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1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

On a legislative level, the Greek Ministry of Health is competent for planning and implementing the national health policies. In addition, the National Organization for Medicines (the "EOF", as per its Greek acronym), is the competent overseeing body for regulating and supervising pharmaceuticals, medical devices, supplements, over-the-counter ("OTC") products, and cosmetics.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Art. 6 of Law 2251/1994 on Consumer Protection (as amended), that transposed into Greek law the Product Liability Directive 85/374/EC, applies. Law 2251/1994 on Consumer Protection applies also in the event of damages sustained and caused by defective medical devices (Directive 2001/83/EC and Regulations n. 2017/745 and 2017/746). General provisions of the Greek Civil Code (art. 914 *et seq.* establishing tortious liability) are also applicable in case they afford consumers more effective protection.

Approval of a product by the competent regulatory authorities ("EOF") does not preclude nor limit any civil and criminal liability of the producer and, where applicable, of the marketing authorisation holder ("MAH") (see Ministerial Decision ("MD") No. Δ.ΥΓ.3α/Γ.Π. 32221/29.04.2013 which incorporated the Directive 2001/83/EC on the Community Code relating to medicinal products for human use). Although regulatory approval (marketing authorisation – "MA") does not shield producers from liability, and although the courts will not defer to it, it is considered a relevant fact.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

MA and compliance with the requirements of the regulatory authorities do not exclude the producer's liability as set out above. In reverse, non-compliance may be either a standalone ground for a finding that a product is defective or a critical indication to the same effect. Further on, in cases in which regulatory standards are heightened, the courts that are called upon to decide on a matter relating to the previous state of affairs may treat this change in regulation as a critical indication that the *status quo ante* was problematic.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

With regard to pharmaceutical products (including prescription-only medicines and OTCs), the Hellenic Association of Pharmaceutical Companies ("SFEE"), a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA") and the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA"), is the competent self-regulatory body which, by virtue of its Code of Ethics, governs the interactions between its member pharmaceutical companies and various stakeholders of the industry (including HCPs, HCOs, POs, etc).

With regard to medical devices, the Association of Health – Research and Biotechnology Industry ("SEIV") is competent for regulating, under its Code of Ethical Business Practice which transposes the respective MedTech Code, interactions between its members and the industry.

Lastly, the Hellenic Cosmetic, Toiletry & Perfumery Association ("PSVAK") is the competent self-regulatory body for representing the cosmetics, perfumes, and personal care industry in Greece.

The codes of conduct constitute soft law, and thus do not directly affect litigation and liability. However, when under applicable law trade usages are to be taken into account, they may become relevant. It must be noted that the codes of conduct often reproduce certain legal provisions. In such cases, any litigation or liability will be due to the violation of the legal provision.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Yes, essentially all life sciences companies, but even more stringently pharmaceutical companies, are required to provide warnings with regard to the adverse effects of their products directly to consumers and to the prescribing physician. Possible risks and adverse effects must be included in the pharmaceutical products' Summary of Products Characteristics ("SPC") and in the Patient Information Leaflet ("PIL").

Overall, patients must be in a position to make an educated decision about taking the product that factors in the risks and the benefits involved. Hence, all necessary information regarding a pharmaceutical product must be provided to them in the PIL, which is included in every medicine package. This information must be complete and presented in a way that is clear and understandable to the average patient. The duty to inform (warn) is derived from the general duty of care imposed by the law on Consumers' Protection. In case the PIL does not meet the standards imposed by the duty of care, the producer will be held liable, since the medicine will not provide the safety which a person is entitled to expect with respect to its presentation and, therefore, its use. This applies even when no design or manufacturing defect exists. Litigation in the life sciences sector involves, almost exclusively, alleged violations of the duty to inform. Greek courts scrutinise the content of PILs. Use of technical language not understandable to the average patient/layman and incomplete information (even relating to obvious matters) is always a source for concern. There have been cases in which the courts held that the use of technical language in order to warn of a medical condition, such as inflammation of lungs, did not meet the required standards. In addition, case law exists whereby the courts held, for example, that it is not sufficient to warn the patient of the risk of anaphylactic shock, and that clear or explicit language that the patient could perish as a result should have been incorporated. Life sciences companies are also required to provide detailed information on the use of medicines to healthcare professionals. This information is provided in the Summary of Product Characteristics ("SmPC"). We are not aware of litigation triggered by a fault in the SmPC. In cases in which the pharmaceutical product is prescribed by a healthcare professional, it is disputed whether the conformity of the SmPC with the regulatory requirements may result in the dismissal of a claim against the producer which is based on violation of the duty to inform because of a faulty PIL. The prevailing view answers this question in the negative. The only exception, validated by Supreme Court case law, is hospitalised patients. For them, only the SmPC is deemed of relevance.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

With regard to pharmaceuticals, the manufacturer is subject to the holding of a relevant authorisation/licence, issued at the national level by the EOF; authorisation is also required even when the pharmaceutical products manufactured are designated for export.

The foregoing licensing requirement by the EOF applies *mutatis mutandis* to the manufacturers of medical devices and cosmetics.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

The local regulatory authorities and principally the EOF is responsible for monitoring all aspects regarding the manufacturing, authorisation and circulation of pharmaceuticals and medical devices in Greece. To this end, the EOF cooperates with the European Medicines Agency ("EMA") and other EU institutions as applicable in order to safeguard that the above activities meet the requirements of the law at both a national and European level, on the basis of relevant agreements reached and by virtue of applicable legislation. At the European level, *inter alia*, EMA has entered into the Mutual Recognition Agreement with the US Food and Drug Administration, whereby both counterparts shall recognise each other's Good Manufacturing Practice ("GMP") systems and standards.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

The manufacturer should be able to guarantee the conformity of the product to all manufacturing requirements, including the GMP standards. In case a product does not meet the above requirements, the manufacturer may face an administrative fine and/or suspension or revocation of the GMP Certification. In cases of non-compliance to the manufacturing requirements, the injured person is entitled to seek compensation for injuries suffered due to the defective product. The burden of proof is reversed, and the claimant (injured person) must only prove the defect, the damages sustained, and the causal link between the defect and the damage.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

No such approval exists; the companies involved in the life sciences mergers/acquisitions are only required to notify the EOF for the said corporate restructuring which affect the products' MA, the products' packaging, PIL etc. The same applies with regard to any transfer of ownership of manufacturing facilities that might take place as a result of the merger/acquisition.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

No such limitations exist specifically for the life sciences sector and as regards foreign ownership of life sciences companies or manufacturing facilities. It may be noted, however, that as particularly regards pharmaceuticals, foreign pharmaceutical companies need to appoint a local representative, if they do not have an establishment in Greece, in order to place their products on the Greek market and to serve as their representative before the EOF, for all matters concerning the marketed product. The said representatives may be held jointly and severally liable with the MAH for any injuries caused through the use of a pharmaceutical product. The manufacturer's liability is governed by the provisions of Law 2251/1994 on Consumer Protection.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

In terms of drugs, the MD 32221/2013 is the main piece of legislation that governs the advertising of prescription-only pharmaceuticals and OTCs.

With regard to medical devices, the MDs 130648/2009 and 130644/2009 govern the medical devices and *in vitro* diagnostics presentation and advertising in Greece, respectively. Despite the fact that the Regulations 2017/745 on Medical Devices (the

"MDR") and 2017/746 on *In Vitro* Diagnostic Medical Devices (the "IVD") have entered into force, the aforementioned MDs have not yet been abolished, amended or replaced.

With regard to cosmetics, advertising is subject to the provisions of the MD 91512/2018, transposing the EU Regulation 1223/2009 into the Greek legal order. Lastly, in terms of food supplements, the MD 53625/2017, providing for the harmonisation on a local level with the provisions of the Directive 2002/46, provides for the particular requirements that relate to the food supplements' labelling, presentation and advertising in Greece.

On a regulatory level, EOF issues on a regular basis Circulars that regulate advertising of all product categories that fall under its remit.

From a soft law perspective, the self-regulatory bodies listed in Question 1.4 regulate, by virtue of their codes or guidelines, advertising of the products of their competent. In this respect, it should be noted that the SFEE's Code of Ethics – which regulates, among others, the promotion of pharmaceutical products by its members (mostly multinational pharma companies) – can be considered a useful tool, as it incorporates concise and updated provisions in alignment with the relevant regulatory framework.

Lastly, the Greek Advertising Code of the National Advertising Self-Regulation Council ("SEE") provides general rules and guidelines with respect to the promotion and advertising of cosmetics and food supplements to consumers.

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

It is prohibited to promote medicinal products for which an MA has not been granted or for which an application for the MA has been filed but has not yet been issued. In this context, it is explicitly prohibited to promote indications which are not covered by the MA (off-label products) or which have not yet been approved.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

Litigation on advertising, promotion and sale of drugs and medical devices can either be initiated between competing companies or between producers and consumers.

In the former case, legal proceedings can be initiated with the civil courts invoking the provisions of Law 146/1914 on unfair competition. The options afforded to the claimant include both main litigation proceedings and interim measures. In both cases, the claimant may seek that the anti-competitive business practices be ceased and that its competitor refrain from any subsequent acts under penalty per violation. Concerning the interim measures proceedings, the claimant has the option to request that a provisional order be rendered until the hearing of its petition.

In the latter case, a complaint may be brought against the producer on the basis of art. 9 of Law 2251/1994 on Consumer Protection implementing the Directive 2005/29/EC concerning unfair business-to-consumer commercial practices. The consumer may request that the producer ceases the unfair commercial practices and refrains from any similar acts in the future. The consumer may also seek compensation in case damages have been sustained due to said unfair practices.

Any infringement of the provisions of advertising and promotion of drugs may also lead to the imposition of a fine by the competent authorities and revocation of the producer's MA.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with data privacy standards such as GDPR and other similar standards?

Given the high fines which can be imposed for infringements of the data protection legislation provisions (including the GDPR and the national legislation supplementing the GDPR), life sciences companies place great importance in ensuring compliance with all the relevant obligations they are subject to. This is especially the case when it comes to processing special categories of personal data which require additional considerations, in particular in relation to conducting/participating in clinical trials and performing marketing activities.

The most common compliance actions in relation to their day-to-day activities which involve the processing of personal data include keeping a record of processing activities, ensuring that any processing activity is based on a lawful basis and is conducted in line with the GDPR principles, ensure that any person whose personal data is being processed has been informed pursuant to articles 13 and 14 of the GDPR, have in place data processing agreements/terms with any third party who processes personal data on its behalf, implement appropriate technical and organisational measures for the protection of the personal data, appoint a data protection officer, etc.

Particularly for activities relating to the distribution of products globally, special attention must be placed towards the obligations that may be triggered due to the potential transfer of personal data outside the EU/EEA. Such transfers may require the implementation of appropriate safeguards, such as the execution of the European Commission's standard contractual clauses. Moreover, clinical trials may require carrying out a data protection impact assessment, given the special categories processed (health data), the large scale of processing and the permanent nature of the processing.

In practice, life sciences companies usually assign to an external advisor the task of conducting a GDPR compliance audit, which comprises a gap analysis, preparation of all documentation to ensure compliance and trainings on data protection issues.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

Although it is expressly provided in recital 20 of the General Data Protection Regulation (Reg. EU 2016/679) that the Regulation is applicable to courts and judicial authorities, confidentiality of documents produced may not be ensured, given the public nature of state court civil litigation. Access to the case file, and hence to the documents produced in litigation, is granted only to the parties, their counsel, and the court. This does not preclude, however, a potential leak of a confidential document. Further on, hearings are held publicly (art. 113 Greek Code of Civil Procedure (GrCCP)), subject to very strict exceptions not applicable here. Hence, in case the content of a document is discussed at the hearing, any bystander will effectively have this information. In addition, a great number of court decisions are published in law reviews (the consent of the parties is not requested for this), whereas all Supreme Court decisions are published on the Supreme Court's website, and the decisions are anonymised. However, this anonymisation does not include the removal of the evidentiary findings of the court in which the content of documents produced may be discussed in great detail.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

The project on Digitization of the Archives of the Public Health System is currently in the pipeline, aiming at providing comprehensive information for patients by integrating medical information from the historical archive. Moreover, the Individual Electronic Health Record has been put into effect, which enables, *inter alia*, the electronic perception of medicines by the treating physicians.

GDPR standards and obligations, as well the provisions of intellectual property laws, must be taken into consideration in the context of digital health. In addition, digital health apps and software may qualify as medical devices, and thus must comply with the respective statutory provisions.

The Greek Government recently introduced a digital application named "MyHealth", which essentially allows the user to have immediate access to his/her medical file, results of medical exams (of both public and private hospitals), hospitalisation documents, as well as electronic prescriptions or referrals. The use of the app seems safe, so far, as access requires the user's personal username and password, and his/her Social Security Number.

Moreover, a proposal for a Regulation on the European Health Data Space (COM/2022/197) is about to be adopted by the European Parliament and Council. The proposed regulation provides for the use of personal electronic health data not only for primary use, i.e. by the user itself, but also for secondary use, meaning that such data may be used further, under certain conditions, and contribute, for example, to the support of the public sector bodies or EU institutions, agencies and bodies, including regulatory authorities in the health or care sector, as well as to the training, testing and evaluation of algorithms in medical devices, AI systems and digital health applications, or even to the development and innovation of products or services, medicinal products or of medical devices, with the aim to ensure a high level of quality and safety of health care. Said proposal provides for the establishment of a centralised platform for digital health (MyHealth@EU) for the support and exchange of electronic health data between national contact points for digital health of the EU Member States.

Thus far, the above developments have not had an impact on litigation.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Clinical trials are governed by Regulation (EU) n. 536/2014, the MD G5(a)/59676/2016 and Law 3418/2005 (Code of Medical Ethics), which incorporated the Oviedo Convention into Greek law. The aforementioned MD provides for the transposition of the EU Regulation 536/2014 on clinical trials on medicinal products for human use; therefore, the regulatory standards, guidelines, or rules that govern clinical testing are *grosso modo* aligned with the respective standards and guidelines determined by the Regulation. It should be noted that clinical trials in Greece are subject to the EOF's approval. In this regard, the EOF has issued a national clinical trial template which must be signed by the parties engaged in the trial (including the sponsor, the hospital, the principal investigator, etc.)

The subject who suffered injuries or damages resulting from participation in a clinical trial is entitled to seek compensation alleging either tortious liability (art. 914 *et seq.* GrCC) of the investigator, the hospital and/or the sponsor or breach of contract against the investigator. It could be further argued that a drug under clinical testing qualifies as a drug already in use but not yet placed on the market, and thus the provisions of Law 2251/1994 on Consumer Protection apply by analogy. It is debated, though, whether the participant in a clinical trial qualifies as a consumer under Law 2251/1994 on Consumer Protection.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

There is no explicit liability for failure to test in certain patient populations. However, Regulation (EU) n. 536/2014 provides that the study protocol must include a justification for the gender and age allocation of subjects and, if a specific gender or age group is excluded from or underrepresented in the clinical trials, a justification for the exclusion criteria should be provided. Pursuant to the Code of Medical Ethics, discrimination and exclusion of the patients are prohibited. It is thus suggested that people of diverse populations are included in the process or at least in Phase III of the clinical trials. The aim is to provide access to the process to more people and thus have more possible adverse effects recorded.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

In principle, no medicinal product may be circulated in Greece without an MA. However, a medicinal product that has not yet obtained an MA can be brought in Greece through early access schemes, according to MD 85037/2011, as amended and currently in force, which provides for the early access to pharmaceutical products in groups of patients or individuals.

In particular, a personal or individual licence for early access to medicinal products (the Named Patient Program – "NPP") applies under the terms and conditions defined in detail in the aforesaid MD (i.e., in specifically justified cases, for a specific patient, upon the request of the treating doctor and under the doctor's exclusive and unlimited liability, and provided that it is ascertained, based on the available data, that the benefit/risk ratio is in favour of the anticipated benefit).

The same MD provides for the "group scheme for early access to the medicinal product". This scheme applies for a specific group or subgroup of patients that are included in a general group treatment and follow-up scheme. This scheme is based on the analytical criteria that are included in an approved therapeutic protocol for the administration of an "early access" medicinal product. In both schemes, what must be established is that, based on the available scientific data, the existing and in-use product for the clinical need in question (if any) is not appropriate from a medical perspective for the particular patient or patients.

Both schemes need the EOF's prior approval, which is valid for a maximum of one year and can be renewed, provided that the approval's conditions are still applicable. The early access licence is terminated as soon as the medicine in scope obtains an MA, or in case the application for the granting of an MA is rejected on substantial grounds. Lastly, the pharmaceutical company concerned undertakes to provide the unlicensed product free of charge, unless specific reimbursement has been introduced, whereupon the relevant decision of the competent social security fund must be provided.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

An *ex-ante* waiver of a claim in tort is considered null and void. Further on, exclusion or limitation of liability clauses are non-enforceable in cases where the harm is inflicted by wilful conduct or caused by gross negligence.

By virtue of article 15 of MD G5(a)/59676/2016, the sponsor of a clinical trial must enter an insurance contract with a trustworthy EU-based insurance company to cover any liability of the sponsor, the main researcher, and the members of the research team. The insurance amount shall cover potential damages due to injuries or disabilities that may incur because of the participation in the clinical trial, and shall amount to a minimum of 300,000 Euro per participant in the event of death or permanent incapacity to work.

The only defence that might be brought against the participant in cases of non-compliance to the instructions of the investigator/physician is the contributory fault defence (article 330 GrCC) which may limit the physician's liability significantly, depending on the facts of the case.

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

There are no such explicit regulatory or other guidance in this respect, apart from the insurance coverage of clinical trials mentioned above under question 6.4.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

The MD 14709/2018 which provides for the adaptation of the Greek legislation to the provisions of the Directive 2017/1572 as regards the principles and guidelines of good manufacturing practice for medicinal products for human use provides, *inter alia*, for the course of actions that must be undertaken for product recalls. In this context, the EOF must be notified immediately. In addition, the EOF may request for the recall of specific batch(es) of products which are the subject of dispute.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

In general, product recalls of life sciences products are subject to the same notification to the EOF obligation. There are of course specific legislative and regulatory provisions that explicitly govern each category of products; however, there are no particular differences to be reported compared to the recall of medicinal products.

7.3 How do product recalls affect litigation and government action concerning the product?

A product recall will most certainly qualify as an out-of-court admission of the existence of a defect, whatever language is used in the announcement to the public. It will thus have an adverse impact on pending litigation in which such a defect is alleged. On the other hand, not moving forward with a product recall in cases in which this may be deemed required may be a standalone tortious liability ground.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Recalls effected by the EU authorities or other EU Member States are almost immediately enforced on a national level by the EOF. Recalls by the United States authorities, despite not having the same immediate effect, may trigger an investigation proceeding either on a European or national level. In any case, the manufacturer's and/or the MA holder's liability to notify the EOF for the recall of products (or specific batch(es)) is not abolished.

If an EMA-approved product is recalled, and litigation is already pending on the defect that caused the recall, the court will most definitely consider it as relevant fact. If a product is recalled by authorities such as the FDA or national organisations of EU members, this will also be considered by the Greek courts when deciding a case involving the same alleged defect.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

To the best of our knowledge, there are no specific protections for internal investigations or risk assessments.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

It is important that the companies cooperate with the National Organization for Medicines and comply with the issued guidelines and decisions. It is thus suggested that all corrective measures be taken swiftly and in full transparency. Failure to do that may result in additional ground for tortious liability.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

Article 10 of Law 2251/1994 on Consumer Protection has implemented the Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers, and provides for collective actions pursuant to the Directive.

Collective actions may thus be filed by consumers' associations that have been registered as qualified entities for bringing representative actions with the civil courts. The reliefs sought may pertain to the cessation of any unlawful conduct causing damages to the collective interests of consumers or to the implementation of corrective measures, including compensation paid to the consumers, price reduction, contract termination, replacement of the product, etc.

In the former case, the *res judicata* effect of the decision applies on an *erga omnes* basis, thus also binding third parties that did not participate in the trial. Further on, a final court decision, holding that an infringement harming collective interests of consumers has taken place, may be used as evidence in the context of any other subsequent action for implementation of corrective measures before the Greek courts.

Collective actions are commonly utilised to combat misleading advertising practices.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Plaintiffs usually prefer to bring personal injury/product liability claims as individual lawsuits against the producer.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

Product liability claims are brought under article 6 of Law 2251/1994 on Consumer Protection, as amended and in force. The claimant must prove the defect, the damage sustained, and the causal link between the defect and the damage. Hence, the claims brought under Law 2251/1994 on Consumer Protection are strict liability claims.

In cases where the consumer invokes in its lawsuit general provisions of the GrCC to establish producer's tortious liability, the burden of proof is reversed. As a result, the producer when defending a claim against it must argue and prove lack of fault.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

Lawyer solicitation is expressly prohibited (article 10 of the Code of Conduct for Lawyers). Lawyers are only permitted to inform on their professional activities, providing general information on their expertise which is accurate and not misleading (article 9 of the Code of Conduct for Lawyers and article 40 of Law 4194/2013).

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

Concerning individual plaintiff lawsuits, legal aid is granted to citizens with low income pursuant to Law 3226/2004.

Third-party litigation funding is prohibited concerning collective actions filed under article 10 of Law 2251/1994 on Consumer Protection.

In general, third-party litigation funding is strange to Greek law, and to practice.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

The *res judicata* effect of a final decision binds only the parties to the dispute. Hence, a finding against the producer will not prejudice the outcome of subsequent litigation involving a different plaintiff or a different producer. In practice, however, courts do consider past decisions rendered in cases involving essentially the same facts and/or the same claims, and tend to adopt the reasoning employed therein.

In cases of collective actions pursuant to article 10 of Law 2251/1994 on Consumer Protection, the final decision of a court seized with an action pertaining to the cessation of any unlawful conduct causing damages to the collective interests of consumers will be binding on third parties who have not participated in the proceedings. This, however, is the exception and not the rule.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

A subsequent remedial measures rule is not applicable under Greek law. Evidence relating to the steps taken by the company to improve their product or correct product deficiencies will be admissible. However, regarding litigation, said improvements may be seen as supporting the claimant's allegation that the product was defective. In fact, there is case law in which the court held that the subsequent change in the PIL aiming to make certain disclaimers more comprehensible to the average patient was proof that the previous version (which was under consideration) did not meet the standards imposed by the duty of care.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Adverse events experienced by product users other than the plaintiff qualify as relevant facts. Hence, the plaintiff may produce evidence available to him. Discovery is strange to the Greek Civil Procedure. There are, however, functionally equivalent remedies which are less effective and subject to strict requirements. Given the relevance of the evidence, the plaintiff could request that the defendant produce certain documents as evidence. The requirements for said request, apart from its relevance, are (a) that the plaintiff identifies the documents requested specifically, and (b) that the plaintiff establishes that the documents are in the possession of the defendant. The court on its motion or upon request of a party may order a defendant or even third parties to produce such documents as evidence.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

In Greece, a testimony can be conducted: (a) before the competent Magistrate, Notary Public, Attorney or Greek Consul, upon summoning of the adversary, two days before its execution; or (b) before the Court on the hearing date, depending on the nature of the action and the courts' procedures. Each party is allowed to execute and present up to three sworn testimonies with its pleadings, and up to two with the rebuttal. Sworn testimonies of the members of the Board of Directors or the legal representative of the company are not acceptable. In principle, sworn testimonies of the company's employees are acceptable.

Legal assistance for conducting depositions of company witnesses for use in litigation pending abroad can be sought under the rules of Regulation (EC) 1206/2001 for EU Member States or, for non-EU Member States, through the Hague Convention on the taking of Evidence Abroad in Civil or Commercial Matters of 18 March 1970.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

According to article 38 of Law 4174/2013, the latter must observe strict confidentiality regarding the information they are entrusted with from their principals upon assignment of a mandate or case and during the performance of their duties. In the event of breach of such obligation, attorneys shall face not only civil but also disciplinary penalties, imposed by the Bar Association they are registered with. In addition, criminal penalties for breach of the confidentiality obligation may be imposed according to article 371 of the Greek Criminal Code, upon complaint of the client. The same applies with in-house counsel. In practice, however, companies tend to include Non-Disclosure Agreements with in-house counsel and associates. We note that under the provisions of Law 4174/2013, in-house counsel may not be considered employees, and they enjoy full autonomy in the way they dispose of their duties. Under this approach, attorney-client privilege is applicable to in-house counsel as well.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

The confidentiality of communications with Greek counselsis expressly provided under article 38 of Law 4174/2013. The attorney-client privilege may only be lifted due to public interest, or pursuant to Law 4557/2018 regarding prevention of money laundering and terrorist financing. As a result, a confidentiality agreement is not necessary. Concerning communications with counsel outside the jurisdiction, one should assess the relevant provisions of the counsel's law or code of conduct governing confidentiality, and proceed with a confidentiality agreement in case similar rules are not applicable to the foreign jurisdiction. It is noted that, since confidentiality for purposes of litigation is a question of procedure, Greek courts will apply the *lex fori* standards also to counsel residing outside Greece.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

Greek civil procedure law does not impose limitations to foreign defendants which are treated equally. On the contrary, deadlines set by the GrCCP for the service of the lawsuit and the filing of the pleadings are extended to safeguard due process and fair treatment of the defendant located abroad.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

The *res judicata* effect of the US court decision will be recognised in Greece *ipso jure,* as long as certain prerequisites are met. These prerequisites are examined incidentally by Greek courts before which the *res judicata* effect of a foreign judgment is invoked. A standalone request for the recognition of the *res judicata* effect of the foreign judgment is also not precluded. In light of the question posed, the most relevant prerequisites are: (a) that US courts shall have both personal and subject-matter jurisdiction to adjudicate the case according to Greek law; (b) that the US court decision is not contrary to a Greek court decision having a *res judicata* effect between the same parties; and (c) that the US court decision is not contrary to Greek public policy. It will be difficult for prerequisite (a) above to be met, given that personal and subject-matter jurisdiction will lie either with the US or with the Greek courts. Therefore, in cases in which Greek courts will have jurisdiction to hear a "follow-on" claim, such jurisdiction would encompass also the infringement matter already adjudicated by the US courts. That being said, Greek courts may look into a US court decision as a persuasive authority. They will differ, though, and they will relitigate the infringement question *de novo*.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

It depends on the particularities of each individual case. The rule of thumb, however, is that US litigation will not trigger litigation before the Greek courts. This is due to the substantial differences between the two legal systems in terms of the applicable procedural and substantive law.

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