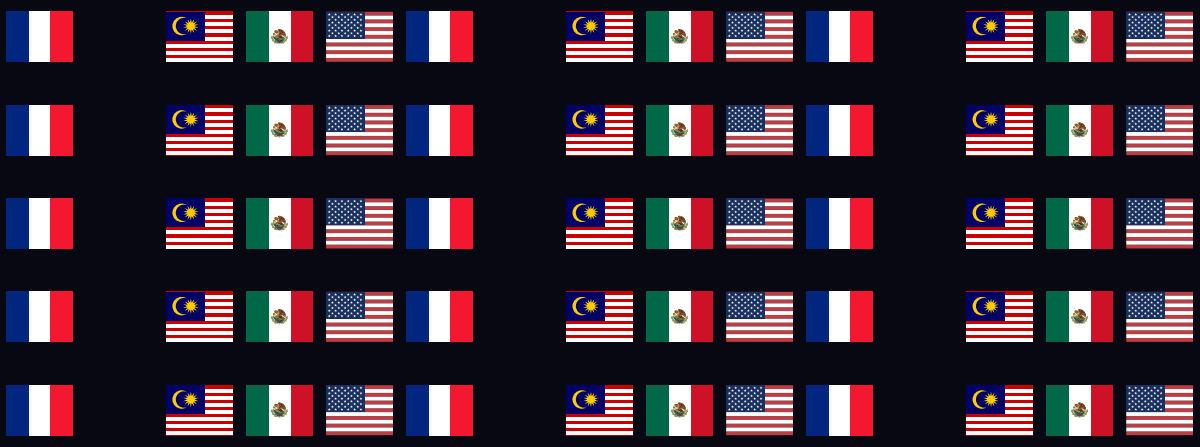
HEALTHCARE ENFORCEMENT & LITIGATION

Malaysia



LEXOLOGY
Getting The Deal Through

Consulting editor
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Healthcare Enforcement & Litigation

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Quick reference guide 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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Malaysia

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OVERVIEW

Healthcare funding

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 Malaysian healthcare system is a dual system whereby healthcare is provided by both the public and the private sectors. The Ministry of Health is the main provider of public healthcare services in the country. Its nationwide network of clinics and hospitals provides healthcare to approximately 65 per cent of the population for free or at very affordable rates. The public healthcare system is mainly funded by the government and financed primarily through public tax revenue. The private healthcare sector is funded by private medical insurance, employers and directly by patients. The fees payable consist of the professional fees of the medical practitioners, which are regulated by the Private Healthcare Facilities and Services Act 1998 and the regulations enacted thereunder, and hospital charges, which are not regulated.

Law stated - 26 June 2023

Delivery

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

Healthcare services are delivered in Malaysia in both public and private healthcare facilities. The public healthcare system is the main healthcare provider in Malaysia. Based on the latest available data , as at 2021, there were 135 government hospitals and 11 special medical institutions with 39,263 and 5,586 beds respectively, 1,057 health clinics, 1,749 rural clinics and 86 maternal and child health clinics. There were also 255 community clinics nationwide focused on providing immediate healthcare to the population. Pre-pandemic, the public and private sectors acted independently of each other, although private wings in many public hospitals have been mushrooming in recent years. However, the pandemic brought about more public-private partnerships and collaborations to alleviate the public sector's burden.

Law stated - 26 June 2023

Key legislation

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

The healthcare industry is highly regulated in Malaysia. Key specific legislation would include:

- the Private Healthcare Facilities and Services Act 1998, which regulates the delivery of private healthcare;
- the Medical Act 1971 and the Medical (Amendment) Act 2012, the Dental Act 2018, the Traditional and Complementary Medicine Act 2016 and the Allied Health Professions Act 2016, which regulate the registration and standards of various healthcare professionals;
- the Poisons Act 1952, which deals with the regulation of poisons;
- the Medicines (Advertisement and Sale) Act 1956, which governs advertising related to medical matters and regulates the sales of substances recommended as medicine;
- the Medical Device Act 2012; and
- the Sale of Drugs Act 1952.

With the increasing popularity of online healthcare delivery, legislations such as the Communications and Multimedia Act 1998 and the Digital Signature Act 1997 have also gained greater prominence. Online prescriptions, in particular, need to ensure compliance with the provisions of the Digital Signature Act 1997.

Law stated - 26 June 2023

Responsible agencies

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

The Ministry of Health plays an overarching regulatory role in the practice of medicine and the general delivery of healthcare in Malaysia. There are many specific units and departments that oversee various aspects of the delivery of healthcare. The main and most active enforcement units include the Private Medical Practice Control Section (CKAPS) under the Medical Practice Division and the Pharmacy Enforcement Division, as well as the National Pharmaceutical Regulatory Agency. All these units are publicly funded. There is no publicly available information that would suggest that any part of their funding is dependent on enforcement activities.

Law stated - 26 June 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

The scope of responsibilities of each enforcement unit under the Ministry of Health is governed by the specific legislation being enforced. Most units have investigative powers and responsibilities that are, in some cases, relatively wide-reaching. For example, the Private Healthcare Facilities and Services Act 1998, which is a key piece of healthcare legislation, permits the Director General of Health to appoint inspectors for enforcement and regulatory purposes. The inspectors have the powers, among other things, to enter and inspect premises; search, seize and remove items; and detain and seal premises. Some enforcement units undertake their own prosecution in court, while others work with the Attorney General's Chambers to prosecute alleged breaches of various legislation.

Law stated - 26 June 2023

Regulation of pharmaceutical products and medical devices

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

The principal regulatory agencies responsible for the regulation of pharmaceutical products and medical devices are the Medical Device Authority, the Medicine Advertisements Board and the National Pharmaceutical Regulatory Agency of Malaysia. All these agencies come under the auspices of the Ministry of Health and are publicly funded. There is no publicly available information that would suggest that any part of their funding is dependent on enforcement activities. The Medical Device Authority Fund (the Fund) was established pursuant to the Medical Device Authority Act 2012, and the Fund is administered and controlled by the Medical Device Authority. Aside from being publicly funded, the Fund is funded by, among other things, registration or licence fees, monies earned from consultancy and advisory services provided by the Medical Device Authority, and monies derived from the sale or disposal of any property, mortgages, charges or debentures vested in or acquired by the Medical Device Authority.

Law stated - 26 June 2023

Scope of enforcement

What is the scope of their enforcement and regulatory responsibilities?

The scope of responsibilities of each enforcement agency is governed by the specific legislation being enforced. For example, the Medical Device Authority is authorised under the Medical Device Act 2012 to license and approve any instrument, apparatus or other medical device as defined under the Act for, among other things, the purpose of treatment, diagnosis or monitoring of diseases or injuries, including the advertising of such products. The Medical Device Authority also has extensive powers to investigate and search premises and seize items if the contravention of any provision is suspected. The Medicine Advertisements Board is responsible for the approval of advertisements relating to the sale or display of medical products and services. The National Pharmaceutical Regulatory Agency of Malaysia and the Pharmacy Enforcement Division are largely concerned with registration, regulation and enforcement relating to the sale of drugs. The Pharmacy Enforcement Division can carry out investigations, raids and seizures.

Law stated - 26 June 2023

Other agencies

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

Any entity doing business in Malaysia will be under the jurisdiction of all Malaysian regulators. In addition to the specific healthcare enforcement agencies, with the increasing usage of online healthcare delivery, the Malaysian Communications and Multimedia Commission is also regularly engaged by the Ministry of Health to assist in enforcing alleged breaches committed online. This commission was created under the Communications and Multimedia Commission Act 1998 and has powers to require internet service providers to assist the authorities, including restricting access to websites. Consumer-related issues such as the sale of misleading products claiming healthcare benefits and the control of the prices of healthcare products, such as face masks and covid-19 home test kits, would come under the purview of the Ministry of Domestic Trade and Cost of Living.

Law stated - 26 June 2023

Simultaneous investigations

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?

There are no barriers to multiple agencies simultaneously investigating the same circumstances. A completed investigation by one agency does not technically bar another agency from its own independent investigation of the same facts and circumstances. In practice, however, usually only one agency undertakes an investigation at a particular time.

Law stated - 26 June 2023

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

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

The relevant regulatory authority relating to medical devices is the Medical Device Authority. The Medical Device Act 2012 provides the Medical Device Authority with wide-ranging powers to investigate, carry out search and seizure on and examine orally any person supposed to be acquainted with the facts and circumstances of the case. The Poisons Act 1952 and the Sale of Drugs Act 1952 allow officers authorised under the respective Acts to enter, search and examine premises, and to seize items that are reasonably believed to be evidence of offences under the respective Acts.

Law stated - 26 June 2023

Investigation time frames

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

The duration of investigations largely depends on the nature of the investigation and the suspected offence or offences. There is no typical time frame that can be identified. Investigations are usually initiated by complaints lodged with the authorities, through random spot checks and monitoring activities carried out by the authorities.

Law stated - 26 June 2023

Access to investigation materials

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

Generally, the subject of an investigation does not have an automatic right of access to government investigation files and materials, unless the subject is subsequently prosecuted in court and is then granted the usual rights of discovery under the rules that govern the proceedings.

Law stated - 26 June 2023

Investigations abroad

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?

Establishments with a principal place of business outside Malaysia but with an authorised representative in Malaysia may be subject to investigations. However, there is no statutory provision that expressly grants powers to the authorities to conduct investigations in other jurisdictions. Authorities may refer the matter to their counterparts in other jurisdictions and enlist assistance where necessary. The Mutual Assistance in Criminal Matters Act 2002 and the regulations enacted thereunder set out the mechanism for international cooperation with foreign counterparts in respect of serious criminal matters. However, this does not afford the authorities powers to conduct extraterritorial investigations.

Law stated - 26 June 2023

Enforcement proceedings

Through what proceedings do agencies enforce the rules?

The Medical Device Authority refers the matter to the public prosecutor, and enforcement proceedings are generally carried out by bringing criminal charges in court against the alleged perpetrators. Offences committed under the Sale of Drugs Act 1952 are summarily taken before a subordinate court (the Sessions Court or First Class Magistrate). The Poisons Act 1952 allows for prosecution to be conducted by any registered pharmacist in public service, and the Medicines (Advertisement and Sale) Act 1956 allows for authorised officers to prosecute. No prosecution under the aforementioned legislation can be carried out without the written consent of the public prosecutor.

Law stated - 26 June 2023

Sanctions

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

Pursuant to the relevant legislation, authorities can seek sanctions of substantial fines or even imprisonment through the appropriate legal process. Authorities also retain the right of seizure of goods under the Medical Device Act 2012, subject to the court's approval if the seizure is challenged by the manufacturers or distributors. Any goods seized under the Medical Device Act 2012 can also be liable to forfeiture.

Law stated - 26 June 2023

Actions against employees

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

Yes, individuals are also subjected to enforcement actions such as criminal or civil proceedings. However, typically the company itself would be the subject of any prosecution. The Medical Device Act 2012 provides that a director, manager, secretary or other officer may be charged jointly or severally in the same proceedings. The Poisons Act 1952 similarly allows for a director or officer to be jointly or severally charged in the same proceedings, whereas the Sale of Drugs Act 1952 only allows for prosecution against the body corporate itself.

Law stated - 26 June 2023

Defences and appeals

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

The defences available to drug and device company defendants would largely depend on the alleged offence and the legislation under which the enforcement action is carried out. Decisions by the authorities may be challenged in court proceedings through judicial review, civil action or appeals. The Medical Device Act 2012 allows for an appeal to the Minister if a person is aggrieved by a decision of the authority under any one of several sections of the Act. If criminal prosecution is brought by the authorities, any adverse finding by a court of first instance would be amenable to an appeal to a court of higher jurisdiction.

Law stated - 26 June 2023

Minimising exposure

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

It would be imperative for companies to establish a clear and effective corporate compliance programme to ensure that the company is operating in accordance with the applicable laws, regulations and guidelines. In a situation where enforcement action is imminent, it would be prudent for a company first to clearly identify its practices that may be under investigation or that are allegedly contravening legislative or regulatory provisions. The offending practices should be ceased immediately to mitigate any exposure. The company should assess the offending practices and implement changes where possible. This would then allow for representations to be made to the authorities. It is, of course, pivotal to obtain appropriate legal advice and representation.

Law stated - 26 June 2023

Recent enforcement activities

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

Recent enforcement activities include acting on the sale of unregistered or fake drugs and the use of devices outside the scope of their licences. Authorities have also been investigating digital healthcare platforms to ensure compliance with applicable regulations on the provision of healthcare services and the sale of drugs. Offending companies have been sanctioned with fines.

Law stated - 26 June 2023

Self-governing bodies

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

The Malaysian Pharmacists Society (the Society) is a society registered under the Societies Act 1966. It serves to uphold, among other things, the ethics, practices and development of the pharmaceutical industry. The Society can revoke membership if a member is struck off the Pharmacists' Register pursuant to any legislation or if by majority opinion the member is found guilty of infamous conduct or has acted prejudicially to the interests of the Society. The Association of Malaysian Medical Industries seeks to promote the relationship between the medical technology industry and healthcare providers. Its members are subject to its Code of Ethical Conduct for Interactions with Healthcare Professionals .

Law stated - 26 June 2023

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

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

The Malaysian Medical Council has published a guideline titled ' Relationship Between Doctors and the Pharmaceutical Industry '. This guideline recognises the important relationship between the healthcare industry and the pharmaceutical industry and was published with the aim of assisting doctors in achieving and preserving the highest quality of healthcare, to the benefit of both the medicine and pharmaceutical industries. While the guideline refers to pharmaceutical companies, it is equally applicable to all companies supplying therapeutic or diagnostic material and devices, or other health products and services. The guideline covers an array of issues, including how healthcare professionals should ensure that disclosures of potential conflicts of interest are made and beware of having any interest in pharmaceutical companies that may conflict with their professional responsibilities.

Law stated - 26 June 2023

Enforcement

How are the rules enforced?

Breach of the guideline may trigger disciplinary proceedings by the Malaysian Medical Council against healthcare professionals.

Law stated - 26 June 2023

Reporting requirements

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

There are no specific reporting requirements on such financial relationships. The guideline generally stresses the need for openness and transparency in dealings between doctors and pharmaceutical companies. This may, in some cases, require disclosure of financial or other arrangements to institutions, ethics committees, patients, potential research subjects and others. The disclosure is not publicly available and appears to be to specific parties given specific circumstances. However, the guideline makes mention that when doctors receive remuneration for services provided to the pharmaceutical industry, the relationship should be public knowledge. How it becomes publicly known is unclear.

Law stated - 26 June 2023

REGULATION OF HEALTHCARE DELIVERY

Authority powers

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

The private sector is regulated under the Private Healthcare Facilities and Services Act 1998, among other regulations, which grants wide powers to the Ministry of Health to carry out investigations, raids and seizure of items if private healthcare facilities are suspected to be contravening provisions of the Act. In respect of the public sector, the Ministry of Health is the internal regulator of its own facilities and employees. There is no independent external body except for the Malaysian Medical Council, Malaysian Dental Council, Nursing Board Malaysia and Traditional and Complementary Medicine Council, which are creatures of statute. These bodies have disciplinary jurisdiction over registered healthcare practitioners in Malaysia.

Law stated - 26 June 2023

Investigation time frames

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

The duration of investigations depends on several factors, including the nature of the matter investigated and the number of healthcare providers involved. The investigation process can last between a couple of weeks and a year and may, in some circumstances, extend beyond a year. Investigations are generally prompted upon receipt of written complaints lodged with the Ministry of Health, councils or healthcare facilities. Regulatory authorities regularly conduct spot checks to ensure compliance with the relevant legislation and rules. In the event of suspected contravention, the authorities may initiate investigations of their own volition.

Law stated - 26 June 2023

Access to investigation materials

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

During the course of an investigation, the subject of the investigation does not have an automatic right of access to the investigation files and materials. If criminal charges are proffered, or a civil action is initiated in court, the subject would be entitled to documents related to the investigation subject to the applicable rules of court and legal principles. Documents that are deemed to be confidential by the authorities or the government, or both, may be exempted from disclosure in the regular course of legal proceedings.

Law stated - 26 June 2023

Enforcement agencies

Through what proceedings do agencies enforce the rules?

Breaches of regulatory or statutory provisions generally attract criminal charges, and enforcement of these would be through the courts. The Malaysian Medical Council, Malaysian Dental Council, Nursing Board Malaysia and Traditional and Complementary Medicine Council are statutorily empowered to conduct disciplinary proceedings in respect of ethical or professional misconduct.

Law stated - 26 June 2023

Sanctions

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

Pursuant to the relevant legislation, authorities can seek sanctions in the form of fines or imprisonment, depending on the nature of the offence committed. The authorities may also restrict access to healthcare websites, in the case of online healthcare providers, with the assistance of the Malaysian Communications and Multimedia Commission. The Malaysian Medical Council, Malaysian Dental Council, Nursing Board Malaysia and Traditional and Complementary Medicine Council are vested with the power to impose punishments such as ordering the name of a registered healthcare provider to be struck off or suspended from the register, reprimanding a registered healthcare provider or

making such other order as the respective authority may deem fit.

Law stated - 26 June 2023

Defences and appeals

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

The defences available to healthcare providers would largely depend on the legislation under which they are prosecuted or sanctioned. For enforcement decisions by the authorities, healthcare providers may appeal against the decision made by a public authority by initiating judicial or administrative review of the decision in the High Court. All parties are entitled to the two-tier rights of appeal, with the final appellate court being the Federal Court.

Law stated - 26 June 2023

Minimising exposure

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 put in place robust quality control and compliance systems to ensure that the provision of healthcare services is in line with the applicable legislation and regulations. In the event of enforcement being initiated, healthcare providers ought to take reasonable steps to mitigate any further damage, danger or contravention as soon as they are notified of this. Once an enforcement is underway, it is prudent for the healthcare provider in question to cease the practices that are alleged to be in contravention of legislative or regulatory provisions and improve its internal processes in a timely manner. By doing so, the healthcare providers may negotiate with or make representations to the authorities to allow for an agreement to be reached. It is, of course, pivotal to obtain legal advice and to ensure that all relevant parties are represented in any criminal or civil action brought against a healthcare provider.

Law stated - 26 June 2023

Recent enforcement activities

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

Based on media reports, it appears that over the past couple of years, the authorities' focus has been on enforcement of the laws applicable to online and digital healthcare services, and licensing regulations for healthcare services and devices. Various entities involved in the selling of fake, adulterated or unauthorised medication, or providing services beyond the ambit of licensing, have been subject to prosecution by the authorities. Likewise, given the steep increase in online healthcare patronage by the public, the authorities have investigated online healthcare providers, with some facing prosecution for failure to adhere to legislation such as the Medicines (Advertisement and Sale) Act 1956. To date, the sanctions imposed on healthcare providers have included fines.

Law stated - 26 June 2023

Self-governing bodies

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

There are several self-governing councils that have been established to govern various healthcare providers. Of note, the Malaysian Medical Council, Malaysian Dental Council, Nursing Board Malaysia and Traditional and Complementary Medicine Council regulate healthcare providers under their respective purviews. In general, these self-governing bodies are largely concerned with the ethical aspects of the provision of healthcare and are statutorily empowered to conduct disciplinary proceedings. These proceedings are usually triggered by the receipt of a written complaint or based on information received by the respective bodies through their investigations.

Law stated - 26 June 2023

Remedies for poor performance

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

Contracts between the government and its employees generally contain remedial provisions for breach of contract, which may include poor performance, allowing for, among other things, termination and recourse in damages where applicable.

Law stated - 26 June 2023

PRIVATE ENFORCEMENT

Causes of action

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

Private individuals who are affected by an act or omission, or both, by a healthcare provider or healthcare facility may institute a civil suit premised upon a breach of statutory duty. With regard to decisions of healthcare authorities, private individuals may seek a judicial or administrative review of the decision in the High Court. An application for judicial review is governed by Order 53 of the Rules of Court 2012. It is a two-stage process. The first stage is obtaining leave of the court. Once leave is obtained, the matter proceeds to a full hearing whereby the merits of the applicant's case are deliberated upon in court.

Law stated - 26 June 2023

Framework for claims

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

An aggrieved party may institute a civil claim against a medical practitioner and the healthcare facility involved premised on a breach of contract for the medical services rendered or in tort for professional negligence. A medical practitioner has two duties towards a patient, namely, the duty to diagnose and treat and the duty to advise of risks. In respect of the duty to diagnose and treat, a breach of the standard of care occurs when a medical practitioner fails to act with the skill and diligence expected of a medical practitioner of the same standing and position or in accordance with the practice accepted as proper by a responsible body of medical opinion. As for the duty to advise of risks, a

medical practitioner is required to advise a patient of the material risks of an intended procedure and the options that are available to the patient.

To succeed in a claim for negligence, a plaintiff must establish, on a balance of probabilities, that:

- the defendant owed the plaintiff a duty of care;
- the defendant breached his or her duty of care;
- the act or omission, or both, of the defendant caused or materially contributed to the plaintiff's injury and losses; and
- the damage claimed is not too remote.

A plaintiff who succeeds in establishing liability will be entitled to damages as pleaded in the claim to the extent that each head of damages is proven. The heads of damages that are usually awarded in negligence cases are general and special damages. The Malaysian courts have also awarded aggravated damages in exceptional circumstances where the defendant's conduct has aggravated the suffering of the plaintiff.

Judicial trends do not indicate any reluctance to penalise public or quasi-public healthcare providers. There are numerous successful claims brought by aggrieved claimants against public healthcare practitioners and facilities. Likewise, there are also numerous claims that have been successfully defended by public healthcare practitioners and facilities.

Law stated - 26 June 2023

Seeking recourse

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

Individuals who received pharmaceutical goods or products with misleading trade descriptions, or that are not of acceptable quality (ie, they are unsafe or not fit for purpose), can submit a claim for compensation of up to 50,000 ringgit with the Tribunal for Consumer Claims. The Tribunal is under the purview of the Ministry of Domestic Trade and Cost of Living. Alternatively, an individual who has suffered harm as a result of the pharmaceutical product or device can bring a civil claim against the manufacturer to seek damages or, alternatively, to enforce breaches of a statutory duty (if any). The affected individual can also lodge a complaint with the regulatory authorities, which may then carry out investigations on the purported breaches.

Law stated - 26 June 2023

Compensation

Are there any compensation schemes in place?

The Tribunal for Consumer Claims may award compensation of up to 50,000 ringgit.

Law stated - 26 June 2023

Class and collective actions

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

Class actions or representative actions are available in Malaysia. Order 15, Rule 12 of the Rules of Court 2012 provides for 'representative action', where parties sharing the same interest may bring a claim in the same proceedings. The plaintiffs would have to show that the members of the class have a common interest or a common grievance and that the relief sought would be in its nature beneficial to them all.

Law stated - 26 June 2023

Review

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?

Parties who are adversely affected by acts, omissions or decisions of a public institution (or private institution exercising a quasi-public role) in the healthcare sphere may initiate judicial review proceedings in the High Court within three months of the grounds arising. Acts, omissions or decisions of private institutions are not amenable to judicial or administrative review. The grounds for judicial review include illegality, ultra vires actions, unreasonableness, procedural impropriety, irrationality and disproportionality. The courts, pursuant to the Courts of Judicature Act 1964 , may order writs of certiorari or mandamus, among other things, and may also order injunctions, declarations and damages.

Law stated - 26 June 2023

Whistleblowers

Are there any legal protections for whistleblowers?

The Whistleblower Protection Act 2010 provides protection to a person who makes disclosure of improper conduct to an enforcement agency, irrespective of whether this disclosure leads to prosecution or disciplinary action of the alleged offender. The whistleblower is given protection from the consequences of the disclosure of any confidential information and immunity from any civil or criminal action and any detrimental action taken against the whistleblower or associated person arising from his or her whistleblowing.

Law stated - 26 June 2023

Does the country have a reward mechanism for whistleblowers?

Pursuant to the Whistleblower Protection Act 2010, the relevant enforcement agency may order any reward, as it deems fit, to be paid to the whistleblower for any disclosure of improper conduct, or any complaint of detrimental action in reprisal for the disclosure of improper conduct, that leads to the detection of cases on improper conduct or detrimental action or prosecution of the person against whom the disclosure of improper conduct was made or the person who commits the detrimental action.

Law stated - 26 June 2023

Are mechanisms allowing whistleblowers to report infringements required?

There are no explicit requirements that make whistleblower mechanisms mandatory.

Law stated - 26 June 2023

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

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

The Mutual Assistance in Criminal Matters Act 2002 and the regulations enacted thereunder set out the mechanism for international cooperation with foreign counterparts. The Mutual Assistance in Criminal Matters Act 2002 provides for mutual assistance in criminal matters to be rendered and sought between Malaysia and other countries in respect of serious offences. The Attorney General is vested with the power to make requests to and receive requests from foreign countries. These requests are to be made through diplomatic channels. An important feature in considering a request from a foreign counterpart is dual criminality (ie, the act or omission must constitute an offence in both Malaysia and the foreign country).

Law stated - 26 June 2023

Triggering investigations

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

Any enforcement activity that gives rise to the suspicion of criminal acts being committed in Malaysia may trigger a local investigation. Furthermore, findings of a foreign medical council, such as the United Kingdom's General Medical Council, may be referred to the Malaysian Medical Council, which is empowered to carry out its own investigation or inquiry, or both.

Law stated - 26 June 2023

Pursuing foreign entities for infringement

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

Foreign companies and foreign nationals are subject to Malaysia's healthcare laws if they are operating within the jurisdiction. Authorities may, and do, carry out investigations and enforcement against foreign entities operating or practising in Malaysia.

Law stated - 26 June 2023

UPDATE AND TRENDS

Key developments of the past year

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?

Authorities involved in the provision of healthcare have been, and are likely to be for the foreseeable future, involved in enforcement actions against the sale of fake medication and unregistered drugs.

Given the acceleration of the adoption of digital and online healthcare tools, there has been a continued increase in investigations and enforcement against providers of online healthcare services. This trend is likely to continue pending the development of a regulatory framework for online healthcare services, as the legislation currently in place was promulgated decades ago and fails to contemplate the intricacies involved in the provision of virtual healthcare.

Law stated - 26 June 2023

Jurisdictions

France	LexCase
Japan	Mori Hamada & Matsumoto
Malaysia	Raja, Darryl & Loh
Mexico	OLIVARES
USA	Mintz