France

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

In France, the manufacture, distribution and sale of pharmaceutical products are strictly regulated by the Public Health Code (PHC). Price-fixing and product reimbursement rates (total or partial) by the French healthcare system are regulated by the Social Security Code.

Pharmaceutical products are supervised by the French Agency for the Safety of Health Products (*Agence Française de Sécurité Sanitaire des Produits de Santé, AFSSAPS*) which is the regulatory body designated to control healthcare entities. Pharmaceutical products can be placed on the French market provided they have been granted a marketing authorisation by the AFSSAPS under the national procedure or the European Medicines Agency (EMEA) under the centralised procedure (*PHC*).

The centralised procedure is compulsory for biotechnological procedures, new chemical compounds for the treatment of AIDS, cancer, neurodegenerative disorder or diabetes, and treatment of rare diseases (*Regulation (EC) No.726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMEA Regulation)*).

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

In France, the structure and funding of the national healthcare system is delegated to the Ministry of Health and various bodies, such as the AFSSAPS, the Public Health Agency (*Haute Autorité de Santé*) or the Biomedicine Agency. Social security schemes are managed by professional union representatives under government supervision.

Social security schemes are financed from specific contributions paid by employers, employees and other salaried professionals as well as from other sources. The healthcare budget is adopted annually under the Social Security Financing Act. This law also determines the government's yearly public health objectives (for example, public campaigns addressing cancer).

3. In what circumstances are the prices of medicinal products regulated?

In principle, the price of pharmaceutical products is freely determined by pharmaceutical companies. However, this is not the case for products which are prescription-only medicines and/or are reimbursed by social security schemes. The price of those products is determined after negotiations between the pharmaceutical company and the Economic Committee for Health Products (*Comité économique des produits de santé*) acting under the supervision of the Ministry of Health. If no agreement can be reached, the price is determined unilaterally by the Committee. The applicable rate for reimbursement by social security schemes is also determined by public authorities (*see Question 4*).

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

To be reimbursed by social security schemes, pharmaceutical products have to meet a certain degree of efficacy (*Amélioration du Service Rendu*) and must be registered on a specific list of products. The reimbursement rate for each product is evaluated by the *Commission de la Transparence* under the supervision of the Ministry of Health. The reimbursement rate depends on the product's efficacy improvement (as compared to therapies which are already available) and is applied to the price of the product (from 15% to 65%, or in certain circumstances 100%).

The application for the product to be registered on the list is filed with the Ministry of Health and a copy of the application is transmitted to the *Commission de la Transparence* for its opinion. The decision must be made within 180 days of receiving the completed application.

In principle, pharmaceutical product users are reimbursed since they pay directly for the products. However, in recent years, French authorities have set up a new system under which the reimbursed price is advanced by pharmacies, which are then reimbursed by social security schemes (*tiers payant*).

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **Are there specific restrictions on foreign applicants?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Application

The manufacture of pharmaceutical products is subject to obtaining prior authorisation. Each manufacturing site must be AFSSAPS authorised and any variation of an authorised site, technical equipment or the nature of the manufactured products or process must be authorised as well.

Conditions

Any pharmaceutical establishment that manufactures pharmaceutical products is required to meet regulated quality and safety conditions and good manufacturing practices (GMP) and must have a qualified pharmacist as head pharmacist (*pharmacien responsable*) involved in its management.

Restrictions on foreign applicants

There are no specific restrictions.

Key stages and timing

The manufacturing authorisation is subject to the opinion of the relevant professional board of pharmacists and to an investigation performed by AFSSAPS inspectors. The decision must be given within 90 days of receipt of the application.

Fee

The initial authorisation is not subject to a fee.

Period of authorisation and renewals

The manufacturing authorisation is not subject to a time limit. However, as mentioned above (*see above, Application*), any modifications to one of the elements on which the authorisation had been based requires a new authorisation. In addition, periodic inspections are performed by the AFSSAPS to enforce compliance with the terms of the authorisation.

6. What powers does the regulator have to:

- **Monitor compliance with manufacturing authorisations?**
- **Impose penalties for a breach of a manufacturing authorisation?**

AFSSAPS inspectors can perform periodic inspections to enforce compliance of the pharmaceutical establishment's activities with the terms of the authorisation and the PHC requirements. In addition, they ensure that pharmaceutical establishments apply GMP. Inspectors can take and analyse samples of manufactured products, and are entitled to seize products if granted authorisation by a judicial power.

After the AFSSAPS inspection a specific report is issued. Should any breach of a manufacturing authorisation or non-conformity with applicable regulations be discovered, the AFSSAPS is entitled to require from the establishment justifications and corrective measures. The AFSSAPS can also suspend the authorisation until compliance with requirements has been reached. In addition, criminal prosecutions can be pursued. Any breach of regulations is punished by a fine of EUR3,750 (about US$5,120) (EUR18,750 (about US$25,600) if a legal entity is held responsible).

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- **Which legislation and regulatory authorities regulate clinical trials?**
- **What authorisations are required and how is authorisation obtained?**
- **What consent is required from trial subjects and how must it be obtained?**
- **What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?**
- **What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?**

Legislation

Clinical trials are strictly regulated by specific legislation. Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive) was implemented in France by Law no. 2004-806 on 9 August 2004 and by Decree no. 2006-477 on 26 April 2006. In addition, any clinical trial performed must comply with the good clinical practices implemented by the decree.

Authorisation

All clinical trials must be submitted to the relevant public ethic committees (*Comité de protection des personnes*) and receive a favourable opinion. In addition, the clinical trial must then be authorised by the AFSSAPS. The application for opinion and for authorisation is

filed by the sponsor of the clinical trial. The review of the application by the AFSSAPS cannot exceed a time period of 60 days from the date of receipt, knowing that in the absence of response at the end of said time period, the authorisation is considered to be granted.

Consent

As a general principle, the risks to the subjects of clinical trials must not be disproportionate to the potential benefit of the scientific research. The informed consent of any person involved in the trial must be obtained before participation. The PHC requires that certain information be communicated to the subject, such as the purpose of the trial and the procedures to be followed, the foreseeable risks that could arise from the trial, and the reasonably expected benefits. In addition, the written consent form must be revised whenever new important information becomes available that may be relevant to the subject's consent.

Other conditions

Certain other conditions must be met before the clinical trial begins. By law, the sponsor must ensure adequate compensation for all damages or injuries arising from the performance of the trial. In this respect, the sponsor must obtain insurance to cover its civil liability before the clinical trial begins. In addition, if the site where the trial is expected to be performed is not usually used for the healthcare activities envisioned by the trial, the site must be authorised by the AFSSAPS.

Procedural requirements

The sponsor must notify the relevant ethics committees of all information regarding serious adverse drug reactions and must report all adverse reactions to the committees and to the AFSSAPS. At the end of the trial and within 90 days from its termination, the sponsor must notify the AFSSAPS and the relevant ethics committees of the effective date of termination of the trial. In addition, within one year from the termination or suspension of the trial, a final report of the research, including its results, must be sent to the AFSSAPS.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Application

Every pharmaceutical product must be granted a French or a centralised marketing authorisation before it is placed on the market. The AFSSAPS grants marketing authorisations. After the marketing authorisation has been granted, the holder of the authorisation must inform the AFSSAPS of the actual marketing of the product. Any modification of the terms of the marketing authorisation must be approved by the AFSSAPS.

Conditions

To be granted a marketing authorisation, all pharmaceutical products have to meet certain conditions of quality, safety and efficacy which must be demonstrated by the applicant. The authorisation cannot be granted by the AFSSAPS if the risk-benefit balance is not considered to be favourable or if the therapeutic efficacy of the product is insufficiently substantiated by the applicant.

Key stages and timing

The application for marketing authorisation is filed by the pharmaceutical company and submitted to the AFSSAPS. The application must contain all required administrative information as well as scientific information regarding the product (that is, the information listed in the summary of the product's characteristics and in particular the qualitative and quantitative composition of the product). The application is assessed by an expert called a *rapporteur*, who advises an expert commission (*Commission d'autorisation de mise sur le marché*) on the application. During the instruction of the application, the AFSSAPS can order any inspection or survey or test it considers necessary. The decision is to be rendered within 120 days from the receipt of the completed application.

Fee

The application is subject to a progressive fee, collected by the AFSSAPS, that cannot exceed EUR25,400 (about US$34,700). In addition, each authorised pharmaceutical product is subject to an annual tax that cannot exceed EUR17,000 (about US$23,200), also collected by the AFSSAPS. The tax is calculated on the amount of sales of each pharmaceutical product in the preceding financial year, excluding export sales.

Period of authorisation and renewals

The marketing authorisation is granted for a period of five years. It can then be renewed for an unlimited period of time (unless the AFSSAPS considers that additional monitoring is necessary). The renewal is subject to the assessment that no modification has been made to the elements presented in the first application. In addition, the pharmaceutical establishment must adapt the manufacturing and safety of its authorised product to the latest scientific knowledge. In the absence of a response at the end of authorisation period, the renewal is considered to be approved.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- **Which medicinal products can benefit from the abridged procedure (for example, generics)?**
- **What conditions must be met?**
- **What procedure applies and what information can the applicant rely on?**

The AFSSAPS is entitled to grant marketing authorisations via an abridged procedure. Under this abridged procedure, the applicant

is exempt from providing the pharmacological, toxicological and clinical data to the AFSSAPS. The abridged procedure can be used for the following pharmaceutical products:

- Those that are essentially similar to a pharmaceutical product authorised, provided the holder of the authorisation for the reference medicinal product consents to the use of data and information contained in the reference product's file.
- Those which have well-established medicinal use, with recognised efficacy by means of a detailed scientific bibliography.
- Those that are essentially similar to a pharmaceutical product authorised for not less than ten years in France or in another EU member state.

A decree amending the above requirements will likely be published in the coming months to finalise implementation of Directive 2004/27/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Second Amendment Directive).

Under French law, a pharmaceutical product is essentially similar to another if it has the same qualitative and quantitative composition in active substances, the same pharmaceutical form and if its bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. If reference is made to an essentially similar product, the applicant can rely on the documentation provided by the reference product holder for the reference product marketing authorisation if:

- The holder has consented to such reference.
- The protection time period for the documentation provided for the reference product marketing authorisation has expired.

The period of time required for establishing a "well-established medicinal use" must not be less than ten years from the first use of that substance as a medicinal product in the EC (*Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive)*). If reference is made to a well-established medicinal use, the documents submitted by the applicant must refer to all relevant literature, taking into account pre and post-marketing studies and published scientific literature.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

The mutual recognition procedure allows marketing authorisations granted in other EU member state to be recognised in France. Under this procedure, the holder of the marketing authorisation can submit an application to the AFSSAPS for the pharmaceutical product's approval in France. The holder must inform the member state which has issued the authorisation (reference member state) of this application and the reference member state must forward the assessment report to the concerned member states. Within 90 days of receipt of the assessment report the concerned member states must either:

- Recognise the decision of the other member state.
- Consider that the medicinal product may present a risk to public health.

If required a conciliation procedure can be initiated before EMEA.

In addition, the Code for Human Medicines Second Amendment Directive established a new decentralised procedure for simultaneous applications within the EC.

11. What powers does the regulator have to:

- **Monitor compliance with marketing authorisations?**
- **Impose penalties for a breach of a marketing authorisation?**

The AFSSAPS can monitor compliance with marketing authorisations with periodic inspections and surveys at any pharmaceutical site. AFSSAPS inspectors are authorised to take and analyse samples of manufactured products and are entitled to seize products if granted authorisation by a judicial power.

In the case of a breach of a marketing authorisation, the AFSSAPS can require justifications and corrective measures from the marketing authorisation holder. The marketing authorisation holder has the right to defend itself by following a written appeals procedure. If the holder does not remedy the breach or the AFSSAPS still believes it is non-compliant, the AFSSAPS can suspend the marketing authorisation for not more than one year, or withdraw the authorisation.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Parallel imports, which consist of the distribution of pharmaceutical products outside the manufacturer's official channels, are permitted under the PHC but are subject to a five year authorisation granted by the AFSSAPS. The authorisation is granted provided:

- The product has been granted a marketing authorisation in France.
- The qualitative and quantitative composition of active substances, and the pharmaceutical form and the therapeutic effects of the imported products are identical to those of the authorised product.

The authorisation can be refused for public health reasons, but not for intellectual property rights reasons. Under the principle of exhaustion of the rights conferred by a patent or trade mark (*épuisement des droits*), the holder of an intellectual property right protected by law cannot rely on that right to prevent the importation of a product which has been marketed in another EU member state by the holder itself (or with its consent). For trade marks, however, this principle does not apply if there are legitimate reasons for the holder to oppose further commercialisation of the product, especially where the nature of the product has been changed or impaired after being put on the market.

13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

Article L. 4113-6 of PHC contains a general provision under which pharmaceutical companies that produce or market products or services reimbursed by social security schemes are prohibited from granting free advantages, whether directly or indirectly, to healthcare professionals. However, pharmaceutical companies can provide advantages or compensation to healthcare professionals in the following circumstances:

- Advantages granted in the context of research and scientific evaluation activities.
- Hospitality offered in the context of scientific or promotional congresses.
- Reasonable compensation for services performed by the healthcare professionals.

Any advantage or compensation granted according to the above exceptions must be provided for in a written contract submitted to the relevant professional bodies for review and opinion.

The distribution of free samples is also limited. Pharmaceutical companies can provide free samples to healthcare professionals on request only, and the number of samples is limited to ten samples of a given product per professional per year.

Gifts or donations to a medical institution to finance research activities or training of healthcare professionals are acceptable provided that the pharmaceutical company makes a specific declaration to the *Préfecture*, and these gifts/donation do not provide any individual advantage to healthcare professionals (that is, they are intended for collective use only).

Charitable donations do not need to be declared to the *Préfecture*.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

The PHC does not provide any specific prohibition on the marketing of medicinal products authorised in France via the internet. However, mail delivery is restricted by the general regulations governing pharmaceutical activities. Only pharmacists are allowed to sell pharmaceutical products, and only in their pharmacies. In addition, pharmacists have an obligation to give customer advice.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What types of medicinal product cannot be advertised?**
- **What restrictions apply to advertising that is allowed?**

Medicinal product advertising in France is governed by the following set of regulations:

- Code for Human Medicines Directive.
- Provisions of the PHC concerning promotion of pharmaceutical products.
- Guidelines issued by the AFSSAPS.

Although the AFSSAPS guidelines are not legally binding, French courts consider that they must be taken into account by pharmaceutical companies.

Advertising for medicinal products must strictly comply with the product's marketing authorisation. The PHC distinguishes between advertising directed to the general public and advertising directed to healthcare professionals. As a general principle, advertising directed at the general public is not allowed if the product is subject to prescription or is reimbursed by social security. Advertising directed at the general public is allowed for other medicinal products, provided prior authorisation has been granted by the AFSSAPS.

All medicinal product advertising must contain objective information and be consistent with the appropriate use (*bon usage*) of the product. More specifically, advertising directed at healthcare professionals must contain legal information set out in Article R. 5122-9 of the PHC, as well as all relevant information for professionals to form their own opinion as to the therapeutic worth of the product. The information must be accurate, up to date, verifiable and exhaustive. The price of the product (if determined by the authorities), the daily cost of the treatment and its reimbursement by social security schemes must be mentioned in any promotional material directed at healthcare professionals.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What information must the packaging and/or labelling contain?**
- **What other conditions must be met (for example, information being stated in the language of your jurisdiction)?**

The packaging and labelling of pharmaceutical products is subject to specific regulations provided by the PHC (for example, Article R. 5121-137 et. sec.). The AFSSAPS is the regulatory body which controls compliance of pharmaceutical products' packaging and labelling.

All packages and leaflets constitute part of the marketing authorisation granted by the AFSSAPS. The following information must appear on, among other places, the outer packaging of pharmaceutical products:

- Name of the medicinal product.
- Qualitative and quantitative composition in respect to active substances.
- Pharmaceutical form and contents by weight.
- Route of administration.
- List of excipients.
- Expiry date.
- Special storage precautions.
- Disposal of unused medicinal products or waste materials.
- Authorisation number and manufacturing batch number.
- Special warnings.

If the required information is not on the outer packaging, it must be on the immediate packaging. The information must be legible, understandable and indelible. For reimbursable medicinal products, the outer packaging must also mention information related to the price and the conditions for reimbursement by social security schemes.

The above items must appear on packaging in French. Other languages can be used, provided identical information appears in all languages.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

The manufacture and marketing of traditional herbal pharmaceutical products is regulated by the PHC. Such pharmaceutical products can be authorised through the abridged procedure of marketing authorisation used for products with well-established medicinal use by means of a detailed scientific bibliography. Directive 2004/24/EC on traditional herbal medicinal products, recently implemented in France, contains provisions to facilitate the marketing of such products. Certain listed products can be authorised under a special and simplified registration procedure. The application for registration is made to the AFSSAPS.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

The patentability of pharmaceutical products is subject to general regulations governing patents. Any medicinal product or related substance can be patented provided the conditions required by the Intellectual Property Code are met. Patentability is subject to the following conditions:

- Novelty involving an inventive step.
- Potential industrial application.

In addition, the invention must not be contrary to the public order or ethics, or human dignity. Some inventions are not patentable, such as discoveries, scientific theories, mathematical methods, aesthetic creations, games or computer programs. The human body, at the various stages of its formation and development, including the embryo, is not patentable. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of a patent application.

In addition, specific regulations apply to pharmaceutical products protection. As the active ingredient of a pharmaceutical product is usually patented long before its effective marketing, the parts of the patent that correspond to the authorisation can be protected for an additional period of time (*see Question 20*). This is called a supplementary protection certificate (*certificat complémentaire de protection*).

19. How is a patent obtained? In particular:

- **To which authority must the application be made?**
- **What fee must be paid?**
- **What are the key stages and timing?**

The authority

The application for the patent is filed with the National Institute of Industrial Property (*Institut National de la Propriété Industrielle*, INPI). (*www.inpi.fr*)

Fee

Progressive annual fees must be paid for the patent application. EUR35 (about US$48) must be paid within one month of filing the application. The fees increase progressively up to EUR600 (about US$820) per year from the 16th year. The annual fee for the supplementary certificate of protection is EUR500 (about US$680). Additional fees must be paid for the instruction of the application by the INPI (that is, EUR500 for the search report, EUR85 (about US$116) for the granting of the patent).

Process and timing

The application must contain all information relating to the invention, including:

- A description of the invention, accompanied by drawings where appropriate.
- One or more claims to define the scope of protection the inventor is applying for.
- An abstract of the technical content of the invention.

Within 18 months of the application date, the INPI is required to publish a notification of the filing of the application in the *Official Bulletin of Industrial Property*. This publication procedure aims to ensure that third parties are informed of the patent application.

The patent is delivered after a search report (*rapport de recherche*) has been issued by the INPI. The report summarises the elements of prior art that can be taken into consideration for assessing the patentability of the invention. A reference to granting the patent must be published in the *Official Bulletin of Industrial Property* within one month of the date of notification.

20. How long does patent protection last? How is a patent renewed or patent protection extended?

Patents are granted for a term of 20 years from the day of the application and are not renewable. However, supplementary certificates of protection can be granted for pharmaceutical products. They enter into effect at the end of the statutory term of the patent, for a period of not more than seven years from the end of the patent and 17 years from issue of the marketing authorisation.

21. In what circumstances can a patent be revoked?

The granting of a patent is subject to limited investigations performed by the INPI. Once the patent has been granted, a subsequent more complete investigation can be initiated and the patent revoked in court. Any person with an interest is entitled to ask for revocation of the patent by a civil court if the patent does not comply with the substantial requirements of the Intellectual Property Code (that is, the invention is not disclosed in a manner sufficiently clear and complete to be used by a person skilled in the art).

In addition, the preservation of the patent is subject to payment of the annual fees. If the fees are not paid, the holder has an additional six-month period to pay them, as well as a surcharge, and if they are still not paid after this period, the patent holder loses all rights.

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

The patent gives the holder the right to prohibit the direct use of the invention, in particular, manufacturing, offering, putting on the market, importing, and all indirect uses of the invention (through supplying it). Any violation of these rights constitutes an infringement and the infringer is civilly liable. As a principle, infringement proceedings must be brought by the patent holder. At the holder's request, the judge can order the seizure of the infringing products and subsequent measures to stop the infringement. In addition, damages can be awarded to the patent holder.

The infringement can constitute a criminal offence, provided the holder can prove that the counterfeiter acted dishonestly. Any breach of these rules is punishable by three months' imprisonment and a fine of EUR300,000 (about US$410,000).

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

The registration of pharmaceutical product brands are subject to the general regulations governing trade marks. A trade mark is defined as a sign capable of graphic representation which serves to distinguish the goods or services of a natural or legal person (*Intellectual Property Code*). The PHC contains specific additional rules regarding trade marks. The name of the pharmaceutical product can be either an invented name, a common name or a scientific name followed by the trade mark or the name of the manufacturer. To be accepted, the registered mark must not create any confusion with other pharmaceutical products.

24. How is a trade mark registered? In particular:

- **To which authority must the application be made?**
- **What fee is payable?**
- **What are the key stages and timing?**

The authority

The application for registration of a trade mark is filed with the INPI.

Fee

The fee depends on the number of international classes of products and services for which protection is required. The initial application is subject to the payment of EUR225 (about US$307) for the first three classes and EUR40 (about US$55) for each additional class. No additional fee is required for the continuation of protection during the following years.

Process and timing

Ownership of a trade mark is acquired by registration. The application must contain, in particular, administrative information related to the applicant's identity, a sample of the item to be trade marked and a list of the goods and services to which it applies. A registration number is then attributed to the application and within six weeks, the INPI publishes notification of the filing in the *Official Bulletin of Industrial Property*. Within two months of the date of the publication, any concerned person can submit observations to the Director of the INPI or lodge a formal opposition to contest the trade mark registration (for example, if the trade mark has already been registered). If it is not contested and the trade mark complies with the requirements of the Intellectual Property Code, the trade mark is registered in the National Register of Marks and published in the *Official Bulletin of Industrial Property*.

25. How long does trade mark protection last? How is a trade mark renewed?

The effects of registration begin on the application filing date for a ten year period. The trade mark can be renewed without limitation.

26. In what circumstances can a trade mark be revoked?

The trade mark can be revoked in the following circumstances:

- The owner of the registered trade mark can renounce the effects of the registration for all or part of the goods or services to which the trade mark applies (by means of a notice of renunciation).
- The registration can be declared void if it does not comply with the legal requirements.
- An owner who has not exploited his trade mark during an uninterrupted period of five years, without good reason, is liable to revocation of his rights by court order.

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

Trade mark registration provides the holder with exclusivity of use (for the goods and services designated in the application) and a right to prevent all third parties from using the mark in the course of trade without its consent.

An offender can be civilly liable for any infringement of the holder's rights. Infringement can consist of:

- Use or reproduction of an identical trade mark (for example, the use of an identical trade mark for goods or services identical to those designated for the trade mark registration).
- Use by imitation implying a risk of confusion (for example, the use of an identical trade mark for goods or services that are similar to those designated in the registration or the use of an imitative trade mark for goods or services that are similar or identical to those designated).

The trade mark holder can pursue infringement proceedings before the civil courts, which can order the seizure of the infringing products and subsequent measures to terminate the infringement. Damages can be awarded to the trade mark holder. As with patent infringement, criminal prosecution can also be pursued. Any breach of these regulations is punished by three months' imprisonment and a fine of EUR300,000 (about US$410,000).

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

France is a party to the following conventions:

- WIPO Paris Convention for the Protection of Industrial Property 1883.
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).

PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

Legal provisions

Liability can arise under tort, contract and defective products liability law.

Under tort law, a fault can result from an act or an omission. The claimant must establish:

- A fault.
- An injury.
- A causal link between the fault and the injury.

Under contract law, a party to a contract is liable for the damage caused by the non-performance of its contractual obligations, unless it proves that the non-performance resulted from an external cause. Courts have also established specific obligations, such as the obligation to deliver the product, the safety obligation, the counsel or advice obligation and the guarantee against latent defects (for example, latent defect of the product that makes it improper for the use for which it was intended).

Defective product liability stems from Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning the liability of defective products, which was implemented in France by law No. 98-389 on 19 May 1998 which established a specific defective product liability regime.

In addition, claimants can also pursue pharmaceutical companies under criminal law. A manufacturer of a dangerous product can be liable for involuntary homicide or the infliction of an involuntary injury resulting in the victim's total incapacity for more than three months.

Substantive test

Under tort liability, the claimant must give evidence of an existing fault, an injury and a causal link between the fault and the injury. The fault can be negligence in the conception or manufacture of the product.

Under contract law, the claimant must prove that the product does not comply with the contract or was affected by a manufacturing vice or defect that made it improper for the use for which it was intended, or that information delivered regarding the product was incomplete.

Under defective product liability, the product is considered to be defective when it does not provide the safety which a person is legitimately entitled to expect. The claimant must give evidence of the actual damage, the defect in the product and the causal link between the damage and the defect.

Liability

Under tort liability, any person can be liable provided that a fault, an injury and a direct causal link are proven. However, the manufacturer would generally be liable.

Under contract law, the supplier (for example the physician, the pharmacist or the hospital) would most often bear responsibility for the default or defect (except for the safety obligations where the manufacturer could also be held responsible).

Under defective product liability, the principle is that the "producer", which is defined as the manufacturer of a finished product, the producer of any raw material, the manufacturer of a component part, when acting in professional capacity, bears ultimate responsibility for the defect. In addition, if the producer remains unknown, the seller or any professional supplier is responsible for defective products under the same conditions as the manufacturer, unless it discloses the name of its supplier or producer, within three months of the notification of the claimant.

THE REGULATORY AUTHORITY

French Agency for the Safety of Health Products (*Agence Française de Sécurité Sanitaire des Produits de Santé*, AFSSAPS).

T + 331 55 87 30 00
F + 33 1 55 87 33 20 (marketing authorisation service)
+ 33 1 55 87 39 70 (pharmaceutical establishments service)
W *http://afssaps.sante.fr/*

Main areas of responsibility. These include:

- Clinical trials.
- Marketing authorisations.
- Pharmaceutical establishment authorisations.
- Advertising.
- Pharmacovigilance.
- Import and export of healthcare products.

30. What are the limitation periods for bringing product liability claims?

Under tort liability, the common law time limit for bringing an action in France is ten years from the date when the cause of the action arose. Under contract law, the limitation period is 30 years from the time of the damage.

A specific time period is provided for the contractual guarantee against latent defects. Liability claims must be brought within two years of the discovery of the defect (*Article 1648, Civil Code*).

Under defective product liability, the limitation period is ten years after the product was put into circulation. Proceedings for the recovery of damages based on defective product law are time-barred after a period of three years from the date on which the plaintiff became aware or should have become aware of the damage, defect and identity of the producer.

31. What defences are available to product liability claims?

Under contract law, valid defences are that the defect or fault arose as a result of a *force majeure*, an external cause (third party action), or from the buyer's own fault.

Under tort liability, the defendant must prove that the defect or fault arose as a result of external causes or of the attitude of the victim (fault or consent of the victim).

Under defective product liability, the producer is not responsible if it can prove one of the following:

- It did not place the product into circulation.
- The defect that caused the damage did not exist at the time the product was placed into circulation or the defect arose after it was put into circulation.
- The product was not manufactured for distribution or sale.
- The state of scientific or technical knowledge at the time the product was placed into circulation was not such as to enable the discovery of the defect.
- The defect was due to compliance of the product with mandatory provisions or regulations emanating from public authorities.

In addition, the producer of the component is not responsible if it can prove that the defect in the component is attributable to the design of, or the directions given by the producer of the product in which the component has been fitted.

The defence based on scientific knowledge does not apply to injuries caused by pharmaceutical products using compounds coming from human bodies, such as blood.

32. What remedies are available to the claimant?

Under tort and contract law, pecuniary damages resulting from material damage are recovered if the damage is certain, direct and foreseeable. This includes the loss incurred, as well as missed gain or loss of opportunity. Damages for bodily injuries are also recoverable. In addition, remedies for moral damages are also recoverable, but are difficult to evaluate.

Under defective product liability, compensation is limited to all damages resulting from harm to a person or goods other than the defective product itself.

33. Are class actions allowed for product liability claims? If so, are they common?

Class action procedures do not exist in France. However, under Article L. 421 *et seq.* of the Consumer Code, the *action collective* authorises registered consumer associations to bring legal proceedings before all jurisdictions for compensation for damages sustained by consumers collectively. Damages are claimed for the loss sustained by the community of consumers to the extent that such loss is distinct from the losses sustained by individual consumers.

In 2006, a draft law was presented by the French government in this respect. The purpose was to maintain the mandate requirement while allowing consumer associations to publicly solicit such mandates and therefore favour group actions. This new form of collective action, if adopted, would only apply to economic damages and would exclude medical liability and body harm. The draft law has been abandoned but the implementation of a class action in French law is again being debated.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

In the near future, full implementation of the Code for Human Medicines Second Amendment Directive should be finalised by the publication of a decree relating to the marketing and distribution of pharmaceutical products. In addition, modifications to pharmaceutical product reimbursement rules may be introduced in the draft bill of the 2008 Social Security Financing Act. Also, the implementation of a non-reimbursable fixed fee for each medicinal product for the purpose of funding public health projects is currently being debated.

Country Q&A