GETTING THE DEAL THROUGH

Life Sciences

in 24 jurisdictions worldwide

2014

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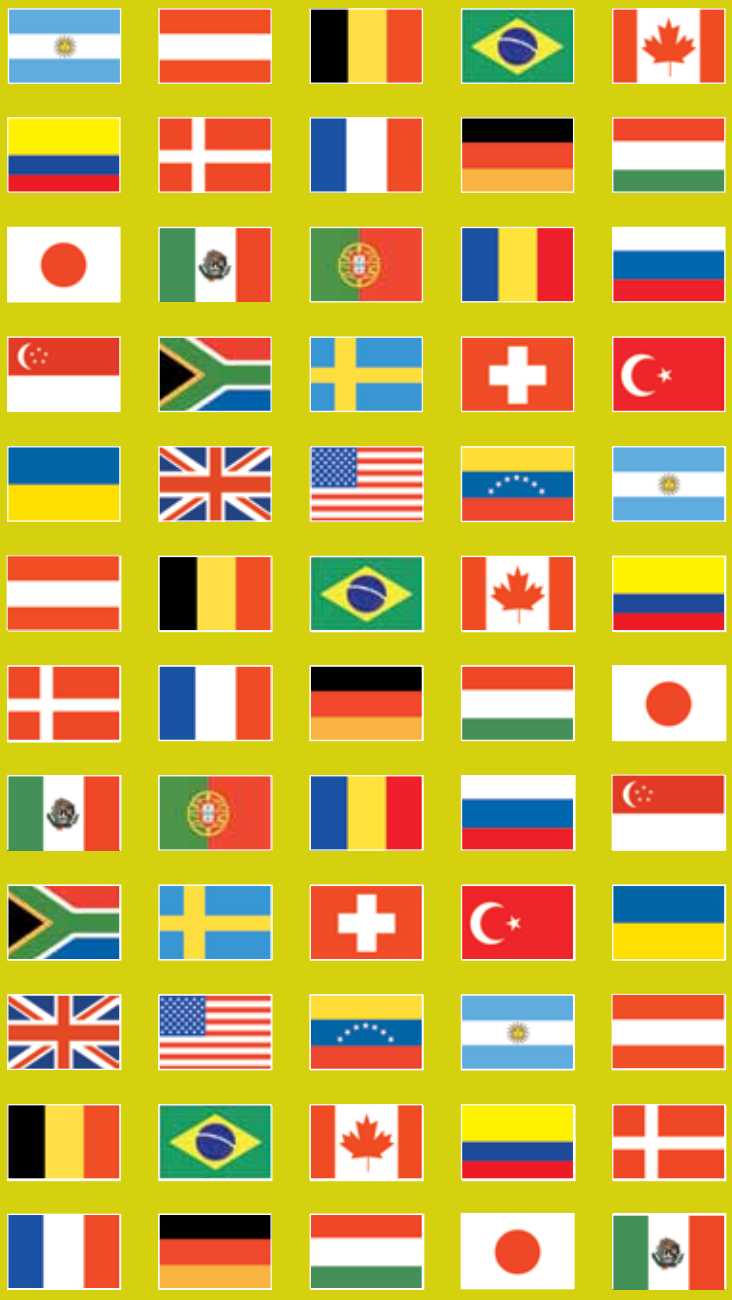

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Life Sciences 2014

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Life Sciences 2014
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
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First published 2010
5th edition
ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

Law Business Research

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Mexico

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Olivares

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

Pursuant to article 5 of the General Health Law, the health-care system as a whole is formed through a combination between the federal and local public administrations and the individuals and private entities who provide health services.

Article 34 of the same law establishes that the health-care system is divided among the service providers as follows:

- general health-care services to the public is provided by the Mexican Institute of Social Security (IMSS) and the Federal Public Health Insurance Company;
- general health-care services to state workers, are provided by the Institute of Social Security and Services for State Workers (ISSSTE);
- private social services, including private practice and private medical insurance services, are regulated by the Ministry of Health; and
- other services such as the 'Seguro Popular', which is a new scheme where one can voluntarily pay lower fees to have social security subsidised by the government. Through this scheme, the government aims for universal coverage including people without formal jobs or with lower incomes.

The main authority governing the health-care system is the Ministry of Health. The General Health Council, which works under directives from the Office of the President, is responsible for policy and advisory work regarding health care. The General Health Council comprises the head of the Ministry of Health and 13 board members, several of whom are medical professionals.

For drugs and authorisations, the main authority in charge is the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), which is also responsible for many other aspects of health care.

2 How is the health-care system financed in the outpatient and in-patient sectors?

Health care is mostly financed through contributions from public and private sector workers. Employers and employees both pay a sort of tax solely used to provide health-care services. There are special rules for those who are incapable of paying but are still eligible to benefit from the health care system.

According to official figures, up to 50 per cent of annual health spending in Mexico comes from out-of-pocket expenses, related to private doctors and insurance, and drug acquisitions.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and health-care professionals?

In addition to some provisions in the General Health Law, advertising activities are governed by the Health Law Regulations concerning Advertising, enacted on 4 May 2000. These regulations were partially modified on 19 January 2012 to address the issue of 'miracle products' (baseless claims about the properties of health and dietary supplements).

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The Health Law Regulations concerning Advertising contain the main rules and principles for ads directed to both the general public and to health-care professionals.

Articles 16–19 of these regulations refer to advertisements concerning health services, and mainly establish the characteristics and purposes of advertisements, as well as prohibiting advertising without authorisation from the Ministry of Health, or advertising that uses false or inaccurate information. The regulations also oblige all advertising material to contain the authorisation number granted to the health professionals by the state.

In article 40, these regulations differentiate between advertising aimed at health-care professionals, including general information on characteristics and use of drugs and their promotion with advertising purposes or promotions of general medical or scientific information, either through films, print-outs, samples, expositions and the like; and advertisement aimed at the public, including general information, which can only be made for non-prescription drugs and herbal remedies.

Regarding advertisements aimed at health-care professionals, article 42 states that they may only be communicated through sector-specific media, including the handbook and health guides. In any event, advertisements need authorisation from COFEPRIS, and must include the marketing authorisation number. In the specific case of information about prescription drugs, advertisements must include, among other items, the distinctive name, generic denomination, formulation; therapeutic use; counter-indications; cautions and limitations including among others restrictions on use by pregnant women and small children; information on adverse reactions and interactions with other drugs.

Notwithstanding the above, under certain circumstances it is possible to use a reduced version of an advertisement, excepting part of the information requirements. This is also possible when providing physicians with promotional samples.

On the other hand, the regulations state that when dealing with products that contain stupefacient or psychotropic substances, these should comply with the above regulations as well, which could only be authorised when such stupefacient and psychotropic substances prove to have a therapeutic use.

5 What are the main rules and principles applying to advertising aimed at the general public?

The rules and principles concerning advertisements aimed at the general public are somewhat dispersed within the Health Law Regulations, but can be found mainly in articles 20–35 and 40, 41, 43, 44 and 45.

Articles 20–35 refer to advertising regarding food products, baby formulas, supplements, and alcoholic and non-alcoholic beverages.

Articles 40, 41 and 43–45, contain rules on advertising aimed at the general public for non-prescription drugs, and the information that can be contained in such advertisements. They require, among other things, that the source of the product be identified.

Advertising non-prescription drugs and herbal remedies requires previous authorisation, cannot be misleading or be referred to as an 'ultimate therapeutic solution', and should always include the phrase 'consult a physician'.

Among several other prohibitions, it is worth noting that advertisements may not use cartoons, which may mislead or confuse children.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

Probably the most renowned recent infringements have been committed by manufacturers of health or dietary supplements and so-called 'miracle' products, which launched aggressive infomercial campaigns with exaggerated claims about the benefits of such products. The Health Law Regulations were reformed concerning advertisements to allow COFEPRIS to order both manufacturers and media outlets to cease advertising activities. Infringements can lead to high fines and closure of business.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

Whereas there is no specific provision in the Health Law Regulations concerning advertisements for off-label use, advertising addressed to health-care professionals does not require a permit from COFEPRIS, but a notice of such advertisement is sufficient. Article 87 of these regulations state that the notices must include the documentary evidence supporting the claims made in the advertisement, which would allow for some off-label claims to be included. Violation to this general rule can be sanctioned by the Health Law and Regulations.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the in-patient and outpatient sector?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and the health-care professionals, including the General Health Law, the Health Law Regulations concerning advertisements, and the Health Law Regulations concerning sanitary control of activities, establishments, products and services.

Other than regulations concerning pharmaceutical investigation, there are no specific rules related to collaboration between pharmaceutical companies and physicians, differentiating between the in-patient and outpatient sectors.

9 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The main rules and principles concerning this collaboration can be found in the Code of Ethics of the National Chamber of the Pharmaceutical Industry. Providing samples of products to health care professionals is expressly allowed by article 49 of the Health Law Regulations concerning advertisements.

Gifts or donations to medical practitioners are not forbidden outright, but doctors working for public hospitals are considered to be government officers and are therefore not allowed to receive donations or direct payments from pharmaceutical companies. Gifts are limited to certain amounts of money, and any activity from those professionals working by the government can only be allowed through public contracts.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

There have not been any recent noteworthy instances of such infringements in Mexico. However, there have been some complaints by ONG´s, generic companies and patients, regarding activities by manufactures to discredit low standard generic products. Generally speaking, the courts have decided that serious and well-grounded scientific literature, even if is sponsored by a manufacturer, cannot be forbidden and does not violate any regulation or ethic conduct.

11 What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

The Code of Ethics for the National Chamber of Pharmaceutical Industry contains a specific chapter on collaboration by the industry with patient organisations.

The main guidelines, enforced by the Pharmaceutical Ethics and Conduct Council (CETIFARMA), indicate that the following principles must be observed:

- respect must be shown to the autonomy and independence of patient organisations;
- collaborations must respect diversity and inclusion;
- conditioning support or promoting specific drugs is prohibited;
- there must be transparency in objectives, reaches and support to patient organisations which will be made publicly available on a yearly basis; and
- the patient organisation cannot be used to include a drug in a public formulary for purchases.

12 Are manufacturers' infringements of competition law pursued by national authorities?

Whereas Mexico does have a Federal Antitrust Law and an active Antitrust Commission (COFECO), there have been few investigations initiated against manufacturers of pharmaceutical products.

A notable exception is a 2011 investigation which reviewed public tender proceedings before the IMSS after evidence was found of collusion between manufacturers in order to set prices. A fine was imposed and the case is still under appeal. Another investigation took place which was related to the distribution of medicines, which is dominated by only three companies in Mexico.

COFECO has broad jurisdiction to investigate future cases of infringements to the Federal Antitrust Law.

13 Is follow-on private antitrust litigation against manufacturers possible?

The Federal Antitrust Law allows for private entities to request investigations, as well as to provide all kinds of elements and evidence related to a certain investigation in process.

Further, once the preliminary determination of antitrust practices has been declared and published in the Mexican Government Official Gazette, anyone related or affected with the decision has the opportunity to provide arguments and evidence.

Follow-on private litigation against manufacturers is possible, but has not been as widely spread as in other jurisdictions, such as the United States.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

It would be fair to say that regulation regarding medical devices is lighter than that for drugs and other substances. Advertising in this regard is regulated in articles 52–56 of the Health Law Regulations concerning advertising, which establish that, upon issuing the marketing authorisation, COFEPRIS will determine whether the specific product can be advertised to the general public or only to health-care professionals.

Advertisements for medical devices are also not allowed to include messages that promote self-treatment, and permission from COFEPRIS is required before publishing the advertisement.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The General Health Law contains the main provisions on this issue. The Health Law Regulations for Supplies is also relevant.

16 Which authorities may grant marketing authorisation in your jurisdiction?

Marketing authorisations are granted by COFEPRIS, which is subordinate to the Ministry of Health. The granting of authorisations for innovator drugs is also reviewed by the New Molecules Committee, which includes physicians from the National Academy of Medicine.

17 What are the relevant procedures?

The proceedings set forth in the Health Law Regulations for Supplies are different for innovator and generic drugs.

Innovator drugs

Before an application can be submitted, relevant information must be analysed by the New Molecules Committee. This committee has jurisdiction over:

- drug products containing a compound not previously authorised in Mexico;
- new formulations of existing drug products; and
- new indications for previously authorised compounds.

Once the committee has approved the proposed submission, the application is filed with COFEPRIS. A decision takes between six and 12 months.

COFEPRIS has also been pushing forward a project to get new drug products approved in Mexico as a first country, provided that clinical trials are conducted with the local population.

Regulatory data protection for innovators was recognised in mid-2012, and was limited to synthetic molecules, excluding biologics, new formulations, combinations and indications.

Generic drugs

Once an innovator drug is approved, COFEPRIS will assign it as a reference drug for interchangeability testing.

To greatly reduce approval times, submissions for generic drug approval can be analysed by a third-party reviewer authorised by COFEPRIS.

Furthermore, Mexico has a linkage-type system, where patents covering allopathic drugs are included in a special gazette issued by the Mexican Patent Office and have to be observed by COFEPRIS before the authorisation for a generic drug is launched.

The current administration has made the quick issuance of authorisations for generic drugs a major policy point. As a result, instead of individual authorisations, there have been three 'packages' of authorisations granted and announced in the national media by COFEPRIS, making wide references to savings derived from these authorisations.

Biotechnology drugs

Mexico is one of the first countries worldwide to have established a full body of legislation and regulation for the approval of both innovators and follow-on drugs (referred in Mexican legislation as 'biocomparables').

Once an innovator has been approved, and assigned as a reference drug, a third party can request COFEPRIS to determine comparability tests, which can include clinical trials, in order to obtain the authorisation of a biocomparable drug.

There are unsettled issues and some litigation cases concerning a number of follow-on biologics which were authorised before the full body of legislation and regulation were enacted, and for which the requirements were therefore similar to those for generic drugs.

Orphan drugs

Until a few months ago, due to lack of specific provisions in Mexican legislation, COFEPRIS granted 'orphan drug status communications' instead of marketing authorisations. These communications were obtained quickly and allowed for the import or manufacture of the corresponding drug. The legislation was recently amended to include this type of drug.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

Before 2010 all marketing authorisations were issued without any sort of time limit, and therefore were not subject to expiration.

Since 2010 a reform to the law and regulations has established a five-year term on marketing authorisations. Even though proof of use is not a requirement for renewal, technical reports on pharmacoviligance are. Therefore authorisation for a drug that is not on the market can be denied renewal.

19 Which medicines may be marketed without authorisation?

According to article 376 of the General Health Law, all medicines require a marketing authorisation. Health supplements and herbal remedies are excluded.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Yes. Article 102 of the General Health Law establishes that COFEPRIS can authorise the use of drugs or materials that have not been previously authorised, within an investigation protocol, for the purposes of clinical trials.

In addition, according to article 103 of the same law, a physician can authorise therapeutic or diagnostic resources which are still in the research phase when the potential to save lives, restore health or diminish suffering exists, as long as there is written consent, and an authorisation is provided by the Ministry of Health.

A special marketing authorisation for the distribution of an unauthorised medicinal product may also be granted if a medicine meets most of the criteria, but the requirements on effectiveness and the risk/benefit ratio are merely suspected and cannot be confirmed, since the number of patients involved in the clinical trial of the product is insufficient due to the rarity of the disease.

Compliance with the requirements is assessed at least once a year. At the manufacturer's request the time limit of such provisional marketing authorisation may be extended by a maximum of one year.

Update and trends

A review of the Official Regulations for approval of biologics and biocomparables, that will substitute the current transitory regulation, is under discussion. There is also a proposal in Congress to modify the rules for prescription of medicines, giving the obligation to the physicians to prescribe medicines by the generic name but with the discretion to include in the prescription the commercial name or the brand of medicine. This rule will also apply for the first time to biologic products. Regarding health regulations and legislation, the government is waiting for the final outcome of the negotiations of the Transpacific Partnership (TPP) Agreement with 11 countries, including the United States, Japan and Canada.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

Mexican laws do not establish specific provisions concerning medicinal product pricing for either the outpatient or in-patient sectors. However, several mechanisms are in place that lead to a certain degree of control of such prices in practice.

Specifically, the price for public acquisition of innovator drugs covered by patent rights, is negotiated in bulk between the patent or licence holder and a government commission for price negotiation. The negotiation proceedings end with a single yearly price for all public sales.

Off-patent drugs are purchased through public tender proceedings, where a reference price is set, based on previous purchasing experiences (ie, a maximum amount that can be paid for a specific drug), and the lowest bidder is assigned the tender.

Since the government is the main purchaser of drugs, pricing for publicly acquired drugs helps regulate prices in the private sector.

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

Yes. As mentioned above, prices for patented drugs are negotiated with a commission and set for every public acquisition. When patent rights have expired (or in some cases when there is more than one participant in the market), drugs are acquired through public tender proceedings.

23 In which circumstances will the national health insurance system reimburse the cost of medicines?

The major public national health insurance providers, the Seguro Popular, and the Mexican Institute of Social Security, provide medicines free of charge directly through government-run pharmacies. Congress is currently reviewing an initiative to oblige the federal government to reimburse individuals for purchases of drugs when state-run pharmacies do not hold such drugs, or in the case of private insurance.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

The Commission for Drug Price Negotiations is made up by several public offices, including the Ministries of Economy and Health, and major public insurance providers.

The commission reviews which drugs in the National Formulary are subject to patent rights – and may request information from IMPI – and then analyses whether therapeutic alternatives exist for each drug. After, the Commission initiates a negotiation process with the patent holder or licensee to establish a single price for all public sales.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

There is no obligation in Mexican law for this specific point, but sales to public institutions are generally done at much lower prices than sales in the private market.

Medicine quality and access to information

26 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The manufacturing and sales of counterfeiting or falsificated medicines is classified as a crime by the General Health Law. In addition, COFEPRIS commonly enters into collaboration agreements with the Federal District Attorney's office (PGR) and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

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Private companies have also run successful collaboration campaigns with COFEPRIS to counter these actions, including funding investigations and providing full packages of information to the authority.

27 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

As a general rule, laboratories are forbidden from any form of advertisement to the general public concerning prescription-only medicines. The public policy in place in this regard is that the public's access to information on these medicines must be limited to avoid self-prescription (since sales of drugs without a prescription is a common practice in Mexican pharmacies).

28 Outline major developments to the regime relating to safety monitoring of medicines.

Whereas there have not been any major modifications in Mexico's legal system concerning pharmacovigilance, the current administration at COFEPRIS has made it a priority point, and several actions are described on the official website www.cofepris.gob.mx, including the 2012 report containing international and national alerts, modifications to prescribing information and general information.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

Within the Ministry of Health there is a National Committee for Vaccination, which implements and elaborates the public policies for vaccination and the prevention of diseases in Mexico. There is no obligation for an individual to be vaccinated unless it is an emergency situation requiring vaccination. The obligation to vaccinate the population is on the government through the different federal, local or municipal health entities, which should provide the population with the required vaccines free of charge in order to obtain universal coverage.

On 28 September 2012, Official Regulation (NOM) NOM-036-SSA2-2012 was published in the National Gazette. The Regulation establishes the standards and goals for vaccination of the population, listing the required vaccines and identifying the characteristics of the subjects of the vaccination. Control of vaccination through the National Health Card and the safety, efficacy and quality of the vaccines and biologics are also warranted in this official regulation. There is a principle of free and universal coverage for the listed vaccines in this Official Regulation.

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LIFE SCIENCES 2014 ISSN 2042-4329