The Life Sciences Law Review

Third Edition

Editor
Richard Kingham

Law Business Research

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For further information please email
Nick.Barette@lbresearch.com

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EDITOR'S PREFACE

The third edition of *The Life Sciences Law Review* extends coverage to a total of 36 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. As before, the chapters are arranged to describe requirements throughout the life cycle of a regulated product – from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2015

Chapter 4

BELGIUM

Peter Bogaert and Sarah Forest[1]

I INTRODUCTION

Since Belgium is an EU Member State and has implemented the EU medicines and medical devices regimes, this chapter will not repeat the substantive content of the EU chapter. This chapter will focus on unique features of the Belgian regime and should be read in conjunction with the EU section.

Medicines for human use are regulated primarily by the Medicines Act of 25 March 1964 (the Medicines Act) and the Royal Decree on Medicines for Human and Veterinary Use of 14 December 2006, as amended (the 2006 Decree), but several other legislative documents regulate more specific aspects, such as advertising or clinical trials.[2] Together, these rules implement EU Directive 2001/83/EC[3] and most other EU medicines laws into Belgian law. They also supplement the EU Regulations, such as Regulation (EC) 726/2004 on the centralised procedure and Regulation (EC) 141/2000 on orphan medicinal products.

1 Peter Bogaert is a partner and Sarah Forest is an associate at Covington & Burling LLP.

2 Royal Decree of 7 April 1995 on the Information and Advertising regarding Medicinal Products for Human Use, as amended; Law concerning Experiments on Human Beings of 7 May 2004, as amended.

3 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended.

Medical devices are regulated by three Royal Decrees[4] that implement the three EU Medical Devices Directives[5] into Belgian law.

The Federal Agency for Medicines and Health Products (FAMHP), a public institution under the control of the Minister of Social Affairs and Public Health, is the Belgian national competent and control authority for the regulation of medicinal products and medical devices. The Agency has just under 400 staff members and supervises the quality, safety and efficacy of medicines for human or animal use and also has responsibilities for medical devices and blood, tissues and cells. It is also responsible for the EU procedures under the decentralised procedure, the mutual recognition procedure and referrals, and for participation in the centralised procedure.

II THE REGULATORY REGIME

i Classification

The FAMHP plays an important role with regard to borderline decisions. It provides advice on product classification and assesses the correct regulatory classification of products when taking regulatory decisions, such as the granting or refusal of a marketing authorisation. In addition, the FAMHP operates a 'mixed commission' responsible for borderline reviews.[6] The commission consists of representatives of the federal public service in charge of public health, the federal public service for economic affairs, the Belgian food agency and the FAMHP itself. The commission reviews specific borderline aspects and provides an opinion to the Minister of Public Health, who takes a formal decision.

In addition, the FAMHP has issued a list of claims that are not considered medicinal, which helps in making borderline determinations based on the presentation of products. The claims are mainly relevant for determining the borderline between medicines and foods, and between medicines and cosmetics. Examples of non-medicinal products are those used to provide a soothing effect on the airways, in the event of a sore throat, to ensure regular bowel movements, to prevent caries, in the event of hair loss, or for red and sensitive skin. Some of these claims are, however, subject to EU approval under the Nutrition and Health Claims Regulation for Foods.[7] The mixed commission also issued guidance on the borderline between biocidal products, cosmetics and medicines, on the classification of products containing Bach flowers and an indicative list of claims that are considered as not describing curative or preventive properties.

4 Royal Decree of 18 March 1999 on Medical Devices; Royal Decree of 15 July 1997 on Active Implantable Medical Devices; Royal Decree of 14 November 2001 on Medical Devices for In Vitro Diagnostics; each as amended.

5 The Active Implantable Medical Devices Directive 90/385/EEC, the Medical Devices Directive 93/42/EEC, and the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

6 Royal Decree of 28 October 2008 Laying Down the Composition and Operation of the Joint Commission and Implementing Article 1, Paragraph 2 of the Medicines Act.

7 Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended.

Borderline determinations can also be made by the courts. This typically happens in criminal courts if the public prosecutor brings a criminal action for unlawful marketing of a product because, for instance, it is positioned as a cosmetic but in reality is an (unapproved) medicine; and by commercial courts in unfair trade practices litigation where, for instance, a competitor seeks an injunction against the marketing of a product as a food while, in reality, it is an (unapproved) medicine. Older case law is summarised in a ministerial circular of 1987.[8]

ii Non-clinical studies

The Act on the Protection of Animal Welfare of 14 August 1986, as amended,[9] implements Directive 2010/63/EU[10] into Belgian law from early 2013. The Act, combined with an implementing Royal Decree,[11] permits research involving animals only in premises licensed by the Federal Public Service of Health, by appropriately qualified staff and in accordance with procedures designed to minimise animal pain and suffering. The facilities must also have an ethics committee and there is a federal ethics committee that can provide recommendations to the Federal Public Service.

The Royal Decree on Good Laboratory Practices of 6 March 2002[12] lays down the main GLP requirements. It applies to non-clinical testing of ingredients used in medicines, cosmetics, pesticides, veterinary medicines, food and feed additives and industrial chemicals. The decree requires that all animal studies be conducted in accordance with sound standards of GLP. These standards reflect the Organisation for Economic Co-operation and Development requirements.

iii Clinical trials

The Act on Experiments on Humans of 2004[13] has a broad scope of application. It covers clinical trials with medicines and any other experiment that aims at 'the development of the knowledge that is proper to the exercise of health-care professions' such as physicians,

8 Ministerial Circular of 28 July 1987 on Article 1 of the Medicines Act.

9 The Law on the Protection and Welfare of Animals of 14 August 1986, as amended by, *inter alia*, the Act of 27 December 2012 on Various Provisions concerning Animal Welfare, CITES, Animal Health and Consumer Health Protection and the Act of 7 February 2014 on Various Provisions concerning Animal Welfare, CITES and Animal Health.

10 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

11 Royal Decree of 29 May 2013 on the Protection of Animals used for Experiments.

12 Royal Decree of 6 March 2002 laying down the Principles of Good Laboratory Practice (GLP) and the Verification of their Application for Trials on Chemical Substances, as amended. There is so far no formal transposition of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

13 The Law concerning Experiments on Human Beings of 7 May 2004, as amended. The act is implemented in a Royal Decree determining the Measures of Implementation of the

dentists, pharmacists, physiotherapists and nurses. It does not apply, however, to purely retrospective observational studies based on existing data. All experiments require scientific justification, a properly substantiated purpose, an acceptable level of risk and detriment for the subjects, an expected benefit that outweighs the possible risks, ethics committee approval and informed consent. Specific rules apply to clinical trials with medicines and, under the medical devices rules, to clinical trials with medical devices.

Sponsors of experiments are liable for damage suffered by subjects as a direct or indirect consequence of the experiment. The liability is not dependent on any fault or negligence and must be covered by an insurance policy. Subjects have a direct action against the insurance company.

A specific act regulates experiments on *in vitro* embryos.[14]

Medicines

The Act on Experiments on Humans of 2004 and the implementing Royal Decree contain specific provisions on clinical trials with medicines, which implement the EU Clinical Trials Directives 2001/20/EC[15] and 2005/28/EC.[16] Clinical trials of medicinal products in humans are generally only permitted if the FAMHP has granted a clinical trial authorisation and an ethics committee has issued a favourable opinion. Non-interventional trials, where the medicinal product is used within the scope of the marketing authorisation, in line with current medical practice and without additional diagnostic measures or controls, are subject to the general rules on experiments.

The Belgian legislation on experiments will have to be amended in light of the new EU Regulation on clinical trials,[17] which will repeal the current Directive 2001/20/EC once it becomes applicable, in 2016 at the earliest (see the EU chapter).

Approval process

Applicants for an approval must first have obtained an EudraCT number and must then submit the relevant application form and investigational medicinal product dossier (IMPD) to the FAMHP. The agency must react within 15 days for single-centre

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Law of 7 May 2004 on the Experiments on Human Beings in Relation to Clinical Trials of Medicines for Human Use of 30 June 2004, as amended.

14 The Law on Research on Embryos In Vitro of 11 May 2003, as amended.

15 Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, as amended.

16 Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products.

17 Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

Phase I trials and within 28 days for other trials. In the absence of objections, the trial is deemed approved. For trials with gene or cell therapy medicines and with medicines that contain genetically modified organisms, longer periods apply and an express approval is required.

All investigational medicinal products must have been manufactured or imported by the holder of a manufacturer's authorisation in the European Economic Area (EEA). The manufacturer or importer must ensure that a qualified person has performed batch release of the products for clinical trial use, which is only possible if the product is in accordance with an appropriate standard of good manufacturing practice (GMP) and if the product conforms with the specifications in the IMPD.

Sponsors have reporting obligations for suspected unexpected serious adverse reactions.

Medical devices

Clinical investigations of medical devices are subject to the general rules on experiments and to specific provisions in the medical devices decrees. In addition to obtaining research ethics committee approval, the manufacturer must notify the FAMHP prior to the conduct of a clinical investigation involving a non-CE marked medical device. For Class III devices and implantable or long-term invasive devices of Class IIa and IIb, the notification must be made 60 days before commencement of the trial, and the FAMHP can raise objections during that period. There are also obligations to report adverse events.

There is a different process for performance evaluation of a non-CE marked *in vitro* diagnostic medical device (IVD). Manufacturers must draw up a declaration and follow the procedure set out in Annex VIII of the IVD Directive and must keep the documents available for inspection.

iv Named-patient and compassionate use procedures for medicines

The Medicines Act and the 2006 Decree allow for different ways to make a medicine available outside the marketing authorisation system.

Pharmacists can prepare medicines for an individual patient or a group of patients on the basis of a medical prescription. For certain types of products and under specific conditions, the preparation can be subcontracted to a licensed manufacturer. This allows a higher level of quality and GMP compliance.

A non-approved medicine can be used under the compassionate use provisions laid down in Article 83 of Regulation (EC) 726/2004. Compassionate use programmes are defined in the Regulation as:

> *making a medicinal product belonging to the categories referred to in Article 3(1) and (2) [i.e., products covered by the centralised EU procedure] available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product.*

The product concerned must either be the subject of an application for a centralised marketing authorisation or must be undergoing clinical trials.

The specific procedure to be followed in Belgium is set out in Article 106 of the 2006 Decree and was amended in 2014. The applicant must submit an application for a compassionate use programme to the FAMHP, which includes a review by an ethics committee. The decree sets out what information is required in the application, including a standardised informed-consent form for the patient. The applicant must specify whether it requests the intervention of the compulsory health insurance for reimbursement purposes. The FAMHP forwards the application to the European Medicines Agency (EMA) and may request, in consultation with the EMA and the applicant, an opinion from the Committee for Medicinal Products for Human Use. The Minister of Health must adopt a decision on the compassionate use programme within 55 business days from the decision on the admissibility of the request, failing which the decision is deemed positive. Decisions are published on the website of the FAMHP and are regularly reassessed.

In emergency situations, an unauthorised medicinal product can be used without requesting a compassionate use programme if a number of conditions are met, in particular: the urgency is motivated by the fact that a patient is in immediate risk of dying or that the risk from non-treatment is higher than the inherent risks of the treatment; informed consent was obtained from the patient; the medicinal product is not being used in clinical trials; it does not concern a medicinal product that does not need a registration or marketing authorisation; there is no other available treatment on the market, under hospital exemption or as a magistral preparation; there are no authorised products in other countries worldwide; and it is impossible to submit a request for a compassionate use programme. While it is recommended to notify the FAMHP and the ethics committee of the site concerned, this is not a legal requirement to start the treatment. Treatment is provided under the responsibility of the health-care professional and the entity arranging the supply.

A medical need programme can be put in place by the marketing authorisation holder for an approved medicine but in an indication that is still under clinical development or regulatory review, or that is approved but for which the product is not yet marketed. The specific procedure is set out in Article 108 of the 2006 Decree and was amended in 2014. The procedure is somewhat similar to this for compassionate use programmes. The applicant must submit a request to the FAMHP, including the specified information. An opinion from an ethics committee is also required. The decision on the medical need programme is published on the FAMHP website.

Named-patient imports of medicines that have a marketing authorisation in the country of origin are allowed for patients who cannot be adequately treated with authorised and available medicines. This option is available for specific patients and for groups of patients, and the imports are made by a pharmacist.

v Pre-market clearance

The Belgian rules on marketing authorisations for medicinal products and on CE marking for medical devices closely follow the EU rules. The procedures are administered by the FAMHP.

vi Regulatory incentives

Medicines

The Medicine Act and 2006 Decree implement the EU periods of eight years of regulatory data exclusivity (during which generic and biosimilar applicants cannot file) followed by two years of market protection (during which regulators may review generic or biosimilar applications, but generic or biosimilar manufacturers cannot launch) under Directive 2001/83/EC for products for which qualifying national applications were submitted after 30 October 2005. For complete free-standing applications submitted on or before that date, holders of Belgian marketing authorisations would benefit from 10 years of data exclusivity protection, during which generic applicants cannot file. These regulatory exclusivity periods begin when the product is first approved anywhere in the EEA, not necessarily in Belgium.

The additional data exclusivity provisions for 'orphan medicinal products' and for products with paediatric indications developed in accordance with an approved paediatric investigation plan under Regulation (EC) No. 141/2000[18] and Regulation (EC) No. 1901/2006[19] apply directly.

The Belgian Office for Intellectual Property is responsible for granting supplementary patent certificates for medicinal products that meet the criteria under Regulation (EC) No. 469/2009[20] and for the paediatric extensions. There is no patent linkage under Belgian law (i.e., no linkage between the regulatory approval process and patent expiry). The Medicines Act contains a *Bolar* provision, making it possible to perform any necessary trials for approval during the patent protection period.

Medical devices

Belgian legislation does not provide specific regulatory exclusivity periods for medical devices. A device may be protected by a patent if it satisfies the requirements for patentability under the relevant rules.

vii Post-approval controls

Post-approval controls over marketing authorisation holders for medicines and manufacturers of medical devices in Belgium closely mirror the EU requirements subject to the following of local requirements and procedures.

18 Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, as amended.

19 Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, as amended.

20 Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, as amended.

viii Manufacturing controls

The substantive requirements governing the manufacture of medicinal products, including the need for a manufacturing or import authorisation, a qualified person and compliance with GMP, are discussed in the EU chapter.

The FAMHP regulates pharmaceutical manufacturing operations within Belgium and conducts inspections of manufacturing facilities pre-authorisation and periodically thereafter.

Changes to the manufacturing authorisation require variations to be submitted to the FAMHP.

ix Advertising and promotion

Medicines

Key principles on advertising are set out in the Medicines Act. They are supplemented by the 1995 Royal Decree on Information and Advertising for Medicines for Human Use and a 1993 Royal Decree on samples,[21] which implement the EU advertising rules into Belgian law. These include the general requirements that advertisements should not be misleading, that they should be substantiated and that they should be accompanied by appropriate prescribing information. There is also a prohibition on pre-approval or off-label promotion of medicines, advertisements of prescription-only medicines to the general public, and illegal inducements to prescribe.

Some provisions go beyond what is required under EU law. Some forms of advertising media are prohibited (such as billboards or via telephone or SMS). Advertising to the public must be notified in advance to the FAMHP and, for radio and television advertising, prior approval must be obtained. This takes the form of a visa, granted by the Minister of Health, upon advice of the Control Commission of Medical Advertising.

The statutory scheme is supported by a self-regulatory system based on the Pharma.be practice code. The code is enforced through an ethics commission within Pharma.be. For non-interventional studies, the code also requires prior approval from the Visas Bureau of Pharma.be. The visa procedure is intended to check compliance of the study with the legal and ethical requirements.

The rules restricting benefits to health-care professionals, including a review of scientific meetings and hospitality, are discussed in Section V, *infra*.

Medical devices

The rules on advertising for medical devices are much less elaborate. The key provision is that non-CE marked medical devices cannot be promoted (subject to an exception for showing the devices at fairs with an indication that they are not yet in compliance with the rules). Advertising of implantable medical devices to the public is prohibited. Advertising of medical devices is also subject to general advertising rules, requiring that advertisements be substantiated, factual, balanced and not misleading.

21 Royal Decree of 11 January 1993 establishing the Conditions under which the Supply of Medicinal Products for Human Use in the Form of Samples can be Performed, as amended.

The Belgian medical devices industry association UNAMEC operates a code of practice, which is enforced through an ethics commission.

x Distributors and wholesalers

Medicines

As under EU law, Article 12-ter of the Medicines Act provides that distributors of medicinal products must hold a wholesale distributor's authorisation and specific obligations are laid down in the 2006 Decree. In particular, wholesale distributors must operate appropriate facilities and staff under the supervision of an appropriately qualified responsible person. They must comply with good distribution practices and maintain appropriate batch records.

Wholesale distributors are also subject to supply obligations that are aimed at ensuring adequate availability of medicines throughout Belgium. These obligations have also been invoked by parallel exporters.

The FAMHP is responsible for issuing, suspending and revoking wholesale distributors' licences in Belgium. It conducts inspections prior to the grant of such a licence and then periodically thereafter.

Medical devices

Distributors of certain medical devices, such as sterile products that come into contact with patients, implants and dental equipment, need to notify their activities to the Federal Public Service for Health and are subject to control by the FAMHP. The FAMHP and UNAMEC also issued a guideline on good distribution practices.[22]

xi Classification of products

Medicines

The Belgian rules on prescription status for medicines are based on the EU provisions.

Medical devices

Some medical devices are subject to restrictions in the distribution chain (for instance, via pharmacists or dentists).

xii Imports and exports

The Belgian regulations governing the import and export of medicinal products reflect those at the EU level.

22 Proposal for guidelines on the best practice for the distribution of CE-marked medical devices.

xiii Controlled substances

Belgium implemented the UN Single Convention on Narcotic Drugs 1961 and the UN Convention on Psychotropic Substances 1971.[23] The licences for manufacturing, distributing, importing or exporting such substances are issued on a national basis by the FAMPH and must be renewed annually. As a rule, specific authorisations must be obtained for the import or export of narcotic or psychotropic substances. Close collaboration also exists with Luxembourg.

xiv Enforcement

Medicines

Breaches of the medicines rules are often investigated by inspectors of the FAMHP. They can result in administrative fines or a referral to the Public Prosecutor. The latter can propose a settlement or bring the case before the criminal courts. There are not many criminal court cases for infringement of the medicines rules.

Competitors or non-profit organisations can also bring cases before the commercial courts, typically with a request for an injunction.

Finally, enforcement through the self-regulatory system operated by Pharma.be is possible.

Medical devices

The enforcement mechanisms for medical devices are very similar to those for medicines.

III PRICING AND REIMBURSEMENT

Belgium operates strict controls on the prices of certain classes of medicines and medical devices and on their reimbursement status. The controls have a cumulative effect as, for many products, marketing is only viable when they are at least partially reimbursed.

23 See, in particular, Royal Decree of 31 December 1930 Regulating Soporific and Narcotic Substances, and on Risk Reduction and Therapeutic Advice, as amended; Royal Decree of 22 January 1998 Regulating certain Psychotropic Substances, and on Risk Reduction and Therapeutic Advice, as amended.

i Medicines

Pricing[24] and reimbursement[25] rules are very complex in Belgium. The competent authorities for price determination are the Federal Public Service for Economic Affairs, encompassing two specialised commissions: the Commission for Price Regulation and the Commission for Pricing of Medicinal Products.

The applicable procedure for price determination depends on the type of medicine[26] and whether it is considered new. Price determination will either require notification to Federal Public Service for Economic Affairs or prior approval from the Minister for Economic Affairs. Price increases are also subject to either authorisation or notification requirements, and price decreases must be notified. Decisions by the Minister for Economic Affairs can be challenged before the Council of State (see Section IV, *infra*). The price-approval process is based on an application dossier that comprises a justification for the requested price (including production cost, a copy of the company's annual accounts for the past three years and a description of the market). A simplified pricing procedure applies for medicines approved on the basis of an abridged, bibliographical or hybrid application. In addition, margins applied throughout the distribution chain are subject to control and limitations.

Reimbursement is decided upon by the Minister of Social Affairs, following a recommendation by the Medicines Reimbursement Committee, which forms part of the Federal Health Insurance Service. The decision process and the dossier to be submitted depend on the category of medicine. There are three main categories, depending on whether the medicine represents added therapeutic value over existing products and whether it is innovative or generic. As a rule, the Medicines Reimbursement Committee adopts a proposal based on the elements submitted by the company and the medical and therapeutic value of the product. The proposal is then presented to the Minister of Social

24 Pricing rules are set in a number of instruments, including the Code of Economic Law of 28 February 2013; Royal Decree establishing the Conditions, Time Frames and Practical Modalities regarding Pricing and Price Increases Requests, Pricing Notifications and Communications of the Price of Medicinal Products, Objects, Appliances, Substances assimilated to Medicinal Products and Raw Materials, as referred to under Title V of the Code of Economic Law of 10 April 2014; Ministerial Decree determining the Objects, Appliances, Substances assimilated to Medicinal Products referred to under Title V of the Code of Economic Law, and determining the Maximum Prices and Maximum Margins for Medicines, Objects, Appliances and Substances assimilated to Medicinal Products of 17 June 2014; Ministerial Decree of 20 April 1993 laying down Specific Provisions on Pricing; the Law on Economic Regulation and Pricing of 22 January 1945, each as amended.

25 Reimbursement rules are primarily set out in the Law on the Compulsory Health Insurance of 14 July 1994, as amended; and Royal Decree establishing the Procedures, Time Frames and Conditions for the Intervention of Mandatory Health Insurance in the Cost of Pharmaceutical Specialties of 21 December 2001, as amended.

26 Namely, whether the product is an innovative medicine (and, within this category, whether the medicine is reimbursable or not) or whether the product is approved on the basis of an abridged, bibliographical or hybrid application.

Affairs, who takes the final decision. The reimbursement decision fixes the reimbursement price (which may be lower than the price initially approved by the Federal Public Service for Economic Affairs) and the category of reimbursement (which determines the level of co-payment required from the patient). Decisions by the Minister of Health can be challenged before the Council of State (see Section IV, *infra*). In addition, specific procedures apply for amending the reimbursement modalities of a medicine (or group of medicines), which can be initiated by the marketing authorisation holder, the Medicines Reimbursement Committee or the Minister of Social Affairs.

Since 2010, the rules also allow for managed entry agreements to be entered into between the company and the Federal Health Insurance Service. The agreements regulate the reimbursement of the medicine in question and must contain a number of elements, including details on the price and reimbursement basis of the product, tools to control the budgetary risks (for instance, by controlling the volume of products prescribed), follow-up measures and details for compensation if the budget is exceeded (e.g., in the form of rebates).

ii Medical devices

Certain implantable devices and hearing instruments require price approval by the Minister for Economic Affairs, on the basis of an opinion from the Commission for Pricing of Medicinal Products. Maximum margins may also apply. Some devices can be reimbursed as such (such as implants) while others may be covered by the general expenses of the hospitals where they are used. There are also detailed rules on the levels of payment or co-payment by patients.[27]

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

In Belgium, the decisions of authorities, including the FAMHP, the Minister of Health and the Minister of Social Affairs, can be challenged before the highest administrative court, the Council of State. The procedure allows for interim relief but the standards are very high.

27 See in particular the Code of Economic Law of 28 February 2013; Royal Decree establishing the Conditions, Time Frames and Practical Modalities regarding Pricing and Price Increases Requests, Pricing Notifications and Communications of the Price of Medicinal Products, Objects, Appliances, Substances assimilated to Medicinal Products and Raw Materials, as referred to under Title V of the Code of Economic Law of 10 April 2014; Ministerial Decree determining the Objects, Appliances, Substances assimilated to Medicinal Products referred to under Title V of the Code of Economic Law, and determining the Maximum Prices and Maximum Margins for Medicines, Objects, Appliances and Substances assimilated to Medicinal Products of 17 June 2014; Law on the Compulsory Health Insurance of 14 July 1994; and the Royal Decree establishing the Procedures, Time Frames and Conditions regarding the Intervention of the Compulsory Health Insurance in the Costs of Implants and Invasive Medical Devices of 25 June 2014, each as amended.

When the administrative decision also infringes civil rights, an action before the civil courts may be possible.

Each court may refer a question under EU pharmaceutical or medical devices law to the Court of Justice for a preliminary ruling. Such referrals are not infrequent.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Article 10 of the Medicines Act contains a broad prohibition on benefits to wholesalers, to health-care professionals who can prescribe, dispense or administer medicines, and to institutions (such as hospitals) where medicines are prescribed, dispensed or administered. Article 10 contains specific exceptions, including:

a benefits of negligible value and that are relevant for the exercise of a health professional;

b invitation to and hospitality at meetings, provided the meeting is purely scientific in nature, hospitality is limited, the timing and location does not trigger doubts as to the scientific nature, and the support is limited to attending health-care professionals and to the duration of the meeting. If the event takes place on several consecutive calendar days, the programme must be approved by the Minister of Health or an officially recognised body. The non-profit association Mdeon is recognised and operates the review procedure; and

c reasonable compensation for scientific services, in particular for clinical trials.

The same rules, including the Mdeon review, apply to medical devices.

These rules have been further implemented by the Belgian pharmaceutical industry association, Pharma.be, in its code of conduct. Restrictions on benefits have recently been strengthened, through the inclusion of maximum expenditure limits for meals and drinks offered to health-care professionals during scientific events, and by prohibiting gifts (even of negligible value) to health-care professionals in relation to prescription-only medicines, subject to limited exceptions.

In accordance with the EFPIA Code on disclosure of transfers of value from pharmaceutical companies to health-care professionals and health-care organisations, Pharma.be has also implemented 'sunshine' rules, which require the annual disclosure of a number of transfers of value to health-care professionals or organisations. The first reporting is required in 2016, for transfers of value during 2015.

The Royal Decree of 10 November 1967 also contains a general prohibition on agreements between health-care professionals and pharmaceutical or certain medical devices companies when the agreements provide benefits to the health-care professionals.[28] The scope of the prohibition is unclear and, in many instances, is superseded by Article 10 of the Medicines Act.

28 Article 18 of Royal Decree No. 78 of 10 November 1967 on the Practice of the Health-Care Professions, as amended.

Health-care professionals, hospital staff and payor representatives can be officials, in which case the official bribery rules may apply. In the private sector, more limited private bribery rules can also be relevant.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

In addition to the general product liability principles, based on liability for defective products, Belgium has a special regime for compensation for medical damage.[29] The regime is based on automatic compensation for damage caused as a result of health-care treatment (other than non-reimbursable aesthetic treatment and experiments) where there is no liability of the health-care provider and the damage is not the result of the condition of the patient. The compensation covers damage that is 'abnormal' (i.e., goes above what could be expected based on scientific knowledge, the status of the patient and the normal evolution) and that is sufficiently serious (at least 25 per cent permanent incapacity, at least six months' temporary incapacity, particularly heavy impact on living conditions, including economic conditions, or death). Compensation is paid by a special fund. The fund can also cover certain cases where the health-care provider may be liable (in the event civil liability is not (sufficiently) covered by the insurance or liability is challenged). In those cases, the fund is subrogated in the rights against the provider.

The terms of the Act do not exclude cases where the damage is caused by a defective product, such as a medicine or medical device, but it does not seem to be the legislator's intention to include these cases within the regime.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Belgian competition law is heavily based on EU competition law and in particular the principles laid down in Articles 101 (anti-competitive agreements) and 102 (abuse of dominant market position) of the Treaty on the Functioning of the European Union. It is enforced through the Competition Council on the basis of reasoned reports presented by the College of Competition Prosecutors. There are complaints from time to time concerning practices in the pharmaceutical sector and much more rarely in the medical devices sector. The complaints cover similar types of problems that are reviewed at EU level, such as restrictions on supplies to competitors, restrictions of supplies to wholesalers who wish to engage in parallel export activities, and alleged abuse of patent or other exclusivity rights.

ii Transactional issues

The considerations and issues outlined in the EU chapter apply equally in Belgium.

29 Under the Act on Compensation for Damage caused by Health Care of 31 March 2010, as amended.

VIII CURRENT DEVELOPMENTS

As an EU Member State, developments in the Belgian regimes governing medicines and medical devices will be driven largely by developments at the EU level; these are discussed in the EU chapter. In particular, Belgium will need to adapt its clinical trials legislation to the new Regulation (EU) No. 536/2014 on clinical trials adopted at the EU level. The Belgian pharmaceutical industry association, Pharma.be, has also implemented sunshine rules in its code of conduct in accordance with the EFPIA Code on disclosure of transfers of value from pharmaceutical companies to health-care professionals and health-care organisations. The first reporting is required in 2016, for transfers of value during 2015. The code of conduct has also been recently strengthened with respect to benefits provided to health-care professionals.

At the purely national level, there is a strong emphasis on limiting the expenditure for health-care coverage. As part of this effort, new rules on public procurement require more hospital purchases to be organised by way of tender. The rules and procedures for pricing of medicinal products and medical devices, and for early access schemes for medicines (in particular compassionate use and medical need programmes) have been recently amended.

Appendix 1

ABOUT THE AUTHORS

PETER BOGAERT

Covington & Burling LLP

Peter Bogaert is a managing partner of the Brussels office, and has a broad European life sciences practice. He has detailed regulatory expertise under EU and national laws, handles legislative and other policy assignments and provides strategic advice. He also represents life sciences companies before the European courts in Luxembourg and in local litigation in Belgium. Mr Bogaert's practice covers pharmaceuticals, biotechnology, medical devices, special foods and feed, cosmetics and other consumer products and he represents numerous innovative life sciences companies, including start-ups, as well as several industry associations. He is consistently ranked by PLC as one of the leading life sciences lawyers globally, and *The Legal 500 EMEA* and *Chambers Europe* note Mr Bogaert's prominent regulatory pharmaceutical and environmental practice. The 2011 edition of *The Legal 500 EMEA* noted that he is 'a superb lawyer who is very pleasant to work with'. Mr Bogaert regularly writes and speaks on life sciences issues. He is a founding member of the Brussels pharma law group.

SARAH FOREST

Covington & Burling LLP

Sarah Forest is an associate in the firm's Brussels office. She provides legal, regulatory and procedural advice regarding the application of pharmaceutical law and the rules governing other health products, cosmetics and foods. Ms Forest's experience includes regulatory exclusivity rights, the implementation of recent European pharmaceutical legislation, pharmacovigilance obligations, rules related to falsified medicines, borderline decisions, orphan medicines and EU administrative procedures.

COVINGTON & BURLING LLP
Kunstlaan 44/44 Avenue des Arts
1040 Brussels
Belgium
Tel: +32 2 549 5230
Fax: +32 2 502 1598
pbogaert@cov.com
sforest@cov.com

www.cov.com