Belgium

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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.

The rules governing medicines are, generally, a close implementation of the relevant EC 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, in principle, limited to pharmacies.

The main legislative acts regulating medicinal products are the:

- Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use.

The Federal Agency for Medicines and Health Products (Federaal Agentschap voor geneesmiddelen en gezondheidsproducten - Agence fédérale des médicaments et des produits de santé) (FAGG) (see box, The regulatory authorities) is the regulatory authority in charge of these matters. The FAGG 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. Rules on reimbursement of medicines are becoming increasingly complex as new mechanisms and policies are implemented to safeguard the healthcare budget and promote use of cheaper medicines. The main legislation regarding reimbursement of medicines is the:

- Royal Decree of 21 December 2001 concerning the procedures, terms and conditions for contribution by mandatory insurance for healthcare and benefits towards the costs of pharmaceutical specialities.

The most important body for reimbursement of medicines is the Commission for Reimbursement of Medicines (Commissie Tegemoetkoming Geneesmiddelen - Commission de Remboursement des Médicaments) of the National Institute of Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering - Institut national d’assurance maladie-invalidité (RIZIV - 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). In 2006 and 2007, the budget for medicines was under control, and even in surplus in 2006.

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 such a 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. In principle, a price application is only possible when the product has marketing authorisation. However, the price application can also be submitted as soon as the Committee for Medicinal Products for Human Use (CHMP) issues a positive opinion, if both of the following apply:

- The medicine is designated as an orphan medicine or the company requests reimbursement status as a Class 1 product (see Question 4).
- The product is going through the centralised approval procedure under Regulation (EC) No. 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMEA Regulation).

In this case, 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 maximum profit margins for wholesalers and pharmacies.

Other medicinal products are governed by the:

- Ministerial Decree of 20 April 1993, which contains a general price control mechanism not limited to medicinal products.
- Ministerial Decree of 2 April 1996 regarding 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)?

Generally, the Minister of Social Affairs 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 (Article 35 bis, Law on the Mandatory Health Insurance of 14 July 1994) is the therapeutic value of the medicinal product, which is expressed in three classes (each class has a different reimbursement procedure):

- 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.

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

- The price and proposed reimbursement basis.
- The importance of the product in medical practice in relation to therapeutic and social needs.
- Budgetary implications for the health insurance system.
- The 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:

- 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 was introduced in Belgium. Physicians are still free to prescribe a specific branded medicine, but must meet certain targets of generic prescription to avoid penalties. In the case of a generic prescription, pharmacists must in principle dispense the cheapest product.
- 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 other things, the prices of medicinal products the active substance of which had been reimbursed for more than 12 years decreased by 14%, and the prices of medi-
cines reimbursed for more than 15 years decreased by an additional 2.3%. Additionally, the levels of patient contributions for Class 2 and 3 medicines 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 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

Companies or individuals wishing to manufacture medicinal products in Belgium must file a dossier with the FAGG. The requirement to hold a licence also applies where medicinal products are manufactured for export purposes only.

Conditions

Generally, the following information must be included in the application:

- A list of the products and preparations used in the manufacturing process.
- 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, to guarantee appropriate and continued supplies of medicinal products for the needs of patients in a particular geographical area. The correct interpretation of this supply obligation is currently unclear.

There are special rules for investigational medicinal products.

Restrictions on foreign applicants

There are no restrictions on foreign applicants.

Key stages and timing

A FAGG 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 the FAGG intends to reject the authorisation, the applicant will receive a draft of the decision within the 90-day deadline and can request that the dossier be 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, the FAGG 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 the FAGG’s website.

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?

Inspectors of the FAGG have broad powers to monitor compliance with the manufacturing authorisation and the rules on manufacturing medicines. For example, the inspectors can enter premises where medicines are being manufactured and/or interrogate all persons they think can provide useful information. Inspections are frequently performed. For example, in 2005 there were 198 inspections in the pharmaceutical industry, including inspections relating to importation, exportation and distribution.

If the licence holder breaches the applicable requirements, the FAGG can suspend or revoke the licence. First, 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 FAGG 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.
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There are also criminal sanctions or administrative measures 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 on Experiments with Humans regulates experiments on humans, including clinical trials with medicines, and implements 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 FAGG is in charge of clinical trials in Belgium.

**Authorisations**

In general, an experiment with humans can 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**

In principle, a person can only participate in an experiment if he has given free and informed written consent, after being informed of at least 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 on Experiments with 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 on Experiments with Humans does not apply to purely retrospective studies based on past data contained in the medical or patient dossiers, if those studies do not require the collection of new data from the human subjects (Law on Various Provisions regarding Healthcare 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 marketing authorisation from the Minister of Health or EC marketing authorisation under the centralised procedure (EMEA Regulation). Marketing authorisations obtained from the EMEA under this centralised system are valid in all EU member states.

**Conditions**

To obtain marketing authorisation, the applicant must file an application with the FAGG, including, among other things:

- 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 marketing authorisation can be made available to specific patients under "compassionate use" and "medical need" programmes (EMEA Regulation, Law of 1 May 2006 modifying the Medicines Law and Royal Decree of 14 December 2006 regarding Medicines for Human Use and Veterinary Use).

**Key stages and timing**

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

The completed application is filed with the FAGG 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 FAGG’s website.

**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 that case, the applicant is not required to provide results of pre-clinical tests and clinical trials.
- The generic product can, however, only be marketed after a period of ten years from the grant of marketing authorisation for the reference product. An extra year of market protection is obtained in the 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 on 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 product (normally 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 and the new test data.
- Pharmacological, toxicological and clinical data can be based on scientific literature (bibliographic application) where all the following apply in relation to the active substance of the medicinal product:
  - it has been used for at least ten years in medical practice;
  - it has a recognised efficacy;
  - it has an acceptable level of safety.
- The holder of a marketing authorisation can permit third parties to refer to the dossier of its product (informed consent).
- Where a biological medicinal product is similar to a reference medicinal product, but does not meet all conditions necessary to be considered a generic (which is usually the case, in particular because of differences related to raw materials or in manufacturing processes), the results of appropriate tests must be provided covering safety and/or efficacy, according to relevant criteria in Annex I to the Code for Human Medicines Directive and related guidelines.

The concept of “global marketing authorisation” has been included in the Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use. Under this concept, approvals of new strengths, pharmaceutical forms, routes of administration and presentation (as well as other variations or extensions) must be considered as belonging to the same global marketing authorisation for the purposes of the abridged application rules.
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 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 the following and forward them to the other member states:

- A draft assessment report.
- A draft summary of product characteristics.
- A draft of the labelling.
- A draft package leaflet.

If the medicinal product has already received 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 approve the following, the points of disagreement are forwarded to the co-ordination group for discussion:

- The assessment report.
- The summary of product characteristics.
- The labelling and package leaflet.

In the case of an unresolved disagreement, the matter is referred to the 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?

Inspectors of the FAGG 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 the case of a breach, the Minister can suspend or revoke the marketing authorisation. In addition, the inspectors can, among other things, 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 (Parallel Import Royal Decree) provides for notification of parallel distribution of centrally approved medicines and for a simplified authorisation procedure for parallel imports of nationally approved products.

In general, a parallel import authorisation is granted if all of the following apply (Parallel Import Royal Decree):

- 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; and
  - 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 Parallel Import Royal Decree was amended to safeguard the intellectual property rights of the reference product against imports from (most of) the new eastern European 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 who 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 (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, an authorisation in the form of a “visa” must be obtained for every scientific conference with at least one overnight stay. The obligation to obtain a visa came into force on 31 December 2006. From 1 January 2007, the management of the visa obligation was retrospectively assigned to the private institution Mdeon (www.mdeon.be) (Royal Decree of 25 February 2007 on the Recognition of Institutions Described in Article 10(3) of the Medicines Law), Mdeon’s management responsibility was extended for a year by the Royal Decree of 11 March 2008 and for a further year by the Royal Decree of 30 March 2009. 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 will be amended to allow mail order of the counter (OTC) medicines, taking into account the ECJ decision in Deutscher Apothekerverband eV v 0800 DocMorris NV and Jacques Waterval (case C-322/01), 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, in any event, prohibited.

On 26 September 2008, the Council of Ministers approved the Royal Decree setting the conditions for mail ordering of OTC medicines. It will allow mail order by pharmacies of OTC medicines registered in Belgium and sets out minimum information that must appear on websites where OTC medicines are sold.

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?

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 governed by the Royal Decree of 11 January 1993, modified by the Royal Decree of 26 April 2007, which imposes more restrictive conditions, such as that samples can only be provided if at least one package is already marketed. The FAGG is also in charge of medicine advertising. 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.
- Reimbursed medicines.
- Medicines indicated for treatment of specific diseases listed by royal decree.
- Medicines containing narcotic substances.

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 “not satisfied, money back” schemes cannot be used. Some means of communication, such as through
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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 Medicines Law and the Royal Decree of 14 December 2006 on Medicines for Human Use and Veterinary Use. The FAGG 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).

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.

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?

In general, medicines can 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.
- The result of an inventive step.
- Capable of industrial application.

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 it is up to the courts (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?

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 must be made to the Service for Industrial Property (SIP) (a division of the Federal Public Service Economy, SMEs, Self Employed and Energy) (Federale Overheidsdienst Economie, KMO, Middenstand en Energie; Dienst voor de Intellectuele Eigendom - Service public fédéral Economie, PME, Classes moyennes et Energie; Office de la Propriété intellectuelle).

Fee

These are set out at www.mineco.be/ministry/organization/mission_nl.asp?dep=60 (SIP website).
Process and timing

SIP reviews the application regarding content and form. For 20-year patents, a novelty search is required, which is performed by the European Patent Office. After receipt of results of the novelty search, the conclusions, description and drawings can be amended, provided they remain within the scope of the original application. The applicant can also ask for a “written opinion” of the EPO, that is, non-binding advice regarding the patentability of the invention. At the earliest, 18 months after the application is filed, the patent is officially granted by Ministerial Decree and published in the Register of Patents. At this stage, the file becomes public. Although the patent is protected from the filing date, the patent owner cannot enforce its rights until publication, subject to a right to reasonable compensation in certain circumstances.

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

Protection lasts for 20 years from the filing of the application, provided the necessary fees are paid. Under EC law, it is possible to obtain a supplementary protection certificate to extend the national patent protection period by up to five years, under certain conditions. Under Regulation (EC) No. 1901/2006 on medicinal products for paediatric use (Paediatric Medicines Use Regulation), a six-month extension of this supplementary protection certificate is available under certain conditions.

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?

In general, the holder of a valid patent can 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, or 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 is also of particular importance (implemented in Article 6 bis, Medicines Law).

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 through any of the following:
- A Benelux registration.
- An EC 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). 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 www.boip.int (BOIP website).

Process and timing
A written application must be submitted to one of the national trade mark offices or to 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, 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?

In general, a Benelux trade mark can 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.

In general, Benelux trade marks can 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 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.
THE REGULATORY AUTHORITIES

Federal Agency for Medicines and Health Products (Fédéral Agentschap voor geneesmiddelen en gezondheidsproducten - Agence fédérale des médicaments et des produits de santé) (FAGG)

T +32 2 524 80 00
F +32 2 524 80 01
E info.dgg@fagg.afmps.be
W www.fagg.be

Main areas of responsibility. The FAGG’s responsibility is to safeguard, from development until use, the quality, safety and efficacy of medicines for human and veterinary use, medical devices, magistral preparations, official preparations, and basic substances used for preparing and producing medicines. The FAGG must also ensure the quality, safety and efficacy of all operations with blood, tissue and cells from their removal until their use. The Mixed Commission (Gemengde Commissie - Commission Mixte) established by the Royal Decree of 28 October 2008, advises the FAGG on the classification of products in the “grey zone” between medicines, foods, cosmetics, biocides and other products.

The Law on Various Provisions regarding Healthcare of 19 December 2008 introduced the possibility for the FAGG to request the assistance of non-profit third party associations in the performance of its duties. The FAGG would cover the costs of this assistance by granting subsidies to the legal entities concerned.

Information on the FAGG’s areas of responsibility, applicable legislation and procedural aspects are detailed on its new website (www.fagg.be).

Commission for Reimbursement of Medicines (Commissie Tegemoetkoming Geneesmiddelen - Commission de Remboursement des Médicaments)

T +32 2 739 71 11
F +32 2 739 72 91
W www.inami.fgov.be

Main areas of responsibility. The Commission is part of the National Institute of Health and Disability Insurance (Rijksinstituut voor ziekte- en invaliditeitsverzekering - Institut national d’assurance maladie-invalidité (RIZIV - INAMI)). Its function is, among other things, to issue opinions on the reimbursement of medicines.

Federal Public Service Economy, SMEs, Self-Employed and Energy; Directorate General Regulation and Organisation of Markets; Section Prices

T +32 2 277 72 95
F +32 2 277 52 78
E price@economie.fgov.be
W www.mineco.fgov.be

Main areas of responsibility. This organisation deals with the approval of prices and price increases for medicinal products.

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

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 in practice often combined with professional liability claims against the treating physician.

30. 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 normally 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.

31. 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.

32. 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.

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

Class actions are not available.

REFORM

34. 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.

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