Healthcare Enforcement & Litigation 2022

Contributing editors
Grady Campion, Laurence Freedman, Caitlin Hill, Samantha Kingsbury and Karen Lovitch

LEXOLOGY®
Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the seventh edition of *Healthcare Enforcement and Litigation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on European Union.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

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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 Portugal, healthcare services are mostly provided by the Portuguese National Healthcare Service (NHS), which is funded by the state. As a result, healthcare services are predominantly administered by public hospitals, units and services. Specific healthcare services provided by NHS hospitals are subject to the payment of user charges. However, users may be exempted from such payments in the case of economic insufficiency or of clinical conditions with high health risks.

Healthcare services may also be provided by private healthcare entities and entities of a social nature. The majority of private healthcare services are funded through private insurance policies.

Medicines and medical devices may be fully or partially funded by the state under specific legal requirements.

Delivery

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

Healthcare is delivered through the NHS institutions that are under the authority of the Ministry of Health, such as public hospitals and local health units. The NHS comprises primary, continued and hospital care.

Healthcare is also provided by private healthcare units and hospitals and healthcare units of a social nature.

The regulation, planning, financing, guidance, monitoring, evaluation, auditing and inspection of the NHS and the regulation, inspection and supervision of the healthcare activities and services rendered by private concerns and respective healthcare professionals is carried out by the Ministry of Health, whose respective services and bodies are under its direct and indirect administration.

Each of the Autonomous Regions of Madeira and Azores have specific healthcare regional systems and services frameworks, in accordance with specific regional legislation on the organisation and operation of healthcare services.

The role of public and private sectors is the provision of primary, continued and hospital healthcare services in the areas of the prevention, diagnosis and treatment of diseases, and continuous care.

Key legislation

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

The key Portuguese legislation governing the delivery of healthcare is as follows:

- Law No. 95/2019 of 4 September 2019, the Health General Law, which approves the legal bases on which the protection of health is to be executed;
- Law No. 56/79 of 15 September 1979, as amended, establishing the NHS by means of which the state secures citizens the constitutional right to health protection through general and tending-towards-free health services;
- Decree Law No. 11/93 of 15 January 1993, as amended, approving the NHS Statute;
- Decree Law No. 124/2011 of 29 December 2011, the Ministry of Health Organic Law, as amended; and
- Decree Law No. 126/2014 of 22 August 2014, approving the Portuguese Healthcare Regulatory Authority Statute.

Responsible agencies

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

The Portuguese Healthcare Regulatory Authority (ERS) is the independent public body responsible for the supervision and regulation of the activity of public, private and social healthcare units (excluding pharmacies), and for the registration of healthcare providers and granting of the healthcare units' operating licences. The ERS is funded by a grant from the national budget and by its own revenue, of which 40 per cent is from fines and other pecuniary sanctions arising from the breaches and offences enforced by the ERS.

The General Inspectorate of Health Activities (IGAS) is a central service under the direct administration of the state responsible for public law enforcement and compliance in all areas of healthcare provision. The IGAS is funded by the state budget and by its own resources, such as the revenue from fines collected in administrative offence proceedings, among others, in the proportion attributed by the specific laws under enforcement by the IGAS.

The General Health Directorate (DGS) is a central service under the direct administration of the state, funded by the state budget and by its own resources, such as the revenue from fines collected as a result of administrative misdemeanour proceedings in the proportion attributed by the specific laws regarding enforcement by the DGS. The DGS designs and coordinates health promotion and disease-prevention activities, defines the technical conditions for the adequate provision of healthcare, programmes the national policy for the quality of the health system, secures the development and implementation of the National

Health Plan and coordinates the international relations of the Ministry of Health.

Scope of enforcement

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

The ERS regulates the activity of healthcare facilities located in Portuguese mainland territory, of public, private or social ownership (except pharmacies and pharmaceutical companies). ERS enforcement and regulatory activities include:

- the registration of healthcare service providers;
- the handling of complaints from users, competitors or other individuals and entities;
- executing inspections and audits to the healthcare facilities;
- investigation of situations that have a significant adverse impact on patients' rights or on the quality and safety of care;
- carrying out administrative offence procedures involving healthcare providers and applying resulting sanctions; and
- studying the healthcare system organisation, including providing instructions, advice updates and recommendations.

The IGAS enforces compliance with the applicable law by the Ministry of Health bodies and services under its control, and by public and private entities or entities of social nature. IGAS's main activities include:

- executing of inspections and audits;
- initiating and deciding on disciplinary proceedings and administrative offences;
- providing public awareness campaigns, information and training programmes; and
- issuing opinions and non-binding recommendations.

The main scope of the DGS's activity is as follows:

- coordinating and developing health plans and programmes;
- coordinating and assuring epidemiological surveillance;
- analysing and disclosing health information;
- regulating and assuring health quality;
- managing public health emergencies;
- supporting the implementation of National Health Authority capabilities;
- coordinating the Ministry of Health's European Union and international activities;
- monitoring the NHS care call centre; and
- coordinating and monitoring the performance evaluation system of the Ministry of Health's public administration.

Regulation of pharmaceutical products and medical devices

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

The National Authority of Medicines and Health Products IP (Infarmed) is a public institute under Ministry of Health auspices, funded by an annual grant from the state budget and also by its own resources, which include, among others, medicines, health products, cosmetics, personal hygiene products, medical devices and homeopathic pharmaceutical products commercialisation fees, as well as from licences, fees and fines, in the percentage defined by law. Regarding the fines, part of its amount is destined to Infarmed (eg, 40 per cent of fines for breaches to medicines legislation and 40 per cent of the fines arising from breaches of the medical devices rules).

Scope of enforcement

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

Infarmed governs and supervises the sectors of medicines for human consumption, medical devices and cosmetics and other health products in accordance with public health protection standards and warrants the access of the health professionals and citizens to medicines and health products regarding quality, efficacy and safety. Among others, Infarmed is responsible for:

- the licensing of activities and or certification of the same as established in the applicable law (eg, medicines and medical devices wholesale distribution, manufacturers and importers, pharmacies;
- the granting of marketing authorisations to medicines for human consumption;
- the register of medical devices;
- authorising clinical trials;
- securing pharmacovigilance procedures for medicines and health products;
- ruling on (and authorising) the prices of medicines subject to medical prescription or non-medical prescription (both reimbursable and non-reimbursable by the NHS);
- conducting the reimbursement process of medicines and the previous evaluations procedure of medicines, medical devices and of health technologies and the acquisition of the same by NHS hospitals;
- enforcing and supervising compliance with applicable laws and regulation on medicines, medical devices, cosmetics and of other health products; and
- initiating administrative offence procedures in case of breach of the applicable law and imposing fines and other established sanctions in the case of infringement.

Infarmed may undertake inspections of the entities under its supervision.

Other agencies

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

The Portuguese Competition Authority under the National Competition Act (Law No. 19/2012, 8 May 2012, as amended) has public enforcement powers over healthcare, pharmaceutical and medical devices activities, including merger control, illegal agreements, abuse of dominance and abuse of economic dependency conducted by participants within the pharmaceutical industry. Applicable sanctions for illicit conduct include misdemeanour fines that can amount to 10 per cent of the infringer's annual turnover.

The public prosecutor's office, in accordance with its responsibilities, leads and directs criminal investigations over crimes committed by healthcare providers or pharmaceutical companies and respective legal representatives and employees.

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?

The same subject or facts may be investigated by different government agencies, because they might potentially constitute, for different reasons, a legal infringement under enforcement and supervision by several agencies. However, during simultaneous investigations, each

agency is required to act and decide on the facts in accordance with the scope of its specific responsibilities and applicable law.

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?

Infarmed has enforcement powers to inspect and supervise the activity of entities and of their respective products, namely medicines for human consumption, medical devices and cosmetics, and also the performance of clinical trials. The inspection and supervision activities may comprise of the manufacturing, import, export of medicines and medical devices, wholesale distribution activity, of medicines and medical devices and the dispensation of the same to the public. Infarmed's inspection unit handles the inspection and supervision actions and manufacture and wholesale distribution sites may be inspected as well as market holders and distributors head offices, the premises of pharmacies located in hospitals or opened to the general public and entities authorised to sell medicines not subject to medical prescription.

Entities such as manufacturers, market holders, wholesale distributors, pharmaceutical services of hospitals, pharmacies and entities authorised to sell medicines not subject to medical prescription are subject to inspection and supervision activities.

Investigation time frames

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

The law does not foresee a specific time frame for investigations. As such, time frames depend on the scope of the investigation and the related facts. However, the investigation report has to be concluded by Infarmed inspectors within 60 days following the end date of the inspection or visit. The inspected entity has 10 days, beginning from the notification of the report, to submit its reply in writing. Infarmed subsequently assesses the inspectors' report and the reply of the inspected entity, where it may issue an official report of administrative offence if any infringement is found.

Furthermore, specifically in relation to the wholesale distribution activities of medicines and medical devices, such activities require an Infarmed's inspection of the wholesale distribution premises to be executed in a 30-day period, following the documentation review of the application request submitted by the applicants to obtain the medicines wholesale distribution authorisation or to execute the notification for medical devices wholesale distribution . However, if changes are required to the premises, an additional 30-day period is granted for the applicant to execute the changes.

Access to investigation materials

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

Entities under investigation have access to the investigation report by the National Authority of Medicines and Health Products IP (Infarmed) and if applicable to the official decision of administrative offence. In both cases, as stressed in the previous reply, the defendant is entitled to defence rights by means of reply to the investigators' report and opposition to the administrative offence preliminary decision. Following the issuing of Infarmed's administrative offence final decision, defendants are entitled to challenge the decision before the competent court.

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?

Infarmed may inspect, in conjunction with local authorities, facilities and establishments located in or outside the European Union, regarding the manufacturing of medicines, active substances or excipients, and also the laboratories committed to certain manufacturing phases or equipment authorised by Infarmed or used for the manufacturing purposes foreseen in the Portuguese Human Medicine Act (PMA) approved by Decree Law No. 176/2006 of 30 August 2006, as amended.

In this regard, Infarmed may request the European Commission or a local agency, that a manufacturer located in a third country is subject to an inspection.

Enforcement proceedings

14 | Through what proceedings do agencies enforce the rules?

Infarmed is entitled to handle investigations, supervision and administrative offence procedures to enforce the applicable law. Final decisions adopted by Infarmed can always be subject to judicial review.

The proceedings are ruled by administrative law because they are not of a civil or criminal nature.

Sanctions

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

Besides the imposition of fines, Infarmed may also take decisions on the suspension, revocation or modification of the terms of a marketing authorisation or register of a medicine, or on its withdrawal from the market or prohibition on its dispense whenever the medicine in question does not comply with the applicable law and regulations or does not meet the conditions of the respective authorisation. Some contraventions are clarified in the PMA.

In the event of infringed legal provisions contained in the PMA, Infarmed can also impose violation fines and the following ancillary penalties:

- the seizure of objects, equipment and illegal devices by the state;
- a ban on a defaulter's activities for a maximum two-year period;
- a ban on a defaulter from participating in public tenders for a maximum two-year period; and
- suspending authorisations, licences or other titles granting rights for a maximum two-year period.

In the event of breaching the PMA legal provisions on publicity requirements of medicines reimbursed by the State, besides the administrative offence proceeding determined by such infringement, the additional sanction on the exclusion of such medicine from State reimbursement may be also imposed.

Regarding medical devices, Decree Law No. 145/2009 of 17 June 2009, as amended, which approves the Portuguese Medical Devices Act, besides the imposition of fines, Infarmed may also impose corrective measures on breaches found in the course of an investigation and may also impose violation fines in the administrative offence procedure.

Sentencing and fines owing to the violation of publicity and promotion law on medicines and medical devices may also be published online and on social media, as well as a two-year suspension of the publicity and promotional claims on the product.

Furthermore, breaching rules concerning medical sales representatives of medicines and medical devices visiting NHS healthcare units

and services and respective healthcare professionals, may lead to sales representatives and the respective market holder being banned from accessing all such units and services.

Actions against employees

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

The PMA is clear on this topic. It foresees that individuals, legal entities (regardless the legality of incorporation), companies and associations without legal personality may be responsible for the administrative offences arising from the breach of the PMA's legal provisions when the facts were executed by the respective bodies during the performance of their duties. The PMA also determines that the members of such entities' boards of directors may also be convicted by sanctions applicable to the entity, specially attenuated unless a more serious sanction is attributed by other legal provisions, when such a natural person was aware, or ought to have been aware, of the infraction, did not adopt adequate measures to terminate the infringement immediately.

The PMA does not contain a similar provision as the one referred above for the remaining employees. Therefore, as a rule, employees are excluded from Infarmed's administrative offence proceedings. However, Infarmed may notify the relevant authorities and public prosecutor of the infringements committed by the entities' employees, depending on the nature of the infringement.

Defences and appeals

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

Defendants' procedural and due-process rights are secured in accordance with the applicable legal provisions of the General Regime on Administrative Offences, approved by Decree Law No. 433/82 of 14 September 1982, as amended.

Under this regime, no fines may be determined or applied by Infarmed without the defendant being assured that it had the opportunity to provide its defence on the legal and factual reasoning on the alleged wrongful conduct and respective sanction.

From the outset, all decisions, dispatches and further measures adopted by Infarmed are mandatorily notified to the infringers or defendants, and if such decisions and measures are likely to be challenged, Infarmed's notification must contain the necessary information on legal acceptability, terms and challenging form before the courts under the dual-tier judicial system.

Hence, decisions and measures taken in the course of the administrative proceeding may be challenged by the defendants before the competent court. Defendants may also try to obtain the suspension of the enforcement of the administrative offence decisions taken by Infarmed by means of protective measure submitted to the competent court and subsequently challenge the decision before the same court. First instance court decisions are subject to appeal.

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?

In our view, such strategies should be focused on preventive measures such as the definition and implementation of strict compliance procedures for critical topics, such as pharmacovigilance, clinical trials, publicity, transparency relationships and interaction with healthcare professionals, as well as training and updating of the employees on the applicable law, regulation and on compliance procedures.

While the enforcement action is under way, cooperation with agencies is a legal requirement in the investigation phase and is also recommended, acting as a mitigating factor in terms of applicable sanctions. Grounded substantiated evidence that compliance procedures are implemented in the company to secure conformity with the law, subject to a case-by-case analysis, can assist in mitigating applicable sanctions.

Recent enforcement activities

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

The main focus of Infarmed have been the supervision on pharmacovigilance and safety issues (namely in what concerns to fake medicines and covid-19 vaccines), and on ensuring the access to medicines. Information on applied sanctions is not publicly released on the Infarmed website.

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 most relevant industry bodies are the Portuguese Pharmaceutical Industry Association (Apifarma) and the Portuguese Association of Medical Devices Companies (Apormed).

Apifarma approved two codes of ethics:

- the code of ethics for promotional practices of the pharmaceutical industry and for the interactions with the healthcare professionals and institutions, organisations or healthcare professional associations; and
- the code of conduct for the relations between the pharmaceutical industry and patient associations, patients advocates, patients experts, patients and caregivers.

The implementation and enforcement of the codes are entrusted to Apifarma's council of ethics, which, in the instance of code violation, may ask the offender to immediately cease the violation or to promise in writing not to undertake such practices again. Violation of the codes' provisions constitutes a disciplinary offence and may lead to disciplinary measures, such as:

- a simple warning;
- a written reprimand;
- a penalty up to the amount of five years' membership fees;
- a suspension of up to one year; and
- expulsion order of associates.

Enforcement proceedings may be triggered by Apifarma or based on a complaint.

In 2018, Apormed approved a Code of Good Commercial Practices, based on MedTech Code of Ethical Business Practice. Apormed's articles of association establish disciplinary sanctions applicable to the respective members in case of infringement of the provisions of both the Code of Good Commercial Practices and Apormed's Articles of Association, which are the following:

- a simple warning;
- a written reprimand;
- a penalty up to double the amount of the highest membership fee;
- a suspension of the associate one month up to six months; and
- expulsion.

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?

Relevant rules are provided in article 158 of the Portuguese Human Medicine Act (PMA) and in article 51 of the Portuguese Medical Devices Act (PMDA). Both provisions prohibit the giving or promise to give, directly or indirectly, awards, gifts, bonus or pecuniary or benefits in kind to healthcare professionals, except in cases where objects are of negligible value (eg, up to €60), that are cumulatively relevant for the health professional practice.

The above-mentioned benefits cannot be also granted to healthcare professionals' patients, as determined by article 158 of the PMA.

Enforcement

22 How are the rules enforced?

The enforcement of rules may start with an investigation, and if an infringement of the above-mentioned rules is established, an administrative offence procedure may be initiated, and fines may be imposed in accordance with article 181 of the PMA and article 61 of the PMDA.

Reporting requirements

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

Entities under the scope of the PMA are required, as set by respective article 159, to report in Infarmed's transparency platform in a 30-day period the granting of any benefit (eg, any advantage, value, payment, delivery of goods or granting of rights of pecuniary value, regardless the form of attribution, either as premium, subsidy, sponsorship, fees, or other), to any entity, legal person, individual, company, association (regardless of its nature or form), medical society of a scientific nature, clinical trials, patient organisations, Portuguese National Healthcare Service units and services, and Ministry of Health services and bodies.

In the case of sponsorship of congresses, symposia or of any events of scientific nature of direct or indirect disclosure of medicines are to be previously reported to Infarmed in 10 working days before the scheduled date of the event and the respective amount of the granted sponsorship is to be reported in Infarmed´s transparency platform in the terms mentioned in the previous paragraph.

The PMDA foresees in respective article 52 the same reporting obligation to Infarmed, as described above.

REGULATION OF HEALTHCARE DELIVERY

Authority powers

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

The Portuguese Healthcare Regulatory Authority (ERS), as supervising and regulatory authority of all healthcare units, has broad powers and is authorised to monitor compliance by the following:

- to perform inspections and audits to healthcare providers' facilities;
- to handle investigations of situations of significant adverse impact on the rights of patients or on the quality and safety of care;
- to handle complaints from users, competitors or other individuals and entities;
- to conduct administrative offence procedures involving healthcare providers and applying sanctions; and
- to produce studies, opinions and recommendations.

The General Inspectorate of Health Activities (IGAS) is entitled to audit, inspect, supervise and develop disciplinary action in the healthcare sector, to secure compliance with the applicable law and ruling in every domain of healthcare services provision activity carried out by establishments or bodies of the Ministry of Health or those supervised by it, as well as by private entities, individuals or legal persons.

Regarding private healthcare providers, IGAS may carry out inspections on private and social healthcare units concerning additive dependency and behaviour. IGAS is also committed to ensuring the prevention and detection of corruption and fraud, by promoting the adequate procedures.

Investigation time frames

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

There is no established legal time frame. The duration depends on the extent of the investigation, complexity, respective facts and related findings.

The investigation may start as a result of a complaint or as a consequence of an audit or inspection of the healthcare provider's premises or health units. In the specific case of the ERS, inspections and audits may occur as a result of the execution of inspection plans previously approved and whenever circumstances indicate disturbances in the respective activity sector.

Access to investigation materials

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

As a rule, no access to the inquiry file is granted until the end of investigation, although defence rights are secured by the applicable law, namely after the adoption of the terms to the infringement notice.

During the investigation, the legal representatives of the investigated companies and respective employees are obliged to cooperate with the regulatory authorities (the ERS or the IGAS), notably by providing the requested information and documents in the terms defined by the authority, usually within a 30-day period.

Enforcement agencies

27 Through what proceedings do agencies enforce the rules?

National agencies can enforce the applicable rules by means of audits and inspections, and if circumstantial evidence of an infringement is found, administrative offence proceedings may be initiated to investigate such facts in depth. These proceedings are handled directly by the agencies and are not of civil or criminal nature.

Decisions adopted by the regulatory and supervising authorities are subject to judicial review before courts.

If potential criminal conduct is found by the regulatory agencies, they are obliged to report such facts to the public prosecutor for criminal enforcement purposes.

Sanctions

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

As a result of audits and inspections, the ERS may issue recommendations and impose fines and other sanctions to remedy, replace or restore the conformity of the healthcare providers' activity and respective premises with the applicable laws and regulations and to comply with healthcare users' rights.

The ERS may also decide on applying precautionary measures when in the course of an investigation activities are discovered that can seriously and irreparably damage the regulated sector or healthcare users or may be difficult to remedy. In this regard, the ERS may decide on the suspension of such activities by the infringer or on any measures to prevent or repair such damage that are likely to affect the final decision adopted in an administrative offence procedure.

Defences and appeals

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

Defendants' procedural and due-process rights are secured in accordance with the applicable legal provisions of the General Regime on Administrative Offences, approved by Decree Law No. 433/82 of 14 September 1982, as amended.

Under this regime, no fines may be determined or applied by Infarmed without the defendant being assured that it had the opportunity to provide and state its views on the legal and factual reasoning on the alleged wrongful conduct and respective sanction.

From the outset, all decisions, dispatches and further measures adopted by Infarmed are mandatorily communicated to the infringers or defendants, and if such decisions and measures are likely to be challenged, Infarmed's notification must contain the necessary information on legal acceptability, terms and challenging form before the courts under the dual-tier judicial system.

Hence, decisions and measures taken in the course of the administrative proceeding may be challenged by the defendants before the competent court. Defendants may also try to obtain the suspension of the enforcement of the administrative offence decisions taken by Infarmed by means of protective measures submitted to the competent court and subsequently challenge the decision before the same court. First instance court decisions are subject to appeal.

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?

Such strategies should be focused in the definition and implementation of strict compliance procedures to secure compliance with the applicable laws and regulations, as well as recurrent training and updating of healthcare providers' employees on the applicable laws, regulations, best practices and compliance procedures. Internal audits should also be performed to monitor employees' strict compliance with company procedures.

While the enforcement action is under way, cooperation with agencies is not only a legal requirement in the investigation phase but is, subject to a case-by-case analysis, also recommended, because it can be assessed as a mitigation factor in terms of applicable sanctions. Sound and effective compliance procedures in a healthcare provider's company are always advisable to minimise enforcement risks.

Recent enforcement activities

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

Quality and safety of the healthcare services, treatments and diagnosis, as well as adequacy of the healthcare unit facilities, constitute the main breadth of the enforcement activity by the authorities.

Most of the sanctions published on the ERS website correspond to the imposing of fines on healthcare units for the breach of legal requirements of healthcare unit operation and violation of users' rights.

Self-governing bodies

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

No.

Remedies for poor performance

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

The majority of healthcare providers are Portuguese National Healthcare Service (NHS) hospitals (public hospitals) and facilities that operate under specific legislation and not under contracts.

However, there are NHS hospitals that operate under a public-private partnership regime by means of distinguished management contracts: one concerning the management of the hospital, medical equipment and of healthcare services; and the other on the management of the hospital premises. The conclusion of these management contracts is subject to public procurement procedures.

In the case of poor performance or breach of contractual and legal obligations, the most common remedies are the enforcement of penalties and the termination of contracts in the case or public-private partnerships. The same remedies are usually ruled in contractual conventions concluded with individuals or legal persons for the provision of specific healthcare services provision to NHS users.

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?

There are three levels of accountability depending on the specific requirements laid out in law.

Civil liability

Civil liability may occur whenever damages and losses arise from infringements of civil law or of contractual provisions. State and other public entities (namely, individuals and entities of the public healthcare sector) may also be held liable under a specific extra-contractual civil liability.

Criminal liability

Health-related criminal liability exists if the crime is actually undertaken by an individual and if the conduct is classified as a crime. The following crimes are to be highlighted:

- medical and surgical treatments in violation of current and common medical practices (article 150.º, No. 2 of the Portuguese Criminal Code (PCC);
- medical and surgical treatments against the patient's will (article 156.º of the PCC);

- dissemination of disease and provision of medicinal substances disregarding the medical prescription (article 283.º of the PCC);
- refusal of medical aid (article 284.º of the PCC); and
- breach of secrecy (article 195.º of the PCC).

Disciplinary liability

Disciplinary liability mainly occurs whenever deontological law and ruling are breached. Depending on the sector (public or private) in which the healthcare provider commits the infringement, the law enforcement may be of a public or private nature.

Framework for claims

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

The framework may correspond to the violation of the good practices established for healthcare professionals and healthcare institutions as well as of guidelines issued by public agencies, such as the General Health Directorate. Apart from the specific ruling arising from the above-mentioned practices and guidelines, the general standard is the *bonus pater familia* (ie, that every healthcare professional shall act with the diligence and correctness that a 'normal' and typical healthcare professional would act in that specific situation).

From a civil perspective, it is widely accepted by the Portuguese courts that the requirements for civil liability are the following:

- action or relevant omission;
- breach of law or of contractual provisions;
- the occurrence of damage;
- guilty behaviour; and
- causality between the damage and the defaulting conduct.

Courts are not reluctant to penalise public or quasi-public healthcare providers if the legal requirements are fully satisfied.

Seeking recourse

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

Users may submit complaints and report events and even submit suggestions to Infarmed on the following areas and subjects:

- services provided by entities regulated and supervised by Infarmed;
- products regulated by Infarmed; and
- services provided by Infarmed.

Besides the civil and criminal liability and respective grounds, product liability and adverse reactions may also serve as grounds.

Compensation

37 | Are there any compensation schemes in place?

There are no specific compensation schemes. The compensation is determined on a case-by-case basis and is fixed in accordance with the court criteria and respective assessment of the facts, means of proof and also in accordance with the nature and extension of the damages and losses.

Class and collective actions

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

The popular action, governed by Law No. 83/95 of 31 August, as amended, is a collective claim that can be brought by those seeking compensation for offences against public health or quality of life. In accordance with specific legislation, this action may be of administrative (public) or civil nature.

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?

Public institutions are subject to administrative and judicial review. The statute of limitations for the interested parties to challenge the respective acts or omissions is dependent on the nature of the infraction. Remedies may consist of the revocation, suspension, amendment of an act or decision in the breadth of administrative offence or by judicial review. The enforcement of a specific conduct or the performance of a specific act and compensation of damages may also be granted by the judicial decision. In this regard, public entities may also be challenged for damages within the parameters of the extra-contractual civil liability regime pointed out above. Such claims are handled by administrative courts.

The challenging of private institutions may be of an administrative nature if the grounds of the complaint relate to infringements of regulatory duties, in which case the complaint may be enforced at the start before the competent regulatory authority and may be subsequently submitted to the competent courts. In the case of damages of a civil nature, challenging is subject to judicial civil review. The statute of limitations for the interested parties to challenge the acts or omissions of these private entities is also dependent on the nature of the infraction, and the remedies may be the same as the ones quoted for public entities.

Whistle-blowers

40 | Are there any legal protections for whistle-blowers?

There is no general regime for whistle-blowers even though specific regimes are set for money laundering, terrorism and drugs traffic. However, whistle-blowers may be criminally and civilly liable for defamation, namely in the case of persons of high reputation.

41 | Does the country have a reward mechanism for whistle-blowers?

There is no reward mechanism for whistle-blowers in Portugal.

42 | Are mechanisms allowing whistle-blowers to report infringements required?

There is a specific mechanism for reporting corruption and fraud available on the website of the Central Bureau of Investigation and Prosecution of the Attorney General's Office.

The reporting mechanism is accessed online and whistle-blowers should identify the following:

- the acts of corruption or fraud;
- the date on which such acts occurred; and
- the identities of the suspects.

Whistle-blowers may also inform on the quantities at stake, individuals who may be relevant for ascertaining the facts and who may also submit documents to support such a complaint.

Whistle-blowers may choose to remain anonymous.

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. Prosecutors and law enforcement authorities in Portugal do cooperate with foreign authorities, as governed by Law No. 144/99 of 31 August, as amended.

Triggering investigations

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

Investigations are triggered whenever an illegal action has been committed and investigated for which the Portuguese jurisdiction is competent.

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?

Whenever an infringement of Portuguese law occurs, foreign companies and foreign nationals may be pursued once the Portuguese jurisdiction and competence requirements laid out in law are fully met.

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?

Apart from the measures taken to face coronavirus pandemic, with potential lingering impacts, the coming year will probably be marked by the strengthening of the ensuring of the access to medicines, following the implementation of legislation recently approved

In addition, Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council, of 5 April 2017, on in vitro diagnostic medical devices, are now applicable (since 26 May 2021), which is relevant development on the sector and is expected to be an enforcement priority.

Coronavirus

47 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

The Portuguese state implemented a comprehensive range of legislation, programmes and initiatives aimed at facing the coronavirus (SARS-CoV-2) pandemic, focusing mainly on preventing the spread of the disease and preparing and providing the Portuguese National Healthcare Service (NHS) and other healthcare establishments with the required resources to face the inevitable increase in demand.

With direct impact on our practice area, it is possible to highlight:

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- Decree-Law No. 14-E/2020 of 13 April 2020, established an exceptional and transitional regime regarding the manufacturer, import, placement and availability on the national market of medical devices and personal protective equipment, for the purposes of preventing contagion of SARS-CoV-2;
- the Infarmed, and the Economic and Food Safety Authority guidelines 'Import and Manufacture of Medical Devices and Personal Protective Equipment in the context of the covid-19 Pandemic';
- the Infarmed guidelines on Exceptional measures for Clinician Trials during the period of risk to public health;
- the Infarmed guidelines and initiatives for responsible management of medicines availability;
- Order No. 5315/2020 of 7 May 2020, which establishes that medicines dispensed by a hospital pharmacy on an outpatient basis may, exceptionally, under request of the patient, be dispensed in the community pharmacies indicated by him or her, or at his or her home, as long as the country's epidemiological situation justifies it; and
- Ministerial Order No. 56/2021, of 21 March 2021, which establishes an exceptional and temporary regime for self-testing with rapid antigen tests.

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