipating the evolving needs of its clients, thus acting as a pioneer in the field.

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The regulatory authorities competent in these fields are:

- the Ministry of Health (http://www.ms.ro/);
- the National Agency for Medicines and Medical Devices (https://www.anm.ro/); and
- the National Health Insurance House (http://www.cnas.ro/).

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The main enactment in the pharmaceutical and healthcare fields in Romania is Law no. 95/2006 on healthcare reform, as republished and further amended and supplemented (the "Health Law"), which regulates, amongst others:

- for medicinal products (including biologicals): the marketing authorization, manufacturing, import, distribution, labelling, advertising, promotion and pharmacovigilance activities;
- for medical devices: the trade, distribution and the performance of certain services and activities.

The secondary legislation consists of Government Decisions, Government Ordinances, Orders, Decisions and Norms issued by the Ministry of Health, the National Agency for Medicines and Medical Devices (NAMMD) and the National Health Insurance House (NHIH), such as:

A. Marketing Authorization:

- Ministry of Health's Order no. 1448/2010 approving the Regulations regarding the marketing authorization and supervising of medicinal products for human use;
- Government Decision no. 54/2009 on the conditions for the trade of medical devices;
- Government Decision no. 798/2003 on the conditions for the trade and use of in vitro diagnostic medical devices;
- Ministry of Health's Order no. 1009/2016 on the registration of medical devices in the national database.

B. Distribution:

- Ministry of Health's Order no. 761/2015 approving the Guidelines on the good distribution practices for the wholesale distribution of medicinal products;
- Ministry of Health's Order no. 131/2016 approving the Norms on the authorization of the wholesale distribution units of medicinal products;
- Ministry of Health's Order no. 566/2020 approving the Norms on the authorization of the activities in the medical devices field.

C. Pricing

- Ministry of Health's Order no. 368/2017 approving the Norms regarding the calculation method and the approval procedure of the maximum prices of medicinal products for human use.

D. Reimbursement

- Government Decision no. 140/2018 for the approval of services packages and of the Framework Agreement on the conditions of providing medical assistance within the social health insurance system for 2018-2019;
- Government Decision no. 155/2017 for the approval of national health programs for 2018 and 2019;
- Government Decision no. 720/2008 for the approval of the List of international non-proprietary names (INNs) of medicines out of which insured persons benefit with or without personal contributions, based on medical prescription, within the social health insurance system, and of the international non-proprietary names of medicines provided under the national health programs.

3. What are the steps to obtaining authorization to develop, test, and market a product?

A. Medicinal products (including biologicals):

In order to perform clinical trials on medicinal products for human use, it is necessary to obtain the authorization of the National Agency for Medicines and Medical Devices ("NAMMD") and the favorable opinion of the National Bioethics Committee for Medicinal Products and Medical Devices ("NBCMMD"). The laboratories and the other units performing the tests should be duly authorized by NAMMD and by the Ministry of Health and/or the competent health department.

To trade a medicinal product on the Romanian market, it is necessary to obtain a marketing authorization and a price approval order for the respective product.

The marketing authorization is issued either:

- at national level, by NAMMD, under the national evaluation procedure or under the mutual recognition or decentralized procedures; or
- at centralized level, by the European Medicines Agency ("EMA").

The authorization procedure should be completed within a maximum of 210 days from the date of filing of a valid application. During this procedure, the regulatory authority shall assess, amongst others, the results of the pharmaceutical and pre-clinical tests, as well the results of the clinical trials.

After obtaining the marketing authorization, the medicine's price should be approved by the Ministry of Health. By law, the Ministry should issue an order approving the medicine's price within 90 days from the date of filing of the price application dossier.

The prices of medicinal products (i.e., the manufacturer price and the maximum wholesale and retail prices) are published in the National Public Catalogue (the "Public Catalogue") and in the National Catalogue of the Prices of Medicinal Products Authorized for Marketing in Romania (also known as the "CANAMED").