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Practical cross-border insights into drug and medical device litigation

Drug & Medical Device Litigation

2022

Third Edition

Contributing Editors:
Alan E. Rothman & Daniel A. Spira
Sidley Austin LLP

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Publisher
Jon Martin

Associate Publisher
Oliver Smith

Production Editor
Jane Simmons

Senior Editor
Sam Friend

Head of Production
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Expert Analysis Chapters

Q&A Chapters

Cyprus


Eleni Neoptolemou


Munevver Kasif

Harris Kyriakides

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.

In Cyprus, the regulation of pharmaceuticals, medical devices, supplements, over-the-counter products and cosmetics falls within the remit of specific regulatory bodies directed by the Services of the Ministry of Health. First of all, the Council of Medicine (***CoM***), operating under the authority of the Pharmaceutical Service, is the regulatory body responsible for providing marketing authorisations for medical products for human use, before as well as after their circulation on the Cyprus market. This includes pharmaceuticals, supplements and over-the-counter products. For the circulation of cosmetic products, the Council of Cosmetics (also adhering to the Pharmaceutical Service) is the body responsible for providing appropriate authorisation and licensing. Furthermore, the competent government authority responsible for the regulation of medical devices in accordance with Cypriot and European law is the Competent Medical Equipment Authority.

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?

The Medicines for Human Use (Quality, Supply and Price Control) Law of 2001 (***Law 70(I)/2001***), in case of violation of its provisions, provides for the imposition of administrative fines of up to £25,000 (Cypriot pounds) by the CoM, as well as criminal penalty of imprisonment not exceeding five years or a criminal fine not exceeding £50,000 (Cypriot pounds) or both, for natural and legal persons. In the case of criminal liability of legal persons, Law 70(I)/2001 states that directors or managers of a company will be subject to criminal penalties and/or fines. There is also the possibility of pursuing civil liability against the manufacturer or market authorisation holder. It is important to note that, according to Article 102 of Law 70(I)/2001, if a manufacturer and holder of the marketing authorisation of the medicinal product obtain a marketing authorisation by the CoM, he is exempt from any civil or criminal liability, should a violation of the provisions of Law 70(I)/2001 occur.

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

The newest reforms in the regulatory framework concerning medicinal or life sciences products have helped promote a higher standard of quality and consumer protection. The existence of administrative, civil and criminal liability ensures that manufacturers and market authorisation holders in general will strive to ensure compliance with the national legal framework and the national competent authority's guidelines and directions. Moreover, it urges increased transparency and a system of continuous checking of the upholding of standards of safety and quality.

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?

In Cyprus, there are no self-regulatory bodies in regard to the monitoring and circulation of drugs, medical devices, supplements, over-the-counter products or cosmetics, other than those adhering directly to the Ministry of Health as described in question 1.1.

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?

With regard to the manufacturing and circulation of medicinal and other pharmaceutical products, the manufacturer is required by Law 70(I)/2001, even during the stage where he has applied for a manufacturing authorisation, to provide a leaflet of the product which would include a description of the adverse reactions that may occur during normal use of the medicinal product and, where appropriate, the actions to be taken by the user of the product in this case; the label may also include a specific warning if necessary. Moreover, the Essential Requirements (Medical Products) Regulation 2003 (***R.A.A. 598/2003***) expressly states that every product must be accompanied by all the necessary information regarding (i) safe use of the product, taking into account the knowledge of the common user, and (ii) who the manufacturer of the product is. The product must clearly state all necessary warnings and possible precautions, and such information must be featured on both the label and the user instructions/leaflet.

2 Manufacturing

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

Under Cyprus law, the complete or partial manufacture of medicinal products, and the division, packaging and display operations, shall be permitted only with the authorisation of the CoM, at the request of the person concerned, in a form specified by the CoM. Manufacturing authorisation is required even if the medicinal products manufactured are intended for import and export. In order to obtain manufacturing authorisation, the applicant must specify the products, stages and details of their manufacturing, including the place of manufacturing and testing. The applicant must also have adequate and sufficient premises, technical equipment, necessary staff and manufacturing facilities, inspection and storage procedures, and must have at least one qualified person permanently and continuously on the premises, for the purposes of ensuring that the provisions of Law 70(I)/2001 are upheld.

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 CoM, in cooperation with the European Medicines Agency (***EMA***), ensures that the provisions of Law 70(I)/2001 are complied with by conducting regular inspections – if necessary, unannounced – and can request that the State General Laboratory or any other designated laboratory carry out sample checks of the products. The cooperation between the CoM and the EMA involves, but is not limited to, the exchange of information on planned and completed inspections, cooperation regarding inspections in third countries, and the provision of information on manufacturers located within the EU or in third countries, and wholesalers of medicinal products, who are subjected to repeated inspections.

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

Any violation of the provisions of Law 70(I)/2001 on manufacturing requirements may result in the imposition of an administrative fine of up to £25,000 (Cyprus pounds) depending on the nature, gravity and duration of the infringement. There is also potential criminal liability found for natural and legal persons, with a penalty of imprisonment not exceeding five years or a fine not exceeding £50,000 (Cyprus pounds) or both, and the confiscation of the relevant medicinal products. Legal persons, directors or managers of legal entities are not exempt from criminal liability and may be subject to the above mentioned criminal penalties and fines. However, it is important to note that Law 70(I)/2001 states that no criminal proceedings can be brought without the consent of the Attorney General. Lastly, it must be mentioned that civil action may also be pursued against the manufacturer and holder of the marketing authorisation of the medicinal product.

3 Transactions

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

Under Cyprus law, there is no legal provision requiring additional approvals regarding mergers/acquisitions of life sciences companies, other than the standard procedure set out in Articles 201A to 201KZ of the Companies Law (Cap. 113).

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 specific limitations are imposed via Cyprus law on foreign-owned life sciences companies, other than the general obligations imposed by the Companies Law on all companies.

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.

The legislation governing the regulation of advertising, promotion and sale of drugs and medical devices is Law 70(I)/2001. It appoints the CoM as the regulatory body responsible for monitoring and governing the advertising, promotion and sale of drugs and medical devices. Law 70(I)/2001 regulates the advertising of medicinal products, including any information given on the product for attracting customers and anticipating or exhorting the purpose of promoting the prescription, supply, sale or consumption of medicinal products and homeopathic medicinal products. The CoM is under obligation to examine on appeal or even on its own motion, whether any advertising of medicinal and pharmaceutical products – published or imminent – is misleading or generally inconsistent with the provisions of Law 70(I)/2001, and to grant market authorisation for the advertising of any such products accordingly. The CoM can also prohibit the advertising of certain medicinal products to the public, the costs of which may be reimbursed from any insurance or social security organisation, or may be covered by any social security organisation, or which are directly promoted for use to the public by the pharmaceutical companies.

The Pharmacy and Poisons Law, Cap 254, also regulates the sale of drugs to the public, with Section 4A(1) mentioning that no other persons except registered pharmacists are allowed to provide or sell drugs to anyone. However, Section 4A(2) of Cap 254 provides an exception to this, namely other persons are allowed to sell specified drugs to the public, under the condition that such drugs are in their original packaging, or in a package that was first sealed by a pharmacist. The specified drugs under Cap 254 are: acetylsalicylic acid tablets; acriflavine solution; castor oil; magnesium sulfate (Epsom salt) containing effervescent preparations thereof; hydrogen peroxide solution; weak iodine solution; porous plasters; sodium bicarbonate; liquid antiseptics or disinfectants in which the only active ingredient is chlorinated phenol; liquid antiseptics or disinfectants in which the only active ingredient is cetrimide or any other cationic surface active agent; soft paraffin (*paraffinum molle*); effervescent formulations of sodium bicarbonate in which the active ingredients are sodium bicarbonate, citric or tartaric acid and/or the salts of the above acids; and pastilles or lozenges that do not contain any amount of any poison or antibiotic.

Lastly, Section 4A(1) does not apply to commercial or technical drugs or chemicals, aromatic or essential oils, natural or synthetic colours, food colours, insecticides, medicated soaps or cosmetics.

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")?

Under Cyprus law, any medicinal or pharmaceutical product not having acquired the appropriate market authorisation by the CoM is expressly prohibited from being advertised or promoted in any manner to the public. Failure to comply with Law 70(I)/2001 will result in the imposition of an administrative fine of up to £25,000, depending on the nature, gravity and duration of the infringement.

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?

According to Law 70(I)/2001, any natural or legal person or legally incorporated organisation may seek the issuance of a prohibiting, protective or interim order by the Court against the publication of any advertisement of any medicinal or pharmaceutical products, depending on whether they have sufficient legitimate interest in prohibiting misleading advertising or advertising in general that is inconsistent with the provisions of Law 70(I)/2001.

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with GDPR standards?

Compliance with GDPR standards is an ongoing process and adapts according to the passing of new legislative provisions both on a European and a domestic level. Firstly, privacy notices need to be written via which individuals are informed as to the processing of their data, where their data will be sent, how long it will be kept, and what rights individuals have in relation to that data.

In order to process personal data in compliance with the GDPR, it requires companies to identify a valid lawful ground. There are six lawful bases for processing and the most appropriate ground will depend on the specific nature, purpose and context of the processing activity. If consent is used as a lawful basis, consent must be freely given, informed and unambiguous. The consent cannot be labelled as an "agreement to all processing"; it must specify the kind of processing activity. Consent has to be verifiable and, in practice, if the organisation is asked, it must be able to prove that consent was given.

Life sciences companies need to demonstrate that there are appropriate technical and organisational measures in place, and that the data is protected sufficiently. Third-party contracts in and outside the EU for the transfer and processing of data must be reviewed/refined to address the new compliance standards under Articles 45–49 of the GDPR. Life sciences companies should also pay attention to the enhanced data subject rights for individuals that may have implications for medical research.

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?

The Safeguarding and Protection of Patients' Rights Law (***Law 1(I)/2005***), the Application of the Rights of Patients in the Context of Cross-Border Healthcare Law (***Law 149(I)/2013***), and Law 125(I)/2018 on the Protection of Personal Data, govern the rules in relation to the patient's right to confidentiality. Law 1(I)/2005 establishes the rights of patients regarding healthcare, as well as the control mechanism for securing these rights. One of the rights that is inherent to the right to privacy is the patients' right to confidentiality, which provides for all information regarding the patient's medical condition, diagnosis, prognosis and treatment, and any other personal data to be kept confidential even after the patient's death.

The only situations where the medical institution or healthcare provider can disclose medical information to third parties are: with the written consent of the patient; when the disclosure is made for treatment purposes by another healthcare provider; for purposes of processing and archiving information or for opinion purposes; when there is a legal obligation to do so; for purposes of publication in medical journals or for research or teaching purposes; or when the CoM decides that the concealment of information might cause serious harm to the health or integrity of other people or that disclosure of information is in the public interest.

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

The General Health System, implemented in 2019, is the new comprehensive system of digital health in Cyprus and acts as the main database for the aggregate of pharmacies, hospitals, clinics and other medical practices and services. With the implementation of the GDPR and Law 125(I)/2018 in Cyprus, personal data related to health, genetics or biometrics is classed as data of a special category and is subject to increased protection under Article 9. According to the GDPR, it is prohibited to process special category data, notwithstanding the exceptions expressly provided. With regard to developments in litigation, Article 79 of the GDPR provides the right of any person to seek judicial remedy against a processor or controller for any infringement of the provisions of the GDPR; in addition, Article 80 states the right to compensation and liability, for a person who has suffered damage as a result of infringement as previously mentioned. Apart from civil liability, the GDPR and Law 125(I)/2018 set administrative fines of up to €20,000,000, or 4% of the annual turnover, for infringement of Article 9; and Article 33 of Law 125(I)/2018 imposes the criminal penalty of imprisonment for up to three years or a fine of up to €30,000, or both.

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.

According to the Medicines for Human Use (Good Clinical Practice) Regulations (Regulation 452/2004) issued by the Council of Ministers, a clinical trial can be conducted only when the participant's rights concerning their physical and mental integrity, right to private life and personal data are duly safeguarded. Moreover, the execution of a clinical trial can only take place so long as the positive results and the possible adverse effects and dangers placed on the participants are duly considered and carefully weighed. For a clinical trial to be initiated, it is

required that the National Bioethics Committee and the CoM are in agreement that the expected merits of the trial will outweigh the risks, and the trial can proceed accordingly, as long as it constantly shows compliance with the above requirement, always under the constant scrutiny of the Committee and the CoM. The participant should be duly informed of all aspects of the clinical trial, be presented with the aims and also with the possible adverse effects and risks it entails and give their consent without any reservations. The participant must be informed of their right to withdraw from the trial at any stage, even if they have not suffered any negative effects. Moreover, in 2020, Law 70(I)/2001 was amended to implement the provisions of Regulation (EU) 536/2014 on clinical trials on medicinal products for human use, which provides, among other things, for more transparency on clinical trial data and ensures effective supervision of the conduct of clinical trials. More specifically, Law 70(I)/2001 safeguards that clinical trials are undertaken under the supervision of the CoM and the National Bioethics Committee of Cyprus and ensures adequate compensation schemes are in place, in case damages are caused to a participant, as further explained in question 6.4. We note that there is no case law involving clinical trials in Cyprus.

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 specific provision or case law in Cyprus law regarding the existence of liability for failure to test in certain patient populations.

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

Regulation 452/2004 allows the compassionate use of unapproved tested pharmaceuticals on patients or participants of clinical trials, at no expense, including the means to administer such medication, if needed. The CoM, in such exceptional cases, will have to specify the precise terms for allowing such products to be administered to patients and the means by which to do so. In cases where the CoM allows the compassionate use of a medicinal or other product of such nature, it must inform the National Bioethics Committee of its decision.

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

Concerning the execution of clinical trials, Regulation 452/2004 and EU Directive 20/2001 indicate that when consent from the participants in a clinical trial is requested, there should be specific provisions included that would constitute an insurance or compensation policy protecting the person conducting the clinical trial from liability in case of an adverse event. However, according to Article 76 of Regulation (EU) 536/2014, a clinical trial may be undertaken only if provision has been made for ensuring that a subject is compensated for any damage suffered that resulted from participation in a clinical trial. In Cyprus, this provision is implemented by Law 70(I)/2001, which ensures that systems for compensation for any damage suffered by an individual resulting from participation in a clinical trial are in place by the National Bioethics Committee of Cyprus. Such compensation can be in the form of insurance, a guarantee, or a similar arrangement that is appropriate to the nature and the extent of the risk. The purpose of the said Law is to ensure that a clinical trial subject will obtain compensation for damages caused by participating in the clinical trial conducted in Cyprus, independently of the financial capacity of the investigator/sponsor of the clinical trial.

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 is no such regulation or guidance provided in the Cypriot legal framework.

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.

According to Law 70(I)/2001, the CoM may decide to prohibit the circulation of a medicinal product and withdraw it from circulation if it considers that the medicinal product is harmful, the therapeutic efficacy of the medicinal product is non-existent, the risks of said product exceed the benefits, the medicinal product does not have the stated qualitative and quantitative composition, or the medicinal product and/or its ingredients, while being manufactured, have not been subject to checks or have not complied with any of the requirements or obligations laid down in Law 70(I)/2001. The CoM has the authority to withdraw and remove from circulation the entire, or part of the product under inspection. It can also authorise the supply of a banned medicinal product to patients already using it, only in exceptional cases, for a transitional period. Lastly, matters regarding the recall of pharmaceutical products can be referred to the European Committee for Medicinal Products for Human Use, which was set up in accordance with Article 5 of Regulation (EC) 726/2004.

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?

With regard to the recall of medical devices, the procedure is quite similar to the one applied for medicinal products. According to Articles 94 and 95 of Regulation (EU) 2017/745, when the competent authority – in the case of Cyprus, the Competent Medical Equipment Authority – has reason to believe that a device may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, or otherwise does not comply with the requirements laid down in this Regulation, it shall carry out an evaluation of the device concerned. Where, having performed an evaluation pursuant to Article 94, the authority finds that the device presents an unacceptable risk, it will require the manufacturer of the device concerned to take all appropriate measures to restrict the circulation of the device or withdraw it from the market.

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

In regard to litigation, Law 70(I)/2001 presents to both natural and legal persons the possibility of pursuing civil action against the manufacturer or importer of the recalled medicinal products

in question, according to Article 102. In cases where the recall of products is effectuated by a CoM decision, it may also be possible for CoM to opt for the revocation of the market authorisation granted to the manufacturer or importer, according to Article 53.

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?

According to the EMA's Compilation of Community Procedures on Inspections and Exchange of Information, it is the responsibility of the competent authority of each Member State to notify other national authorities, the EMA and the other competent authorities in other Member States of the recall. For this purpose, the EMA maintains both a reporting system and a rapid alert list of contact points, which includes national competent authorities in EEA Member States, the European Commission and international partner regulatory authorities and organisations in case the defect of a medicinal product presents a serious risk to public and animal health.

Accordingly, the U.S. Consumer Product Safety Commission (***CPSC***) is the governing regulatory authority for consumer products in the U.S. and works closely with other regulatory and government agencies, such as the U.S. Food and Drug Administration.

Through procedures like the CPSC Fast-Track Program for quick and efficient removal of potentially hazardous products from the marketplace, manufacturers are able to recall products on a global scale. With regard to litigation, a consumer wishing to claim a remedy due to damage suffered by a recalled medicinal product can, under Chapter 148 (Cyprus Tort Law), bring claims against the product manufacturer; they can also bring claims against other parties in the supply chain if fault can be established. Moreover, Chapter 149 (Cyprus Contract Law) allows for a claim to be filed for breach of contract against the immediate supplier, on the basis of receiving a defective product.

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

According to Law 70(I)/2001, holders of marketing authorisations issued before 21 July 2012 are not required to apply a risk management system for each medicinal product they handle. However, the CoM may impose on the marketing authorisation holder the obligation to apply a risk management system if there is increased risk regarding a certain product and may require a detailed description of the risk management system it intends to implement for the medicinal product concerned.

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

It is important to conduct a product risk assessment within 24 to 48 hours of the identification of an issue, classify the type of recall internally and maintain constant communication with the CoM.

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.

Class actions are not available in Cyprus.

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

Any personal injury/product liability claims can be brought as individual plaintiff lawsuits. In Cyprus, there is no case law involving class actions.

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?

There are no specific standards for claims concerning life sciences products in regard to seeking remedies. Claimants wishing to receive compensation for injuries can, under Chapter 148 (Cyprus Tort Law), bring claims against the product manufacturer; they can also bring claims against other parties in the supply chain if fault can be established. Moreover, Chapter 149 (Cyprus Contract Law), allows an injured purchaser to bring a claim for breach of contract against the immediate supplier of a defective product only.

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

According to the Lawyers' Code of Conduct, issued by the Cyprus Bar Association, any form of client solicitation is expressly prohibited.

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

Commonly, commercial litigation is funded by the parties themselves and, most often, the losing party bears the costs of the winning party. There are instances where a party who cannot afford to pay the litigation costs may request the provision of legal assistance from the state. There are no known instances of litigation funding by a disinterested third party or any such regulation.

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?

Cyprus is a common law jurisdiction, and its justice system is based on the adversarial model. Most Cypriot law has been modelled on English common law, the basic principles of which are directly applied by Cyprus Courts (Article 29, Courts of Justice Act). The Courts are bound by the doctrine of precedent, according to which the Supreme Court's (second instance) decisions bind Subordinate Courts. If the proceedings and/or causes of action are the same as those in a matter already settled by a binding, final and conclusive judgment by the Court, the principle of *res judicata* will apply.

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?

If a company wishes to bring evidence before the Court, according to the Civil Procedure Rules, the company may submit an oral testimony by summoning a witness to testify and be examined

before the Court, by way of issuing a writ of summons or submitting before the Court any documentary evidence, which can be done at any stage during the proceedings. Such evidence may be used to display the company's efforts to mitigate damage and comply with, if any, directions from the national competent authority. This may have an impact in regard to the penalties and/or fines imposed on the company.

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?

There is no specific provision in the Civil Procedure Rules for admissibility of such evidence. A party may try to submit said evidence and it is up to the Court's discretionary power to decide whether to allow it or not.

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?

According to the Civil Procedure Rules, the Court may order the submission of certain testimony, give specific directions regarding said testimony, or authorise the submission of a deposition taken according to the directions or order provided by the Court, from any person or witness both outside and inside the jurisdiction. The Court, after an application submitted by any of the parties, may request that a foreign Court examine any witness or person residing in the foreign Court's jurisdiction and allow the interested party to bring such deposition as evidence to the proceedings in Cyprus. The laws applied for the submission of depositions in Cypriot proceedings are Order 8 of the Civil Procedure Rules and the relevant provisions of the International Criminal Cooperation Law 2001 (23(I)/2001).

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?

Privileged documents cannot be used as evidence, and their admissibility can be challenged by the party who can claim the privilege. Privileged documents include confidential communications between lawyers and clients, documents that tend to self-incriminate, and documents that are sent for negotiation purposes or "*without prejudice*". The Court will look at the purpose of the document objectively, taking into account all the circumstances. Legal professional privilege, where lawyers' professional opinion or assistance is sought, applies to practising but not in-house lawyers, as in-house lawyers are not members of the Cyprus Bar Association.

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?

In order for a company to protect the confidentiality of communications with its counsel, as mentioned above, the principle of special privilege applies and therefore it is important to state in a clear and discernible manner, on all such documents regarded as confidential by a company, that the contents of the documents exchanged between the company and its legal advisors are subject to and protected by special privilege and therefore cannot be admitted as evidence in any proceedings.

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

The service of the writ or notice of the writ of summons must be effected after obtaining the leave of the Court. Leave is granted if the plaintiff satisfies the Court that the applicable conditions imposed by the Civil Procedure Rules or the relevant EU Directive are satisfied. Before obtaining leave of the Court for service out of the jurisdiction, the plaintiff must first obtain leave of the Court for sealing the writ of summons.

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

There is no extensive experience of "follow-on" litigation in Cyprus.

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

Cyprus case law is heavily influenced by English law. Consequently, we note that U.S. litigation is unlikely to have a significant impact on the evolution of Cypriot litigation, as there is no extensive U.S. case law in Cyprus as of yet. However, it could affect the development of case law depending on the circumstances. It should be mentioned that Cypriot citizens are not generally litigious.

Eleni Neoptolemou is a Partner in the Department of Competition, Public Procurement and Regulatory and the Department of Data Protection and Cyber Law at Harris Kyriakides. Eleni specialises in the areas of oil and gas, administrative law, tender processes and data protection. She regularly appears before the Administrative Court of Cyprus and other authorities, such as the Tenders Review Authority and Consumer Protection Service, and assists in cases challenging decisions of public authorities on behalf of private clients. She also provides opinions regarding oil and gas matters regarding legal and contractual matters.

Harris Kyriakides
1 Kinyra street, 5th floor
1102 Nicosia
Cyprus

Tel: +357 22 057 754
Email: e.neoptolemou@harriskyriakides.law
URL: www.harriskyriakides.law

Munevver Kasif is an Associate in the Department of Competition, Public Procurement and Regulatory Law, Data Protection and Cyber Law at Harris Kyriakides. She specialises in the areas of oil and gas, shipping and data protection. She assists on the review of various contracts and agreements relating to the above industries. In addition, she prepares legal documents regarding GDPR compliance.

Harris Kyriakides
1 Kinyra street, 5th floor
1102 Nicosia
Cyprus

Tel: +357 22 057 758
Email: m.kasif@harriskyriakides.law
URL: www.harriskyriakides.law

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