PANORAMIC

HEALTHCARE ENFORCEMENT & LITIGATION 2025

LEXOLOGY

Healthcare Enforcement & Litigation 2025

Panoramic guide (formerly Getting the Deal Through) enabling side-by-side comparison of local insights into the applicable regulatory, enforcement and litigation framework (for pharmaceutical products and medical devices, relationships between healthcare professionals and suppliers, and healthcare delivery); private enforcement, cross-border enforcement and extraterritoriality; and recent trends.

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Ireland

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OVERVIEW

Healthcare funding

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

There is a two-tier health service in Ireland, comprising the public healthcare system and the private healthcare system. The public healthcare system is funded by the state. The private healthcare system is funded by private funds and private insurance.

Healthcare policy and expenditure in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, receive state funding but are owned by religious orders or similar institutions. Private hospitals are owned by private entities and receive no state funding.

In Ireland, every citizen is entitled to free or subsidised medicines and certain medical and surgical aids and appliances. The prices paid by the HSE for medicines are maintained on an official reimbursement list, and are set by reference to the Health (Pricing and Supply of Medical Goods) Act 2013 and industry agreements.

In 2015, the government introduced Lifetime Community Rating loading, which means that the older a person is when they first buy health insurance, the higher their premium will be. This loading is applied only where a person is aged 35 or older when they first buy health insurance.

Health insurance in Ireland is regulated by the Health Insurance Authority. There is a minimum level of cover specified in legislation that all in-patient health insurance contracts must include. Community rating in the Irish health insurance market means that the cost of health insurance premiums are based on the services covered by the plan, not on the purchaser's medical or claims history.

On 30 May 2017, the All-Party Oireachtas Committee on the Future of Healthcare published the Sláintecare Report, making recommendations on the future of healthcare in Ireland. The report makes recommendations such as free general practitioner (GP) care for all, free public hospital care, cuts to the prescription charge and the cost of monthly drugs. All of the benefits listed in the report were to be phased in over the preceding years.

Throughout the covid-19 pandemic and the HSE cyber-attack, work progressed on the implementation of the reform priorities. There were, however, some inevitable impacts on timelines, as responding to the pandemic and maintaining service provision had to be prioritised.

In 2023, the government published the Sláintecare 2023 Action Plan. This plan sets out the ongoing reform priorities aligned with the Programme for Government, the Sláintecare Implementation Strategy and Action Plan 2021 – 2023, Department of Health priorities and the HSE's National Service Plan 2023.

In 2024, the Minister for Health published the Sláintecare Implementation Strategy and Action Plan 2021 – 2023 Final Progress Report. The Report highlights the significant public

investment in health and social care services. Notably, more than half the population of Ireland is now eligible for either a medical card or a GP visit card. Charges for inpatient stays in public hospitals have been abolished. A free contraception scheme has been introduced and a state-funded in vitro fertilisation scheme was launched in 2023.

Law stated - 25 November 2024

Delivery

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Healthcare is mainly delivered by way of primary or secondary care. Primary healthcare services are provided outside of hospitals to people living in the community, for example, by general practitioners, nurses, health clinics and so on. Secondary healthcare is delivered in hospitals to patients normally living at home (eg, outpatient clinics, accident and emergency clinics). In recent years, more health insurers have provided secondary care such as 'home nursing' or 'treat at home' schemes.

Most medical treatment is available free of charge or subject to a subsidised charge under the public health system. In addition to private hospitals, a limited number of private beds in public hospitals facilitate the treatment of patients who opt for private health insurance. Recent Health Insurance Authority statistics suggest that approximately 47 per cent of the Irish population had private health insurance in 2023, a key benefit of which is avoiding lengthy public waiting lists for elective procedures.

Law stated - 25 November 2024

Key legislation

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

A wide variety of legislation governs the delivery of healthcare, including:

- the Health Acts 1947–2023: the statutory framework governing the national healthcare system;
- the Health Act 2007: establishing the Health Information and Quality Authority (HIQA); and
- the Medical Practitioners Act 2007 (as amended): establishing the Medical Council.

Other legislation governs healthcare professions such as the Dentists Act 1985, the Nurses and Midwives Act 2011, the Pharmacy Act 2007 and the Health and Social Care Professionals Act 2005.

Law stated - 25 November 2024

Responsible agencies

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

A number of bodies are responsible for the enforcement of laws and rules applicable to the delivery of healthcare. For example:

- HIQA is responsible for setting standards for the safety and quality of public or publicly funded hospitals and healthcare services, and social care and residential services. HIQA is responsible for the registration, oversight and scrutiny of designated health and social care services, which include public and private residential facilities for children and adults with disabilities and nursing homes (called designated centres). HIQA is funded by the Irish government and does not currently regulate private hospitals; and
- the Medical Council is responsible for regulating doctors in Ireland. It is funded by the registration fees of medical practitioners.

Numerous other statutory bodies regulate other healthcare professionals, such as the Dental Council of Ireland, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland and the Health and Social Care Professionals Council.

Many statutory bodies have the power to prosecute summary offences under applicable legislation. In Ireland, a summary offence is one that can only be dealt with by a judge in the lower courts sitting without a jury. Summary proceedings carry lower fines and penalties. Indictable offences are more serious and are heard in the higher courts and, in certain circumstances, must be tried before a judge and jury. The Director of Public Prosecutions (DPP) directs and supervises public prosecutions on indictment.

Law stated - 25 November 2024

Scope of enforcement

5 What is the scope of their enforcement and regulatory responsibilities?

HIQA sets standards for safety and quality in healthcare. It has a monitoring function and carries out investigations as to the safety, quality and standards of healthcare and social care services under its remit. Designated centres under its remit can be de-registered for failure to comply with safety and quality standards. HIQA can also bring summary proceedings for offences under the Health Act 2007, which carry penalties of:

- on summary conviction, a fine not exceeding €5,000 or imprisonment for up to one year, or both; or
- on conviction or indictment, a fine up to €70,000 or imprisonment for up to two years, or both.

The Medical Council investigates complaints against doctors and can impose sanctions. Other regulators have investigative and enforcement powers.

Law stated - 25 November 2024

Regulation of pharmaceutical products and medical devices

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The Health Products Regulatory Authority (HPRA) is responsible for regulating medicinal products, medical devices, controlled drugs and cosmetic products. The HPRA was established under the Irish Medicines Board Act 1995 (as amended) – before 1 July 2014, the HPRA was called the Irish Medicines Board.

The HPRA is predominantly self-funded through the collection of fees, with any shortfall provided by the Department of Health. The National Standards Authority of Ireland (NSAI) is the notified body in the country responsible for performing conformity assessments to ensure compliance with medical device legislation and for awarding CE (European conformity) marks.

Law stated - 25 November 2024

Scope of enforcement

7 What is the scope of their enforcement and regulatory responsibilities?

The HPRA is responsible for authorisations for manufacturing, marketing, importing, exporting or distributing medicinal products, and for the assessment of clinical trials. The HPRA is also responsible for monitoring the safety and quality of medicinal products placed on the Irish market, and it is the competent authority for monitoring the safety of medical devices.

The HPRA investigates activities associated with the illegal supply, manufacture or advertising of health products or devices. Where significant risk to public health has been detected, or where compliance cannot be achieved or other aggravating factors exist, the HPRA will prosecute the offender. The HPRA can prosecute certain summary offences. Indictable offences are prosecuted by the DPP.

Summary offences under the NSAI Act 1996 (as amended) may be prosecuted by the Minister for Business, Employment and Retail. Indictable offences are prosecuted by the DPP.

Law stated - 25 November 2024

Other agencies

8 Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

Other agencies that have jurisdiction over healthcare, pharmaceutical and medical device cases include:

- the Data Protection Commission, responsible for the enforcement of data protection laws;
- the Corporate Enforcement Authority, responsible for the enforcement of company laws;
- the Competition and Consumer Protection Commission, responsible for the enforcement of competition and consumer laws;
- the Health and Safety Authority, responsible for the enforcement of occupational health and safety laws; and
- the Revenue Commissioners, responsible for the assessment and collection of taxes and duties.

Law stated - 25 November 2024

Simultaneous investigations

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations. However, agencies are usually obliged to ensure that their investigations do not interfere with another investigation.

Law stated - 25 November 2024

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The Health Products Regulatory Authority (HPRA) – and its authorised officers – have wide-ranging powers under the Irish Medicines Board Act 1995 (as amended) (the IMB Act) to investigate regulatory breaches for both medicines and medical devices. For example, authorised officers can enter premises to carry out inspections, investigations, tests or examinations and can inspect, copy, remove and detain records, documents or samples for review and testing.

Law stated - 25 November 2024

Investigation time frames

11 How long do investigations typically take from initiation to completion? How are investigations started?

The HPRA annual report for 2015 outlined that on average an inspection and audit took 106 days to close out. More recent statistics are, unfortunately, not available.

The HPRA may conduct 'for cause' inspections in response to market issues, such as device safety issues. 'For cause' inspections are conducted in the interest of public health and the HPRA may request to go on site at once to conduct the inspection. The HPRA may also conduct proactive inspections, which may be announced or unannounced.

Before conducting an audit, the HPRA will contact the company to arrange the date, time and duration of the audit. In the case of a proactive audit, the company will generally be given at least four weeks' notice prior to the audit. A confirmation letter will be sent to the company specifying the date and time agreed and a list of the areas the audit will cover.

Law stated - 25 November 2024

Access to investigation materials

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

In the context of a prosecution, the accused is entitled to certain evidence. For prosecutions on indictment, the prosecution has a statutory duty to provide the accused with the Book of Evidence intended to be given at trial. In summary prosecutions, there is no general duty on the prosecution to provide the accused with the statements of witnesses or documents. However, a District Court judge may order that statements and documents are handed over to the defence if it is deemed necessary in the interests of justice. The criteria used to determine a judge's decision include:

- the seriousness of the charge;
- the importance of the statements or documents;
- whether the accused had been adequately informed of the nature and substance of the accusation; and
- the likelihood of risk of injustice in failing to furnish the statements or documents to the accused.

This order is commonly known as a 'Gary Doyle' order.

An individual may submit a data subject access request under article 15 of the General Data Protection Regulation. However, the Data Protection Act 2018 restricts this right in certain circumstances, including for the prevention, detection, investigation and prosecution of criminal offences and in connection with legal claims or proceedings. This restriction may not apply, however, in the case of regulatory investigations. The Freedom of Information Act 2014 also contains exceptions that allow a body to decline access to data or records kept for the purpose of investigating offences.

Law stated - 25 November 2024

Investigations abroad

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes. This is generally done with the cooperation of the local, national or EU regulatory authority. The HPRA has carried out inspections of manufacturing sites and clinical trial sites in many countries in recent years.

Law stated - 25 November 2024

Enforcement proceedings

14 Through what proceedings do agencies enforce the rules?

Depending on the severity of the offence, a regulator may try to work with an offender to correct non-compliances in a non-adversarial manner. For example, the HPRA typically notifies the offender that they are in breach and affords them an opportunity to cease the offending practice before more serious action is taken. The HPRA's policy on enforcement is to 'prosecute where significant risk to public health has been detected, or where compliance cannot be achieved, or other aggravating factors exist'.

The HPRA and other entities have the authority to initiate proceedings to prosecute summary offences through the Irish criminal justice system. For summary offences under the IMB Act, proceedings may be brought by the Minister for Health, the Chief Executive of the HPRA, the CEO of the Health Service Executive or the Council of the Pharmaceutical Society of Ireland. More serious indictable offences are prosecuted by the Director of Public Prosecutions.

Law stated - 25 November 2024

Sanctions

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Any person found guilty of an offence under the IMB Act is liable:

- on summary conviction to a fine not exceeding €2,500 or imprisonment for up to one year, or both; or
- on conviction on indictment to a fine up to €120,000 or imprisonment up to 10 years, or both in the case of a first offence, or to a fine up to €300,000 or imprisonment up to 10 years, or both in the case of subsequent offences.

Law stated - 25 November 2024

Actions against employees

16 | Can the authorities pursue actions against employees as well as the company itself?

Yes. When an offence under the IMB Act has been committed by a company with consent, connivance or attributable neglect on the part of directors, managers or other officers, they may also be prosecuted. A company does not have to be charged with, or convicted of, an offence for a director, manager or other officer to be charged or convicted.

Law stated - 25 November 2024

Defences and appeals

17 | What defences and appeals are available to drug and device company defendants in an enforcement action?

The defences available typically depend on the nature of the allegations. Summary proceedings under the IMB Act must be initiated within two years of the date of the offence. There is no time limit for the prosecution of indictable offences.

An appeal of a prosecution for breaches of pharmaceutical products and medical devices laws is taken through the criminal justice system. For criminal cases, the Circuit Criminal Court hears appeals of decisions from the District Court, and the Court of Appeal hears appeals against convictions or sentences imposed by the Circuit Criminal Court, the Central Criminal Court (High Court) and the Special Criminal Court.

Law stated - 25 November 2024

Minimising exposure

18 | What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should have in place appropriate policies and procedures to ensure regulatory compliance and minimise risk. These policies should contain appropriate reporting lines, record-keeping requirements and regular reviews. Once an enforcement action is under way, the company should immediately seek to remedy any breach and cooperate fully with the investigation by complying with all directions and recommendations of the investigating body. The company should also seek legal advice.

Law stated - 25 November 2024

Recent enforcement activities

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

A key focus for the authorities has been on falsified medicines that pose a health risk to the public. Operation Pangea X, a cross-border coordinated effort targeting the sale of falsified medicines and illicit medical devices, was conducted in September 2017. It resulted in the detention of medicines including dietary supplements, pain reduction pills, epilepsy medication, erectile dysfunction pills, anti-psychotic medication and nutritional products. In total, more than 200,000 units of illegal prescription medicines were detained, compared with 60,000 in 2016.

Recent enforcement data released by the HPRA showed that it detained over 700,000 dosage units of falsified and illegal medicines in the first six months of 2024.

The most significant categories of illegal products detained included:

- anabolic steroids (23 per cent);
- analgesics (14 per cent);
- sedatives (11 per cent); and
- erectile dysfunction medicines (10 per cent).

In the first six months of 2024, the HPRA initiated one prosecution, issued four voluntary formal cautions, and amended or shut down 1,603 e-commerce listings and (or) social media pages.

Law stated - 25 November 2024

Self-governing bodies

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

There are self-governing bodies in Ireland representing companies that manufacture and sell medicinal products and medical devices.

The Irish Pharmaceutical Healthcare Association (IPHA) is the industry association that represents the international research-based pharmaceutical industry in Ireland. Its member companies include manufacturers of prescription and non-prescription medicines. The IPHA is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and has published the Code of Practice for the Pharmaceutical Industry Edition 8.5 (IPHA Code) that reflects the standards of the July 2021 edition of the EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals. The IPHA Code also provides practical guidance on implementing the Medicinal Products (Control of Advertising) Regulations 2007.

Although the IPHA Code is a self-regulatory code and is only binding on members of the IPHA, it reflects best practice in Ireland. The IPHA has a Code of Practice Panel, a Code Council that hears complaints in the first instance and an appeals board. The Code Council has the authority to impose sanctions including:

- reprimanding a company;
- ordering the recovery of material or correction of inaccurate information;
- publishing a decision;
- referring a matter to the Minister for Health (in the case of difficult or persistent breaches); and
- recommending the suspension or expulsion of the offending party to the IPHA board of directors.

Medicines for Ireland (formerly the Irish Generic Medicines Association) is an industry body representing manufacturers of generic and biosimilar medicines.

The Irish Medtech Association has published a Code of Ethical Business Practice that reflects the Code of Ethical Business Practice of MedTech Europe.

Law stated - 25 November 2024

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

The Medicinal Products (Control of Advertising) Regulations 2007 prohibit the supply, offer or promise of any gift, pecuniary advantage or benefit in kind to persons qualified to prescribe or supply medicinal products in the course of promoting medicinal products to those persons, unless it is inexpensive and relevant to the practice of medicines or pharmacy. This does not prohibit the provision of hospitality at sales promotion events or other events for purely professional or scientific purposes, provided such hospitality is reasonable, strictly limited to the main purpose of the event and not extended to persons other than health professionals. There are also restrictions around the provision of free samples to healthcare professionals (HCPs). These provisions do not, however, apply to the negotiation of prices, margins and discounts in the ordinary course of business, provided such prices, margins and discounts are incorporated in the sales invoice as a consequence of such negotiations.

The Code of Practice for the Pharmaceutical Industry Edition 8.5 (IPHA Code) contains similar provisions and more detail around the provision of hospitality, grants and donations and consultancy arrangements with HCPs and healthcare organisations (HCOs).

Law stated - 25 November 2024

Enforcement

22 How are the rules enforced?

The Medicinal Products (Control of Advertising) Regulations 2007 are enforced by the Health Products Regulatory Authority.

Law stated - 25 November 2024

Reporting requirements

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The IPHA Code aims to bring greater transparency to the interaction between pharmaceutical companies, HCPs and HCOs. It contains a set of industry rules relating to the disclosure of transfers of value from pharmaceutical companies to HCPs and HCOs. The IPHA Code provides a template form for the disclosure of transfers of value.

The disclosure rules oblige every member company to document and publicly disclose all transfers of value (subject to certain exceptions) it makes to HCPs or HCOs. These include items such as:

- donations;
- grants;
- consultancy or speaking fees; and
- hospitality, sponsorship or funding for attending medical meetings, conferences or symposiums.

The IPHA Code provides that contractual provisions consenting to disclosure must be incorporated into contracts with HCPs and HCOs.

The disclosure of transfers of value must be made on an annual basis within six months of the end of the reporting period. A reporting period is a full calendar year. The first reporting period was 2015. Disclosures may be made on a company's website, provided that they are unrestricted and publicly available. The information must remain in the public domain for three years.

The IPHA Code provides for two forms of disclosure: individual and aggregate. Individual disclosure is where the monetary amounts attributed to all transfers of value to each clearly identifiable HCP or HCO are disclosed. The IPHA Code provides that, as a preference, individual disclosure should be used, except where certain information cannot be disclosed on an individual basis for valid legal reasons. In those circumstances, the transfers of value can be disclosed on an aggregate basis. Aggregate disclosure is where a company discloses the aggregate amounts attributable to transfers of value under specific categories.

Law stated - 25 November 2024

REGULATION OF HEALTHCARE DELIVERY

Authority powers

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The Health Information and Quality Authority (HIQA) has powers of entry and inspection of premises under its remit. Authorised officers have broad powers, including the power to take copies and remove documents and records, inspect computers and interview patients and staff.

The Medical Council is responsible for investigating complaints about doctors. If a complaint against a doctor is upheld, the Medical Council has the power to impose sanctions such as:

(a) an advice or admonishment, or a censure, in writing;

(b) a censure in writing and a fine not exceeding €5,000;

(c) the attachment of conditions to the practitioner's registration, including restrictions on the practice of medicine that may be engaged in by the practitioner;

(d) the transfer of the practitioner's registration to another division of the register;

(e) the suspension of the practitioner's registration for a specified period;

(f) the cancellation of the practitioner's registration;

(g) a prohibition from applying for a specified period for the restoration of the practitioner's registration.

Law stated - 25 November 2024

Investigation time frames

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The length of an investigation can vary, depending on the complexity of the issue.

HIQA is responsible for undertaking investigations as to the safety, quality and standards of services if it believes there is a serious risk to the health or welfare of a person receiving those services. The Minister for Health may require HIQA to undertake an investigation.

Medical Council investigations of complaints can last for months or years, depending on the issues being considered. The Medical Council provides an online and postal complaints procedure, and any person can complain to the Medical Council about a doctor through this forum.

Law stated - 25 November 2024

Access to investigation materials

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

In the case of complaints to the Medical Council, a doctor is provided with the core evidence during the investigation process, including witness statements and expert reports, and is allowed an opportunity to comment on new evidence.

Law stated - 25 November 2024

Enforcement agencies

27 Through what proceedings do agencies enforce the rules?

HIQA inspectors engage directly with service providers under its remit to address non-compliance with standards and regulations, including through issuing safety notices. HIQA can prosecute certain summary offences.

The Fitness to Practise Committee of the Medical Council conducts inquiries of complaints about doctors. Hearings are generally held in public. For serious sanction, the Medical Council must apply to the High Court to affirm its decision.

Law stated - 25 November 2024

Sanctions

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

HIQA sets standards for safety and quality in healthcare. It has a monitoring function and carries out investigations as to the safety, quality and standards of healthcare and social care services under its remit. Designated centres under its remit can be de-registered for failure to comply with safety and quality standards.

Under the Health Act 2007, enforcement action may be taken through:

- civil action (refusing registration, imposing new conditions, varying or removing conditions, or cancelling registration); or
- criminal prosecution (fines and (or) imprisonment).

HIQA has powers of entry and inspection of premises under its remit. Authorised officers have broad powers, including the power to take copies and remove documents and records, inspect computers and interview patients and staff.

The Medical Council is responsible for investigating complaints about doctors. If a complaint against a doctor is upheld, the Medical Council has the power pursuant to section 71 of the Medical Practitioners Act 2007 to impose one or more than one of the following sanctions:

(a) an advice or admonishment, or a censure, in writing;

(b) a censure in writing and a fine not exceeding €5,000;

(c) the attachment of conditions to the practitioner's registration, including restrictions on the practice of medicine that may be engaged in by the practitioner;

(d) the transfer of the practitioner's registration to another division of the register;

(e) the suspension of the practitioner's registration for a specified period;

(f) the cancellation of the practitioner's registration;

(g) a prohibition from applying for a specified period for the restoration of the practitioner's registration.

The Nursing and Midwifery Board of Ireland is responsible for investigating complaints about nurses and midwives. If a complaint against a nurse or a midwife is upheld, the Nursing and Midwifery Board has the power pursuant to section 69 of the Nurses and Midwives Act 2011 to impose one or more than one of the following sanctions:

(a) an advice or admonishment, or a censure, in writing;

(b) a censure in writing and a fine not exceeding €2,000;

(c) the attachment of conditions to the nurse's or midwife's registration, including restrictions on the practice of nursing or midwifery that may be engaged in by the nurse or midwife;

(d) the transfer of the nurse's or midwife's registration to another division;

(e) the suspension of the nurse's or midwife's registration for a specified period;

(f) the cancellation of the nurse's or midwife's registration from the register of nurses and midwives or a division of that register;

(g) a prohibition from applying for a specified period for the restoration of the nurse's or midwife's registration in the register of nurses and midwives or a division.

The Dental Council is responsible for investigating complaints about dentists. If a complaint against a dentist is upheld, the Dental Council may decide that the name of the person should be erased from the relevant register or they should be suspended from the register.

Whether or not there is a finding of professional misconduct or unfitness to practise, the Dental Council can also:

- attach such conditions as it thinks fit to the retention of the name of the relevant person on the relevant register; and
- advise, admonish or censure such person in relation to his or her professional conduct.

Law stated - 25 November 2024

Defences and appeals

29 What defences and appeals are available to healthcare providers in an enforcement action?

In relation to HIQA, an appeal of a prosecution for breach of the Health Act 2007 can be brought through the criminal justice system. Designated centres for children or adults with disabilities or the elderly who are refused registration or are deregistered can appeal HIQA's decision to the District Court.

When the Medical Council imposes sanctions such as advice, admonishment or censure in writing, there is no statutory right of appeal, and the only option available is judicial review. If the Medical Council imposes sanctions such as conditions, suspension or cancellation of a doctor's registration, there is a statutory right of appeal to the High Court.

Law stated - 25 November 2024

Minimising exposure

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare providers should familiarise themselves with all rules and guidelines applicable to their activities. Once an enforcement action is under way, the healthcare provider should attempt to remedy the breach and cooperate with the body bringing the action. The healthcare provider should also seek legal advice.

Law stated - 25 November 2024

Recent enforcement activities

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In 2023, HIQA continued to place a focus on safeguarding and human rights, including in the national standards and guidance, and in how services are regulated.

It also carried out 2,189 inspections of health and social care services, including:

- 1,268 inspections of centres for people with disabilities;
- 785 inspections of designated centres for older people;
- 55 ionising radiation inspections in public and private hospitals and dental facilities;
- 48 inspections of children's services; and
- 33 inspections of public acute hospitals under the 'National Standards for Safer Better Healthcare'.

HIQA noted there was a significant increase in escalating regulatory action in relation to nursing homes in 2023 due to serious concerns regarding non-compliance with the regulations and regarding the care and welfare of residents. The Chief Inspection used its power to vary or impose additional conditions of registration of a designated centre on 31 occasions in 2023. Where such conditions do not remedy the situation, the Chief Inspector can decide to cancel or refuse to renew the registration of a designated centre and this power was exercised on a number of occasions in 2023.

The Medical Council must investigate all of the complaints it receives.

Law stated - 25 November 2024

Self-governing bodies

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The Medical Council is the self-governing body for medical practitioners.

The Medical Council has a statutory role in protecting the public by promoting the highest professional standards among doctors practising in Ireland. The Medical Council also sets the standards for medical education and training in Ireland.

Allegations made in respect of a medical practitioner in respect of public protection or a breach of standards is investigated by the Medical Council and its various investigatory committees.

Similar processes exist with the Dental Council of Ireland, the Nursing and Midwifery Board of Ireland, the Pharmaceutical Society of Ireland and the Health and Social Care Professionals Council.

Any proven allegations will result in a sanction.

Law stated - 25 November 2024

Remedies for poor performance

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Typically, government contracts contain performance issue procedures that give contractors multiple opportunities to correct non-compliance. However, where non-compliance persists, it can result in the contractor having to undergo mandatory training, withholding of funding, suspension of certain services or termination of the agreement.

Law stated - 25 November 2024

PRIVATE ENFORCEMENT

Causes of action

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The enforcement of healthcare regulations or laws is generally undertaken by the appropriate regulatory body or a state prosecutor. However, there are some instances where citizens may bring private enforcement actions when they are directly affected by the breach or infringement of that regulation or law; for example, in cases of personal injuries arising out of medical or clinical negligence (malpractice) by a healthcare professional or out of a defective pharmaceutical product or medical device.

Law stated - 25 November 2024

Framework for claims

35 What is the framework for claims of clinical negligence against healthcare providers?

In Ireland, the law of tort governs the framework for clinical negligence claims. To succeed in a clinical negligence action, the plaintiff must prove that a duty of care exists between the plaintiff and a healthcare provider, and that there has been a breach of that duty, causing the plaintiff's injuries.

The principles for establishing breach of duty against a healthcare provider are set out in the seminal case of *Dunne v National Maternity Hospital*. The test is the 'reasonable standard of care', in other words, whether a healthcare practitioner is guilty of such failure as no practitioner of equal status and skill would be guilty if acting with ordinary care. Provided that the practitioner acted in accordance with a practice accepted as proper by a body of responsible opinion within their profession, it does not make them negligent if a separate body would have adopted a different practice. The test acknowledges that there may be a variance of medical opinion within a particular field. However, the practice followed by the practitioner must have been free of any inherent and obvious defects.

The plaintiff must then prove that this breach of duty caused or made a material contribution to the plaintiff's injury. The standard of proof is 'on the balance of probabilities'. However,

in certain circumstances, the doctrine of res ipsa loquitur may be applied. This means that negligence is presumed on the part of the defendant since the object causing injury was under their control. It reverses the burden of proof and places the onus on the healthcare provider to disprove an allegation of negligence.

The Irish courts are not reluctant to penalise public or quasi-public healthcare providers.

In Ireland, damages are awarded to put the plaintiff as far as possible back in the position they would have been had the wrong not occurred. There are two main categories of damages available: general and special damages. General damages compensate for non-pecuniary losses suffered by the plaintiff as a result of the wrongdoing. Such losses include pain and suffering, loss of amenity and loss of expectation of life. Special damages may also be awarded for any financial loss suffered and expense incurred by a plaintiff as a result of the wrongdoing. A claim for special damages is usually formulated based on expenses and liabilities incurred up to the date of trial and future loss, being the estimated anticipated loss, usually based on actuarial evidence. In exceptional circumstances, exemplary or punitive or aggravated damages may also be awarded.

Recent legislative developments in Ireland will have an impact on the management of clinical negligence claims. A pre-action protocol in clinical negligence actions was introduced under the Legal Services Regulation Act 2015 and is expected to be published shortly. The protocol will focus on reducing the number of claims, early resolution of claims, early identification of issues and promoting timely communication between parties.

Clinical negligence claims will also be affected by amendments to the rules of the court. The new rules provide that personal injuries claims, including clinical negligence actions, may be time managed by the court with a trial judge making orders as to time limitations and the manner in which a case is presented. There is a marked emphasis in both the protocol and the new rules on the expedient resolution of clinical negligence claims.

Furthermore, the Mediation Act 2017 came into force on 1 January 2018. The Act obliges solicitors to provide advice and information on mediation prior to initiating proceedings, and allows the court to invite parties to a dispute to consider mediation and take an unreasonable refusal to engage in mediation into account when making an order on costs. This reflects a general shift towards facilitating methods of alternative dispute resolution and attempting to minimise the quantity of cases that reach trial.

Law stated - 25 November 2024

Seeking recourse

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

The purchaser or a user of pharmaceuticals or devices can seek recourse for regulatory and legal infringements through the Irish courts, for example, under product liability rules. In Ireland, liability for defective products falls under four main headings: statute, tort, contract and criminal. The principal product liability statute is the Liability for Defective Products Act 1991. This Act supplements the remedies in tort and contract and provides for a strict liability regime, making a producer of the defective product liable in damages in tort for

damage caused wholly or partly by a defect in the product. A purchaser or user may also sue in tort for any reasonably foreseeable damage caused to them, or in contract where the pharmaceutical or device was not of merchantable quality. A business cannot limit liability for death or personal injury.

It is also open to the purchaser or user of a pharmaceutical product or a device to make a complaint to the Health Products Regulatory Authority. Furthermore, any proposed recall of medical products must be notified to the Health Products Regulatory Authority (HPRA). The HPRA also has the power to order a recall under the Manufacturing Regulations.

Law stated - 25 November 2024

Compensation

37 | Are there any compensation schemes in place?

In Ireland, compensation schemes have been set up in circumstances where an organ of the state may have liability. Such schemes are ad hoc, rather than statutorily required.

The State Claims Agency manages these schemes. Examples of compensation schemes include the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with hepatitis C, having been transfused with infected blood products during pregnancy. In July 2013, the government approved the establishment of the Lourdes Hospital Redress Scheme, to compensate former patients of an obstetrician who performed unnecessary surgeries. More recently, a state compensation scheme was set up for women seeking damages in respect of symphysiotomy operations carried out between 1945 and 1982.

In 2020, the Minister for Health established the CervicalCheck Tribunal. This Tribunal had the jurisdiction to hear and determine a certain limited number of claims arising in respect of the state's cervical screening programme. With the consent of the parties concerned, it provides an alternative legal mechanism, outside of the court process, for the hearing and determination of eligible claims. Its determinations are subject to confirmation by the High Court and parties enjoy a right of appeal.

Law stated - 25 November 2024

Class and collective actions

38 | Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The EU Directive on Representative Actions for the Protection of the Collective Interests of Consumers (RAD) requires EU member states, by June 2023, to fully implement its terms. The RAD will enable consumers to seek collective redress when they claim to have been harmed by a business through breaches of certain European consumer laws.

The Representative Actions for the Protection of the Collective Interests of Consumers Act 2023 signed into law in Ireland on 11 July 2023 and was commenced on 30 April 2024. This Act allows for representative actions to be brought on behalf of groups of consumers by designated qualified entities (QEs) in respect of infringements of a wide range of EU consumer protection laws in areas such as financial services, data protection, medical devices and telecommunications. Representative actions can only be brought in relation to alleged breach of a 'relevant enactment', which are various pieces of consumer-focussed EU law. The Schedule of the 2023 Act sets out the specific legislative enactments that are classified as 'relevant enactments' for the purposes of the Act.

A consumer can apply to be part of a representative action through the submission of a prescribed form and payment of the prescribed fee to the QE. Under Irish law, the prescribed fee cannot exceed €25 per consumer per representative action. Individual consumers will not be liable to pay the costs of the proceedings, this is the obligation of the QE. The consumer is, however, entitled to the benefit of any relief granted by the court and the consumer will be bound by the outcome of the representative action.

Law stated - 25 November 2024

Review

39 Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Judicial review proceedings are heard in the High Court. Judicial review in Ireland is a two-stage process, comprising:

- an application to the High Court for permission to bring judicial review proceedings; and
- the substantive hearing.

The time limit for commencing judicial review proceedings can vary depending on the applicable legislation; however, typically, an application for leave to apply for judicial review must be made within three months from the date when the grounds for the application first arose. The Irish courts apply a 'sufficient interest' test to determine whether a party bringing judicial review proceedings has the requisite standing to litigate. However, the courts apply this test liberally. In judicial review, the High Court's primary focus is not whether the public entity made the right decision, but to see that the decision was made in the proper manner. The common grounds for judicial review include that there has been an error of law, a procedural error, lack of fair procedures, an error of fact or, in limited circumstances, that the decision is manifestly unreasonable. The High Court can quash the decision or remit the decision back to the public entity to be re-decided.

Law stated - 25 November 2024

Whistleblowers

40 | Are there any legal protections for whistleblowers?

While Irish legislation contains provisions for whistleblower protection in relation to discrete offences, the principal protections are contained in the Protected Disclosures Act 2014, which protects workers in circumstances where they report suspicions of illegal activity.

Where a worker makes a protected disclosure, the employer in question is prevented from:

- dismissing or penalising the worker;
- taking an action for damages or an action arising under criminal law; or
- disclosing any information that might identify the person who made the disclosure.

The Act also makes provision for a cause of action in tort for the worker for detriment suffered because of making a protected disclosure.

However, a disclosure is only considered to be a 'protected disclosure' when it is a disclosure of information, made by a worker, which in their reasonable belief tends to show a 'relevant wrongdoing' and came to their attention in connection with their employment. A relevant wrongdoing is broadly defined as relating to:

- the commission of an offence;
- non-compliance with a legal obligation (except one arising under the worker's employment contract);
- a miscarriage of justice;
- endangerment of health and safety;
- damage to the environment;
- misuse of public funds;
- mismanagement by a public body; or
- concealing or destroying information relating to any of the above.

The definition of 'worker' is very broad and covers employees (including temporary and former employees), interns, trainees, contractors, agency staff and consultants.

If the protected disclosure is part of an unfair dismissals claim by the worker, and a Workplace Relations Commissioner finds in favour of the worker, the worker can require the employer to pay them compensation of up to 260 weeks' remuneration.

While the motivation for making the disclosure is irrelevant, these protections are not available to those who deliberately make false disclosures, as these are not considered to meet the test for having a 'reasonable belief' that a wrongdoing has occurred.

Law stated - 25 November 2024

41 | Does the country have a reward mechanism for whistleblowers?

The purpose of the Protected Disclosures Act 2014 is to protect workers who make protected disclosures from penalisation. Consequently, there is no reward mechanism for

whistleblowers in the Act. However, in relation to competition law, the Irish Competition and Consumer Protection Commission operates an immunity programme for members of a cartel who confess their involvement in breaches of the Competition Act 2002 (as amended). To benefit from this immunity, a number of requirements must be met, most notably that the whistleblower is the first member of the given cartel to have satisfied the requirements.

Law stated - 25 November 2024

42 | Are mechanisms allowing whistleblowers to report infringements required?

Under the Protected Disclosures Act 2014, public sector bodies must put whistleblowing policies in place. While there is no such requirement for private sector businesses, such policies are strongly recommended.

Law stated - 25 November 2024

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 | Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. For example, the Health Products Regulatory Authority (HPRA), the Irish Revenue Commissioner's Customs Service and the Irish police took part in Operation Pangea X, which is an international campaign that targets the sale of falsified medicines online.

Law stated - 25 November 2024

Triggering investigations

44 | In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

This is determined on a case-by-case basis. The Health Products Regulatory Authority will take enforcement activities by foreign authorities into account when deciding whether an investigation is required.

A complaint can be made to the Medical Council about a medical practitioner on the grounds of a conviction outside of Ireland that would constitute an indictable offence in Ireland.

Law stated - 25 November 2024

Pursuing foreign entities for infringement

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Enforcement of Irish healthcare laws is applied to offences committed in Ireland, and whether foreign companies or nationals are pursued will depend on who is the offender. If the entity does not have an establishment in Ireland, prosecution can be more difficult.

Law stated - 25 November 2024

UPDATE AND TRENDS

Key developments of the past year

46 What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

The Health Products Regulatory Authority's (HPRA) legislative changes will occur over the next few years, with the implementation of EU regulations on clinical trials, veterinary medicines, medical devices and in-vitro diagnostics, and each regulation will impact significantly on the operation of the relevant regulatory system. For the HPRA, these constitute major projects that require contribution to national legislation, extensive engagement with all stakeholders and development of information resources for those affected by the legislation. The European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 requires that, by 31 January 2025, all clinical trials must be transitioned to the Clinical Trial Regulation, which aims to balance the creation of a favourable environment for conducting clinical trials in the European Union while maintaining high standards of patient safety.

The Health Information and Quality Authority's (HIQA) corporate plan 2022–2024 outlines that they will continue to address the outcomes and recommendations of the Nursing Home Expert Panel on covid-19. This will include an expanded and more diverse programme of inspections across nursing homes and residential disability services. HIQA will also build on its successful National Care Experience Programme, with the introduction of a survey of nursing home residents and their relatives, as well as a survey on end-of-life care across acute, community and other home-based services. In addition, HIQA will continue to undertake a programme of evidence synthesis to assist with the government's policy formation as we continue to respond to the impact of covid-19 on our health and social care services.

The Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023 took effect on 26 September 2024. The Act aims to strengthen openness and transparency in the Irish healthcare system and applies to both public and private healthcare services. The Act creates an obligation to disclose certain patient safety incidents, called 'notifiable incidents', to patients and (or) their families in an open and timely manner. The Act also mandates notification of notifiable incidents to the relevant regulatory body. Information disclosed as part of this process cannot be used for certain legal or regulatory purposes.

The Human Tissue (Transplantation, Post-Mortem, Anatomical Examination and Public Display) Act 2024, once commenced, will create an opt-out system for organ donation, will introduce regulations for post-mortem examinations and will empower HIQA to inspect hospital-based mortuary services.

Law stated - 25 November 2024

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OVERVIEW

Healthcare funding

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In Japan, under the universal healthcare insurance system designed by the government, all Japanese citizens are covered by public health insurance. Under this system, Japanese citizens receive high-quality medical treatments at relatively low cost from healthcare providers and facilities of their choice. While there are several types of public health insurance systems, Employees' Health Insurance (EHI) and National Health Insurance (NHI) are the most commonly used. The EHI covers employees employed by the public sector and private entities and the NHI covers individual businesses (including the self-employed) and the unemployed.

The universal healthcare insurance system is funded by insurance premiums, subsidies from central and local governments, and co-payments from patients. Patients generally pay between 10 per cent and 30 per cent of their medical costs.

Law stated - 12 November 2024

Delivery

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

The type of healthcare insurance system or the health insurer a resident of Japan decides to use does not limit the choice of healthcare provider. Healthcare for residents is provided by both public and private hospitals. Under the universal health insurance system, Japanese citizens are free to choose their healthcare providers and facilities.

Law stated - 12 November 2024

Key legislation

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

The Health Insurance Act and the Mutual Aid Association Act govern EHI, and the National Health Insurance Act governs NHI. The Minister of Health, Labour and Welfare has the authority to decide the Uniform Fee Schedule, which sets the fees that the health insurance system will pay to a healthcare provider for each healthcare service. The minister, in consultation with the Central Social Insurance Medical Council, revises the Uniform Fee Schedule every two years.

The Medical Practitioners' Act and the Medical Care Act are the two key pieces of legislation that regulate the provision of healthcare. The Rules for Professionals in Charge of Healthcare Services under the Health Insurance Programs are also relevant, as they provide for the rules applicable to healthcare providers covered by the health insurance system.

Law stated - 12 November 2024

Responsible agencies

4 | Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The Ministry of Health, Labour and Welfare (MHLW), is responsible for the enforcement of the laws and rules applicable to the delivery of healthcare. The public health centres established by local governments also play important roles in maintaining public health and in regulating the provision of healthcare.

Law stated - 12 November 2024

Scope of enforcement

5 | What is the scope of their enforcement and regulatory responsibilities?

Generally, the MHLW deals with nationwide issues, while public health centres deal with regional and local public issues.

Law stated - 12 November 2024

Regulation of pharmaceutical products and medical devices

6 | Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The MHLW is responsible for the regulation of pharmaceutical products and medical devices. Some of its power and activities have been delegated to local governments (such as prefecture governors) and the Pharmaceuticals and Medical Devices Agency (PMDA).

Law stated - 12 November 2024

Scope of enforcement

7 | What is the scope of their enforcement and regulatory responsibilities?

The MHLW deals with nationwide issues relating to pharmaceutical products and medical devices and local governments deal with regional and local issues regarding the same. The PMDA deals with or assists the MHLW in:

- the review of applications for marketing approval for drugs, medical devices, and cellular and tissue-based products;
- implementing post-marketing safety measures; and
- providing relief services for adverse health effects that were caused by reactions to pharmaceuticals.

Local governments are also given authority over certain matters, for example, licensing and supervision of pharmacies, and monitoring of compliance with regulations on drugs and devices.

Law stated - 12 November 2024

Other agencies

8 Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices provides for criminal penalties for certain violations. Therefore, prosecutors have the primary authority in deciding whether to prosecute criminal cases for violations of this act.

Competition and securities regulators also have jurisdiction over business activities related to pharmaceuticals and medical devices, to the extent that these business activities violate relevant competition and other laws.

Law stated - 12 November 2024

Simultaneous investigations

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

This is decided on a case-by-case basis. In Japan, various government agencies typically act in close consultation and cooperation with each other.

Law stated - 12 November 2024

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

The Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the PMD Act) authorises the Ministry of Health, Labour and Welfare (MHLW), itself or through the Pharmaceuticals and Medical Devices Agency (PMDA), to require marketing authorisation holders and manufacturers to submit reports and, more importantly, issue inspection orders to marketing authorisation holders and manufacturers. The MHLW (or the PMDA) carries out inspections of marketing authorisation holders and manufacturers' facilities, offices and other sites where the companies carry out business, interviews employees, inspects books and records, and tests drug samples to monitor compliance with the laws and regulations.

The MHLW also has the power to issue orders to marketing authorisation holders and manufacturers to improve their manufacturing controls, quality controls or post-marketing safety controls, or to suspend their operations until a required improvement is implemented.

In certain cases, local governments, such as prefectural governors and city or ward mayors, have the authority to require certain marketing authorisation holders, manufacturers, sellers of drugs and devices (such as pharmacies and store-based distributors) and clinics and hospitals to submit reports, and to conduct site inspections, interview employees, inspect books and test drug samples. In certain cases, the prefectural governors may issue orders for these entities to improve their facilities if those facilities fail to meet certain standards.

Law stated - 12 November 2024

Investigation time frames

11 How long do investigations typically take from initiation to completion? How are investigations started?

There is no typical length of time for investigations as they depend on the facts of each case. Investigations are usually initiated by regulators, especially if they involve matters that are considered important to Japanese society or are government priorities, or when regulators receive information of wrongdoing from whistleblowers or complaints from consumers.

Law stated - 12 November 2024

Access to investigation materials

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

Generally, under the Act on Access to Information Held by Administrative Organisations, the subject of an investigation has the right to access administrative documents, such as documents relating to an administrative investigation. The administrative authority that

receives a request for disclosure of administrative documents is obligated to disclose those documents, unless they fall within information specifically excluded by article 5 of the Act. Excluded information includes personal information concerning individuals, and information that, if made public, may pose a threat or risk to state security, prevention or investigation of crimes, maintenance of prosecutions and other matters concerning public safety and public order.

Law stated - 12 November 2024

Investigations abroad

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes, the MHLW has the authority to conduct the same investigations it can conduct on domestic authorisation holders, and the MHLW conducts investigations outside Japan from time to time.

Law stated - 12 November 2024

Enforcement proceedings

14 Through what proceedings do agencies enforce the rules?

The regulators hold their own proceedings and investigations, which are administrative in nature. They do not need to apply to the courts before initiating and carrying out those investigations.

However, with respect to certain violations that are punishable by criminal penalties, investigations are initiated by a prosecutor's office as they are criminal in nature. Generally, prosecutors do not need to apply to the courts to conduct their investigations, although they need to apply to the courts for warrants to conduct searches.

Law stated - 12 November 2024

Sanctions

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

In certain cases, the MHLW and the local governments have the authority to issue orders to improve manufacturing control, quality control or facilities, and to suspend business operations of, or the use of facilities by, manufacturers and distributors until necessary improvements are made. They also have the authority to order manufacturers and distributors to dispose of, recall or take other measures to prevent hazards to public

health and hygiene caused by drugs and devices that do not meet the required standards. More importantly, they have the power to cancel the authorisation given to manufacturers and distributors to provide pharmaceuticals, quasi-drugs, cosmetics, medical devices or regenerative medicine products.

The PMD Act imposes penalties consisting of fines or imprisonment, or both, on certain violations of the PMD Act and its regulations by manufacturers and distributors.

Law stated - 12 November 2024

Actions against employees

16 | Can the authorities pursue actions against employees as well as the company itself?

An officer or employee who directly violates the PMD Act is subject to fines or imprisonment, or both. Furthermore, the representative and employees of the company may also be subject to fines along with the company.

Additionally, under the PMD Act, the MHLW may order manufacturers and distributors to change certain supervisor-level employees if they are found to be inappropriate as supervisors or technical supervisors or if they are found to have violated the PMD Act. These supervisors include the marketing supervisor-general of pharmaceuticals or medical devices, manufacturing supervisors of pharmaceuticals and technical supervisors of medical devices.

The MHLW may order pharmacies, or proprietors, sellers or lessors of drugs or devices to change the supervisors of pharmacies or certain managerial-level employees of such establishments, if these employees are found to be inappropriate or if they are found to have violated the PMD Act.

Law stated - 12 November 2024

Defences and appeals

17 | What defences and appeals are available to drug and device company defendants in an enforcement action?

If a person is dissatisfied with an agency's decision, that person may file a request for a review or re-examination of this decision with that agency in accordance with the Administrative Complaint Review Act. If such a filing is made, the relevant agency will examine its decision-making process and whether any error was made in the process or in its decision.

If a person wishes to cancel an agency's decision, that person may file a suit in court against the agency to ask the court to cancel the decision in accordance with the Administrative Case Litigation Act.

Law stated - 12 November 2024

Minimising exposure

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

One recommendation is for companies to establish and implement internal policies and systems on regulatory compliance, and to have a robust system of regular checks and audits to make sure that these policies and systems are being complied with by everyone in the company. Companies are encouraged to have more open working environments to encourage employees and officers to report irregularities or possible violations of the standards and requirements of the PMD Act, or of any other laws or regulations.

Law stated - 12 November 2024

Recent enforcement activities

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

Regulators have issued orders for improvements, and have suspended certain business operations for failure to comply with these improvement orders in a timely manner.

Law stated - 12 November 2024

Self-governing bodies

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The major self-governing bodies include the Japan Pharmaceutical Manufacturers Association (JPMA) and the Japan Federation of Medical Devices Associations (JFMDA). These self-governing bodies and associations have issued practice standards, compliance guidelines, codes of practice, promotion codes and transparency guidelines that their members are expected to follow.

The JPMA consists of around 70 companies and is a member of the Federation of Pharmaceutical Manufacturers' Associations of Japan, which consists of 15 industrial organisations and 16 regional organisations. It deals with inquiries and complaints and imposes improvement measures on violating members in accordance with its internal regulations.

The JFMDA consists of 21 associations (which represent about 4,280 companies), associate members' organisations and individual companies. If the JFMDA receives complaints of possible violations of one of its codes by a member, it will investigate and examine whether a violation exists. If it determines that such a violation exists, it will notify the violating member to comply with the code. The JFMDA's members are obliged to cooperate with investigations conducted by the JFMDA's committees.

Law stated - 12 November 2024

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are fair competition codes for drugs as well as for medical devices that aim to prevent unfair inducement of customers by restricting unjustifiable premium offers and to ensure fair competition and order within the industry. For example, the Japan Fair Trade Council of the Medical Devices Industry has issued the Fair Competition Code of the Medical Devices Industry in Japan; and, in the pharmaceutical industry, the Japan Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry has issued the Fair Competition Code concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry.

Industrial groups such as the Japan Pharmaceutical Manufacturers Association (JPMA) also issue their own guidelines or codes of ethics and practice to guide their members. For example, the JPMA has its Code of Practice, which provides the principal rules that pharmaceutical manufacturers must comply with in their activities, including the promotion of drugs. The JPMA also issues Transparency Guidelines that require pharmaceutical manufacturers to disclose certain financial relationships in research and development activities with medical institutions.

Law stated - 12 November 2024

Enforcement

22 How are the rules enforced?

Each industry's Fair Trade Council operates the relevant fair competition codes. The relevant industrial group enforces industry guidelines or best practice standards.

Law stated - 12 November 2024

Reporting requirements

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The Transparency Guidelines of the JPMA require pharmaceutical companies to disclose financial relationships with medical institutions. In addition, under the Clinical Research Law, which was enacted on 1 April 2018, pharmaceutical and medical device companies

are required to disclose if they provide funding for clinical research conducted on their products by medical institutions.

Law stated - 12 November 2024

REGULATION OF HEALTHCARE DELIVERY

Authority powers

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Under the Medical Practitioners' Act, when the Minister of Health, Labour and Welfare finds that it is necessary to investigate whether a disposition should be made regarding a medical practitioner under the Act, he or she may seek the opinion of, and collect reports from, persons who are connected with the circumstances in question or from witnesses; may order owners of medical records or other articles to submit those records and articles; and may have its officials enter a hospital or any other location that is connected with the relevant circumstances and inspect medical records and other articles.

Law stated - 12 November 2024

Investigation time frames

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

There is no typical length of time for investigations as they depend on the facts of each case. Investigations usually start upon the initiative of the regulators, especially in areas which are considered important to Japanese society or government priorities, or when regulators receive information of wrongdoing from whistleblowers or complaints from consumers.

Law stated - 12 November 2024

Access to investigation materials

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

Generally, under the Act on Access to Information Held by Administrative Organisations, the subject of an investigation has the right to access administrative documents, such as documents relating to an administrative investigation. The administrative authority that receives a request for disclosure of administrative documents is obligated to disclose those documents, unless they fall within information specifically excluded by article 5 of the Act. Excluded information includes personal information concerning individuals and information that, if made public, may pose a threat or risk to state security, prevention or investigation

of crimes, maintenance of prosecutions, and other matters concerning public safety and public order.

Law stated - 12 November 2024

Enforcement agencies

27 | Through what proceedings do agencies enforce the rules?

Regulators hold their own proceedings and investigations, which are administrative in nature. They do not need to apply to the courts before initiating and carrying out such investigations.

However, with respect to certain violations that are punishable by criminal penalties, these investigations are initiated by a prosecutor's office as they are criminal in nature. Generally, prosecutors do not need to apply to the courts to conduct their investigations, although they need to apply to the courts for warrants to conduct searches.

Law stated - 12 November 2024

Sanctions

28 | What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Under the Medical Practitioners' Act, if a medical practitioner acts in a way that damages his or her respectability as a medical practitioner, the Ministry of Health, Labour and Welfare (MHLW) may issue an order admonishing the medical practitioner, suspending him or her from medical practice for up to three years, or revoking his or her licence.

Additionally, it is necessary for healthcare providers to obtain insurance authorisation from the MHLW because healthcare insurance held by each patient only applies to services provided by healthcare providers that have that insurance authorisation. If a healthcare provider violates the Health Insurance Act and other laws and regulations related to insurance, the MHLW has the authority to cancel its insurance authorisation.

Criminal penalties consisting of fines or imprisonment may be imposed in the case of violation of certain provisions of the relevant laws.

Law stated - 12 November 2024

Defences and appeals

29 | What defences and appeals are available to healthcare providers in an enforcement action?

If a person is dissatisfied with an agency's decision, that person may file a request for a review or re-examination of this decision with that agency in accordance with the Administrative Complaint Review Act. If such a filing is made, the relevant agency will examine its decision-making process and whether any error was made in the process or in its decision.

If a person wishes to cancel an agency's decision, that person may file a suit in court against the agency to ask the court to cancel the decision in accordance with the Administrative Case Litigation Act.

Law stated - 12 November 2024

Minimising exposure

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

One recommendation is for companies to establish and implement internal policies and systems on regulatory compliance, and to have a robust system of regular checks and audits to make sure that these policies and systems are being complied with by everyone in the company. Companies are encouraged to have more open working environments to encourage employees and officers to report irregularities or possible violations of the standards and requirements of the Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, or any other laws or regulations.

Law stated - 12 November 2024

Recent enforcement activities

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

The authorities have focused on improper billing and false claims under healthcare insurance, which are among the most common forms of misconduct committed by healthcare providers.

Law stated - 12 November 2024

Self-governing bodies

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

The Japan Medical Association (JMA) is the largest physicians' organisation in Japan. It has about 167,000 members, or about 60 per cent of all licensed physicians in Japan.

Under its internal regulations, the JMA may expel any member who violates the JMA's ethical standards or internal regulations.

Law stated - 12 November 2024

Remedies for poor performance

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Not applicable.

Law stated - 12 November 2024

PRIVATE ENFORCEMENT

Causes of action

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Enforcement actions in case of breach of healthcare regulations are generally conducted by either the Ministry of Health, Labour and Welfare or a prosecutor's office. Citizens or other private bodies may file civil actions against healthcare providers only in accordance with the framework of torts or breach of contract if they are directly affected by a healthcare provider's actions, negligence or decisions.

Law stated - 12 November 2024

Framework for claims

35 What is the framework for claims of clinical negligence against healthcare providers?

Civil actions for medical injury against healthcare professionals may be based on either torts or non-performance of contract, both of which are provided for under the Civil Code. In order to prove liability, a patient must establish the doctor's negligence, the damage to the patient's life, body or property, and the causation between the negligence and the damage.

The applicable standards are essentially the same under either theory. Japanese courts generally consider the standard of care that is expected of a healthcare professional to be the standard prevailing in clinical medical practice at the time of the treatment, considering various circumstances such as the specialisation, size, functions or resources of the relevant medical facility and its personnel.

Damages awarded in medical injury cases are standardised in accordance with levels of severity of injuries, out-of-pocket medical expenses that were or will be incurred, the

present amount of expected earnings of the injured person, and a standardised amount for mental suffering. Punitive damages are not available under Japanese law.

Law stated - 12 November 2024

Seeking recourse

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Purchasers or users of pharmaceuticals or medical devices may seek liability against any person who manufactured, processed or imported the pharmaceuticals or the devices, if they can establish a defect in the product, damage to their life, body or property, and the causation between the defect and the damage. The injured person is not required to prove negligence with respect to a defect. 'Defect' is defined under the Product Liability Act as a lack of safety that the product ordinarily should provide, considering the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the product was delivered and other circumstances concerning the product. There are three categories of defects: defect in manufacture, defect in design, and defect in instructions or warnings.

Law stated - 12 November 2024

Compensation

37 Are there any compensation schemes in place?

The Pharmaceuticals and Medical Devices Agency has drawn up a compensation scheme called the Relief System for Adverse Drug Reactions, which provides relief benefits and compensation relating to damage to one's health, body and life, such as diseases and disabilities requiring hospitalisation that were caused by adverse reactions to prescription drugs, over-the-counter drugs and certain other products, even if the drugs were properly used. This scheme started in May 1980 and covers medical expenses and allowances, disability pensions, funeral expenses and bereaved family compensation.

Law stated - 12 November 2024

Class and collective actions

38 Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

In Japan, the concept of class litigation does not have a long history. However, in October 2016, the Act on Special Measures concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers came into force. This Act introduced a new type of litigation that allows for the filing of certain collective consumer actions to seek damages.

Under this Act, a specified qualified consumer organisation (SQCO) may file a lawsuit that demands the declaration of payment obligations commonly owed by a business operator to consumers in certain categories of cases. If the SQCO prevails, then the SQCO may file a petition for a special proceeding to obtain an order from the court regarding the substance and amount of each claim of target consumers. However, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, and mental suffering are expressly excluded from the scope of claims that can be brought by an SQCO. Therefore, this collective action will have limited influence on the practice of bringing legal actions in cases related to drugs, medical devices and the provision of care.

Law stated - 12 November 2024

Review

39 | Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Not applicable.

Law stated - 12 November 2024

Whistleblowers

40 | Are there any legal protections for whistleblowers?

The Whistleblower Protection Act protects persons who expose information pertaining to certain criminal conduct or statutory violations from unfair treatment as a result of their disclosure. Under this Act, whistleblowers who uncover information on criminal or unlawful acts at their place of employment and inform their employers of the information are protected from retribution in the form of dismissal, demotion, salary cuts, termination of dispatch arrangement and other disadvantages. If whistleblowers expose information to a third party, they only enjoy statutory protection if they meet certain conditions, such as that evidence would likely be destroyed or that the employer failed to notify a whistleblower within 20 days that it will investigate the complaint.

Law stated - 12 November 2024

41 | Does the country have a reward mechanism for whistleblowers?

There is no reward mechanism for whistleblowers.

Law stated - 12 November 2024

42 | Are mechanisms allowing whistleblowers to report infringements required?

There are no legal requirements for the establishment and implementation of such mechanisms. However, the Whistleblower Protection Act imposes certain mandatory obligations upon private and public organisations upon receipt of a report from a whistleblower. An employer must notify a whistleblower in writing and without delay as to what steps it will take to remedy the problem or whether there is insufficient evidence to support the complaint. Government agencies must respond by investigating the whistleblower's complaint and taking any necessary remedial action.

Law stated - 12 November 2024

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) collaborate with foreign authorities, such as the US Food and Drugs Administration and the European Medicines Agency, on various activities, such as good manufacturing practice inspections.

Law stated - 12 November 2024

Triggering investigations

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

The MHLW and PMDA collaborate with foreign authorities when necessary. Memoranda and confidentiality arrangements have been executed by Japan with certain countries to ensure effective collaboration. This collaboration includes the exchange of information between the Japanese authorities and their foreign counterparts.

Law stated - 12 November 2024

Pursuing foreign entities for infringement

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

In principle, the Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices does not apply outside Japan. However, if a foreign company holds a marketing approval or authorisation in Japan, such an approval or authorisation may be cancelled, which would prevent the company or its distributor from manufacturing or distributing the product in Japan.

Law stated - 12 November 2024

UPDATE AND TRENDS

Key developments of the past year

46 What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

Now that the worst effects of the covid-19 pandemic appear to be behind us, discussions on the new healthcare legislation, which had been slower during the pandemic, are expected to accelerate again. One of the new legislations attracting market attention is an amendment to the Cannabis Control Law, which enables the marketing of certain drugs containing ingredients extracted from cannabis.

Law stated - 12 November 2024

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UPDATE AND TRENDS

Key developments of the past year

OVERVIEW

Healthcare funding

1 In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

The Ministry of Health governs the health system in Mexico. The Mexican healthcare system comprises public (social security institutions) and private institutions, insurers and independent professionals.

The public sector comprises:

- social security institutions, which exclusively attend to formal workers, the funding of which comes from contributions by the federal government, employers and employees, such as:
    - the Mexican Institute of Social Security (IMSS), which provides social security for the self-employed and employees in private companies;
    - the Institute of Social Security for State Workers (ISSSTE);
    - specialised public institutions for members of the armed forces; and
    - PEMEX Medical Services, for Mexican petroleum workers; and
- public institutions exclusively directed to attend people not covered by social security and which are funded by the federal government and states (although in certain cases patients may be required to pay a contribution, taking into account their financial means and the cost of services).

The public health sector normally faces financial problems and implements measures to limit costs by, for example, pressing for price reductions in consolidated public tenders (involving the most important health institutions) and encouraging competition.

Individuals and private insurers fund the private sector. Private health insurance generally covers professional, executive and higher levels of the private sector. 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, insurance and drug acquisitions.

In the public sector, social security and public institutions provide medicines directly to the public at no cost.

Social security institutions, such as the IMSS and ISSSTE, are responsible for delivering medicines to their beneficiaries. After a medical appointment, the treating doctor delivers a prescription with a validity period that varies depending on the type of condition. To obtain medication free of charge, the patient must present a valid prescription to the pharmacy of the institution itself or any pharmacy designated by the institution.

Public health institutions for people who do not have social security aim to deliver free medical care and medicines, although patients may be required to contribute personally under certain conditions. To date, there are no reports indicating that the Institute of Health for Welfare (INSABI) users are being charged for medication.

On 30 May 2023, the 'Decree reforming, adding, and repealing various provisions of the General Health Law, to regulate the Health System for Welfare' came into effect, establishing the dissolution of INSABI and providing that the functions of INSABI will become part of the Mexican Institute of Social Security for Welfare (IMSS-Bienestar), which, in collaboration with the Ministry of Health, will be the decentralised entity in charge of providing free health services, medicines and other supplies to people without social security in Mexico.

Law stated - 7 October 2024

Delivery

2 In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

In the public sector, employers have the obligation to enrol their workers in the corresponding regime and to pay the required fees so that their beneficiaries can have access to health institutions. It is the obligation and responsibility of the beneficiary to personally carry out the registration procedures in the family medicine unit of initial care that corresponds to them according to their domicile, where they are assigned a general practitioner. Healthcare is structured by levels and includes first, second and third levels, including the free supply of medicines.

At the first level, health promotion, prevention and ambulatory care actions are carried out, provided by general or family doctors and nursing staff. The second level of care is provided essentially in hospitals, with outpatient and inpatient services by specialist doctors. At the third level, specialist care of greater complexity is carried out, as well as clinical investigations by specialist doctors with the support of other professionals.

In the public sector, social security and public institutions provide medicines directly to the public at no cost. Each institution is responsible for the delivery of medications to its beneficiaries. After a medical appointment, the treating doctor delivers a prescription where the number and quantity of medications to be prescribed to the patient will be determined. In all cases, these prescriptions have a validity period to be claimed at the corresponding institution, depending on the type of condition. With a valid prescription, the patient must go to the pharmacy of the institution itself or those alternates designated by each institution so that the medication is delivered at no cost, as the provision of medicines to the beneficiaries of these institutions is completely free. In many cases, the federal or state governments contract with private third parties for the delivery of health services.

Private health services vary depending on whether or not the patient has contracted private health insurance, the chosen hospital unit, the insurer and the coverage of the chosen policy.

Law stated - 7 October 2024

Key legislation

3 Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Key legislation includes the following:

- the General Health Law;
- the General Health Law Regulations;
- the Health Supplies Regulation;
- the Official Mexican Standards (NOMs);and
- the Mexican Pharmacopoeia.

Law stated - 7 October 2024

Responsible agencies

4 Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

The regulatory authorities in this field are the following.

Federal Commission for Protection against Sanitary Risk

Until recently, the Federal Commission for Protection against Sanitary Risk(COFEPRIS) was a decentralised agency of the Ministry of Health, in charge of the control and surveillance of all aspects related to sanitary regulation (in connection with drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides, clinical studies, etc). COFEPRIS had administrative, technical and operational autonomy, as well as its own legal personality and assets. It is now under the authority of the Undersecretary for Prevention and Promotion of Health. The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

General Health Council

The General Health Council is an agency controlled by the Executive and is funded by the federal government.

Law stated - 7 October 2024

Scope of enforcement

5 What is the scope of their enforcement and regulatory responsibilities?

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and their importation and exportation;
- the sanitary control of the processing, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

The General Health Council is responsible for:

- preparing, updating and circulating the National Compendium of Health Supplies through the creation of groups of experts from all public health institutions, which decide on the inclusion of new medicines, therapies, devices and other products in the compendium;
- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests of medicines that are submitted to COFEPRIS for the granting of marketing authorisations of generics.

Law stated - 7 October 2024

Regulation of pharmaceutical products and medical devices

6 Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The regulatory authorities in this field are the following.

COFEPRIS

Until recently, COFEPRIS was a decentralised agency of the Ministry of Health, in charge of the control and surveillance of all aspects related to sanitary regulation (in connection with drugs, medical devices, health services, food supplements, food and beverages, cosmetics, pesticides, clinical studies, and so on). COFEPRIS had administrative, technical and operational autonomy, as well as its own legal personality and assets. COFEPRIS is now under the authority of the Undersecretary for Prevention and Promotion of Health. The General Health Law entitles COFEPRIS to recover income derived from insurance rescue and other exceptional incomes.

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Scope of enforcement

7 | What is the scope of their enforcement and regulatory responsibilities?

The General Health Council is in charge of the following:

- preparing, updating and circulating the National Compendium of Health Supplies through the creation of groups of experts from all public health institutions, which will decide on the inclusion of new medicines, therapies, devices and other inputs;
- preparing and updating the Guidelines for the Evaluation of Health Supplies; and
- preparing the Guidelines for Interchangeability Tests for medicines that will be submitted before COFEPRIS for the granting of marketing authorisation as generics.

In accordance with the General Health Law, COFEPRIS is in charge of the following:

- the sanitary regulation, surveillance and control of public social security institutions and private institutions;
- the sanitary control of products and services, and their importation and exportation;
- the sanitary control of the processing, use, maintenance, import, export and disposal of medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, healing and hygienic products;
- preparing and issuing NOMs relating to health facilities, products and services;
- evaluating, issuing or revoking sanitary authorisations;
- exercising control and sanitary surveillance of drugs and other health supplies;
- disposal of organs, tissues, human cells and their components, toxic or dangerous substances, biotechnological products and raw materials;
- exercising control and surveillance of the advertising of sanitary activities, products and services; and
- imposing sanctions and implementing security measures.

Law stated - 7 October 2024

Other agencies

8 | Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

The following agencies have jurisdiction over healthcare, pharmaceutical and medical device cases:

- the Mexican Institute of Industrial Property;
- the Federal Agency for the Protection of Consumers;
- the Federal Economic Competition Commission; and
- the Federal District Attorney's office.

Law stated - 7 October 2024

Simultaneous investigations

9 Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Multiple government agencies can simultaneously conduct investigations on the same subject, provided that the corresponding actions are independent of each other and are intended for different purposes.

Law stated - 7 October 2024

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

10 What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Pharmaceutical products

Pharmaceutical products are subject to the following provisions.

New molecules

Essentially, applicants for marketing authorisations must prove the safety and efficacy of their products through standard clinical trials, according to the rules set out by the General Health Law, its regulations and the Official Mexican Standards (NOMs) of good manufacturing of medicines and active ingredients. Concurrently, they also have to request approval of their products as new molecules from the New Molecules Committee of the Federal Commission for Protection against Sanitary Risk (COFEPRIS). According to the Health Law Regulations article 2 section XV, a new molecule is:

- an active ingredient or drug not approved worldwide (a new molecular entity);
-

an active ingredient or drug already available in other countries, but with limited clinical experience or disputed information, that has not been approved in Mexico;

- a drug that is a non-marketed combination of two or more active ingredients; or
- an active ingredient or drug already available on the market, but to be marketed for a new therapeutic indication.

R&D companies benefit from a special procedure for drugs that have been previously approved by a regulatory authority abroad to be approved for the first time in Mexico.

Generics

Applicants for marketing authorisations must prove that their products are bioequivalent to the innovator product. They have to provide information concerning dissolution profiles or bioavailability studies regarding the reference product. COFEPRIS periodically issues a reference list of medicinal products. Recently, the NOM setting the test to prove that a generic drug is interchangeable with a reference drug was updated (NOM-177-SSA1-2013). Legally, COFEPRIS should not grant marketing authorisation for generics breaching exclusivity rights.

There is a linkage system between COFEPRIS and the Mexican Institute of Industrial Property (IMPI), which aims to prevent the granting of marketing authorisations in violation of patent rights. According to the Intellectual Properties Regulations, every six months IMPI must publish a gazette that includes patents covering allopathic medicines (the Linkage Gazette). The initial IMPI position was that only patents relating to a compound were relevant to linkage review (excluding formulation and use patents). On 31 July 2012, for the first time IMPI included formulation patents in the Linkage Gazette, in accordance with a 2010 ruling of the Mexican Supreme Court (Jurisprudence No. 2a/J7/2010, Federal Judicial Gazette, No. XXXI, page 135).

Use patents are included in the Linkage Gazette by court order, as IMPI considers that they should not be included in the linkage system.

Under the linkage regulations, at the filing of the application, the applicant must prove that he or she is the owner or licensee of the patent of the active ingredient of the product (recorded before IMPI), or state under oath that their application does not violate the list of products published in the Linkage Gazette and observes patent law.

Biologics

Amendments to the legal framework to regulate the approval of biologics are recent and being tested. Under the General Health Law, applicants have to prove the quality, safety and efficacy of their products, and that they meet their regulations and applicable NOMs, particularly those for good manufacturing practices for medicinal products (NOM–059–SSA1–2015) and for active ingredients (NOM-164-SSA1-2015).

In accordance with NOM–257–SS1–2014, all biological drugs that were authorised before the legal reform and that are still on the market must enter a regularisation process to comply with the latest standards for biologics. NOM 257 emphasises that key points to ensure the safety, efficacy and quality of biologics are already regulated in other NOMs

currently in effect, such as those for clinical trials and pharmacovigilance. NOM 257 empowers the Assessment Subcommittee on Biotech Products (SEPB) to assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables), and to issue opinions to characterise biologics as innovators, reference products or biocomparables.

NOM 257 provides transitional provisions for the renewal of marketing authorisations of biologics granted before the amendments to the Health Law Regulations for Biologics issued in 2011 came into force. These provisions establish that:

- COFEPRIS will assess whether biologics refer to innovators or biocomparables;
- renewal applications for innovators will not require assessment by the SEPB; and
- renewal applications for biocomparables will require prior assessment by SEPB to identify the product of reference in order for applicants to submit the corresponding tests.

These provisions will be applicable only for those renewal applications submitted before 31 December 2015. COFEPRIS, however, missed an opportunity to address the current uncertainty in respect of Regulatory Data Protection for Biologics, as NOM 257 does not provide for guidelines in this regard.

Biocomparables (follow-ons)

Applicants must submit clinical tests, and, when appropriate, in vitro tests, to prove the safety, efficacy and quality of products comparable (similar) to those of the reference biologic. The pre-clinical and clinical test used by an applicant for a biocomparable must use the corresponding reference biologic to perform comparative and physicochemical studies. For this, the applicant must submit:

- in vitro studies;
- the report of a comparative pharmacokinetic test, if determined by the Ministry of Health, to show pharmacokinetic comparability on key parameters between both the follow-on and the reference biologic;
- pharmacodynamics test reports; and
- comparative efficacy and safety clinical test to show the similarity between both the follow-on and the reference biologic.

Although industry participants have welcomed amendments to the approval of biologics, specific rules to approve follow-ons have caused debate. There is currently no indication of a data protection period for biologics. Currently, recognition of data package exclusivity rights for biologics can only be achieved through litigation. Accordingly, there are also concerns regarding the accurate application by COFEPRIS of linkage provisions.

Orphan drugs

Orphan drugs were recently introduced into the General Health Law and the Mexican Pharmacopeia. In practice, they are approved by a particular procedure, following rules for new molecules when applicable and appropriate. Specific rules are still pending. The draft

of the NOM compiling requirements for granting marketing authorisation includes orphan drugs.

Medical devices

The primary legislation for medical devices and diagnostics are the General Health Law, its regulations and the NOM for good manufacturing practices regarding medical devices (NOM–241–SSA1–2012). In general, it would be fair to say that regulation regarding medical devices is lighter than that for drugs and other substances. According to their use, the General Health Law classifies medical devices into:

- medical equipment;
- prosthetics, orthotics and functional supports;
- diagnostic agents;
- dental supplies;
- surgical and healing materials; and
- hygiene products.

Marketing authorisation requirements for these devices depend on the level of risk involved in their use, according to a threefold classification:

- Class I: products that are well known in medical practice and for which safety and efficacy have been proven. They are not usually introduced into a patient's body;
- Class II: products that are well known in medical practice, but may have material or strength modifications. If introduced, they remain in a patient's body for less than 30 days; and
- Class III: products either recently accepted in medical practice or that remain in a patient's body for more than 30 days.

COFEPRIS analyses medical devices and, if applicable, the software that enables them to work. Conversely, mobile medical applications are a new area that COFEPRIS may address in the future with particular regulations, especially if they represent health risks. As an incentive, applicants can benefit from a special procedure for certain devices that have been previously approved by the US Drug and Food Administration and Health Canada to be approved in Mexico. This procedure is essentially based on a dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 30 working days. Industry participants have welcomed these new rules, but they are still being tested.

Powers to monitor compliance

COFEPRIS can request reports from marketing authorisation holders, and make on-site inspection visits in the manufacturing, distribution or storage facilities, essentially to verify that their products meet the approved specifications and do not represent a risk to public health, and to ensure that good manufacturing practices, stability, pharmacovigilance and labelling standards are complied with. COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation.

COFEPRIS is also entitled to implement measures on behalf of public health, such as the seizure of products and ordering a partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to the closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability. Administrative infringements can incur penalties ranging from a fine up to 20,000 times the minimum wage to the final closure of the establishment. Repeated infringements are considered a criminal offence.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The General Health Law classifies the manufacturing and sale of counterfeit or falsified medicine as a crime. In addition, COFEPRIS commonly enters into collaboration agreements with the office of the Attorney General of Mexico (FGR) and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

COFEPRIS has a permanent pharmacovigilance programme. Under the Health Law Regulations and NOMs, COFEPRIS's monitoring is focused, among other things, on the following:

- ensuring compliance with good manufacturing practices and standard operating procedures;
- ensuring that activities performed do not exceed authorised limits or differ from those authorised activities; and
- ensuring that companies perform validation analyses of their manufacturing processes and systems.

COFEPRIS is entitled to implement measures to protect public health, such as:

- seizure of products;
- ordering the partial or total suspension of activities, services or adverts;
- revoke a company's manufacturing approval;
- impose sanctions, ranging from a fine of up to 16,000 times the minimum wage to the closure of an establishment; and
- make on-site inspection visits to manufacturing, distribution and storage facilities.

The imposition of administrative sanctions does not exclude civil and criminal liability. Affected parties are entitled to appeal decisions by COFEPRIS through the applicable administrative or judicial venues.

Law stated - 7 October 2024

Investigation time frames

11 How long do investigations typically take from initiation to completion? How are investigations started?

Investigations conducted by COFEPRIS can be initiated either by the complaint of an individual or by COFEPRIS itself. However, the duration of the investigation varies depending on the complexity of the case. Certain investigations related to the counterfeiting and commercialisation of illegal medicines are generally conducted in a matter of days.

Law stated - 7 October 2024

Access to investigation materials

12 What rights or access does the subject of an investigation have to the government investigation files and materials?

In most contentious administrative and judicial proceedings, the subject of an investigation has full access to the files and materials, except for the information expressly classified as confidential due to the request of an authority or another individual. Third parties are usually restricted from accessing files and materials submitted before COFEPRIS by companies or individuals during the prosecution of administrative proceedings.

Law stated - 7 October 2024

Investigations abroad

13 If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

No, but under article 168 of the Health Law Regulations, to hold a marketing authorisation foreign applicants must have:

- an approval from COFEPRIS for a manufacturing facility or laboratory for medicines or biologic products for human use in Mexico; or
- an equivalent approval (eg, a licence, certificate or another permit document) for any of these facilities abroad from the competent authority in the country of origin.

Law stated - 7 October 2024

Enforcement proceedings

14 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, and the possibility of applying later to a court remains available. COFEPRIS is entitled to revoke sanitary authorisations in the following cases:

- when the corresponding products or activities constitute a risk of harm to human health;

- when exercising an authorised activity exceeds the limits set in the respective authorisation;
- when the authorisation is used for different purposes;
- for non-compliance with the Health Law or Regulations;
- when the product covered by the authorisation does not meet or no longer meets specifications or requirements established by the Health Law, NOMs and other general provisions;
- when information or documents provided by the applicant is false;
- when the reports provided by authorised third parties are false; and
- when the products no longer possess the attributes or characteristics under which they were authorised or lose their preventive or therapeutic properties.

There is also an available action called *accion popular*, whereby any individual with or without proper legal standing can file a complaint before COFEPRIS, arguing and proving that there are certain health risks associated with a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to end a health risk and not to obtain compensation.

In coordination with COFEPRIS, the FGR is entitled to investigate and prevent the commercialisation of illegal medicines and also to implement measures on behalf of public health, such as the seizure of products.

The Federal Agency for the Protection of Consumers (PROFECO) can start proceedings for violations of NOMs. Individuals are entitled to file complaints against the providers of a service or manufacturers of a product. PROFECO, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

The Federal Economic Competition Commission (COFECE) can conduct investigations on many aspects related to the manufacturing and commercialisation of medicines and carry out inspection visits on requests of individuals or on its own initiative. After the conclusion of the investigation stage, COFECE will determine whether to close the case or to start administrative proceedings. In both cases, COFECE can impose preliminary injunctions. The affected party can claim damages before a court. Follow-on private litigation against manufacturers is possible but is not as common as in other jurisdictions, such as the United States. Additionally, COFECE can file criminal complaints.

Individuals can file patent infringement and unfair competition claims with IMPI, which is entitled to implement preliminary measures while investigating the infringement, which includes:

- the recall of infringing goods, or preventing their circulation;
- infringing articles to be withdrawn from circulation, including tools used in the manufacture, production or obtaining of infringing articles;
- the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- suspension of services or closure of an establishment, when other measures are insufficient to prevent or avoid a violation of rights protected by law.

On 1 July 2020, and as a result of the entry into force of the United States–Mexico–Canada Agreement (USMCA), which replaced the North American Free Trade Agreement (NAFTA), the new Federal Law for Protection of the Industrial Property (the IP Law), was enacted. The new IP Law came into force on 5 November 2020. The current system requires parties to first obtain a final declaration of infringement from IMPI before requesting compensation in the civil courts. The new IP Law offers two new options to file a claim for patent infringement.

- File a civil action directly with the civil courts. This gives the civil courts the authority to resolve disputes in accordance with the IP Law. However, if the validity of the IP right is challenged, the civil procedure will be suspended until the IMPI decides on the invalidity action.
- File an infringement action with the IMPI and request the determination of damages in a special incidental proceeding once the infringement is declared. The decision on damages can then be enforced by the civil courts. However, according to the transitory provisions of the new law, this option will only be available when the IMPI is ready to implement it. There are currently no clear indications of when this may occur.

The imposition of administrative sanctions does not exclude civil and criminal liability.

Patent holders can enforce border measures and the remedies provided by the IP Law. If a generic application is approved while the corresponding patent is still in force, the patent holder or licensee can bring a court action against marketing approval and a patent infringement action to stop the manufacture and sale of products.

Law stated - 7 October 2024

Sanctions

15 What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

COFEPRIS can initiate ex officio legal proceedings to sanction non-compliance. Ultimately, these legal proceedings can result in the revocation of the marketing authorisation. It is also entitled to implement measures on behalf of public health, such as the seizure of products and ordering the partial or total suspension of activities, services or adverts.

Under certain conditions, COFEPRIS has statutory authority to revoke any manufacturing approval or impose sanctions, ranging from economic fines to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

COFEPRIS has broad jurisdiction to seize counterfeit or illegal medicines. The General Health Law classifies the manufacturing and sale of counterfeit or falsified medicine as a crime. In addition, COFEPRIS commonly enters into collaboration agreements with the FGR and the Customs Office in order to investigate and prevent counterfeit and illegal medicines.

COFEPRIS can make on-site inspection visits to manufacturing, distribution or storage facilities.

In coordination with COFEPRIS, the FGR is entitled to investigate and prevent the commercialisation of illegal medicines and implement measures on behalf of public health, such as the seizure of products.

COFEPRIS has a permanent pharmacovigilance programme. Under the Health Law Regulations and NOMs, COFEPRIS's monitoring is focused, among other things, on the following:

- ensuring compliance with good manufacturing practices and standard operating procedures;
- ensuring that activities performed do not exceed either authorised limits or differ from those authorised activities; and
- ensuring that companies perform validation analyses of their manufacturing processes and systems.

Individuals can file patent infringement and unfair competition claims before IMPI, which is entitled to implement preliminary measures while investigating the infringement. These measures include:

- ordering the recall of infringing goods, or preventing their circulation;
- ordering the withdrawal of infringing articles from circulation, including tools used in the manufacture, production or obtaining of infringing articles;
- ordering the alleged transgressor or third parties to suspend or cease all acts that violate the law; and
- ordering the suspension of services or closure of an establishment when other measures are insufficient to prevent or avoid a violation of rights protected by law.

Law stated - 7 October 2024

Actions against employees

16 | Can the authorities pursue actions against employees as well as the company itself?

Yes, the General Health Law includes a chapter (Title Eighteenth, Chapter VI) on specific offences in which both individuals and the responsible legal entity may be the subject of an enforcement action.

Law stated - 7 October 2024

Defences and appeals

17 | What defences and appeals are available to drug and device company defendants in an enforcement action?

Company defendants are entitled to file a nonconformity recourse against the decisions issued by COFEPRIS within 15 working days of the issuance of the decision. Likewise, a

decision issued by an administrative authority can be appealed through a review recourse before the corresponding authority within 15 working days of the issuance of the decision. The decision issued in the review recourse can be challenged by means of a nullity trial before an administrative court (the Federal Court for Administrative Affairs), and finally before an administrative Federal Circuit Court.

Law stated - 7 October 2024

Minimising exposure

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Companies should focus on diagnosis of the problem and resolution through institutional proceedings, appealing adverse decisions when applicable.

Law stated - 7 October 2024

Recent enforcement activities

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

In past years, COFEPRIS' enforcement activities have been focused on the seizure of illegal medicines, which has resulted in closure of the establishment and suspension of activities.

Recently, COFEPRIS has been targeting companies that promote, through digital means, the sale of prescription drugs that are either innovative medicines approved in Mexico but manufactured and acquired abroad or generics that have not been authorised in Mexico and that are characterised by having prices considerably lower than those available in Mexico to individuals. Acquisitions of such drugs are made unlawfully through import permits for purported personal use, and sometimes they are not even registered as the quantities are so low. In these cases, the affected companies have filed *acciones populares* claiming the illegal importation and commercialisation of their products and the generics on the grounds of unfair competition, noncompliance with regulatory requirements and, of course, infringement of industrial property rights.

Law stated - 7 October 2024

Self-governing bodies

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

The National Chamber of the Pharmaceutical Industry exercises institutional representation of the pharmaceutical industry before the Mexican authorities. Affiliate members are required to comply with the codes issued by the organisation.

Law stated - 7 October 2024

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

There are several bodies of law that refer in general terms to the relationship between the pharmaceutical industry and healthcare professionals, such as the Health Law and Health Law Regulations (including those that concern the sanitary control of activities, establishments, products and services).

Industry Codes of Practice complement these regulations. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory instruments:

- the Code of Ethics and Transparency of the Pharmaceutical Industry;
- the Code of Good Practices of Promotion (GPP Code); and
- the Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations.

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry (CANIFARMA) are required to follow these Codes. CETIFARMA supervises members' and adherents' compliance.

Law stated - 7 October 2024

Enforcement

22 How are the rules enforced?

Scientific and educational events

The GPP Code states that the main purposes of congresses, lectures, symposia, meetings and other similar scientific or educational events sponsored, financed or supported by pharmaceutical companies or any other third party must be:

- scientific exchange;
- medical education; and
- information about medicines.

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 strict policies that scientific content is sustained, if required, on clinical evidence. Also, most importantly, they must be accredited and certified by the corresponding academic authorities. Under no circumstances will support be offered in order to influence the decision-making process involved in prescribing medicines or buying, including, excluding or modifying official product catalogues.

Samples

According to the GPP Code, samples are provided directly, in fair amounts and without cost to healthcare professionals, so that they may become familiar with the product or initiate treatment. According to article 49 of the Health Law Regulations concerning advertising, providing free samples of products does not require approval, provided that they meet the requirements of the approved medicinal product. These samples should be contained in a package with a smaller number of units than the approved product.

The GPP Code establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. The Code also forbids any trade of samples. 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. We always recommend that our clients have strict control of product samples as there have been cases of resale of said samples.

Gifts and donations

The GPP Code 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. Similarly, 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. The GPP Code delineates an inexpensive promotional aid as one that does not exceed the equivalent of 10 times the minimum wage (around US$85).

Concerning healthcare professionals in government institutions, article 47 of the Federal Law of Responsibilities for Government Officers expressly forbids these 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.

Law stated - 7 October 2024

Reporting requirements

23 What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The GPP Code establishes that collaboration between the pharmaceutical industry and patient organisations must have a written agreement in place that includes:

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

In these agreements, members must follow their applicable guidelines and codes of ethics and conduct, have transparent practices and use deontological instruments approved by CETIFARMA and CANIFARMA. The GPP Code requires members to set forth criteria and procedures for the approval and implementation of these kinds of collaborations. Any other kind of sponsorship provided by social, governmental or private sector organisations should not be excluded.

Law stated - 7 October 2024

REGULATION OF HEALTHCARE DELIVERY

Authority powers

24 What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

The Ministry of Health and the governments of the states are in charge of monitoring health professionals when providing the following services.

- Conducting sanitary evaluations and verification visits and, as a result, issuing an official report that states whether the subject of the investigation complied with laws, regulations and Official Mexican Standards (NOMs). In the case of non-compliance, the health authority in charge of the investigation will initiate the corresponding administrative proceeding.
- Applying sanctions and safety measures when appropriate and verifying compliance.

Physicians are also subject to liability for malpractice. Patients can choose between filing a civil action or requesting medical arbitration from the National Commission of Medical Arbitration (CONAMED). The latter is a quick alternative where a non-judicial solution is proposed. Decisions by CONAMED can be enforced through a judicial process.

Law stated - 7 October 2024

Investigation time frames

25 How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

The duration of an investigation varies depending on the complexity of the case. The establishment or site requiring an evaluation or verification visit is determined by any of the following:

- random selection;
- a previous contingency or health emergency;
- programmes determined by the health authority;
- a claim by a third party;
- the request of the owner; and
- any follow-ups to an administrative procedure initiated by the health authority.

Law stated - 7 October 2024

Access to investigation materials

26 What rights or access does the subject of an investigation have to the government investigation files and materials?

The subject of an investigation has full access to the files and materials, except for any information that has been expressly classified as confidential upon the request of the authority or another individual.

Law stated - 7 October 2024

Enforcement agencies

27 Through what proceedings do agencies enforce the rules?

Most agencies hold their own administrative proceedings, although applying to a court later remains available. The Ministry of Health and governments of the states are in charge of performing regular sanitary evaluations and verification visits to public and private institutions that, depending on the results, can lead to the application of sanctions and safety measures. The imposition of administrative sanctions does not exclude civil and criminal liability.

Law stated - 7 October 2024

Sanctions

28 What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

If the sanitary conditions of the establishment, raw materials, process, procedures or products present a significant risk to health or lack the essential requirements of the law

and other applicable provisions, verifiers should take immediate security measures with the approval or consent of the health authority on which they depend. The competent health authorities may order the application of the following security measures:

- isolation;
- quarantine;
- personal observation;
- vaccination of persons;
- vaccination of animals;
- destruction or control of insects or other vermin;
- suspension of work or services;
- suspension of advertising;
- issue of advertising messages that warn of potential damage to health;
- seizure and destruction of objects, products or substances;
- eviction from houses, buildings, facilities and any property in general; and
- other health measures as determined by the competent health authorities.

The sanitary authority has statutory powers to impose sanctions, ranging from economic fines to closure of the establishment. The imposition of administrative sanctions does not exclude civil and criminal liability.

Law stated - 7 October 2024

Defences and appeals

29 What defences and appeals are available to healthcare providers in an enforcement action?

Healthcare providers are entitled to file administrative, civil and criminal complaints against sanctions or adverse decisions. The National Commission of Medical Arbitration provides guidance and assistance to healthcare providers during the process of any complaint filed against them for medical negligence and during the medical arbitration proceeding.

Law stated - 7 October 2024

Minimising exposure

30 What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

Healthcare providers should focus on the diagnosis of the problem and its resolution through institutional proceedings, appealing adverse decisions when applicable.

Law stated - 7 October 2024

Recent enforcement activities

31 What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

Enforcement activity has been focused on the inspection of private clinics. This has resulted in closures of establishments and suspension of activities due to significant risk to health, lack of essential requirements for operation, and uncertified medical personnel.

Law stated - 7 October 2024

Self-governing bodies

32 Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Healthcare providers in Mexico are grouped and represented by different private associations depending on their specialisation and field of work.

Law stated - 7 October 2024

Remedies for poor performance

33 What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Contracts for the acquisition of health supplies and health services provisions usually include the following sanctions:

- penalties for delays in compliance with agreed dates of delivery or service provision, which shall not exceed the amount of the guarantee of compliance of the contract, and which will be determined according to the goods or services not delivered or rendered on time; and
- where a supplier totally or partially breaches any of the obligations expressly established in a contract, termination of the contract by the appropriate government institution in advance, without liability and without any judicial resolution.

Contracts for the acquisition of medicines or health supplies provide that the appropriate government institution may request that the supplier exchange goods with defects, or the total devolution of the goods where, after delivering the new batches, the same defect is detected.

The supplier of the goods is obliged to respond at its own risk regarding claims that failure or negligence on its part has caused problems for government institutions or third parties.

Law stated - 7 October 2024

PRIVATE ENFORCEMENT

Causes of action

34 What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

Besides civil and criminal actions, to enforce a healthcare regulation or law, citizens or other private bodies can file a constitutional action against a particular act or omission of the authority, grounding their legal standing in article 4 of the Mexican Constitution, which provides the human right of due access to healthcare.

Law stated - 7 October 2024

Framework for claims

35 What is the framework for claims of clinical negligence against healthcare providers?

Patients or relatives of patients who have received medical, public or private care that potentially caused them harm because of malpractice are entitled to file complaints against healthcare providers. The National Commission of Medical Arbitration (CONAMED) provides guidance and expert advice to patients and healthcare providers about their rights and obligations. It also receives and investigates cases related to irregularity or refusal of justified or urgent medical services by public institutions.

Patients are entitled to file a complaint before CONAMED, in which case such authority will be a mediator between the patient and the healthcare provider with the purpose of achieving a settlement agreement. If this is not the case, the patient can choose between submitting to a medical arbitration proceeding before CONAMED or filing a civil action. Decisions issued by CONAMED may include:

- an order for the provision of adequate medical care; and
- an order that the patient receives reimbursement, compensation or both.

Law stated - 7 October 2024

Seeking recourse

36 How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

Individuals are entitled to file complaints against the providers of a service or manufacturers of a product before the Federal Agency for the Protection of Consumers (PROFECO), on the grounds that the product of interest does not comply with the essential requirements

provided by the applicable regulations and Official Mexican Standards (NOMs) or the advertised characteristics and functionality. PROFECO, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. The federal procedural laws have been amended to allow class actions before the federal courts.

The Federal Economic Competition Commission (COFECE) can conduct investigations on many aspects related to the manufacturing and commercialisation of medicines and carry out inspection visits on requests of individuals or on its own initiative. After conclusion of the investigation stage, COFECE will determine whether to close the case or start administrative proceedings. In both cases, COFECE can impose preliminary injunctions. The affected party can claim damages before a court. Follow-on private litigation against manufacturers is possible, but is not as common as in other jurisdictions, such as the United States. Additionally, COFECE can file criminal complaints.

Law stated - 7 October 2024

Compensation

37 | Are there any compensation schemes in place?

There are no specific compensation schemes in place; however, the applicable laws aim to establish the bases and proceedings for recognising the right to compensation of those who suffered damages.

Law stated - 7 October 2024

Class and collective actions

38 | Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

The federal procedural laws have been amended to allow class actions before the federal courts. PROFECO, the Attorney General's Office, non-profit associations and a common representative of a group of at least 30 members can now pursue class actions. These amendments are subject to testing in the courts, and, apparently, there are no precedents of class actions for product liability.

In addition, there is an action available called *accion popular*, whereby any individual with or without proper legal standing can file a complaint before the Federal Commission for Protection against Sanitary Risk, arguing and proving that there are certain health risks in a product in the market. However, the claimant's procedural rights are very limited, and these actions are intended to stop health risks, not to obtain compensation.

Law stated - 7 October 2024

Review

39 | Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Yes. Acts, omissions and decisions of both public and private institutions can be the subjects of administrative, civil and criminal complaints from interested parties before the courts. Actions should be filed as soon as possible to duly attend to and repair the claimed act or omission. In these types of cases, the legal standing of the complainant is grounded in the human right of due access to health. In relevant cases, it has been decided that the state will always be responsible for appropriate healthcare, even if the claimed act or omission derives from a private institution.

Law stated - 7 October 2024

Whistleblowers

40 | Are there any legal protections for whistleblowers?

No, in Mexico we do not have a figure equivalent to a whistleblower. The Federal Law on the Administrative Responsibilities of Public Servants provides that public servants must inform their superiors in writing about any conclusive doubts that arise from the origin of the orders they receive that could constitute an infringement of any legal or administrative provision. However, the law fails to consider the protection that should be granted to the public servant, or the process that should be implemented in order to preserve the confidentiality of the denouncement.

Law stated - 7 October 2024

41 | Does the country have a reward mechanism for whistleblowers?

No.

Law stated - 7 October 2024

42 | Are mechanisms allowing whistleblowers to report infringements required?

Yes. The Ministry of Public Administration is the authority in charge of verifying that public servants act in accordance with the applicable laws during the exercise of their functions, and is the authority in charge of implementing the corresponding sanctions.

Law stated - 7 October 2024

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

Yes. In accordance with the Health Law, its Regulations and the international treaties subscribed to by Mexico, the Ministry of Health is in charge of institutional relationships with the health dependencies of other governments and international organisations in order to facilitate the provision of technical advice, information and assistance in everything related to sanitary regulation, control and health promotion.

Additionally, the Ministry of Health notifies the World Health Organization of all the measures it has taken, temporarily or permanently, in international health, as well as any case that is of interest in the surveillance of the diseases listed in the International Health Regulations.

Law stated - 7 October 2024

Triggering investigations

44 In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

When the Ministry of Health receives an international communication, alert or requirement on health matters, in coordination with the corresponding administrative entities (ie, the Ministry of Foreign Affairs and the Ministry of the Interior) it will conduct inspection visits in order to verify compliance or noncompliance with international sanitation rules, which could lead to an administrative procedure in accordance with the applicable laws.

Law stated - 7 October 2024

Pursuing foreign entities for infringement

45 In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Mexican healthcare laws, regulations and official standards are equally enforceable against foreign companies and nationals.

Law stated - 7 October 2024

UPDATE AND TRENDS

Key developments of the past year

46 What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

On 1 July 2020, as a result of the entry into force of the United States–Mexico–Canada Agreement, the new Federal Law for Protection of the Industrial Property (the IP Law) was enacted. The new IP Law represented an important legislative change as it aimed to match the domestic law with the standards set by the new trade and cooperation agreements signed by Mexico in recent years. It came into force on 5 November 2020. Due to this, amendments to the health laws are expected.

At the end of January 2020, the Ministry of Health published an official administrative decree, establishing new relevant provisions on applications for marketing authorisation and importation of medicines into Mexico. The Ministry of Health confirmed that it recognises various foreign regulatory health authorities' requirements and evaluation procedures to authorise the sale, distribution and use of allopathic and biological medicines in their respective countries as being equivalent to those of the quality, safety and efficacy standards of the General Health Law, the Health Supplies Regulation and other applicable provisions that products must meet to be granted marketing authorisation in Mexico by the Federal Commission for Protection Against Sanitary Risks (COFEPRIS).

Additionally, this decree stated that Mexican authorities were authorised to import medicines that do not have a marketing authorisation in Mexico provided that the importing is carried out due to the necessity of guaranteeing the supply of medicines for the correct and timely provision of health services to the population.

However, on 11 September 2024, a new administrative decree was issued and stated that the provisions that allowed the importation of health products (medicines and medical devices) without marketing authorisation are now rendered void. Therefore, as of 12 September 2024, the provisions that allowed the possibility of importing health products (medicines and medical devices) without marketing authorisation and indicated the requirements to materialise such importation ceased to have effect.

The decree and the technical annex through which the importation of health products without marketing authorisation was allowed indicated the possibility of obtaining marketing authorisation for the imported product through a similar process to the one stated in the Health Law Regulations, but in a much shorter period than the one provided in the regulations, considering that the requirements had been met through equivalence. In this sense and regarding the procedures initiated prior to this latest agreement of 11 September 2024, the prosecution of the applications will continue their course based on the corresponding provisions.

Since the effects of these provisions have ceased, it will no longer be possible to participate in public tenders without a marketing authorisation, so there will undoubtedly be a positive impact on the development of the procurement process for health products.

Since its certification as the first National Regulatory Authority for Medicines with Level IV in Latin America before the PanAmerican Health Organization, and its recognition of the World Health Organization, COFEPRIS is carrying out the corresponding steps to improve the efficiency of the regulation of medicines, encourage the recognition of other jurisdictions' regulatory decisions, and to formulate and implement strategies to strengthen its regulatory system.

On 30 May 2023, the 'Decree reforming, adding, and repealing various provisions of the General Health Law, to regulate the Health System for Welfare' came into effect,

establishing the dissolution of the Institute of Health for Welfare, and providing that the functions of the institute will become part of the Mexican Institute of Social Security for Welfare (IMSS-Bienestar), which, in collaboration with the Ministry of Health, will be the decentralised entity in charge of providing free health services, medicines and other supplies to people without social security in Mexico.

Law stated - 7 October 2024

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