The Pharma Legal Handbook

Croatia

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 · Litigation

PHARMA BOARDROOM

Croatia

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Croatia.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with Danijel Pribanić, one of the most prominent law firms in Croatia, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN MARCH 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
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DANIJEL PRIBANIĆ
Odvjetnik / Attorney-at-Law

We advise corporate clients on labour, business and corporate law, banking regulations and property matters. We structure investments and give support to investors in their projects. We advise on compliance in various industries (banking, pharma, FMCG, etc.). We provide due diligences, and oversee negotiations within M&A projects. We advise on cartel laws and risks of illicit state aid reimbursements.

In resolving disputes, we use our experience and modern techniques to encompass the entire business and other previous relations between parties, with the aim of getting a complete picture of the parties' relations, needs and opportunities for a solution. We use out-of-court dispute resolution models, such as business mediation, bargaining, arbitration and expert arbitration, while bringing a case to a court and insisting on a court dispute is applied only when necessary. Our aim is to reach a final resolution of a dispute within foreseeable time and funds framework for our clients.

We advise businesses on labour law and resolve conflicts in labour relations before they evolve into a court dispute. We carry out negotiations and business mediation during employment terminations, employee's discrimination and mobbing complaints, and in cases of other imbalances in labour relations. We advise on atypical work (working through agencies, service contracts or as interns). We advise on foreigners' work, reassignment of local employees, and issues of salaries and other employment-related tax matters.

We review selling, distribution and franchise agreements and practices, and make sure that those are in line with competition law. We provide tutorials for employees working in sales, procurement and customer relation on effective response to illicit offers for creating a cartel, on issues with resale prices and promotional activities.

The firm has been established in 2008.

THE AUTHORS

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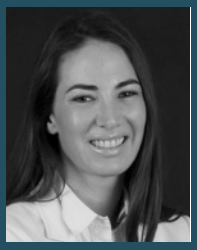
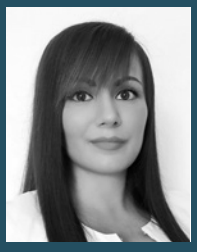
Dora Ljevar has an extensive experience in bringing cases to courts. She is specialized in public and private healthcare matters and administrative barriers to market entry and operations. She holds an international law degree from an Italian university and the Zagreb Law Faculty degree in law. She is an of counsel within the firm.



HELENA IVANDA

Helena Ivanda has a degree from Zagreb Law Faculty. She has special experience from practice at Commercial Court in Zagreb, she then transitioned from judiciary to law firm. She has immense experience in litigation especially within commercial and corporate law with a particular interest in capital market and financial law.



IVANA KUCELJ

Ivana Kucelj graduated from the Faculty of Law in Zagreb. She gained additional knowledge by attending special education in the field of intellectual property, as well as the practical application of Regulation (EU) 2016/679 on the protection of personal data. She has a great interest in litigation, especially in the field of civil and commercial law, as well as a special passion for criminal law.

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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 with jurisdiction over drugs, biologicals, and medical devices in Croatia is the Agency for Medicinal products and Medical devices of Croatia (HALMED or Agency).

The legal aspects of the Agency's operations are supervised by the Ministry of Health. The Agency submits annual reports on its work to the Minister of Heath and to the Government of Croatia.

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

The primary national legislation for the authorization and pricing of medicinal products and biologicals is the Medicinal Products Act (Official Gazette Nos. 76/13, 90/2014, 100/2018), Medical Devices Act (Official Gazette No. 76/13) and its regulations (bylaws).

Authorization of medical devices is not necessary to market a medical device. Requirements that have to be fulfilled in order for the medical device to be placed on the market and administered are set by Medical Devices Act (Official Gazette No. 76/13).

(The criteria for the pricing of medical devices are regulated by the Minister of Health in Ordinance on determination of prices of orthopedic and other aids. Reimbursement of medicinal products and medical devices is mainly regulated by Health Insurance Act and its regulations.)

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

A) MEDICINAL PRODUCT

The Agency or the European Commission grants marketing authorisations for medicinal products in Croatia. For the purpose of placing a medicinal product on the market, its quality, safety and efficacy have to be determined.

The Agency grants marketing authorisations for medicinal products through the national procedure, the mutual recognition procedure and the decentralised procedure by means of the decision which marks the completion of the authorisation procedure carried out in accordance with Medicinal Products Act and ensuing regulations. Croatia can be either the reference state or the concerned state in the mutual recognition procedure and decentralised procedure.

The European Commission grants marketing authorisations based on the centralized procedure in accordance with the provisions of the Regulation (EC) No 726/2004.

Marketing authorisation is also granted for radionuclide generators, radionuclide kits, radiopharmaceuticals, radionuclide precursors and industrially produced radiopharmaceuticals.

When a medicinal product has been granted an initial authorisation for marketing in the European Union, any additional strengths, pharmaceutical, administration routes, types and sizes of packaging, as well as any variations

and extensions have to also be granted an authorisation or have to be included in the initial marketing authorisation. All refered authorisations are considered as belonging to the same global marketing authorisation.

Please see **Chapter 3 Question 22** for details on different procedures for obtaining a marketing authorization in Croatia.

Private individuals and business entities seated in Croatia may manufacture intermediate products, medicinal products and/or investigational medicinal products only in accordance with a manufacturing authorization. The manufacturing authorisation is compulsory for:

- a factory where a pharmaceutical and/or a group of medicinal products will be manufactured;
- the entire manufacturing process or certain parts of the manufacturing process, and
- manufacture of medicinal products intended only for exports and/or exit.
- Importers of medicinal products from third countries have to obtain a manufacturing authorisation.

For marketing authorization, private individuals or business entities engaged in manufacturing, have to comply with the following requirements:

- given the scope and complexity of manufacture of a medicinal product or a group of medicinal products, an adequate number of qualified persons in the field of pharmacy, chemistry, biology, biochemistry, biotechnology, chemical technology, medicine, dental medicine, veterinary medicine or other corresponding professions are required;
- a qualified person for the release of a medicinal product batch who should be permanently available has to be emoployed;
- key personnel for the manufacture, quality checks and distribution of medicinal products have to be employed;
- suitable premises and equipment requisite for the manufacture, quality control, storage and delivery of medicinal products are required, and
- observation of principles and guidelines of Good Manufacturing Practice is neccessary.

For the purpose of obtaining a manufacturing authorisation, a private individual or a business entity seated in Croatia has to submit a motion to the Agency.

Along with the motion and the evidence about the compliance with the requirements of the Good Manufacturing Practice the applicant has to enclose a file containing the following data and documents:

a) name and head office of the business entity or private individual;
b) evidence of registration within a companies registry;
c) evidence of entry of the activity in the companies registry;
d) evidence of professional competencies and employment contract with a person responsible for the release of a medicinal product batch;

e) evidence of professional competencies and employment contract with the key personnel corresponding to the scope of manufacture;
f) personal data of the person responsible for the release of a medicinal product batch and for the key personnel;
g) data on the premises and equipment for manufacture, quality control and storage of medicinal products;
h) description of the manufacturing process or a part of the manufacturing process of a medicinal product for which the authorisation is applied for, or for other parts of the manufacturing process, such as sterilisation of active substances or excipients;
i) a list of medicinal products and pharmaceutical for which the authorisation is applied for, and
j) master file of the manufacturing site.

In the procedure of granting the manufacturing authorisation, an Agency inspector delivers an opinion on the compliance with the requirements of Good Manufacturing Practice.

The Agency grants or refuses the manufacturing authorisation for a medicinal product within 90 days from the date of receipt of a duly filed motion. If the applicant complies with all the requirements laid down by provisions of Medicinal Products Act and the ensuing ordinances, the Agency grants the manufacturing authorisation for an indefinite period of time.

Clinical trials of medicinal products, including non-profit clinical trials, in Croatia may not commence without a favourable opinion of the Central Ethics Committee and the authorisation of the Ministry of Health. If the Ministry does not authorise or refuses to authorise a clinical trial within the referred period, the authorisation is deemed issued, unless a written approval of the Ministry is required before the commencement of a clinical trial in the case of clinical trials intended for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms, and xenogenic cell therapy.

Clinical trials involving persons with mental disorders cannot start without obtaining a positive opinion from the Commission for the Protection of Persons with Mental Disorders of the Ministry of Justice.

The applicant, who has been approved by the Ministry for conducting clinical trials on the basis of a positive opinion of the Central Ethics Commission and seeking approval for conducting clinical trials in additional legal entities, is obliged to obtain the consent of the Central Ethics Committee for each of the following business entity to be included in the clinical testing, as well as obtaining approval from the Ministry of Health.

The Central Ethics Committee has a period of up to 30 days from the date of receipt of a valid request prescribed in Ordinance on Clinical Trials on Medicinal Products and on Good Clinical Practice to give its written opinion concerning the acceptability of the proposed clinical trial. The Central Ethics Committee has to deliver the opinion to the applicant and to the Ministry of Health in written form. The applicant, after a positive opinion of the Central Ethics Committee is obtained, has to submit a request to the Ministry for the