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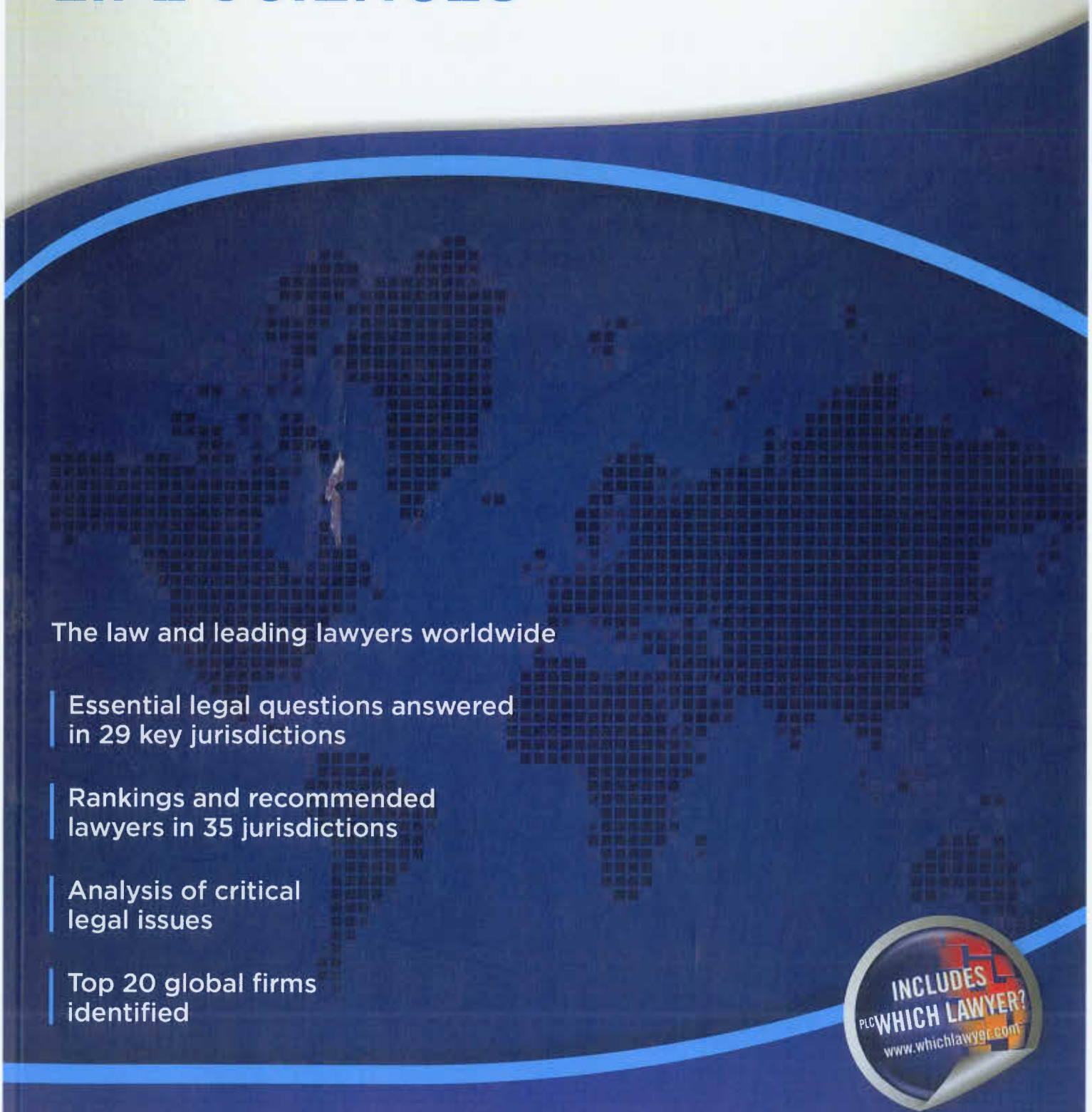

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REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The main legislative instruments are:

- Legislative Decree 96/1973 regarding the trading of pharmaceutical, dietary and cosmetic products, as amended.
- Ministerial Decison 83657/30.12.2005 implementing Directive 2001/83/EC, as amended, on the Community Code relating to medicinal products for human use.

Other important legislative instruments regarding authorisation, pricing and reimbursement of drugs are:

- Market Policy Provisions 07/09 regarding pharmaceutical pricing.
- Law 3918/2011 on structural changes in the healthcare system.
- Law 1902/1990 on the contribution of patients to pharmaceutical expenses.
- Ministerial Decision 3α/79602 implementing Directive 2005/28/EC regarding investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.
- Law 3892/2010 regarding the online record and execution of medicinal prescriptions and examinations.
- Ministerial Decision 8δ/Γ.Π.οικ.130648 implementing Directive 93/42/EC concerning medical devices.

Regulatory authorities

The main regulatory authorities are:

- The Ministry of Health and Social Solidarity (MHSS).
- The National Healthcare System (NHS), supervised by the MHSS.
- The National Agency for Healthcare Services (NAHS), supervised by the MHSS and the Ministry of Employment and Social Protection (MESP).
- Various state-administered social insurance agencies, supervised by the MESP.
- The National Organisation for Medicines (EOF), supervised by the MHSS.

Biotechnology and combination products

No difference exists as to the treatment of biotechnology and combination products.

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

National healthcare is provided mainly through:

- The NHS which is supervised by the MHSS. For the purposes of the NHS, the country is divided on a territorial level into seven Healthcare Districts.
- The NAHS, which was established with recent Law 3918/2011 and is supervised by the MHSS and the MESP.
- Other social insurance agencies which are supervised by the MESP.

The national healthcare system is funded through the government budget and the social security contributions of the citizens.

3. How are the prices of medicinal products regulated?

The legal framework regarding the pricing of medicinal products was drastically reformed in 2011 by several laws amending Legislative Decree 96/1973.

The maximum prices regarding the sale of medicinal products in wholesale, in hospitals, in retail or in any other specific way of sale are determined in the Prices' Reports issued by the MHSS after receiving the opinion of the Medicine's Prices Committee. The Prices' Reports come into force when they are posted on the MHSS's homepage (*www.yyka.gov.gr*).

The price for medicines produced, packaged or imported in Greece is calculated on the basis of the average three lowest prices of the respective medicinal product in the EU member states (for this data exists and is officially announced by the respective country's competent authorities).

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

After the recent law reforms regarding the funding and reimbursement of medicinal products, the legal framework is as follows.

State funding of medicinal products and contribution of the patient

The State and the Social Security Agencies (SSAs) approve and pay medical prescriptions only for medicines included in the catalogue of prescribable medicinal products and only for the recommended indications. Medicinal products which can be medicated without prescription are not funded by the SSAs.

The patient contributes to the expense of the pharmaceutical healthcare provided through the SSAs when having their prescription filled at the pharmacy. This contribution generally accrues to 25% of the state determined price of the medicine, but can be reduced to 10% of the state determined price or even to 0% of it for medicines for the therapy of chronic or particularly heavy diseases.

Compensation of the pharmacist for state funded medicines

For medicines funded by the SSA, the pharmacists who are affiliated with the SSAs are compensated by these agencies, according to the state determined price reduced by a rebate in favour of the SSAs.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Application

Authorisation following the filing of a relevant application is required for each production facility located in Greece. The competent authority for granting the authorisation is the EOF.

Conditions

The manufacturer must meet certain conditions as set out in the National Organisation for Medicines Circular No. 3156/2011, relating to, for example, production facility, personnel, and manufacturing, storage and hygiene requirements in accordance with Directive 2003/94/EC on good manufacturing practice for medicinal products (GMP Directive).

Restrictions on foreign applicants

There are no specific restrictions on foreign applicants.

Key stages and timing

On filing the application, the EOF examines, within 90 days, whether the conditions for granting an authorisation are met. Usually, before granting an authorisation, the EOF inspects the production facility and informs the applicant of any remediable shortcomings. On relevant request, the National Organisation for Medicines can also assist eventual applicants before, during and after the application procedure.

Fee

A fee of EUR3,000 or EUR2,500 is required for granting an authorisation to manufacture sterile or non-sterile drugs, respectively (as at 1 November 2011, US$1 was about EUR0.7). A supplement of EUR500 or EUR400 is also required for each manufacturing form (the form in which the drug is produced) of sterile or non-sterile drugs respectively.

Period of authorisation and renewals

Generally, no time restrictions apply to authorisations granted.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

The EOF is responsible for monitoring compliance with any manufacturing authorisation granted. Monitoring may include on-site controls, review of documents, taking of samples, as well as any other operation deemed necessary in order to verify compliance.

Imposing penalties

In cases of non-compliance, the EOF may suspend or withdraw the manufacturing authorisation and impose fines up to EUR44,000.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

The main legislation regulating clinical trials is:

- Ministerial Decree 3/89292 on the conduct of clinical trials, implementing Directive 2001/20/EC.
- Ministerial Decree 3α/79602 on good clinical practice as regards investigational medicinal products for human use, implementing Directive 2005/28/EC.
- Ministerial Decree 3α/69150 on the establishment and organisation of the National Deontological Committee for Clinical Trials.
- Law 2472/1997 on the protection of Personal Data.

The EOF is the regulatory authority for clinical trials in Greece.

Authorisations

A clinical trial can only commence after the EOF has granted authorisation. The EOF grants authorisation following the favourable opinion of the National Deontological Committee (NDC). The NDC assesses whether the expected benefits as regards the therapy and the public health justify the risks connected with the clinical trial.

The EOF has 60 days to decide on the request of authorisation.

Consent

The participant's (clinical trial subject) written consent is required. In order for it to be validly provided, the participant must first have an interview with the researcher to understand the aims of the trial, the risks and side effects which may occur, as well as the conditions under which the trial will take place. The participant must also be advised that he has the right to withdraw his consent and exit the trial at anytime.

Trial pre-conditions

A further condition that must be met before the trial can start is that the researcher and the sponsor must have insurance coverage for any liability.

Procedural requirements

Clinical trials are conducted in accordance with the protocol submitted to the EOF. This is the document describing the aims, planning, methodology, statistical views and organisation of a trial. This protocol can be amended during the trial with the consent of NDC.

During the trial the sponsor must immediately notify the EOF of any occurrences which may affect the participants' safety, and both the sponsor and the researcher must take all appropriate emergency safety measures to protect the participants from any immediate risk.

Within 90 days after the trial's completion the sponsor notifies the EOF and NDC of the completion of the trial.

MARKETING

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

The application must be made either to the EOF or to European Medicines Agency (EMA) depending on the authorisation procedure chosen (that is, the national procedure, mutual recognition procedure (MRP) (*see Question 10*), decentralised procedure or centralised procedure).

Authorisation conditions

Medicinal products gain marketing authorisation if their quality, efficacy and safety are proven for specific compositions and therapeutic indications following clinical trials.

Other conditions

No other conditions apply.

Key stages and timing

The authorisation procedure should usually be completed within 210 days starting from the application date. During this period, the EOF verifies that the application complies with both procedural and substantive requirements. It can also submit the medicinal product, its raw materials or intermediary products to laboratory controls and, accordingly, request that the applicant amends or modifies its application.

Fee

The standard fee is EUR20,000 for each single concentration relating to the product in dosage form. The abridged procedure fee is EUR14,000 (bioequivalence required) or EUR9,000 (bioequivalence non-required) payable to the EOF.

Period of authorisation and renewals

Authorisations are usually granted for an initial period of five years. Six months before the expiry of the initial authorisation period, a renewal application must be filed with the EOF. Following a new assessment of the quality, efficacy and safety of the authorised medicine product, the EOF decides whether to renew the authorisation granted. After the first renewal, further renewals are automatic if authorised product is duly marketed. Renewal fees are about EUR5,000.

Post-marketing commitments and pharmacovigilance obligations

The market authorisation holder must have at least one person, established within the EU, readily available for pharmacovigilance purposes. Such person is responsible for reporting to EOF and for the maintenance of an appropriate information system to collect and make available all the necessary data.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

Results of pre-clinical tests and trials are not required for bioequivalent medicinal products with the same qualitative and quantitative composition and the same pharmaceutical form as reference medicinal products, in cases where any of the following apply:

- The application is made with the consent of the holder of the reference market authorisation.
- The reference medicinal product has a clearly established medical use with proven efficacy and security in the EU for at least ten years.
- The reference medicinal product has been authorised in the EU for at least eight years. In this case, the generic product cannot be marketed in Greece until ten years have lapsed since the initial marketing authorisation (or 11 years if a new therapeutic indication was authorised).

10. Are foreign marketing authorisations recognised in your jurisdiction?

A foreign marketing authorisation may be recognised in Greece using the MRP, which is based on the principle of the mutual recognition by EU member states of their respective national marketing authorisations.

Under this procedure, as soon as one member state (reference member state) decides to evaluate the medicinal product, it notifies its decision to the other member states, to which applications have also been submitted. Concerned member states will then suspend their own evaluations and await the reference member state's decision on the product.

Marketing authorisations from outside the EU are not recognised.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

The EOF has the same powers to monitor and enforce compliance as for manufacturing authorisations (*see Question 6, Monitoring compliance*).

Imposing penalties

EOF has the same powers to monitor and enforce compliance as for manufacturing authorisations (*see Question 6, Imposing penalties*).

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports are allowed, following the principle of free trade between EU member-states. In this regard, an authorisation, similar to the manufacturing authorisation (*see Question 5*) is required and medicinal products imported must be authorised in their member state of origin. In addition, labelling, packaging and conditioning requirements as set by Greek legislation must be respected if the medicinal products imported are destined for retail.

Under certain conditions, IP rights could be used to obstruct parallel imports (for example, withdrawal of marketing authorisations and repackaging of products). In general, EU jurisprudence has clarified that the protection of IP rights is not without limits and must be conciliated with other EU principles, such as the free movement of goods, including medicinal products.

Parallel imports are not allowed from non-EU member states.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Legal framework

Gifts to physicians are not permitted (except for gifts of negligible value) (*A6/10983/1984 and 49392/07.07.2011 Circulars by the MHSS* and *Legislative Decree 96/1973*). In addition, the EOF's permission is required for the organisation or sponsoring of scientific conferences and similar events (*14771/10.03.2004 Circular by the MOH*). Pharmaceutical companies can cover only the hospitality costs of the participating physicians in these events. These costs include registration, accommodation and transportation costs.

If medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind can be supplied, offered or promised to these persons unless they are inexpensive and relevant to the practice of medicine or pharmacy (*Joint Ministerial Decision ΔΥΓ3(Α)/83657*). Hospitality at sales promotions must always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to those other than health professionals.

Free samples can be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

- There are limited number of samples.
- There is a written request, signed and dated, from the prescribing physician.
- There is an adequate system of control and accountability.
- The sample cannot be larger than the smallest presentation on the market.
- Each sample must be marked "free medical sample - not for sale" or must show some other wording having the same meaning.
- Each sample must be accompanied by a copy of the summary of product characteristics.
- No samples of medicinal products containing psychotropic or narcotic substances can be supplied.

Ministerial Decision 6a/28403/01 (as amended and in force) on the pharmaceutical products expenditures, sets specific limits to these expenditures (hospitality costs, promotional and advertising costs, gifts costs, and so on).

National restrictions are not intended to apply outside Greece.

The self-regulatory framework

The self-regulatory framework is basically the Codes of Practice (CoP) enacted by the Hellenic Association of Pharmaceutical Companies (SFEE) (*www.sfee.gr/en/node/2717*), binding among the pharmaceutical companies which are members of SFEE.

According to the CoP, the production, importation and free distribution of medical samples to physicians and dentists for information purposes, irrespective of the packaging, are permitted only pursuant to a special permission by the EOF.

The CoP includes analogous prohibitions to those defined in statute for gifts, financial benefits or benefits in kind.

Grants, sponsorships and benefits in kind to institutions, organisations or associations staffed by healthcare professionals or conducting research are only allowed on the condition that:

- They are provided to support the provision of healthcare or research.
- They are documented and kept on file by the financer/sponsor.
- They do not constitute an incentive for the recipients of the grant, sponsorship or benefits in kind to prescribe or supply these particular medicinal products.

In most cases, a permit by the EOF is required for the organisation of conferences, seminars and similar events intending to provide scientific information by pharmaceutical companies or other companies with products within the EOF's competence. The organisation of these events abroad by pharmaceutical companies established in Greece is not permitted.

In particular with regard to the relationship between pharmaceutical companies and patient organisations, a pharmaceutical company cannot demand to be the sole sponsor of a patient organisation or of one of the organisation's major programmes. All events intended for patient organisations and organised or sponsored by or on behalf of a pharmaceutical company must be held in an appropriate venue conducive to the main purpose of the event, avoiding venues which are "luxurious" or "well reputed" for their entertainment facilities. Hospitality must not include the financing or organisation of recreational events, and it must be limited to travel expenses, meals, accommodation and registration fees. A pharmaceutical company cannot, directly or indirectly (through its parent company or other third company

to which it is continually or temporarily associated with by any lawful relationship), organise or sponsor an event held outside the country where it is located (international event). However, exceptions apply to this rule.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

Retail distribution is generally limited to pharmacies (*see also Questions 15 and 16*).

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The applicable regulatory framework on advertising includes the following laws and self-regulatory texts, which apply horizontally and extend to medicinal products as well:

- Law 2251/1994 on consumer protection and unfair commercial practices.
- Presidential Decree 109/2010, implementing Directives 2010/13/EC and 2007/65/EC on audiovisual media services, including audiovisual commercial communication, sponsorships and product placement, which, in general, prohibits the transmission of advertisements and product placements of prescription pharmaceutical products.
- Greek Code on Advertising, the advertising industry's a self-regulatory instrument enforced by the Communication Review Board (*www.see.gr*).

In relation to medicinal products in particular, the following regulatory texts apply:

- Law 1316/1983 on the creation and competences of the National Organisation for Medicines.
- Legislative Decree 96/1973 on the marketing of pharmaceutical dietary and cosmetic products.
- Joint Ministerial Decision 83657/2005 (FEK B' 59/2006), implementing Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive).
- Ministerial Decree 22261/2002 (FEK B' 284/2002) on the advertisement of non-prescription medicinal products.
- Ministerial Decree 28403/01/2002 (FEK B' 684/2002) on expenses for promotion of medicinal products.
- Ministerial Decree 10983/84 (FEK B' 37/1985).

The competent regulatory authorities for monitoring compliance with the aforementioned framework are:

- The National Organisation for Medicines (for sector specific regulation).
- The National Council for Radio and Television (for the application of Presidential Decree 109/2010.
- The Communication Review Board (the Greek Code on Advertising).
- The Consumer Ombudsman (for the application of Law 2251/1994).

Restrictions

In general, medicinal products cannot be advertised before a marketing authorisation has been obtained, and advertising is prohibited for medicinal products which both:

- Are available on medical prescription only.
- Contain psychotropic or narcotic substances, such as those referenced in the United Nations Conventions of 1961 and 1971.

In addition, the EOF may prohibit the advertising of medicinal products which are covered under social security and pension funds, as this cost is reimbursed.

The advertisement of a medicinal product must comply with the particulars listed in the summary of product characteristics, it should contain a minimum amount of information regarding the specific product and it should not contain any material which:

- Gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail.
- Suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product.
- Suggests that the health of the subject can be enhanced by taking the medicine.
- Suggests that the health of the subject could be affected by not taking the medicine (not applicable for vaccination campaigns).
- Is directed exclusively or principally at children.
- Refers to a recommendation by scientists, health professionals or celebrities who could encourage the consumption of medicinal products.
- Suggests that the medicinal product is a foodstuff, cosmetic or other consumer product.
- Suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural.
- Could lead to erroneous self-diagnosis.
- Refers, in improper, alarming or misleading terms, to claims of recovery.
- Uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.
- Falsely mentions that the medicinal product has been granted a marketing authorisation.

In ensuring that the specific regulatory framework is upheld, the EOF may prohibit an advertisement and impose administrative fines.

Internet advertising

The above restrictions apply to internet advertising as well (*see above, Restrictions*).

PACKAGING AND LABELLING

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

Joint Ministerial Decision 83657/2005 regulates labelling and packaging requirements regarding medicinal products for human use. The EOF is the competent regulatory authority responsible for enforcing the respective provisions. The EOF also approves the outer packaging of all medicinal products.

Information requirements

The package must contain the particulars set out in Article 71 of the Joint Ministerial Decision, mainly the:

- Name of the product.
- The product's strength and pharmaceutical form.
- The product's active substance(s) per dosage unit.
- The contents by weight, volume or number of doses.
- The list of excipients known to have a recognised action.
- The method of administration.
- The expiry date.
- Special warnings regarding storage and other special warnings, if necessary.

The package leaflet must be drafted in accordance with the summary of the product characteristics and it must include the information referenced under Article 77 of the Joint Ministerial Decision, which replicates Article 59 of Code for Human Medicines Directive.

Other conditions

All the above information must be in Greek (additional languages may be included, provided they contain the same information). In addition, the name of the medicinal product must also be expressed in Braille on the outer packaging.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Traditional herbal medicines are also regarded as medicinal products for human use. However, a simplified authorisation procedure is provided for traditional herbal medicines which fulfil the criteria set by Directive 2004/24/EC on traditional herbal medicinal products. The simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy, provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the EU. Considering the particularities of herbal medicinal products, a Committee for Herbal Medicinal Products (HMPC) has been established at the European Medicines Agency and has produced a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. Applicants can refer to the list, but must still demonstrate the quality of the medicinal products they apply to register.

If the EOF deems that the traditional herbal medicine for which authorisation is sought on the basis of the simplified procedure also fulfils the criteria for a normal or homeopathic medicinal product market authorisation, then the simplified procedure does not apply.

PATENTS

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patents are regulated primarily by:

- Law 1733/1987 (on Technology Transfer, Inventions, and Technological Innovation).
- Law 1607/1986 which transposed the European Patent Convention 1973, in relation to the granting of European Patents with effect in Greece.

Patents are granted only to inventions that meet both the negative and positive substantial prerequisites provided under Article 5 of Law 1733/1987:

- **Negative requirements.** An invention must not:
  - be contrary to public order or morality;
  - have its subject matter excluded *a priori* from patentability (for example, methods of treating the human body).
- **Positive requirements.** An invention must:
  - be novel (that is, it must not form part of the state of the art);
  - involve an inventive step (that is, it must not be obvious to the person skilled in the art); and
  - be susceptible to industrial application (that is, the subject matter may be produced or used in any sector of industrial activity).

A certified Greek translation of the patent which was granted by the European Patent Office must be filed with the Greek Industrial Property Organisation (OBI) for the patent to be valid in Greece (*Presidential Decree 77/1988 implementing Law 1607/1986*). The European Patent becomes effective on the publication by OBI of the certificate of filing of the translation of the European Patent in the *Industrial Property Bulletin*, maintained by the OBI.

A notable difference regarding the scope of substantial examination performed by the OBI (in relation to the examination performed by the EPO) is that the Greek authority will examine only the negative substantial requirements for patentability and will not assess whether a national patent application meets the positive requirements for patentability, leaving it for the courts to evaluate these requirements in litigation.

Scope of protection

The scope of protection of a patent is set by the patent's claims, which essentially define the extent and content of protection requested on the basis of the characteristics of the invention.

19. How is a patent obtained?

Application and guidance

The competent administrative authority is OBI. As of January 2012, the Organisation's website (*www.obi.gr*) provides detailed guidelines and information in English and Greek regarding the application process.

Process and timing

In general, the procedure for granting a patent includes:

- Filing of the application.
- A four-month period (starting from the filing date) for any corrections to be made or omissions to be supplemented.
- Prior art examination by the OBI. The results of this search are presented in the search report sent to the applicant together with the documents cited therein which demonstrate how the conclusions drawn in the report were reached.
- A three-month term from the date of notification of the search report to the applicant, within which the latter may file comments on the search report.
- If comments are filed and the OBI considers that the search report must be amended, it will prepare a final search report.
- Following the completion of the three-month term or the notification of the search report, the OBI informs the applicant of its decision to grant the patent, and calls the applicant to pay the corresponding fees.

The above process usually takes 14 to 18 months to complete, starting from the filling of the application.

Deposit system

The OBI maintains a "one-stop-shop" service, through which interested parties can make further inquiries in relation to the filing of a patent application. However, at the time of writing (January 2012) the OBI's website does not support electronic filing of patent applications, although it accepts electronic payments for patent annuities.

The OBI examines each patent application to ascertain that the examination meets the minimum formal requirements stipulated under Greek law. If the application contains the above elements, then it is accepted by the OBI as a "regular" filing, and a filing date is allocated.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The patent may last up to 20 years, starting from the filing date, if the relevant annuities are duly paid to the OBI.

Extending protection

Generally, the patent validity term cannot be extended.

However, the term for pharmaceutical products (that is, active ingredients or combinations of active ingredients) which are patent protected and have acquired a valid market authorisation, can be extended effectively using a supplementary protection certificate (SPC), regulated by Joint Ministerial Decision 14905/EFA/3058. An SPC comes into force only after the corresponding general patent expires and lasts for a period equal to the period which elapsed between the filing date and the date of the first authorisation to place the product on the market, reduced by five years. Under Ministerial Decision 11475/EFA/2388, the duration of the SPC can be extended for an additional six months, if the SPC relates to a human medicinal product for which data from clinical trials conducted under an agreed paediatric investigation plan (PIP) have been submitted (as set out in Article 36 of Regulation (EC) 1901/2006 on medicinal products for paediatric use).

21. How can a patent be revoked?

A national patent as well as the Greek part of a European Patent can only be declared null by a national court, following the filing of a corresponding action for nullification, for reasons that are exclusively listed under Article 15 of Law 1733/1987 (for national patents) and Article 138, paragraph 1 of Law 1607/1986 (for the Greek part of European patents, under Article 23, paragraph 8 of Law 1733/1987).

A national patent as well as the Greek part of a European Patent can also be declared null by a national court, by virtue of an invalidity counter-claim, within the framework of infringement proceedings.

22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

A patent confers to its owner the exclusive right, for the duration of the patent, to productively exploit the invention, and particularly to (*Article 10, Law 1733/1987*):

- Produce, offer or make available in the market, to use and to possess for these purposes the products protected by the patent.
- Apply, offer or make available in the market the process protected by the patent.

- Produce, offer or make available in the market, to use and to possess for these purposes the product whose production results from the process protected by the patent.
- Forbid each and every third party from productively exploiting the invention, within the meaning of the above passages, or to import, without prior consent of the owner, the products protected by the patent.

It follows that any act or omission by a third party which interferes with or threatens to interfere with the above exclusive rights of the patentee is considered an infringement.

In addition, the law also sets limits to the above rights. More specifically, a patentee cannot forbid:

- Use of the invention for non-professional or research purposes.
- Use of the invention built in an automobile, railway, vessel or airplane entering the Greek territory on a temporary basis.
- Preparation of a pharmaceutical product in a pharmacy for a specific individual, following medical prescription, as well as the dispensing and use of the said pharmaceutical product.

Claim and remedies

A patent holder or a licensee may claim the following cumulative remedies:

- Filing an action for cessation of the infringement and prohibition against future infringement, including a request for the withdrawal from commerce and the destruction of the infringing material.
- Filing an action for damages. Punitive or statutory damages, however, are not provided by law.
- Filing an action based on violation of unfair competition law by the infringer (unfair competition is a legal doctrine developed under Greek law, sanctioning unfair commercial and business practices, regardless of the existence of the infringer's significant market power or dominant market position).
- Obtaining injunctive relief, provided that the claimant can establish the existence of a clear case of infringement (or threat thereof), validity (of the patent) and urgency (which is usually assumed unless the claimant has remained inactive for months, although he had knowledge of the infringement). The court decision may, in exceptional circumstances (for example, urgency and threat of significant irreparable harm), be taken *ex parte*.

In addition, the claimant may petition the court for the following, in any of the above legal actions:

- To order the defendant to produce specific documentation or other material before the court, in order to obtain evidence of the infringement.
- To order the defendant to provide specific information pertaining to the infringement, including the names and addresses of recipients and manufacturers of the infringing items.
- To allow the publication of the court decision (or of part thereof) in the media (the decision has to be final and must not pertain to injunctive measures).

23. Are there non-patent barriers to competition to protect medicinal products?

An authorised generic medical product cannot be placed on the market until ten years have elapsed from the initial authorisation of the reference product (*Article 11, Ministerial Decision No. DYG3 (A)/83657, implementing the Code for Human Medicines Directive*). This ten-year period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation before their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan medical products have ten years of market exclusivity once authorised (*Article 8, Regulation (EC) 141/2000 on orphan medicinal products*).

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

A trade mark must be capable of both:

- Being represented graphically.
- Distinguishing the applicant's goods or services from those of other undertakings.

The relevant law is Law No. 2239/1994 on trade marks (Trade Mark Law).

Scope of protection

Marks which do not fall within the definition of the Trade Mark Law (*see above, Conditions and legislation*) cannot be registered as trade marks. The Greek Trade Mark Office will refuse to accept for registration marks:

- Devoid of distinctive character.
- Descriptive (that is, marks comprising terms which are used to describe the nature, quality and/or characteristics of the designated products (for example, "smoke" for cigarettes or "telecom" for telecommunications services)).
- That are deceptive.
- That are identical or confusingly similar to earlier IP rights.
- That are applied for in bad faith.

A medical brand can be registered as a trade mark.

25. How is a trade mark registered?

Application and guidance

The application must be made to the competent department of the General Directorate for Commerce, the authority that maintains the trade marks registry. Guidance on the application procedure and fees is provided online in Greek (*www.gge.gr/4/organ.asp?195*).

Process and timing

After filing a hearing will take place within five to seven months and the Trade Marks Administrative Committee will review the application. The decision will be issued within one to two months.

A summary of the decision accepting the trade mark is published within one month of the date of publication of the decision in the *Industrial Property Bulletin* of the *Government Gazette*. Opposition against a decision accepting the registration of a trade mark, in whole or in part, can be filed with the Trade Marks Administrative Committee within four months starting on the 16th day of the month following publication of the decision in the Commercial and Industrial Property Section of the *Government Gazette*.

The decision accepting the trade mark will become final if an opposition has not been filed against it in time or if an opposition filed has been irrevocably rejected. Once the decision accepting the trade mark has become final, registration is recorded with the trade marks registry.

26. How long does trade mark protection typically last?

Duration and renewal

The term of a trade mark registration is ten years as from the day following the date of application. This term can be renewed indefinitely for a further ten-year period each time, provided that a renewal application is filed and the relevant renewal fees are paid before the expiration of the corresponding term. A further (grace) period of six months as from the completion of the corresponding ten-year term is allowed for the filing of the renewal application by paying a fine.

Extending protection

Protection cannot be extended (except for renewals (*see above, Duration and renewal*)).

27. How can a trade mark be revoked?

A trade mark can be revoked, in whole or in part, following a decision of the Trade Mark Administrative Committee or of the competent administrative courts in the following cases:

- If, within five years following the date on which the registration procedure is completed, the owner has not put his trade mark to genuine use in connection with the goods or services in respect of which it is registered or such use has been interrupted for a continuous period of five years.
- If the undertaking for whose goods the trade mark is registered has been inactive for five years.
- If, in consequence of acts or inactivity of the owner, the trade mark has entered into common usage or has become the common name in the trade for a product or service in respect of which it is registered.
- If, in consequence of the use made of it by the owner or with his consent in respect of the goods or services for which it is registered, the trade mark is liable to mislead the public, particularly as to the nature, quality or geographical origin of the goods or services.
- If it does not fall within the definition of trade mark as provided by the Trade Mark Law or has been registered contrary to the provisions of the Law, as described in *Question 24*.

28. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

A trade mark is infringed by any person who either:

- Uses a mark that is identical or confusingly similar to the trade mark for identical or similar goods and/or services.
- Uses a mark that is identical or confusingly similar to the trade mark, and the goods and services are not similar to those for which the trade mark is registered, but both:
  - the earlier trade mark has acquired a reputation in Greece; and
  - the use of that mark without due cause would take unfair advantage of or be detrimental to the distinctive character or repute of the earlier trade mark.
- Protection of the reputation of the trade mark is also afforded in the case of identical or similar goods/services.

Claim and remedies

An infringement action seeking an injunction and/or damages can be filed against infringers. An infringement action can also be complementarily based on tort and unfair competition law provisions.

The main remedies for trade mark infringement include injunctive relief, damages, orders for the seizure and destruction of the infringing goods, as well as the publication of the judgment's operative part in the press.

Due to the difficulties in quantifying pecuniary damages under Greek law, claimants can, in practice, seek only non-pecuniary damages.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

Generally, patent or trade mark rights can be freely licensed exclusively or non-exclusively, for the whole or a part of Greece, following a written agreement.

For patents, no governmental approval is required. The registration of the licence agreement with OBI has only probative value.

For trade marks, the approval of the Trade Marks Administrative Committee is required, following a hearing. The Committee must be convinced that the use under licence of the trade mark does not create a risk of confusion to the public and is not contrary to the public interest.

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Greece is party to all major international patent and trade mark conventions, treaties and agreements, including the following:

- WIPO Convention Establishing the World Intellectual Property Organization 1967.
- Paris Convention (Industrial Property).
- Patent Co-operation Treaty 1970 (PCT).
- WIPO Patent Law Treaty 2000 (PLT).
- Madrid Protocol (International Registration of Marks).
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Strasbourg Agreement Concerning the International Patent Classification 1971.
- Locarno Agreement (International Classification for Industrial Designs).
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

Articles 1(1) and (2) of Law 2251/1994 on consumer protection set out the primary concept that the rights of consumers are under the protection of the Greek state. These provisions also refer to the obligation of the state to procure the health and safety of the consumers, as well as the expression of consumer collective interests through the establishment of consumer associations. Medicines are included in the definition of product of this law.

This position is supported by Ministerial Decision No. DYG3 (A)/83657/2006 (MD) on the harmonisation of the Greek legislation with that of the EU on producing and marketing medicinal products for human use in compliance with the Code for Human Medicines Directive lends support to the above position, which includes an indirect reference that liability for all licensees, health product producers and professionals ultimately lies with Law 2251/1994 (*Article 6 §4, MD*).

A product is defective if it does not have the anticipated performance in accordance with its specifications and/or the reasonably expected safety in view of all the applicable special conditions (*Article 6 §5, Law 2251/1994*). The concept of defectiveness, in particular the "safety" aspect, is supplemented and completed by Article 7 of Law 2251/1994. Therefore, failure to comply with the MD, may result in a finding of defectiveness of the medicine because inadequate information has been provided to the consumer on the use and attributes of the medicine in the package leaflet of the product. Liability is not only attached to manufacturers, but also suppliers in general including product distributors.

When the medicinal product which is the object of sale is defective both as defined in the special provisions (Law 2251/1994 as *lex specialis*) and in the general sale provisions of the Greek Civil Code (GCC), then the claimant (purchaser-consumer) is entitled to pursue against the seller the claims that are provided by both the special and general provisions.

If illegality and fault are also proved, then the claimant can claim damages also under the general tortious provisions of Articles 914 and 919 of GCC. In these cases, the provisions on tortious and contractual liability apply concurrently.

Substantive test

Greek law provides for a strict liability regime rather than a fault-based system. The prerequisites for producer liability are (*Article 6 §1, Law 2251/1994*):

- A defect in the product placed on the market by the producer.
- The occurrence of damage.
- A causal link between the defect and the damage.

Liability

The producer is liable for the damages incurred due to the defect in the product (*Article 6 (1) and (2), Law 2251/1994*). The concept of the producer includes the manufacturer of a finished product or of any raw material or of any component, as well as any other person who presents himself as the producer by placing his name, trade mark or other distinctive sign on the product. Liability is also attached to whoever imports a product for sale, leasing or hire or other form of distribution in the context of his professional commercial activity. However, there is no liability attached to an importer where the import is from an EU country. According to Greek case law it must be accepted that this waiver of liability for an EU importer is based on the need to eliminate technical barriers to intra-community trade.

Where the identity of the producer is unknown, every supplier of the product must be considered as the producer for the purposes of consumer protection, unless the supplier informs the consumer within reasonable time of the producer's identity or of the legal entity/person who supplied him with the product. The same treatment also applies for the supplier of imported goods, where the importer's identity is unknown, even if the producer's identity is actually known.

32. How can a product liability claim be brought?

Limitation periods

Any claims against the producer (as widely defined, see *Question 31*) are subject to a three-year limitation period, as from the date the claimant was informed or ought to have been informed of the damages incurred, the defect and the identity of the producer (*Article 6(13), Law 2251/1994*). All rights of the claimant lapse following a ten-year period from the product's date of circulation.

Tort-based claims are time-barred after five years. The rights of all claims are lost after the lapse of 20 years from the occurrence of the tortious act itself.

A collective action is filed within an exclusive time period of six months following the last occurrence of the unlawful behaviour which forms the basis for the relevant lawsuit. The only exception to this short prescription period is where the relief sought by the consumer association is merely the recognition of the right to legal redress (*Article 10 §18, Law 2251/1994*).

Class actions

Greek law does not provide for class actions per se. There is a comprehensive system of court protection for the general interests of the consumers through a collective action (*Article 10, Law 2251/1994*) (*see above, Limitation periods*).

Foreign claimants

There is no requirement of residency and/or of use of the product within the jurisdiction for a claimant to bring a claim before the Greek courts.

33. What defences are available to product liability claims?

The main defences available to the producer are the following (*Article 6(8), Law 2251/1994*):

- He did not circulate the product.
- There was no defect at the date of circulation.
- He did not produce the product with a view to distribute it and he did not actually distribute it in the course of his business activities.
- The defect is due to the fact that the product was manufactured according to mandatory specifications.
- When the product first entered circulation, the level of scientific and technical knowledge at that time did not allow the detection of the defect.

A producer of components is not liable if he can also prove that the defect is due to the design of the product, in which the component is incorporated or due to the instructions provided by the manufacturer of the product. In this case the manufacturer of the final product in which the component is incorporated is considered to be the producer.

THE REGULATORY AUTHORITIES

Ministry of Health and Social Solidarity (MHSS)

W *www.yyka.gov.gr*

Main areas of responsibility. The MHSS exercises the national policy for Health and Social Solidarity in Greece. Its competences primarily include legislative initiatives and administration of the healthcare policy.

National Healthcare System (NHS)

Main areas of responsibility. The NHS, which is supervised by the MHSS, provides public healthcare services and is comprised of several healthcare units across Greece. For the purposes of the NHS Greece is divided on a territorial basis in seven Healthcare Regions.

National Agency for Healthcare Services (NAHS)

Main areas of responsibility. The NAHS, which was established in 2011, is a social security agency comprising several social security branches providing social security and healthcare services in Greece. The NAHS is supervised by the MHSS and the Ministry of Employment and Social Protection (MESP).

Other social security agencies supervised by the MESP

Main areas of responsibility. These are social security agencies which are not included in the NAHS, but provide similar social security and healthcare services to different interest groups.

National Organisation for Medicines (EOF)

W *www.eof.gr*

Main areas of responsibility. The EOF's aim is to promote public health in Greece in connection with the circulation of medicines, animal feed, medicinal supplements and devices as well as cosmetics. It is supervised by the MHSS.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

The producer is objectively (regardless of fault) liable for all damages caused to a consumer due to the defectiveness in the product, including damages due to death/bodily injury and any damages or destruction of other property belonging to the claimant as a result of the defectiveness in the product, except for the value of the defective product itself (*Article 6(1) and (6), Law 2251/1994*). This includes the right to use environmental goods. For all of the above damages the law stipulates a monetary threshold (lower limit) and subjects them to the condition that the product must be intended for and has actually been used by the claimant for his personal use or consumption.

Medical monitoring costs may be recoverable by a claimant as positive damages suffered by him in cases where the product has not yet malfunctioned and caused injury, but does so in the future.

Non-pecuniary damages are also available. The producer's strict (objective) liability also applies for non-pecuniary damages. Therefore, the claimant does not have to prove the existence of the civil law tort requirements. This element, introduced in 2007, is hailed as strengthening considerably consumer protection, in line with Greek case law on this issue in recent years.

A consumers' association can file a lawsuit in pursuit of individual claims by the members of the association and/or may act as *amicus curiae* in a pending action commenced by a member of the association and/or may file a collective lawsuit. Through a collective lawsuit the following relief may be sought:

- That the producer abstains from any unlawful behaviour even before it occurs. One of the particular occasions where this kind of relief may be sought is in case there is a violation of the MD on medicinal products (*see Question 31*).
- The recall, seizure (as injunctive measures) or the destruction of the defective product.
- Damages for mental distress or moral harm.
- That the court recognises the right of the consumer to have the damage caused by the unlawful behaviour restored.

Individual claimants cannot recover punitive damages. This issue, however, arises in the context of collective lawsuits. The quantum of damages to be awarded depends, among other things, on the extent and gravity of illegality of the defendant's behaviour (*Article 10 (16)(b), Law 2251/1994*). In addition, the quantum is affected by the perceived need for general and individual prevention of unlawful behaviour. It is suggested that the above criteria effectively transpose in Greece the common law concept of punitive damages concept.

Statistically speaking, punitive damages are awarded mainly in cases of tortious behaviour and only as an exception in cases of breach of contract.

In relation to quantum, the Supreme Court (*plenary session decision 17/1999*) dealt with the issue of recognising and enforcing in Greece a US court decision which awarded punitive damages. The basic concept is that the damages should not be excessive. Excessiveness is defined in terms of the gravity and seriousness of the defendant's breach of contract or unlawful behaviour, as well as the degree and extent of culpability. As it can be seen these are not settled rules. The lower courts should use these criteria on an ad hoc basis in calculating the amount of damages.

REFORM

35. Are there proposals for reform and when are they likely to come into force?

A new law on trade marks is currently under public consultation. Since this law is to form part of wider legislative initiative pertaining to economic development legislation, it is not expected to come into force for several months.

In addition, a new law has just been passed with the aim of cutting down on public spending on drugs, which is considered a significant boost for the marketing of generic drugs in Greece. According to this new piece of legislation, drug prescriptions will be provided based on the name of the active pharmaceutical ingredient/substance and not the trade mark/commercial name.

Country Q&A

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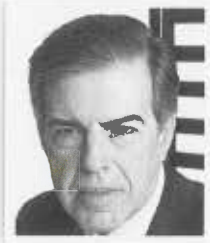

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- *Merck, Sharp & Dome Corp v Teva Hellas SA.*
- *Pharmathen SA v Pharmakern Portugal LDA.*
- *Billev Pharma APS v Daiichi Sankyo Company Ltd, Sanofi-Aventis Deutschland GmbH.*

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- *Pharmathen SA v Merck, Sharp & Dome Corp.*
- *Billev Pharma APS v Daiichi Sankyo Company Ltd, Sanofi-Aventis Deutschland.*
- *Aventis Pharma SA v Teva Pharma BV.*

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- *Merck, Sharp & Dome Corp v Teva Hellas SA.*
- *Pharmathen SA v Pharmakern Portugal LDA.*