Q&A: Regulation of healthcare services in Mexico

OLIVARES

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Regulation of healthcare services

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

The authority in charge of licensing and regulating patient care facilities is the Federal Commission for the Protection against Sanitary Risks (COFEPRIS). The licensing processes apply to:

- the manufacture of drugs that contains narcotics, psychotropics, vaccines, toxoids, serums, animal-based antitoxins and blood products;
- the elaboration, manufacture or preparation of drugs, pesticides, vegetal nutrients or toxic or dangerous substances;
- the application of pesticides; and
- the handling of radiation sources for medical or diagnosis purpose.

They also apply more generally to:

- establishments where surgical or obstetrical acts and haemodialysis services are practised; and
- mixing centres for the preparation of parenteral, nutritionally medicated mixtures.

Also, the authority in charge of licensing and regulating healthcare professionals is the Minister of Education.

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

There are no restrictions that govern the mobility of foreign licensed health professionals across borders. However, a foreign medical degree is not automatically recognised as equivalent to a Mexican medical degree. The foreign degree must be validated by the Mexican educational authorities – namely, the Ministry of Education – and, in

particular, the foreign physician professional may be requested to take a knowledge exam called the 'National examination of aspirants to medical residencies' to obtain a licence authorising the practice of medicine in Mexico.

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

Scientific and educational events

The Code of Integrity, Ethics and Transparency of Healthcare Supply Companies (CIETEMIS), issued by the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA), states that congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by any other third party (eg, pharmaceutical companies or healthcare organisations) must have, as their main purpose, scientific exchange and medical education.

Whenever support for continuing education or independent educational programmes is being provided, the education of healthcare professionals should be encouraged, primarily, to improve their knowledge of patient care. In each case, programmes must comply with the guidelines of the applicable laws; they must have a strict scientific content sustained, if required, on clinical evidence; and, most importantly, they must be accredited and certified by the relevant academic authorities.

Support in general will not be offered, under any circumstance, to have any kind of influence on the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

Samples

According to CIETEMIS, samples are provided directly, in fair amounts and without cost to healthcare professionals so that they may get to know the products or initiate treatment.

According to article 49 of the Health Law and its Regulations, providing samples of products for free does not require approval if the samples meet the requirements of the approved medicinal product. These samples should be contained in a package with fewer units than the approved product.

CIETEMIS establishes guidelines for sampling. It prohibits CETIFARMA members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples.

CETIFARMA members are required to have full and up-to-date control of their samples, including their manufacture, storage, delivery to regional coordinators or others, and provision to medical representatives and physicians.

The authors of this chapter recommend that manufacturers keep strict control of their product samples as there have been cases of sample resale.

Gifts and donations

CIETEMIS essentially states that companies must act responsibly regarding sponsorships and donations. No gifts of significant commercial value or incentives of any kind may be offered to healthcare professionals as an inducement to use, prescribe, purchase or recommend a specific product or influence the results of a clinical study.

No gifts, bonuses, pecuniary advantages, benefits in kind or any sort of incentive may be offered or promised to healthcare professionals, administrative staff or government employees involved in the cycle of prescription, purchase, distribution, dispensing and administration of medicines, except in the case of inexpensive promotional

aids related to the practice of medicine or pharmaceutical activities. CIETEMIS defines an 'inexpensive promotional aid' as one that does not exceed the equivalent of 10 units of measure (around US$50).

Regarding healthcare professionals in government institutions, article 52 of the Federal Law of Responsibilities for Government Officers expressly forbids such officers from requesting, accepting or receiving any gifts or donations from persons whose commercial or industrial activities are directly linked, regulated or supervised by government officers.

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

CIETEMIS establishes that collaboration between patient care facilities and healthcare professionals must have a written agreement in place that will include, at least:

- the activities to be undertaken and their cost, and the source and destination of funding; and
- direct and indirect support and any other relevant non-financial aid.

Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

The educational and training requirements that physicians and healthcare professionals must satisfy to obtain the right to practise in Mexico are:

- to complete an approved study programme in a private or public college;
- to work for one year in social services;
- in the case of physicians and nurses, to complete professional practices and internships; and
- to file all the requested documents with their educational institution in order to obtain their professional licence.

Students enrolled in private colleges must take a specific test (called 'Examination for graduation from a bachelor's degree') to determine whether they possess the key knowledge and skills upon completing their degree.

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

COFEPRIS can request reports from licensed holders, make on-site inspection visits to the facilities and initiate ex officio legal proceedings for non-compliance.

Ultimately, these legal proceedings can result in the revocation of the licence. Also, COFEPRIS is also entitled to implement measures on behalf of public health, such as seizing products or ordering the partial or total suspension of activities, services or advertisements.

Under certain conditions, COFEPRIS has the statutory authority to revoke any health service approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage or unit of measure for sanctions, to the closure of the corresponding establishment or facility.

The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringers can incur penalties ranging from a fine up to 50,000 times the minimum wage to final closure of the establishment. Repeated infringement is also considered to be a criminal offence.

COFEPRIS has broad jurisdiction over illegal health services. In addition, COFEPRIS commonly enters into collaboration agreements with the general attorney to investigate and prevent illegal health services.

Patient complaints

How are patient complaints processed and adjudicated?

Under the Mexico Health Law, complaints filed by users regarding medical care they received must be addressed and resolved in a timely and effective manner by the health service providers or by the entities designated by the health institutions for such purpose, when the solution also falls within their remit.

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