Healthcare Enforcement & Litigation

Contributing editors
Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman

2017

GETTING THE DEAL THROUGH

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CONTENTS

Preface

Healthcare Enforcement & Litigation 2017

Second edition

Getting the Deal Through is delighted to publish the second edition of *Healthcare Enforcement & Litigation*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

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 **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 Portugal and Turkey.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

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.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman of Skadden, Arps, Slate, Meagher & Flom LLP, the contributing editors, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

London
September 2016

Global overview

Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman
Skadden, Arps, Slate, Meagher & Flom LLP

Getting the Deal Through's *Healthcare Enforcement & Litigation* is a practitioner's guide to how government agencies around the world regulate and investigate the healthcare industry, and the unique legal issues presented in the jurisdictions discussed in this edition. The management of cross-border healthcare investigations pose myriad challenges for today's global healthcare corporations. Understanding how the healthcare industry is regulated in different jurisdictions, as well as knowing how such investigations are likely to play out, is crucial to successfully managing business operations in those countries. This book aims to address, on a jurisdiction-by-jurisdiction basis, the questions that arise regarding the way healthcare companies are regulated and the manner in which enforcement of the industry is carried out.

Continued prosecutions of large international healthcare companies underscore the importance of these issues to corporations operating globally today. For more than a decade, the United States Department of Justice has taken an aggressive enforcement stance towards the healthcare industry, and has vowed to continue its zealous enforcement when presented with evidence of wrongdoing. This has resulted in billions of dollars in fines and penalties being paid by healthcare companies, criminal liability and follow-on litigation. Such fines are frequently split between the various law enforcement and regulatory agencies that participate in the investigation. Remedial measures imposed are likewise significant, with companies often required to enter into corporate integrity agreements or, in some cases, to divest of the business that engaged in wrongdoing. As the amount of money the federal government spends on healthcare increases, one can expect that government enforcement of the industry will likewise increase.

The cases brought by the Department of Justice have received widespread international attention, and have prompted law enforcement authorities around the world to increase their own scrutiny of the healthcare industry. In addition, last year the Department of Justice announced new guidance to its criminal and civil prosecutors designed to strengthen the Department's pursuit of individual corporate wrongdoing in corporate investigations, a trend that we anticipate will extend internationally. Indeed, because the government is a primary payer for healthcare in many countries, there is particular interest in trying to detect and punish perceived misconduct. Toward this end, law enforcement entities around the world are increasingly working collaboratively with one another on these investigations. For example, over the course of six years, Siemens AG reached settlements with government entities in Germany, Greece, Italy, Nigeria and the United States and with the World Bank concerning allegations of bribery and corruption. Moreover, the United States and Germany not only coordinated their investigations but also simultaneously announced their separate settlements with Siemens. The recent Olympus Corp of the Americas settlement also suggests that the Department of Justice is expanding its healthcare investigations to conduct outside the United States. The settlement not only resolved charges concerning a scheme to pay kickbacks to physicians and hospitals in the United States in violation of the anti-kickback statute but also resolved charges concerning improper payments by an Olympus subsidiary to health officials in Central and South America in violation of the Foreign Corrupt Practices Act.

There is every reason to expect aggressive law enforcement and regulatory investigation to continue in the United States for the foreseeable future, as well as for collaboration among international law enforcement entities to continue and to increase. Healthcare entities suspected of wrongdoing, regardless of their size or global reach – and perhaps because of it – are likely to face multiple inquiries from law enforcement and regulatory agencies in different countries. Such investigations are expensive, time-consuming and challenging for management, employees and counsel alike. We hope that this edition of *Healthcare Enforcement & Litigation* will serve as a valuable introduction to the unique features of law and practice that shape civil and criminal investigations across multiple jurisdictions.

Portugal

Fernanda Matoso

Morais Leitão, Galvão Teles, Soares da Silva & Associados

Overview

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 budget. As a result, healthcare services are predominantly rendered by public hospitals, units and services. Specific healthcare services provided by NHS units are subject to the payment of user charges. However, users may be exempted from such payment in the case of economic insufficiency or of clinical conditions of high health risk.

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

Medicines and medical devices may be funded by the state under specific legal requirements and may attract full or partial funding.

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: healthcare centre groups, 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 units and respective healthcare professionals is committed to the State Secretariat of the Ministry of Health, respective services and bodies under its direct and indirect administration.

The Autonomous Regions of Madeira and Azores have a specific healthcare regional system and services framework in accordance with specific regional legislation on 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 of continuous care.

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:

- Law 56/79 of 15 of September 1979, as amended, establishing the National Health Service by means of which the state secures citizens constitutional right to health protection through general and tending-towards-free health services;
- Law 48/90, of 24 of August, as amended – the Health General Law, approves the legal bases on which the protection of health is to be executed;
- Decree Law 11/93, 15 January 1993, approving the National Health Services Statute;
- Decree Law 124/2011, 29 December 2011 – the Ministry of Health Organic Law; and
- Decree Law 126/2014, 22 August 2014, approving the Portuguese Healthcare Regulatory Authority Statute.

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

The *Entidade Reguladora da Saúde*, the Portuguese Healthcare Regulatory Authority (ERS), is the independent public body responsible for regulating the activity of all healthcare providers in Portugal. The ERS is funded by a grant of the state budget and by its own revenue, among which, by 40 per cent of the amount of the misdemeanour fines and of other pecuniary sanctions arising from the infractions and offences enforced by the ERS.

The *Inspeção Geral das Atividades em Saúde*, the General Inspectorate of Health Activities (IGAS), is a central service under the direct administration of the state, responsible for the 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 of fines collected in administrative offence proceedings, among others, in the proportion attributed by the specific laws under enforcement by the IGAS.

The *Direção Geral de Saúde*, 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 under enforcement of the DGS. The DGS rules and coordinates the activities of promotion of health and prevention of disease, defines the technical conditions for the adequate provision of healthcare, programmes the national policy for the quality of the health system, secures the elaboration and execution of the National Health Plan and also coordinates the international relations of the Ministry of Health.

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

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

- register of healthcare service providers;
- complaint handling of service users, service providers and institutions;
- in loco inspections and audits to healthcare provider facilities;
- investigations of situations with significant adverse impact on patients rights or on the quality and safety of care;
- administrative offence procedures involving healthcare providers and application of resulting sanctions; and
- studies, advice papers and recommendations.

The General Inspectorate of Health Activities (IGAS), controls the compliance of the applicable law by the Ministry of Health bodies or services under its control or by public and private entities or entities of social nature. The IGAS's main activities include:

- execution of inspections and audits;

- initiation and decision of disciplinary proceedings and of administrative offences;
- public awareness campaigns, information and training actions; and
- issuance of opinions and non-binding recommendations.

The main scope of DGS activity is the following:
- coordination and development of health plans and programmes;
- coordination and assurance of epidemiological surveillance;
- analysis and disclosure of health information;
- regulation and assurance of health quality;
- management of public health emergencies;
- support the exercise of competences of National Health Authority;
- coordination of the Ministry of Health's activity in the domain of European and international relations;
- monitor the care call centre of the NHS; and
- coordination and monitoring of the Performance Evaluation Subsystem of the Ministry of Health Public Administration.

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 the subordination of the Ministry of Health, funded by an annual grant of the state budget and also by its own resources, among others, by the fees on the commercialisation of medicines, health products, cosmetics, personal hygiene products, medical devices and homeopathic pharmaceutical products, as well as by the product of the licences, fees and fines, in the percentage defined by law. Part of the amount of the fines reverts to INFARMED: 40 per cent of the fines applied regarding infringements to medicines legislation and 30 per cent of the fines arising from infractions of medical devices rules.

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

The INFARMED rules and supervises the sectors of medicines for human consumption and health products in accordance with public health protection high standards and warrants the access of the health professionals and citizens to medicines and health products with quality, efficacy and safety. Among other things, the INFARMED is responsible for the licensing, certification, authorisation, register and homologation of entities (pharma companies, distributors, pharmacies, manufactures and importers), activities and procedures, medicines for human consumption, medical devices and health products.

The INFARMED may execute inspections of the entities under its supervision. It authorises clinical trials, secures pharmacovigilance procedures for medicines and health products, rules on (and authorises) the prices of medicines subject to medical prescription or not subject to medical prescription (both reimbursable and non-reimbursable by the NHS), decides and conducts the reimbursement process of medicines, verifies the compliance with applicable laws on medicines and other health products and may impose fines in the case of infringement.

8 Which other agencies have jurisdiction over healthcare, pharmaceutical and medical device cases?

The Portuguese Competition Authority under the National Competition Act (Law 19/2012, 8 May 2012) has public enforcement powers over healthcare, pharmaceutical and medical devices activities, including in the merger control setting, as well as within illegal agreements, abuse of dominance and abuse of economic dependency conduct by player activity in the industry. Applicable sanctions include misdemeanour fines that can amount to 10 per cent of the infringer's annual turnover for illicit conduct.

The Public Prosecutors office in accordance with its responsibilities leads and directs criminal investigations, being, therefore, vested with investigation powers over crimes committed by healthcare providers or pharmaceutical companies and respective legal representatives and employees.

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, as potentially they might constitute, for different reasons, an infringement to the law under enforcement and supervision of several agencies. However, is to be noted that in case of simultaneous investigation, 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

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

The INFARMED is vested with enforcement powers in respect to the compliance with the applicable laws and regulations through inspection and supervision actions of the entities and respective products, namely medicines for human consumption, medical devices and cosmetics and clinical trials. The inspection and supervision activities may comprise the manufacturing, import, distribution and dispensing to the public of the mentioned products. The inspection and supervision actions are handled by INFARMED's Inspection Unit.

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

In addition, in the scope of the distribution activity of medicines, authorisation process of medicines and of the notification process for distribution of medical devices, inspections of the warehouse premises in which the products are to be stored or already are stored are executed to verify the conformity of the premises with the legal requirements applicable to such products.

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 the investigations; as such these depend on the scope of the investigation and related facts. However, the investigation report is to be concluded by the INFARMED's inspectors 60 days after the ending of the inspection. The inspected entity has 10 days counted from the notification of the report to submit in writing its reply. The INFARMED subsequently assesses the inspectors' report and comments of the inspected entity, and an official report of administrative offence may be issued by the INFARMED.

In addition to the above, specifically in the scope of the distribution activities of medicines and of medical devices and the notification referred to in question 10, such activities require an inspection of the wholesale premises to be executed in a 30-day period by the INFARMED, following review of the documents submitted by the applicants. However, if corrections are needed in the premises, an additional 30-day period is applicable for the applicant to execute required corrections.

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

As highlighted in question 11, entities under investigation have access to the investigation report of the INFARMED's inspectors as well as to the INFARMED's official report of administrative offence. In both cases, the defendant in the investigation is entitled to defence rights by means of comments to the investigators' report and opposition to the INFARMED's official report of administrative offence. After the issuance by the INFARMED of the administrative offence final decision, defendants are entitled to challenge such decision before the competent administrative court.

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?

The INFARMED may inspect, in conjunction with local authorities, facilities and establishments located in the European Union or in countries outside the EU, regarding manufacturing of medicines, active

substances or excipients and also the laboratories committed to certain manufacturing phases or equipment authorised by the INFARMED or used for the manufacturing purposes foreseen in the Portuguese Human Medicine Act (PMA) approved by Decree Law 176/2006, 30 August 2006, as amended.

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

14 Through what proceedings do agencies enforce the rules?

As highlighted in questions 10 to 13, the INFARMED is entitled to handle investigation and supervision activities and administrative offence procedures to enforce the applicable law. Final decisions adopted by the INFARMED can always be subject to judicial review.

The proceedings are ruled by administrative law, not being, therefore, of a civil or criminal nature.

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

The INFARMED may 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 of such disconformity cases are enumerated in the PMA.

In the event of infringement of the legal provisions contained in the PMA, the INFARMED can also impose misdemeanour fines and the following ancillary penalties:

- loss of objects, equipment and illegal devices in favour of the state;
- interdiction of the defaulter's activity for a maximum two-year period;
- deprivation of the right to participate in public tenders for a maximum two-year period; and
- suspension of authorisations, licences or of other titles granting rights, up to a maximum two-year period.

In the event of breach of the PMA legal provisions on publicity requirements of medicines reimbursed by the NHS, besides the administrative offence proceeding determined by such infringement, accessory sanctions can include exclusion of such medicine from state reimbursement.

In what concerns medical devices, Decree Law 145/2007, 17 June 2007, as amended, which approves the Portuguese Medical Devices Act (PMDA), the INFARMED may impose corrective measures on breaches found in the course of an investigation and may also impose misdemeanour fines in the administrative offence procedure. The decision of application of fines owing to the infringement of publicity and promotion law on medicines and medical devices may also determine the publishing and disclosure to social media of the essential scope of the condemnation, as well as the suspension for a maximum two-year period of the publicity and promotion actions on the product.

Furthermore, breach of the rules concerning the visiting of medical sales representatives of medicines and medical devices to NHS healthcare units and services and respective health professionals may determine sales representatives and respective market holder interdiction of accessing all such units and services.

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

The PMA is clear on this issue, as it contains specific provisions that foresee 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. It is also determined by the PMA that board of directors members of such entities may also be condemned in the sanction applicable to the entity, specially attenuated unless a more serious sanction is attributed by other legal provisions, when such natural person being or ought to have been aware of the infraction, did not adopt the adequate measures to terminate the infringement immediately.

The PDMA does not contain a similar provision as the one referred to in the previous paragraph. Therefore, as a rule, employees are excluded from the INFARMED's administrative offence proceedings. However, in the scope of its responsibilities, the INFARMED may notify the relevant authorities and public prosecutor of the infringements committed by the entities' employees.

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 433/82, 14 September 1982, as amended.

Under the aforesaid regime, no fines may be determined or applied by the 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 the INFARMED are mandatorily communicated to the infringers or defendants, and if such decisions and measures are susceptible to being challenged, the INFARMED's notification must contain the necessary information on legal acceptability, terms and challenging form before courts under the double-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 proceed with the challenging of the decision before the same court. First instance court decisions are subject to appeal.

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, relationships and interaction with health 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 an attenuating 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.

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 the INFARMED has been the supervision on pharmacovigilance and safety issues, publicity matters, the interaction of pharma companies with healthcare professionals and counterfeit medicines – the latter in conjunction with the Portuguese Tax and Customs Authority. Information on applied sanctions is not publicly released on the INFARMED website.

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:

- Apifarma: the Portuguese Pharmaceutical Industry Association; and
- Apormed: the Portuguese Association of Medical Devices Companies.

Apifarma is ruled by two main Code of Ethics:

- The Code of Ethics for Promotional Practices of the Pharmaceutical Industry and for the Interactions with the Healthcare Professionals

and Institutions, Organizations or Healthcare Professionals Associations; and
- The Code of Conduct Governing the Relations between Pharmaceutical Industry and Patient' Organisations.

The implementation and enforcement of the Codes is entrusted to Apifarma's council of ethics, which in the case of infringement of the ruling of such Codes may ask the offender to immediately cease the default or to undertake in writing the obligation to not relapse in such practice. The violation of the provisions of such Codes constitutes a disciplinary offence and may lead to disciplinary measures, such as:
- simple warning;
- reprimand;
- penalty up to the amount of five years of membership fees;
- suspension up to one year; and
- banishment.

Enforcement proceedings can be triggered ex officio by Apifarma or based on a complaint.

Apormed's statute also includes disciplinary sanctions applicable to the respective members analogous to those provided in Apifarma's Codes.

Relationships between healthcare professionals and suppliers

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 PMA and in article 51 of the PDMA. Both provisions prohibit the giving or promise to give, directly or indirectly, awards, gifts, bonus or pecuniary or in-kind benefits to healthcare professionals, except in case of objects of negligible value (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.

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 founded, an administrative offence procedure may be initiated and fines may be imposed in accordance with articles 181 of the PMA and article 61 of the PMDA.

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

The entities that are under the scope of the PMA are required, as set by respective article 159, to report to the INFARMED in a 30-day period any payment, delivery of goods or granting of rights of pecuniary value, subsidy, sponsorship granted to any entity, legal person, individual, company, association (regardless of its nature or form), medical society of a scientific nature, clinical trials and patient organisations.

The PMDA does not contain a provision similar to article 159 of the PMA, as described above.

Regulation of healthcare delivery

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

The ERS, as supervising and regulatory authority of all healthcare providers, has an extensive array of powers and is vested with the following powers to monitor compliance:
- perform inspections and audits to healthcare providers facilities;
- handle investigations of situations of significant adverse impact on the rights of patients or on the quality and safety of care;
- handle complaints from service users, providers and institutions;
- conduct administrative offence procedures involving healthcare providers and applying sanctions; and
- produce studies, advice papers and recommendations.

The IGAS is entitled to audit, inspect, supervise and develop the disciplinary action in the health 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. With relevance for private healthcare providers, IGAS may carry out inspections on private and social healthcare units in areas of additives dependencies and behaviours. The IGAS is also committed to actions of prevention and detection of corruption and fraud, by promoting the adequate procedures.

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

There is no legal time frame established. The duration depends on the scope 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 offices 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.

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

No access to the inquiry file is, as a rule, granted until the end of investigation although defence rights are secured by the applicable law, namely after the adoption of the infringement notice in the terms highlighted above in reply to question 17.

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

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 a civil of criminal nature.

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

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

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 acts are found 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 acts by the infringer or on any measures to prevent or repair such damage that are indispensable to effect the final decision adopted in an administrative offence procedure.

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

These are same as those referred to in question 17.

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

Update and trends

The ERS 2016 Activity Plan contains the strategic guidelines for 2016, as approved by the ERS' board of directors. The defence of healthcare services consumers is a primary goal. Supervision, regulation and inspection activities are foreseen to be enforced to secure the quality of the information to be provided to consumers and to actively protect their rights in the economic relations established with healthcare providers and financers. Activities related to the measurement of the satisfaction degree of consumers of health services are also foreseen to be implemented, as well as active involvement in the ERS's supervision activities to healthcare providers, namely in inspection activities. Publicity for healthcare practices is also assigned as an ERS strategic goal.

The INFARMED's Strategic Plan 2014–2016 highlights as strategic goals the INFARMED'S contribution to the health system sustainability by means of the rational use of drugs and of health products and an efficient and effective use of resources.

The NHS's sustainability and associated control and reduction of costs constitute a major and increasing concern of the government. In this regard, administrative measures and legislation have been enforced to reduce the price of medicines. In 2016, the acquisition process of products and services for the NHS hospitals and units has become a centralised procedure handled by a specific public entity (SPMS – Ministry of Health Shared Services). As a result, NHS hospitals and units can no longer directly purchase the products (medicines and medical devices included) previously selected and contracted by means of public framework agreements.

Fraud and corruption constitutes also a major concern of the regulatory authorities.

be performed to monitor employees' strict compliance with company's procedures.

While the enforcement action is underway, cooperation with agencies is not only a legal requirement in the investigation phase but is, subject to a case-by-case analysis, also recommended, as 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.

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 scope of the enforcement activity of the authorities.

The majority 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.

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

No.

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

The majority of healthcare providers are NHS hospitals (public hospitals and hospitals centres) and units 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 previous public procurement procedures.

In the case of poor performance or breach of contractual and legal obligations, the most common remedies are the imposition of penalties and the termination of contract. 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

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

Basically 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 may also be held liable under a specific extra-contractual civil liability, namely individuals and entities of the public healthcare sector.

Criminal Liability

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

- medical and surgical treatments in violation of legis artis (meaning the current and common medical practices) (article 150.º, No. 2 of the Portuguese Criminal Code (PCC);
- medical and surgical treatments against the patients' 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, and depending on the sector (public or private) in which the healthcare provider commits the infringement the law enforcement may be of public or private, or labour, nature.

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 health professionals and healthcare institutions as well as of guidelines issued by public agencies, such as the DGS. Apart from specific ruling arising from the above-mentioned practices and guidelines, the general standard is the bonus pater familia, meaning that every health professional shall act with the diligence and correctness that a 'normal' and typical health professional would act in that specific situation.

From 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 a damage;
- guilty behaviour; and
- causality between the damage and the defaulting conduct.

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

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 the INFARMED on the following areas and subjects:

- services rendered by entities regulated and supervised by the INFARMED;
- products regulated by the INFARMED; and
- services provided by INFARMED.

Besides the civil and criminal liability as described in question 34, and respective grounds, product liability and adverse reactions may serve as grounds.

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 nature and extension of the damages and losses.

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

The *ação popular* (popular action), governed by Law 83/95 of 31 August, 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.

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. The remedies may consist in the revocation, suspension, amendment of an act or decision in the administrative offense scope 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, note that public entities may also be challenged for damages in the scope 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 administrative 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.

40 Are there any legal protections for whistleblowers?

There is no general regime for whistleblowers even though specific regimes are set for money laundering, terrorism and drugs traffic. However, it is to be noted that whistleblowers 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 whistleblowers?

There is no reward mechanism for whistleblowers in Portugal.

42 Are mechanisms allowing whistleblowers to report infringements required?

There is a specific mechanism for corruption and fraud available on the website of the Central Bureau of Investigation and Prosecution of the Attorney General's Office (https://simp.pgr.pt/dciap/denuncias/index2.php).

This report mechanism is to be executed online and whistleblowers shall identify:

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

Whistleblowers may also inform on the amounts at stake, on individuals that may be relevant for the understanding of the facts and may also submit documents to support such complaint.

Whistleblowers may choose to remain anonymous.

Cross-border enforcement and extraterritoriality

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 144/99 of 31 August.

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

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

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.

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