The Pharma Legal Handbook

Latin America

Marketing, Manufacturing, Packaging and Labeling Advertising

PHARMA BOARDROOM

Marketing, Manufacturing, Packaging and Labeling Advertising

This Pharma Legal Handbook answers essential questions about the legal and regulatory environment in 12 countries in Latin America.

Prepared in association with leading local and international law firms and consultancies, it is a must-have for any company operating in/or looking to enter these niches in any of these countries.

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Argentina

This chapter about Marketing, Manufacturing, Packaging and Labeling Advertising in Argentina was published in association with:

Founded in 1923, Marval, O'Farrell & Mairal is the largest law firm in Argentina. A market leader at both local and Latin American levels, the firm has been providing sophisticated, high quality advice to international and local clients for more than 95 years. The firm comprises over 300 lawyers and has wide experience of international business issues and the complexities of cross-border transactions.

Our unmatched strength allows us to react quickly and to simultaneously handle large, complex and time-consuming transactions without compromising on quality. All our teams are led directly by highly experienced partners and carefully tailored to meet the specific needs of our clients. We have a strong focus on high-end corporate and finance transactions and the largest, most active litigation and arbitration practice in Argentina. Our leading intellectual property department provides a comprehensive service and has unrivalled experience; the firm was originally founded as an intellectual property office. We are also a market leader in a wide range of other key practice areas including life sciences, healthcare, tax, labor and employment, competition/antitrust, energy and natural resources, administrative and public law, insurance and reinsurance, telecommunications and broadcasting as well as real estate and construction.

We are the Argentine member of Lex Mundi, the world's leading association of independent law firms, comprising more than 160 members. We also have an office in New York, providing invaluable support on US transactions.

With a long history of advising multinational companies and international institutions, we have a unique understanding of the Argentine market and how to help our clients achieve their goals. Marval, O'Farrell & Mairal has a 90-year track record of being prepared to respond to any challenge, both in the country and in complex cross-border transactions.

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THE AUTHORS

Argentina

MARTIN BENSADON

Martín Bensadon joined Marval, O'Farrell & Mairal in 1991 and has been a partner of the firm since 1998. He specializes in industrial property and more particularly in patent law, having advised many national and foreign firms in this area.

He graduated as a lawyer from the Universidad de Buenos Aires in 1991 and obtained a Master in Laws at the University of Illinois at Urbana-Champaign in 1996. In the same year he also worked as a foreign associate in the law firm of Wilmer, Cutler & Pickering.

He has participated in seminars on industrial property and has written various articles on subjects related to his area of specialty in national and international publications as well as a book on Argentine Patent Law.

He used to be a postgraduate Professor of Industrial Property at the Universidad Católica Argentina and the Universidad de Palermo while he currently teaches at the Universidad Austral and Universidad de San Andrés. He was a Guest Researcher of the Max Planck Institute for Intellectual Property, Competition and Tax Law and a Visiting Scholar at The George Washington University Law School.

At present he is a member of the Asociación Argentina de Agentes de la Propiedad Industrial, the Asociación Interamericana para la Protección de la Propiedad Industrial, the Association Internationale pour la Protection de la Propriété Industrielle (AIPPI), the Fédération Internationale des Conseils en Propriété Industrielle (FICPI), American Intellectual Property Law Association (AIPLA) and the Colegio de Abogados de la Ciudad de Buenos Aires.

RICARDO A. OSTROWER

Ricardo A. Ostrower joined Marval, O'Farrell & Mairal in 1993 and has been a partner of the firm since 1999.

He is Head of the Litigation and Arbitration department and Co-Head of the Life Sciences department and provides legal advice to leading multinational companies on regulatory strategies and compliance in the pharmaceutical, healthcare, biotech, medical devices, medical-technology devices, dental products, cosmetics, toiletries and perfumes, household cleaning products and food industries.

Ricardo is an experienced litigator, particularly focused on complex civil and commercial litigation as well as in arbitration, including disputes between shareholders, cross-border cases, product liability and corporate law matters. He has also actively participated in class actions, contentious issues related to administrative law matters and in oil & gas and environmental disputes. He has represented several of the largest companies operating in the region in many judicial and arbitral proceedings.

He graduated with honors from the Universidad de Buenos Aires with a degree in Law. He received the Federal Supreme Court Award for being the top graduate in 1992.

He is a founding member of CARAT (Comité Argentino de Arbitraje Nacional y Transnacional) and a member of the AADP (Asociación Argentina de Derecho Procesal).

For several years Ricardo was selected as one of Argentina's leading commercial litigators by different researchers.

Ricardo has written many articles related to his area of specialization. He regularly participates in conferences and seminars in his field of practice.

MARTÍN J. MOSTEIRIN

Martín Mosteirin joined Marval, O'Farrell & Mairal in 2003 and is a partner of the Life Sciences and Health Care Departments

He provides legal advice (both contentious and non-contentious) to leading multinational companies on regulatory strategies and compliance in the pharmaceutical, healthcare, biotech, medical devices, medical-technology devices, dental products, cosmetics, toiletries and perfumes, households cleaning products and food industries, in a broad spectrum of matters from client's day-to-day business to complex cross-border transactions, start-ups, joint ventures, M&As and spin-offs.

Martín graduated from the Universidad de Buenos Aires with a law degree in 2002 and later completed two specializations: The first in Pharmaceutical Regulatory Matters and the second in Corporate Advice in International Trade of Goods, Financial Operations and Payment Methods in Contemporary Commercial Law, both at the same university.

Martín has often participated in topic-specific conferences and seminars in Healthcare & Life Sciences and has written many articles in his practice area. He is an active member of the Life Sciences practice group of the International Bar Association (IBA - Life Sciences), the Health Care and Life Sciences Practice Group of Lex Mundi and the Colegio Público de Abogados de la Capital Federal.

MARKETING, MANUFACTURING, PACKAGING AND LABELING ADVERTISING

1. What is the authorization process for the marketing of new drugs, biologics, medical devices, over-the-counter medications, and other medicinal products?	See answers to **Questions 2 and 3 of Chapter 1**. (available in **The Pharma Legal Handbook Argentina** and/or **The Pharma Legal Handbook Regulatory, Pricing and Reimbursement Overview: Latin America**)
2. What is the authorization process for the marketing of generic versions of these products?	See answer to **Question 6 of Chapter 1**.(available in **The Pharma Legal Handbook Argentina** and/or **The Pharma Legal Handbook Regulatory, Pricing and Reimbursement Overview: Latin America**)
3. What are the typical fees for marketing approval?	See answer to **Question 4 of Chapter 1**. (available in **The Pharma Legal Handbook Argentina**)
4. What is the period of authorization and the renewal process?	See answer to **Question 6 of Chapter 1**. (available in **The Pharma Legal Handbook Argentina**)
5. What are the requirements, if any, for post-approval pharmacovigilance?	Pharmaceutical companies must comply with local Good Pharmacovigilance Practices. Likewise, pharmaceutical companies must appoint a professional within its company who assumes connection functions with the health authority (through its Pharmacovigilance Department) in order to exchange information regarding adverse effects on medicines marketed by such pharmaceutical company.
6. Are foreign marketing authorizations recognized?	Yes, but only for product registration purposes (Argentina allows registration based on similarity, please see **Question 6 of Chapter 1** for more detail (available in **The Pharma Legal Handbook Argentina**)). Any product to be marketed in Argentina needs to previously obtain the relevant MA with ANMAT.
7. Are parallel imports of medicines or devices allowed?	Yes. The Argentine Supreme Court has accepted the validity of the so-called "parallel imports" in trademark matters. The Trademark Law does not include a specific provision for the "grey market" importation of pharmaceuticals. However, there is some old case law by the Argentine Supreme Court allowing parallel imports. This case law applies the so-called "international exhaustion" of rights.

Case law only refers to "parallel importation" of legitimate products. If the product is altered or if illegitimate products are imported, the trademark owner may seek injunctive relief with the Argentine Courts. If products are legitimate but substantially altered for sale in Argentina, the right holder could also have legal standing to object their import.

With regard to patents, the Patent Law also provides for an international exhaustion regime.

8. What are the restrictions on marketing practices such as gifts, sponsorships, consultancy agreements, travel and entertainment, or other incentives for healthcare organizations and individual medical practitioners?

The relationship between pharmaceutical companies and Healthcare Professionals ("HCPs") is regulated and the regulation provides several ethical standards and guidelines that must be followed, particularly, on how the information to HCPs should be presented and how pharmaceutical companies should manage their relationship with HCPs without inducing them to prescribe their products motivated on non-ethical incentives instead of being a consequence of a professional decision based on scientific evidence. This regulation was enacted with the aim of tackling promotional practices that foster commercial circuits which jeopardize good practices for prescribing and that affect the rational use of drugs.

Promotional activities for prescription drugs are subject to the following principles:

(i) the promotion of a medicine which has not obtained the corresponding MA is forbidden;

(ii) all the contents of the promotion of medicines are adjusted to the characteristic identifying data appearing in the MA; and

(iii) in any case, the promotion of medicines must favor their rational use, presenting them objectively within the framework of their pharmaceutical properties, therapeutic action and indications so approved (on-label). In this sense, the technical-scientific information necessary for the recipient to know about the therapeutic properties of the medicine must be provided.

Scope of MoH Regulation No. 627/2007 is applicable to the:

(i) promotion of medicines sold under prescription addressed to professionals licensed to prescribe or dispense medication;

(ii) promotional visits by reps, medical promotional agents or persons authorized by pharmaceutical companies, addressed to professionals licensed to prescribe or dispense medicines;

(iii) supply of free samples, samples for professionals, samples without commercial value or similar samples;

(iv) sponsorship of promotional meetings where professionals licensed to prescribe or dispense medicines attend;

(v) sponsorship of scientific conferences where professionals licensed to prescribe or dispense medicines participate;

(vi) incitement to prescribe or dispense medicines through the granting, offer, promise of monetary or in kind advantages, except when their intrinsic value is minimum; and

(vii) promotion, offer, commercialization of medicines made through web pages and/or electronic mails and/or in any other way over the Internet.

MoH Regulation No. 627/2007 prohibits the granting, offering or promising by the pharmaceutical companies and/or in their name and on their representation, of any kind of incentive or benefit such as premiums, monetary or in kind advantages or otherwise to HCPs and/or to persons related or close to them. Awards granted by pharmaceutical companies to the participants in the commercialization chain (distributors, drugstores and licensed pharmacies) are the only exception to this prohibition, when this is part of their commercial policy.

This Regulation sets-up the basic framework applicable to: (i) the process for granting scholarships to HCPs and (ii) sponsorship of promotional/educational events. Section 16 aims to provide equitable and clear mechanisms, not based on prescription, for the selection processes of HCPs who applied for scholarships. Thus, in order to achieve the "equitable and clear mechanism" required by law, the proposed process should be based on objective standards (i.e.: qualification, experience, etc.) and can never be based on the prescription of products. Considerations on the publication, terms and conditions, candidate selection process, scholarship reporting, etc., are issues that should be taken into account when drafting internal policies.

MoH Regulation No. 627/2007 does not distinguish whether a promotional activity is conducted under a scientific, educational or strictly promotional event addressed exclusively to HCPs. The general principles established in MoH Regulation No. 627/2007 are applicable for any event.

In regards to the promotion and advertising of medical devices intended for professional use only, it is not yet regulated in Argentina (there is a legal gap). Therefore, it cannot be specified which modes of advertising are expressly permitted when it comes to medical devices intended for professional use only.

There is a legal gap in regards to the relationship between medical devices' companies and HCPs; thus, it would be advisable to consider the ethical standards of MoH Regulation No. 627/2007 to be used as practical guidelines for the medical devices industry, under a conservative approach.

Finally, also consider that the pharmaceutical and medical devices industry relies its common practices on rules contained in its applicable code of ethics enacted by the local industry chamber which the company is a member of. However, it is important to highlight that those chambers are not a government agency and, thus, only its members must comply with its code and the rules under such codes of ethics are, inter alia, not regulations in force (i.e. any defense argument grounded on such internal codes could be dismissed by the health authority and courts).

9. How is the manufacturing of medicines and devices regulated and by which agencies?

The manufacturing of medicines and medical devices products are both regulated by ANMAT.