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. If biotechnology products are treated differently, please specify the differences.

The rules regulating medicines are generally a close implementation of the relevant EU provisions and require:

- Marketing authorisation for placing a medicine on the market.
- A licence for manufacturing.
- A licence for wholesale distribution.
- Compliance with various regulations, such as those concerning advertising.

Retail distribution is generally limited to pharmacies.

The Medicines Law of 25 March 1964 and the Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use are the main legislative acts regulating medicinal products. The Federal Agency for Medicines and Health Products (FAMHP) (Federaal Agentschap voor geneesmiddelen en gezondheidsproducten (FAGG) or Agence fédérale des médicaments et des produits de santé (AFMPS)) (see box, The regulatory authorities) is the regulatory authority responsible for these matters. FAMHP is a public service institute with legal personality. It began operating on 1 January 2007 and took over responsibilities from the Federal Public Service of Health, Food Chain Safety and Environment, Directorate General of Medicines.

Belgium operates strict controls on pricing and reimbursement of medicines. The main legislation regarding reimbursement of medicines is the Law on the Mandatory Health Insurance of 14 July 1994 and the Royal Decree of 21 December 2001 Concerning the Procedures, Terms and Conditions for Contribution by Mandatory Insurance for Health Care and Benefits towards Costs of Pharmaceutical Specialties.

The most important body for reimbursement of medicines is the Commission for Reimbursement of Medicines (Commissie Tegemoetkoming Geneesmiddelen or Commission de Remboursement des Médicaments) (see box, The regulatory authorities) of the National Institute of Health and Disability Insurance (Rijksinstituut voor ziekte-en invaliditeitsverzekering (RIZIW) or Institut National d’Assurance Maladie Invalidité (INAMI)). The main authority for price regulation is the Federal Public Service Economy, SMEs, Self-employed and Energy; Directorate General Regulation and Organisation of Markets; Section Prices (see box, The regulatory authorities).

PRICING AND STATE FUNDING

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

Belgium has an established and efficient healthcare system. It combines private and official healthcare providers, and is funded as part of the general social security system. Funding comes from withholdings on salaries (and similar official funding for civil servants) and social security contributions by self-employed persons, and is supplemented by other funds. Healthcare rules allow patients a wide choice in selecting healthcare providers and define the benefits they can claim. Patients often have to make a co-payment, which, at least in part, is intended to help prevent over-consumption. Coverage provided by the official system can be supplemented by optional additional private insurance.

The system has been facing challenges from increasing costs, which were not offset by increases in funding. This has resulted in increased pressure on healthcare providers and particularly on the pharmaceutical industry. The system is regularly revised to meet these challenges (a typical example being the increasing price-lowering mechanisms for medicines for which generic copies become available). However, efforts have been successful. In 2009, the budget for medicines was under control.

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

Belgium operates strict controls on pricing and reimbursement of medicines for human use. The main procedures for determining prices are set out in two Ministerial Decrees dated 29 December 1989:

- The first deals with medicinal products that are reimbursed under the national health insurance system.
- The second deals with other medicinal products, of which at least one pharmaceutical form is subject to prescription.
After a medicinal product has been registered, the maximum price is fixed by the Minister of Economic Affairs. The Minister takes the decision on the advice of the Price Commission for Pharmaceutical Specialties (for reimbursed medicines) or the Commission for Regulation of Prices (for non-reimbursed medicines).

An important amendment to these Ministerial Decrees was introduced by the Ministerial Decree of 28 June 2007. A price application is generally only possible when the product has a marketing authorisation. However, if a medicine is designated as an orphan medicine or if the company requests reimbursement status as a Class 1 product (see Question 4), and if the product is going through the centralised approval procedure under Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMEA Regulation), the price application can also be submitted as soon as the Committee for Medicinal Products for Human Use (CHMP) issues a positive opinion. In these cases, the reimbursement application can also be filed before a marketing authorisation is obtained.

The Ministerial Decree of 5 May 2006 contains a separate procedure for establishing prices for generic medicines and medicines registered on the basis of a bibliographic application, taking them outside the scope of the other Ministerial Decrees. This decree also contains rules on maximum prices and on maximum profit margins for wholesalers and pharmacies.

Other medicinal products are regulated by the Ministerial Decree of 20 April 1993, which contains a general price control mechanism not limited to medicinal products, and the Ministerial Decree of 2 April 1996 concerning the maximum sales price and the maximum margins for wholesale and dispensing.

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)?

The Minister of Social Affairs generally decides, on the basis of a proposal by the Commission for Reimbursement of Medicines, whether to add a medicine to the list of reimbursed medicines. A company that places medicines on the market must ask the Commission for Reimbursement of Medicines to formulate a proposal for reimbursement, but in specific circumstances the Commission for Reimbursement of Medicines can itself propose adding a medicine to the list. The application must be concurrent with the separate application for price (see Question 3) but, in practice, the public price is an important aspect in the reimbursement procedure.

The main criterion for a decision on reimbursement is the therapeutic value of the medicinal product, which is expressed in three classes (each class has a different reimbursement procedure) (Article 35 bis, Law on the Mandatory Health Insurance):

- **Class 1:** medicinal products with a significant therapeutic improvement in comparison with existing alternatives.
- **Class 2:** medicinal products without a significant therapeutic improvement in comparison with existing alternatives and that do not belong to Class 3.
- **Class 3:** generic medicines and medicines registered on the basis of a bibliographic application.

In 2007, the King further divided Classes 2 and 3 into subclasses (Royal Decree of 15 February 2007 amending the Royal Decree of 21 December 2001), based on:

- Price and proposed reimbursement basis.
- Importance of the product in medical practice in relation to therapeutic and social needs.
- Budgetary implications for the health insurance system.
- Relation between the costs for the health insurance system and the therapeutic value.

The procedure sets specific deadlines for review of applications and must take no more than 180 days. However, this deadline can be suspended in certain circumstances. In 2007, a simplified administrative reimbursement procedure was introduced for certain generic medicines, medicines registered on the basis of a bibliographic application, and parallel imported medicines (Royal Decree of 15 February 2007 amending the Royal Decree of 21 December 2001). Under this procedure, a decision must be taken within 60 days (subject to suspension) and without the involvement of the Commission for Reimbursement of Medicines.

Other important aspects of the reimbursement system include the following:

- A reference reimbursement system (which reduces the reimbursement level of innovative medicines when a generic becomes available) applies to all products containing the same active substance, even when this is in a different dose or pharmaceutical form, subject to possible exemptions.
- In late 2005, the possibility of generic prescription, also called International Non-Proprietary Name (INN) prescription, was introduced in Belgium. Physicians can still prescribe a specific branded medicine, but must meet certain targets of generic prescription to avoid penalties. For generic prescriptions, pharmacists must generally dispense the cheapest product. On 20 November 2009, FAMHP approved a note setting out the principles for defining groups of medicines that can be grouped under a single INN prescription and any mandatory or optional specifications of this prescription.
- As of 1 July 2006, the reimbursement of medicinal products used in hospitals in principle occurs on a fixed basis. The Minister for Social Affairs is responsible for determining the exceptions.
- There are possibilities for making revisions to groups of medicinal products (that is, instead of revising the reimbursement conditions of an individual product, the reimbursement conditions of a whole group of products can be revised at the same time).
- As of 1 January 2009, additional pricing measures came into force. Among others, the prices of medicinal products
of which the active substance had been reimbursed for more than 12 years decreased by 14%, while the prices of medicines reimbursed for more than 15 years decreased by an additional 2.3%. In addition, the levels of patient contributions for medicines of the second and third class were not indexed on 1 January 2009, due to decreased purchasing power.

- A tender concept (referred to as consulting the market, and in practice as the “kiwi model”) has been introduced, inspired by the system in New Zealand. This can result in ad hoc reimbursement categories or in overall reimbursement reductions. A tender can currently only cover products that are off patent. The tender concept was further implemented by the Minister of Social Affairs in 2006, but to date no tender procedure has been successfully finalised.

- Agreements with pharmaceutical companies are now already possible in specific circumstances, and it is possible that in the future, the government will start negotiating price-volume agreements with pharmaceutical companies.

For reimbursed medicines, payment by the patient can be limited to the non-reimbursed part of the price, provided the pharmacy is a member of the “third payer” system. Under this system, the pharmacist collects co-payment and is reimbursed for the remainder by the social security system.

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

A manufacturing authorisation is required for the manufacture of medicines or intermediary products in Belgium (Articles 12b and 12c, Medicines Law). Companies or individuals wishing to manufacture medicinal products in Belgium must file a dossier with FAMHP. The requirement to hold a licence also applies where medicinal products are manufactured for export purposes only.

Conditions

The following information must generally be included in the application:

- A list of the products and preparations used in the manufacturing process.
- The activities that will be performed (manufacture and import, wholesale and export).

- Details of the manufacturing process and the address where it will be undertaken.
- Evidence of adequate staff, premises, and scientific and industrial equipment, as required to comply with the principles of good manufacturing practice (GMP).

More specific information must be provided depending on the type of product the applicant intends to manufacture. In addition, the applicant must commit itself to several obligations, such as performing appropriate batch releases. Applicants (except in the case of contract manufacturing) must also commit to supplying wholesaler-distributors to allow them to comply with their public service obligations, which include, among others, the guarantee of appropriate and continued supplies of medicinal products for the needs of patients in a particular geographical area. The correct interpretation of this supply obligation remains unclear for the moment.

Special rules (laid down in the Royal Decree of 30 June 2004 concerning Experiments on Humans) are in place for investigational medicinal products.

Restrictions on foreign applicants

There are no restrictions on foreign applicants.

Key stages and timing

A FAMHP officer investigates the application to ascertain whether all requirements are met and whether the application dossier is complete. The final decision is normally issued within 90 days of filing, but if further information is requested from the applicant this term is suspended until additional information is received.

If FAMHP intends to reject the authorisation, the applicant receives a draft of the decision within the 90-day deadline, and can request that the dossier is submitted to the Advisory Committee within 15 days after having received the draft decision. If no request is filed in time, the decision becomes final. If a request is filed, FAMHP must take into account the opinion of the Advisory Committee and take a final decision within 90 days after the request to submit the dossier to the Advisory Committee.

Fee

Fees are listed on FAMHP’s website. In 2009 to 2010, the fees are EUR1,327.66 for a new licence application. (As at 1 November 2010, US$1 was about EURO0.7.)

Period of authorisation and renewals

Authorisation is valid for an indefinite term, but the holder of the authorisation must ensure it is always fully up-to-date.

6. What powers does the regulator have to:

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

FAMHP inspectors have broad powers to monitor compliance with the manufacturing authorisation and the rules on manufacturing...
of medicines. For example, the inspectors can enter premises where medicines are being manufactured and/or interrogate all persons they believe can provide useful information. Inspections are frequently performed. For example, in 2009 there were 248 inspections in the pharmaceutical industry, of which a 100 focused on good manufacturing practices (GMP) and 148 on good distribution practices (GDP).

If the licence holder breaches the applicable requirements, the FAMHP can suspend or revoke the licence. The licence holder is informed of the intention to suspend or revoke and can request that the dossier be submitted to the Advisory Committee within 15 days. If no request is filed in time, the decision becomes final. If a request is filed, the FAMHP must take into account the opinion of the Advisory Committee and make a final decision within 90 days after the request to submit the dossier to the Advisory Committee. Emergency measures are possible. Criminal sanctions or administrative measures are available for specific violations.

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 and authority
The Law of 7 May 2004 concerning Experiments on Humans regulates experiments on humans, including clinical trials with medicines, and implemented Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive). The Law of 7 May 2004 has been further implemented by, among others, the Royal Decree of 30 June 2004. The FAMHP is in charge of clinical trials in Belgium.

Authorisations
An experiment with humans can generally only be undertaken if both:
- The experiment has received a positive opinion from an ethics committee.
- For an interventional trial, the Minister has not raised objections or, in specific circumstances, has given his explicit approval.

Consent by trial subjects
A person can generally only participate in an experiment if he has given free and informed written consent, after being informed of the:
- Nature, significance, objectives, implications, and anticipated benefits and risks of the trial.
- Circumstances under which the experiment will take place.
- Identification and opinion of the ethics committee.

The information must be given in writing in advance, in a clear and comprehensible manner. Specific rules are laid down for minors, persons incapable of giving informed consent and emergency situations.

Other conditions
The Law concerning Experiments on Humans imposes a no-fault liability on the sponsor for all damages to study subjects (or their heirs) that result directly or indirectly from the experiment. The sponsor must take out insurance (before the experiment starts) that covers this liability as well as liability of any other person intervening in the experiment, regardless of that person’s relationship with the sponsor. If the sponsor is located outside the EU, a legal representative in the EU must be appointed.

Procedural requirements
The procedural requirements are in line with the Clinical Trials Directive and include:
- Compliance with Good Clinical Practices.
- Specific safety reporting requirements.
- Specific requirements on the manufacturing, importation and distribution of investigational medicinal products.
- Specific procedures for amendments to the protocol.
- Procedural requirements at the end of the trial.

The Law concerning Experiments on Humans does not apply to purely retrospective studies based on data contained in the medical or patient dossiers, if those studies do not require collection of new data from the subjects in question (this clarification was added by the Law on Various Provisions regarding Health Care of 19 December 2008).

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?

The procedure and conditions to obtain a marketing authorisation are set out in the Medicines Law and the Royal Decree of 14
December 2006 on Medicines for Human Use and Veterinary Use.

**Application**

A company wishing to place a medicinal product on the market must obtain a marketing authorisation from the Minister of Health or a Community marketing authorisation under the centralised procedure (see EMA Regulation). Marketing authorisations obtained from the EMA under this centralised system are valid in all EU member states.

**Conditions**

To obtain a marketing authorisation, the applicant must file an application with the FAMHP, including, among others:

- Chemical and pharmaceutical data.
- Results of pharmacological and toxicological tests.
- Results of clinical trials.

Marketing authorisation can be granted under special circumstances, for example, subject to the performance of additional research.

A marketing authorisation is refused if the:

- Risk-benefit balance is not considered favourable.
- Therapeutic efficacy is insufficiently substantiated by the applicant.
- Qualitative and quantitative composition is not as declared.

Authorisation is also refused if the particulars and documents submitted in support of the application do not comply with the relevant legal requirements.

In exceptional circumstances, medicines that have not yet received a marketing authorisation can be made available to specific patients under compassionate use and medical need programmes (see EMA Regulation, Belgian Law of 1 May 2006 modifying the Medicines Law and Royal Decree of 14 December 2006 regarding Medicines for Human Use).

**Key stages and timing**

Authorisation can be granted by Belgian authorities on their own, or on the basis of a marketing authorisation granted by another EU member state under the mutual recognition procedure (see Question 10) or following the decentralised procedure.

The completed application is filed with the FAMHP and passed to the Commission for Medicines for Human Use, which then arranges for the scientific review and prepares an assessment report. During the review, the applicant can be required to submit additional information. A decision on the application must be issued within 210 days of the initial filing of the application, subject to suspension if additional information is required. Specific procedures apply where the mutual recognition or decentralised procedure applies.

**Fee**

Fees are listed on the FAMHP’s website. (For example, since January 2010, the fees for a complete application for a new active substance are EUR8,283.92.)

**Period of authorisation and renewals**

Authorisation is valid for five years and can be renewed for an unlimited time based on a re-evaluation of the risk-benefit balance. However, the competent authority can, on justified grounds relating to pharmacovigilance, decide to proceed with one additional five-year renewal. If a medicinal product is not placed on the market within three years or is not on the market for three consecutive years, the authorisation will cease to be valid.

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?

Based on the revised Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive), the Medicines Law contains the following possibilities:

- An abridged application is possible if the applicant can show that his product is generic to a product that was authorised for at least eight years in Belgium or another EU member state (the typical abridged application). In this case, the applicant is not required to provide results of preclinical tests and clinical trials.
- The generic product can, however, only be marketed after a period of ten years from the grant of a marketing authorisation for the reference product. An extra year of market protection is obtained in case of approval during the first eight years of a new therapeutic indication, which is of significant clinical benefit compared to existing therapies.
- The new data exclusivity periods introduced by Directive 2004/27/EC amending the Community Code relating to Medicinal Products for Human Use (Code for Human Medicines Second Amendment Directive) only apply to innovative products for which a marketing authorisation application is submitted under the revised legislation.
- The new rules continue to allow authorities to accept applications that refer to a reference product but contain data that bridge differences between the reference product and the new product. In that case, appropriate pre-clinical and/or clinical data must be submitted.
- A new indication for a well-established substance (usually a substance approved for at least ten years) or a change in classification of a medicinal product, triggers a one-year data exclusivity period if significant pre-clinical or clinical studies were conducted. The exclusivity relates only to the new therapeutic indication, respectively the new test data.
- Where the active substance of the medicinal product has been used for at least ten years in medical practice, has a recognised efficacy and an acceptable level of safety, pharmacological, toxicological and clinical data can be based on scientific literature (bibliographic application).
10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

The mutual recognition procedure and the decentralised procedure laid down in the Code for Human Medicines Directive apply in the EU.

If an applicant applies for marketing authorisations for a medicinal product in more than one member state, the decentralised procedure applies. The applicant must submit applications based on identical dossiers in all these member states. The reference member state must prepare a draft assessment report, a draft summary of product characteristics, a draft of the labelling and a draft package leaflet, and forward them to the other member states.

If the medicinal product has already received a marketing authorisation in a member state at the time of application in other member states, the mutual recognition procedure applies. The marketing authorisation holder must ask the reference member state to prepare an assessment report on the medicinal product, or if necessary, to update any existing assessment report. The assessment report together with the approved summary of product characteristics, labelling and package leaflet must be sent to the concerned member states and the applicant.

Where Belgium is not the reference member state, the Minister normally approves the assessment report, the summary of product characteristics, and the labelling and package leaflet within 90 days after receiving the assessment report. If the Minister believes that the medicinal product may present a risk to human health, it immediately informs the applicant and other member states. If not all concerned member states have approved the assessment report, the summary of product characteristics, and the labelling and package leaflet, the points of disagreement are forwarded to the co-ordination group for discussion. In case of an unresolved disagreement, the matter is referred to the Committee for Medicinal Products for Human Use (CHMP) for arbitration.

11. What powers does the regulator have to:

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

FAMHP inspectors have broad powers to verify compliance with marketing authorisations. These are similar to the powers to monitor compliance with manufacturing authorisations (see Question 6). In case of a breach, the Minister can suspend or revoke the marketing authorisation. In addition, the inspectors can, among others, seize medicines that do not comply with terms of the marketing authorisation. Criminal sanctions or administrative measures can also apply in specific circumstances.

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 from other member states of the European Economic Area (EEA) are possible under specific conditions. The Parallel Import Royal Decree of 19 April 2001 provides for notification of parallel distribution of centrally approved medicines and for a simplified authorisation procedure for parallel imports of nationally approved products.

A parallel import authorisation is generally granted if all of the following apply (Royal Decree of 19 April 2001):

- There is a reference product in Belgium (that is, there is a valid marketing authorisation).
- The parallel imported product is the same as the Belgian product in terms of:
  - qualitative and quantitative composition in relation to the active ingredient;
  - pharmaceutical form;
  - therapeutic effect.
- The products are manufactured by the same producer or linked producers (common origin requirement).

In the Kohlpharma case (Case C-112/02 [2004]), the European Court of Justice (ECJ) held that the common origin can be a relevant element in deciding on a parallel import application, but is not a separate requirement. The authorisation can also be granted in certain specific circumstances, reflecting rulings of the ECJ. The relevant conditions are, however, not consistently set out.

If a product is marketed by, or with the consent of, the holder of intellectual property rights on the product in any EEA member state, these rights are exhausted and the holder cannot invoke them against parallel imports into other member states. However, on 4 May 2004, the Royal Decree of 19 April 2001 was amended to safeguard the intellectual property rights of the reference product against imports from (most) new eastern EU member states, where the same intellectual property rights could not have been obtained at the time they were obtained in Belgium (the specific mechanism).
13. Please briefly outline the restrictions on marketing practices such as gifts or “incentive schemes” for healthcare establishments or individual medical practitioners.

Article 10 of the Medicines Law contains a broad prohibition on referring to, offering or giving, during the course of the supply, prescription, delivery or administration of medicines, directly or indirectly, benefits or advantages (in money or in kind) to any of the following:

- Wholesalers.
- Persons that can prescribe, dispense or administer medicines.
- Institutions where prescribing, dispensing or administering takes place.

It is intended that all exceptions to this general prohibition are set out in the law itself. However, in reality the exact scope of the prohibition is not always clear. The prohibition does not apply to activities covered by (Article 10, Medicines Law):

- Benefits or advantages with very limited value, and relating to the medical profession. A royal decree can further describe the concept of “very limited value”.
- An invitation to, or payment for, participation in a scientific conference (including hospitality), subject to four specific conditions, one of which is that the conference must have a strictly scientific nature. In addition, for every scientific conference with at least one overnight stay, an authorisation in the form of a “visa” must be obtained. The obligation to obtain a visa came into force on 31 December 2006. As of 1 January 2007, the organisation of the visa obligation was retrospectively assigned to the private institution Mdeon (www.mdeon.be) by the Royal Decree of 25 February 2007 on the Recognition of Institutions Described in Article 10(3) of the Medicines Law of 25 March 1964 (and extended each time for one year by the Royal Decree of 11 March 2008, the Royal Decree of 30 March 2009, and the Royal Decree of 6 April 2010). Mdeon was set up in 2006 by several healthcare partners, including the Belgian pharmaceutical industry association pharma.be, the medical devices industry association Unamec, and the ethics organisations of healthcare professionals.
- Reasonable compensation for legitimate services of a scientific nature, in particular in the framework of clinical trials.

The new Article 10 also allows persons to ask for an opinion on whether a specific benefit falls under the prohibition (except in cases where a visa is required) and creates a reporting point to collect information on violations of the prohibition.

Specific rules also apply to bribery and co-liability for breaching internal rules of healthcare establishments or other contracts between physicians and institutions. These rules are, for example, relevant when a pharmaceutical company enters into a collaboration agreement with physicians who are active in a university or other hospitals.

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

In Europe, there is no prohibition per se of internet sales. However, Article 14 of Directive 97/7/EC on distance selling (Distance Selling Directive) allows member states to prohibit online sales of medicines. There are general rules on dispensing medicines that severely restrict possibilities for internet sales. In Belgium, only retail pharmacists can normally dispense medicines (with only specific exemptions being granted, for example, samples dispensed by physicians), and medicinal products must also be ordered or dispensed in the pharmacy.

Belgian rules were amended to allow mail order of over the counter (OTC) medicines, taking into account the ECJ decision in Deutscher Apothekerverband eV v DocMorris NV and Jacques Waterval (Case C-322/01 (2003)), in which the ECJ ruled that the principles of free movement of goods prevent an absolute prohibition of sales of (authorised) OTC medicines by mail order. The basis for further government rules was included in the Medicines Law in 2006. The new Article 3(4) of the revised Medicines Law provides for the following:

- Every medicine must be personally dispensed by the pharmacist to the patient or his representative, except under conditions to be determined by the King.
- Mail order of prescription-only medicines is prohibited.

Since 2009, mail order of OTC medicines registered in Belgium has been allowed. Article 29 of the Law of 21 January 2009 regarding Instructions to Pharmacists sets out the conditions and the minimum information that must appear on websites that sell OTC medicines. Pharmacies which provide mail order service must notify their websites to the FAMHP. The list of notified internet pharmacies is published on the FAMHP website.

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?
- If advertising over the internet is treated differently, please identify the differences.

The basic principles of medicinal product advertising are set out in the Medicines Law and are in line with provisions contained in the Code for Human Medicines Directive. The principles in the Medicines Law are further implemented by the Royal Decree on Advertising of Medicinal Products for Human Use of 7 April 1995. The provision of samples is regulated by the Royal Decree of 11 January 1993, modified by the Royal Decree of 26 April 2007, which imposes more restrictive conditions, for example, that samples can only be provided if at least one package is already marketed. The FAMHP is also in charge of advertising of medicines. The legal provisions on advertising are supplemented by a code of conduct of the Belgian pharmaceutical industry association, pharma.be and by the Mdeon code of conduct.

Promotion of unapproved medicines is prohibited, as well as promotion of medicinal products subject to suspension or revocation measures. Advertising to the public is prohibited for prescription-only medicines. An exemption to the prohibition on advertising to the public exists for government approved vaccination campaigns.
If medicine advertising is allowed, it must comply with numerous specific conditions set out in the Royal Decree of 7 April 1995. These include, for example, that advertising cannot be misleading and that no “not satisfied, money back” schemes can be used. Some means of communication, such as billboards or text messages, are prohibited. Advertising through television or radio requires prior authorisation from the Minister of Health. Other advertising to the public must be notified in advance.

Following criticism about some disease awareness campaigns, new requirements have been set out for campaigns that contain a direct or indirect reference to a medicine or a group of medicines. Most importantly, these campaigns now also require prior authorisation from the Minister of Health unless they concern government-approved campaigns.

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 rules on labelling are implemented in the Medicinal Law and the Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use. The FAMHP enforces these rules.

The requirements are in line with the provisions of the Code for Human Medicines Directive. The information must be:

- Easily legible.
- Comprehensible.
- Indelibly printed in at least the three official languages used in Belgium (Dutch, French and German). If additional languages are used, the information provided must be exactly the same as that provided in the official languages.

Belgium requires that other information is also provided, such as, in principle, information on price and reimbursement status on the packaging (European Commission Notice to Applicants, Volume 2A, Chapter 7).

TRADITIONAL HERBAL MEDICINES

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

All medicinal products, including traditional herbal medicines, are subject to the requirements for medicinal products.

In line with the revised Code for Human Medicines Directive, the Medicines Law provides for a simplified registration procedure (traditional use registration) for herbal medicinal products that meet certain conditions. This procedure has been further implemented in the Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

Medicines can generally be protected by the following:

- Product patent claims.
- Formulation patent claims.
- Method-of-use patent claims.
- Manufacturing process patent claims.

To qualify for patent protection, an invention must be all of the following (Article 2, Patent Act of 28 March 1984):

- New (novelty).
- The result of an inventive step.
- Capable of industrial application.
- No violation of the public order or good morals.

The Law of 28 April 2005 implemented Directive 98/44/EC on the legal protection of biotechnological inventions. It provides that, to protect public health interests, the King can grant compulsory licences for medicinal products, among other things.

There is an administrative review of the novelty and industrial application requirements, but at the courts’ discretion (when assessing the validity of the patent when proceedings are initiated by a third party) to verify whether the invention satisfied the requirements and was therefore eligible for 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?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

Different procedures apply depending on whether the applicant is seeking patent protection only in Belgium (the national procedure) or also in other countries (the EU and international procedures).

The authority

An application for patent protection (in Belgium) must be made to the Service for Intellectual Property (SIP) (a division of the Federal Public Service Economy, SMEs, Self-employed and
21. In what circumstances can a patent be revoked?

A patent can be annulled by the courts in the following circumstances:

- The criteria for patentability are not met.
- Disclosure was insufficient.
- Disclosure exceeds the patent application.
- The patent holder was not entitled to the patent.

A patent can also be revoked if the fees are not paid.

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

The holder of a valid patent can generally object to the following acts by third parties who did not obtain his permission:

- Making, offering, putting on the market or using the product that is the subject matter of the patent, or importing or stocking the product for these purposes.
- Using the process which is the subject matter of the patent or, when the third party knows, it is obvious in the circumstances that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use within Belgium.
- Offering, putting on the market or using a product obtained directly by a process which is the subject matter of the patent, or importing or stocking the product for these purposes.

Other specific protection also exists, including for biotechnological inventions. The principles of exhaustion of patent rights in the EU must be taken into account.

For medicinal products specifically, the new Bolar-type exemption for generic medicinal products introduced by the Code for Human Medicines Second Amendment Directive (implemented in Article 6 bis, Medicines Law) is also of particular importance.

There are several ways to enforce patents. A patent owner can file:

- A petition for interim measures, in urgent cases, to protect its interests.
- A petition for descriptive measures and/or seizure measures.
- Injunction proceedings on the merits.
- An action on the merits and request for various measures, such as:
  - a cease order ending the infringement;
  - confiscation of the counterfeited goods and production assets;
  - damages.

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?

It is possible to obtain trade mark protection for a medicinal product through any of the following:

- A Benelux registration.
- A Community registration.
- An international registration.

A Benelux registration is governed by the Benelux Treaty on Intellectual Property which came into force on 1 September 2006 and combines the existing Benelux rules on trade marks, designs and models.
The main criterion for trade mark protection is distinctiveness, but this must be interpreted in light of extensive ECJ case law on trade marks.

Obtaining trade mark protection for a product name does not guarantee that the name can be used for a specific medicine. There may be public health reasons preventing this.

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?

This section only discusses the Benelux trade mark.

The authority
Applications for a Benelux trade mark can be filed with the Benelux Office for Intellectual Property (BOIP) (Benelux-Bureau voor de Intellectuele Eigendom - Office Benelux de la Propriété Intellectuelle). Alternatively, an application can be submitted to one of the national trade mark offices of the Benelux countries.

Fee
The fees are set out at the BOIP website (www.boip.int). (In 2010, applying for a Benelux trade mark in three classes costs EUR240.)

Process and timing
A written application must be submitted to one of the national trade mark offices or to the BOIP, which investigates whether the application meets the requirements of trade mark protection. Other trade mark holders can file an opposition until two months after publication of the application. If the trade mark application is approved, the BOIP registers the trade mark and it is published in the Benelux Merkenblad. If no opposition is filed, publication of the approved trade mark usually takes about four months.

25. How long does trade mark protection last? How is a trade mark renewed?
A Benelux registration is effective for ten years. Benelux registration can be renewed for further ten-year periods on payment of the prescribed fees.

26. In what circumstances can a trade mark be revoked?
A Benelux trade mark can generally be revoked if:
- The fees are not paid.
- Protection of a foreign trade mark in the country of origin was cancelled.
- The trade mark was not effectively used for a certain period.
- The trade mark became generic.
- The trade mark is invalid because it does not meet the conditions of protection.

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?
A trade mark holder can oppose:
- Any commercial use of an identical trade mark for identical goods for which the trade mark is registered.
- Any commercial use of the trade mark or a similar sign for the goods for which the trade mark is registered or similar goods, if there is a risk that the public may associate the trade mark and the sign.
- Any commercial use, without valid reason, of a trade mark well known in Benelux or of a similar sign for goods, other than the goods for which the trade mark is registered, where the use can provide the user with an unjustified advantage, or can be detrimental to the distinctiveness or reputation of the trade mark.
- Any commercial use, without valid reason, of a trade mark or a similar sign for a reason other than to distinguish the goods, where the use can provide the user with an unjustified advantage, or can be detrimental to the distinctiveness or reputation of the trade mark.

However, the above rules should always be interpreted in light of extensive ECJ case law on trade marks.

Benelux trade marks can generally be enforced through:
- Summary proceedings (interim measures).
- A petition for descriptive measures and/or seizure measures.
- Injunction proceedings on the merits.
- Action on the merits.

In addition, an opposition procedure is available for trade mark holders when another person applies for a Benelux trade mark.

28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.
A patent or trade mark licence does not need to be formally approved by a government or regulatory body, but the licence must be registered with the competent authorities to be enforceable against third parties.

29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.
There is no such requirement.
30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Belgium is a party to the following:
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement).
- WIPO Paris Convention for the Protection of Industrial Property 1883.

PRODUCT LIABILITY

31. 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
There are no specific provisions on product liability for pharmaceutical products. However, liability can arise:
- Contractually, where the claimant is the buyer of the product.
- Under tort liability, where the claimant can be any person suffering damages.

Substantive test
Product liability for a medicinal product can arise when the product is inherently unsafe, or more frequently, when there is...
a production defect with a specific batch. Damage can also be caused or increased by a therapeutic decision of the physician or by misadministration. Most cases of product liability are settled outside court.

**Liability**

Claims can generally be brought against producers, manufacturers, importers, retailers and pharmacists. Theoretically, claims for defective medicines could also be brought against the government. Product liability claims are generally often combined with professional liability claims against the treating physician.

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

Claims based on the Product Liability Law can be initiated up to three years after the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the manufacturer. However, claims must, in any event, be initiated within ten years from the date on which the producer put into circulation the actual product that caused the damage.

Contractual claims must generally be initiated within ten years from the moment the claim arises. However, claims for hidden defects must be initiated within a short period of time. In practice, courts have a wide discretion in deciding what a short period of time is.

Claims based on tort liability must be initiated within a period of five years from the moment the victim becomes aware of the damage and the identity of the responsible person, and, in any event, within 20 years following the day on which the fact that caused the damage occurred.

In all cases, suspension or interruption of the limitation period are possible.

**33. What defences are available to product liability claims?**

The Product Liability Law provides for the same defences as the Product Liability Directive. These defences include that:

- It is probable that the defect did not exist at the time of placing the product on the market.
- The defect is due to compliance with mandatory provisions.
- The state of scientific and technical knowledge at the time of marketing did not allow the defect to be discovered (state of the art defence).

However, these defences are not necessarily available when liability actions are brought on the basis of a contract or in tort.

**34. What remedies are available to the claimant?**

The scope of strict product liability is limited to damages to the person and to personal goods. The scope of contractual or tort liability is broader but specific limitations may also apply.

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

Belgian law does not explicitly allow class actions for product liability claims. In principle, every claimant must have a personal interest to sue on an individual basis. In practice, however, in recent years some joint or collective actions have been introduced by consumer interest groups (such as Deminor and Gaia) based on creative interpretations of the rules on interdependence of claims under the Belgian Judicial Code.

Several legislative initiatives (such as a proposal of law concerning collective damage claims) are being taken to provide a legal basis in this respect, but have not yet entered into force. Other initiatives (for example the Regulation of 18 May 2009 of the Dutch-speaking section of the Brussels Bar) seek to remove specific obstacles under the rules of ethics regulating Belgian lawyers to fully allow class actions once they are made possible following a legislative change.

**36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?**

Punitive damages are not allowed for product liability claims.

**REFORM**

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

Rules affecting the marketing of medicines, with the exception of European rules, are often amended or reformed. Many of the changes are introduced to promote a more rational use of medicines and to control the healthcare budget, but at the same time measures are also introduced to stimulate a positive investment environment for the pharmaceutical industry.

To stimulate the investment environment, the government has set up a consultation platform with the Belgian innovative industry association pharma.be and the Health Science and Technology Group (grouping four companies with a substantial presence on the Belgian market). The first meeting was held in December 2006. Within this framework, four working groups have been created to advise the government on the following issues:

- Promotion of co-operation between industry and universities.
- Specific fiscal measures to stimulate research and development initiatives.
- Possibilities to optimise early access to innovative medicines.
- Recommendations for development co-operation.
CONTRIBUTOR DETAILS

EVELINE VAN KEYMEULEN
Covington & Burling LLP
T +32 2 549 5233
F +32 2 502 1598
E evankeymeulen@cov.com
W www.cov.com

Qualified. Belgium, 2007; New York, 2010
Areas of practice. Life sciences regulatory and intellectual property law.
Recent transactions
- Advising pharmaceutical and medical device companies on borderline determinations at EU and member state level.
- Advising pharmaceutical and medical device companies on compliance with marketing and advertising laws and codes of practice.
- Advising a large coalition of biotechnology innovators concerning EU biosimilar legislation.
- Representing pharmaceutical companies in product liability litigation and criminal proceedings.
- Representing a collecting society in relation to cable retransmission and direct injection.

PETER BOGAERT
Covington & Burling LLP
T +32 2 549 5243
F +32 2 549 1043
E pbogaert@cov.com
W www.cov.com

Qualified. Belgium, 1982; England and Wales, 1984
Areas of practice. Life sciences regulatory and government affairs law.
Recent transactions
- Regulatory planning for a new advanced therapy medicine, including orphan designation and hospital practices.
- Litigation on supplementary protection certificates before the Court of Justice of the EU and at the national level.
- Legislative and regulatory aspects of the distribution systems for medicines within specific member states and the interconnection with parallel trade.
- Detailed input into the legislative process for the new Directive on Falsified Medicines.
Covington’s extensive transactional, regulatory, litigation, and intellectual property expertise meets the needs of life sciences companies around the world. Our industry-focused approach enables us to achieve cost-effective and enduring solutions. We work across legal disciplines and offer a deep understanding of the business challenges our clients confront to enable them to efficiently and effectively accomplish their immediate needs and to better achieve their strategic goals.