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 11

FINLAND

Hanna Paloheimo and Hilma-Karoliina Markkanen[1]

I INTRODUCTION

The Medicines Directive 2001/83/EC has been implemented in Finland, but national requirements stricter than the Directive's minimal requirements also exist. The position of the generic pharmaceutical industry has been traditionally strong in Finland with good possibilities for early generic entry.

The Finnish Medicines Agency Fimea (Fimea) is the national competent authority for regulating pharmaceuticals. Fimea grants, *inter alia*, marketing authorisations (MA) and wholesale licences for medicinal products (medicines). Reimbursement of medicines in Finland is subject to reimbursement status and reasonable wholesale prices, which are confirmed by the Pharmaceutical Pricing Board, operating under the Ministry of Social Affairs and Health. The National Supervisory Authority for Welfare and Health (Valvira) supervises medical devices and their compliance with legislation.

II THE REGULATORY REGIME

The legislation of medicines and medical devices is harmonised with EU legislation in Finland. The national applicable legislation for medicines includes the Medicines Act (395/1987) and the Medicines Decree (693/1987). Additionally, the national codification is supplemented by the regulations and guidance issued by Fimea. Pharma Industry Finland (PIF), an organisation of the innovative pharmaceutical industry, has also issued the Code of Ethics (PIF Code) containing very detailed provisions regarding marketing of medicines which are binding for members of PIF. The PIF Code is based on medicine, competition and consumer legislation and on the marketing guidelines

1 Hanna Paloheimo is a counsel and Hilma-Karoliina Markkanen is an associate at Castrén & Snellman Attorneys Ltd.

of the equivalent European and international federations, the European Federation of Pharmaceutical Industries and Associations and the International Federation of Pharmaceutical Manufacturers and Associations.

The Finnish Medical Devices Act (629/2010) and orders issued by Valvira govern medical devices and the marketing of such devices. Sailab ry, a registered association of hospital and laboratory product suppliers has issued its own code of ethics as well, which governs, *inter alia*, the marketing of medical devices.

Generally, the marketing of medicines and medical devices to consumers is also regulated by the Finnish Consumer Protection Act (38/1978) and Regulation on Unfair Practices in Marketing and Customer Relations (601/2008).

i Classification

According to the Medicines Act, a medicinal product means a product or substance intended for internal or external use to cure, alleviate or prevent a disease or its symptoms in humans or animals. Medicinal products are also considered to include substances or combinations of substances, used internally or externally, than can be used to restore, correct or modify the vital functions of humans or animals through pharmacological, immunological or metabolic influence or to determine the state of health or the reason for a disease. In ambiguous cases, the provisions of Medicines Act are primarily applied if no special grounds for other interpretation exist. Such borderline cases have concerned mainly dietary supplements, cosmetic products, and medical devices. It should be noted that the definition of medicinal products is rather broad in Finland and may include products that would not be considered medicinal products in some other EU Member States.

The Medical Device Act defines a medical device as any instrument, apparatus, appliance, software, material or other article intended by the manufacturer to be used for human beings for the purpose of, *inter alia*, diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap. Medical device also means any such product intended for the purpose of investigation, replacement or modification of the anatomy or of a physiological process or control of conception. The Medical Device Act states that when assessing the distinction between the Medicines Act and Medical Device Act, the primary action of the product in question must be considered. The final assessment is concluded by Fimea which adheres to the large extent to European Commission's guidance. Finally, the distinction between a medical device and a cosmetic product is defined by the intended purpose of the product itself.

ii Non-clinical studies

The Medical Research Act (488/1999) together with the Medicines Act regulates pre-clinical safety tests of medicines, which are subject to an approval granted by Fimea. Fimea's approval may include restrictions or supplementary conditions for laboratories. The tests are also supervised by Fimea.

The Act on the Protection of Animals Used for Scientific or Educational Purposes (497/2013) is applied to the use and breeding animals for scientific or educational purposes and for the supply of their organs or tissues for scientific or educational purposes. The purpose of the Act is to ensure that animals are kept and used for above-

mentioned purposes only for necessary and important reasons. Additionally, the Animal Welfare Act (247/1996) must be complied with. The Gene Technology Act (377/1995) may also be applicable if gene technology is used. Additionally, good laboratory practice must be complied with in all non-clinical studies intended to be submitted to a national registration authority for the purpose of registering or licensing substances such as chemicals, medicinal products or cosmetic products.

Non-clinical studies are not compulsory before placing medical device on market.

iii Clinical trials

The definition of clinical trial includes intervention research conducted in humans to investigate the effects of a medicinal product on humans and the absorption, distribution, biotransformation or excretion of the product in the human body. Clinical trials are regulated in the Medical Research Act (488/1999), implementing Directive 2000/20/EC and in the Medicines Act and further regulations or guidelines may be issued by Fimea, Valvira and the National Committee on Medical Research Ethics. Fimea has issued a regulation regarding clinical trials.[2]

All clinical trials must be planned, conducted and reported on observing the principles of good clinical research practice set forth in Directive 2005/28/EC. Fimea must be notified of every interventional clinical drug trial on medicinal products regardless of whether the product has an MA or not prior to proceeding. A notification is not, however, required if the trial is non-interventional. In uncertain cases Fimea decides whether or not a notification is required.[3]

A party commissioning a clinical trial of a medicinal product (the sponsor) is obliged to have an insurance policy or other appropriate guarantee to cover the liability of the commissioning party and the researcher. The sponsor is not, however, required to have an established place of residence in Finland. Commencement of the research is subjected to a favourable opinion of the ethics committee and a licence granted by Fimea, if required. There are no particular insurance requirements for a sponsor of research of medical devices.

iv Named-patient and compassionate-use procedures

For special reasons relating to treatment or public health, Fimea may grant a temporary authorisation (special authorisation) for releasing a medicinal product according to the Section 21(f) of the Medicines Act, implementing the Medicines Directive's Article 5(1).

Special authorisation must be granted if no other means are available to treat an individual patient or animal or group of animals, or if an available treatment would not

2 Fimea's Regulation 2/2012 on Clinical Trials.

3 To be classified as non-interventional, the trial must meet the following criteria: the medical product is prescribed in the usual manner in accordance with the terms of the MA during the trial, the prescription of the medicine is clearly separated from the decision to include patient in the trial and assignment of the patient to a particular therapeutic strategy is not decided in advance in research plan. Additionally, no supplementary diagnostic or monitoring processes are applied to the patients and methods shall be used for the analysis of collected data.

yield the desired result. Additionally, such authorisation may be granted when a medicinal product with marketing authorisation is not available to treat a group of patients or the population or to prevent an illness, and there are particularly weighty reasons for granting the special authorisation. Special authorisation is subject to any statement issued by the European Medicines Agency's Committee for Medicinal Products for Human Use.

When special authorisation is granted, the supplier is obliged to ensure that the user of the product receives sufficient instructions on the correct and safe use of the product, and storage and other instructions.

The Medical Devices Act does not include any equivalent provisions regarding named-patient and compassionate-use procedures.

v Pre-market clearance

A medicinal product may be sold to the public or otherwise released for consumption only after it has been granted an MA either nationally by Fimea, or by the European Medicines Agency. A granted MA is valid for five years from being granted, and it may be renewed. After the MA is granted, the MA holder must file a notification to Fimea upon the launch of the product. The MA holder also has an obligation to ensure that medicinal products that have been granted a MA are constantly available to medicinal product wholesalers and pharmacies to meet the needs of patients and other users.

Any medical device placed on the Finnish market must comply with the essential requirements of law, and these requirements can also be defined more precisely by Valvira. Overall, the device must be fit for its intended purpose, achieve the intended functionality and performance when used for its intended purpose, and it must not endanger health or safety of the patient, user or other person. Altogether, the device must bear the 'CE' marking that indicates conformity with the set requirements.

If a medical device may cause severe risk to health, the manufacturer or an authorised agent with a registered office in Finland must file a notification to Valvira before such device is placed on the Finnish market or at most within one week after the sale of the device has begun. Valvira must also be informed of all adverse incidents relating to medical devices as soon as possible. Valvira has issued several regulations regarding medical devices concerning, for example, conformity assessment and the CE marking.[4]

vi Regulatory incentives

Finland grants supplementary protection certificates under Council Regulation 1768/92/EEC and the Patent Act (550/1967, as amended) for the first patent covering a new medicinal substance. The relation between patents and the MA process is clear in Finland, since patents do not have relevance in the MA application process. The *Bolar* exemption of Directive 2004/27/EC has been implemented in the Finnish Patent Act to cover research activities required for the MA application. Patent exclusivity does not, therefore, cover research activities required for applying for an MA. Finland also grants the data exclusivity protection for medicinal products, and recognises the paediatric

4 Conformity Assessment of Medical Devices 1/2011 and CE marking of Medical Devices 2/2011.

investigation plan exemption for paediatric products of the Regulations 1901/2006/EC and 1902/2006/EC. If a medicinal product has been accepted for children, the data exclusivity is extended for six months as a main rule. Finland has no specific national legislation concerning orphan medicine products, but Regulation 141/2000/EC is applied, as is the data exclusivity extension of two years under Regulation 1901/2006/EC for orphan medicine products.

vii Post-approval controls

Finnish national legislation has been updated to conform to the Pharmacovigilance Directive 2010/84/EC, and the Finnish national authority Fimea has issued instructions and guidelines for the national implementation of the Directive.[5] The MA holder is obliged to monitor the safety of medicinal products and to take appropriate measures if changes are identified in the benefit-risk analysis commenced by the MA holder. The MA holder is also obliged to keep a record of possible adverse effects and side effects. According to the Medicines Act, the MA holder must report all serious adverse reactions originating in Finland to Fimea. Fimea's task is to supervise all product defect procedures and to ensure that taken measures by the operators are appropriate.

viii Manufacturing controls

The industrial manufacturing of medicinal products requires a licence granted by Fimea, which may include conditions to the licence. Medicinal products may only be manufactured industrially by medicinal product manufacturers that have acceptable production facilities and equipment for production. If, however, required for technical, economic or production-related reasons, a medicinal product manufacturer may have a medicinal product manufactured or controlled in part or entirely by another medicinal product manufacturer, provided that such contract manufacturer has the industrial manufacturing licence granted by Fimea. Fimea may issue regulations concerning the procedures to be observed. Detailed requirements for an application are stated in the Medicines Decree.

A manufacturer must also comply with the EU Good Manufacturing Practice Guidelines. Only such active substances that have been manufactured in accordance with these guidelines may be used in the manufacture of medicinal products. Medicinal product manufacturers must also have an accountable director who is primarily responsible for ensuring that products manufactured meet the requirements set for them in the Medicines Act. Additionally, at least one person has to meet the qualification requirements set forth in Directives 2001/82/CE, 2001/20/EC and 2001/82/EC.

Unlike the manufacturing of medicinal products, the manufacturing of medical devices is not regulated in such a detailed manner, and thus, no licence or approval for manufacturing is required. Manufactured medical products must, however, meet the

5 Fimea's Instructions to the National Implementation of the Directive 2010/84/EC and Fimea's guidelines for marketing authorisation holders regarding the national implementation of Directice 2010/48/EC.

essential requirements set forth in the Medical Devices Act, namely, the manufactured product must be safe and suitable for its intended purpose.

ix Advertising and promotion

The marketing of medicinal products is regulated under the Medicines Act and Medicines Decree and the concept of marketing is interpreted expansively. Generally, advertising of medicinal products must encourage people to use the products appropriately and it must not induce people to use products unnecessarily. The marketing information provided has to be accurate; it may not include any obsolete information nor omit any essential details. Fimea is the monitoring authority of marketing and advertising.

Additionally, general consumer protection legislation is applied when medicinal products are marketed directly to the general public. The marketing of prescription-only medicines must, however, be targeted only at persons entitled to prescribe or dispense the medicine. Voluntary control of pharmaceutical marketing and self-regulation has traditionally been one of the key forms of activity in Finland. Pharmaceutical marketing is, therefore, also covered under the PIF Code and it is controlled by the Supervisory Commission for the Marketing of Medicinal Products, which operates under the PIF. The PIF Code is binding only on the members of PIF, but it may provide evidence of established practices and acceptable conduct.

The marketing rules for medical devices are mainly the same as general Finnish marketing legislation, orders and principles, such as the Finnish Consumer Protection Act and the Regulation on unfair practices in marketing and customer relations. The marketing of medical devices is therefore generally allowed, but all marketing activities must be objective and give a truthful and reliable description of the product. Marketing of medical devices includes all possible direct or indirect actions, of which purpose is to promote the product and to influence product's sales. Marketing of medical devices is permitted by Valvira and the Consumer Ombudsman.

x Distributors and wholesalers

The wholesale of medicinal products, meaning all activities aimed at receiving and forwarding orders for medicinal products, to acquire and keep medicinal products in order to distribute them and to export medicinal products, is subject to a licence in Finland. The licence is granted by Fimea, which may incorporate certain conditions concerning the operations in a licence. In order to be eligible for a licence, the applicant must be situated in Finland and have proper facilities and equipment for the storage of medicinal products and for ensuring the operations and the personnel required for the operations.

The applicant must also have an accountable director, who is responsible for ensuring that the medicinal products sold by the wholesaler meet the requirements set for them in Medicines Act or in provisions issued pursuant to it. The accountable director is also responsible for ensuring that the wholesaler complies with regulations and guidelines issued on the storage, handling and labelling of medicinal products. The accountable director must have a master of pharmacy certificate and he or she cannot act simultaneously, *inter alia*, as an accountable director in any other licensed medicinal product wholesale company.

Medicinal products may be sold or otherwise supplied by the wholesaler to a medicinal product manufacturer, another medicinal product wholesaler, a pharmacy, subsidiary pharmacy, the Military Pharmacy, a hospital pharmacy or dispensary or to a veterinary surgeon for purposes of veterinary medication. In addition, medicinal products the sale of which has not been restricted by law or other provisions may be sold or otherwise supplied to retailers of these products. Good medicinal product distribution practice based on the EU provisions must be complied with in all medicinal product wholesaling. Fimea has also issued a regulation regarding good distribution practices.[6]

The Finnish Medical Devices Act does not regulate how the distribution of medical devices takes place. Therefore, medical devices can be distributed by different operators, such as pharmacies or other distributors, and the distribution or wholesale of such products is not subject to any licence.

xi Classification of products

In connection with granting an MA for a medicinal product, Fimea decides whether the medicinal product may be sold or otherwise released for consumption only on the basis of a prescription. Fimea may also alter its decision on the basis of new information received on the medicinal product affecting its supply classification.

The classification affects the marketing of medicinal products, since products subject to medical prescription can be marketed solely to individuals authorised to prescribe or dispense medicines.. The Medicines Decree defines detailed requirements for such marketing, and such marketing activities may only take place at medical sales representations organised exclusively for such an audience, in expert field publications or via electronic media targeted and directed solely at such an audience.

Medical devices are classified according to the Directives 93/42/EEC and 98/79/EC. The directives determine the procedures to be used in verifying that the product complies with all applicable requirements.

xii Imports and exports

The import and export of medicines is permitted only under a valid MA. Additionally, if medicinal products are imported to Finland from outside the EEA, a licence for the industrial manufacture of medicines is required (see Section II.viii, *supra*, on manufacturing controls). A national wholesale licence is mandatory for import and export from inside the EEA.

In general, provisions applicable to the distribution and wholesale of medical devices also apply to the import and export of such products (i.e., imported and exported products must meet the essential requirements and bear the CE mark and thus they may be freely imported within the EEA area.) In Finland, the marketing of medical devices and placing them on the local market is not subject to any sales permit or licence, unlike for medicines, but the manufacturer is responsible for the product's compliance with all essential requirements. No permit procedures are applied, and the manufacturer indicates the compliance with all necessary requirements by a mandatory CE mark.

6 Fimea's Regulation 5/2013 on Good Distribution Practices.

xiii Controlled substances

In general, the production, manufacture, import to the territory of Finland, export from the territory of Finland, transportation, transit through the territory of Finland, distribution, trade, handling, possession and use of drugs is prohibited under the general prohibition of the Narcotics Act (373/2008).

Substances regarded as drugs are listed in Finnish Decree 543/2008, as amended, and medicinal products mainly affecting the central nervous system or containing narcotics or psychotropic substances are listed in the Medicines Agency's decision 3176/4.6.4/2009. Fimea grants authorisations for the manufacture, import into Finland, export from Finland and handling of such substances. The operator will need a handling authorisation for a drug that may be granted for a certain limited time. According to the Narcotics Act, the operator is also obligated to notify Fimea every year of drugs, substances, amounts, preliminary estimate of demand, etc.

xiv Enforcement

Intentional or negligent violation of provisions of the Medicines Act, namely, by manufacturing, importing, storing, carrying for sale or supplying medicinal products; or neglecting to make a notification, provide information or keep records concerning medicinal products; or failing to comply with a prohibition issued by Fimea is punishable by a fine for a medicinal product offence. A medicinal product offence may also be punished under the Finnish Criminal Code, in which case the penalty is either a fine or a maximum of one year's imprisonment.

Fimea has the right to prohibit the import, manufacture, distribution, sale or other release for consumption of a medicinal product if conditions for granting the MA or for registration no longer exist, or if the requirements and obligations concerning manufacture or import of the medicinal product are no longer met. Fimea may also revoke, in part or in full, a licence granted for practising the manufacture or wholesaling of medicinal products, if any of the requirements for granting the licence are no longer met or if an obligation essential to safety or quality has not been met.

III PRICING AND REIMBURSEMENT

The Finnish reimbursement system is a national system that forms a part of the Finnish national health insurance system. This insurance scheme covers all permanent residents of Finland. The reimbursements are made directly to the patient when the medicinal product is sold by the Social Insurance Institution of Finland. In Finland, only approved medicinal products may be reimbursed. There are three types of reimbursement: basic, lower special reimbursement and higher special reimbursement. The special reimbursement categories are set according to the severity of the treated condition and the necessity of the drug treatment, and they are specified by a government regulation. Some medicinal products may also have a restricted eligibility for reimbursement.

According to the Health Insurance Act (1224/2004, as amended), the costs of a medicinal product may be reimbursed in Finland only if the valid MA holder has applied for reimbursement and a reasonable wholesale price has been set. The Pharmaceutical Pricing Board, which operates under the Ministry of Social Affairs and Health, confirms

the reimbursement status and the reasonable wholesale price. The medicinal product's therapeutic value is taken into consideration in the decision on basic reimbursement status and the assessment is made by overall consideration. If reimbursement status is not sought and no reasonable wholesale price has been sought to be confirmed, the pricing may be implemented completely without any restrictions. Non-prescription medicines can also be reimbursed, provided that the doctor has prescribed the medicine to the patient and the Board has confirmed a reasonable wholesale price and the reimbursement for the medicine.

Under the reference price system applied in Finland, medicinal products are divided into reference groups by substance. Reference prices are determined based on MA holders' price notifications, and prices are updated four times a year. This determined reference price is the highest possible price based on which the reimbursement can be calculated. The price notification is the prerequisite for the reimbursement of the products in this system. A generic substitution policy is applied in Finland, meaning that if a patient prefers the more expensive medicine prescriber by a doctor, the excess costs are paid by the patient.

Since the pricing of medical devices is not regulated in Finland, the pricing is basically free, taking into account, however, general competition law pricing principles. Generally speaking, medical devices are not reimbursed in Finland, except in certain very limited circumstances, for example when a person has a disability or illness that restricts performing work or study related tasks. In such limited cases the costs incurred by the purchase of such assistive devices may be reimbursed.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decisions of administrative authorities such as Fimea and Valvira may be appealed according to the general provisions and principles concerning administrative matters. According to the Administrative Judicial Procedure Act (586/1996), the appeal must be lodged at the Administrative Court within 30 days from the decision's date of issue. The Supreme Administrative Court is the appellate court for the decisions of the administrative courts. In some specific cases, a leave of appeal is required.

An appeal regarding an unsatisfactory decision of the Pharmaceuticals Pricing Board can be lodged with the Supreme Administrative Court within 30 days of receiving the decision. Courts have ruled their decisions in favour of pharmaceutical companies in many cases, but unfortunately, the appeal process may be rather slow compared to the usual timelines of pharmaceutical pricing.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Financial relationships between prescribers and payers are governed by the Medicines Act, the Medicines Decree and the Criminal Code. According to the Medicines Act, whoever, either intentionally or through negligence, violates the provisions issued in Medicines Act on the marketing of medicinal products, or asks for, accepts or receives prohibited inducements, benefits or gifts, will be sentenced to pay a fine for a medicinal product offence, or ultimately, the Criminal Code may be applied. Self-regulatory

systems like the PIF Code also include provisions applicable to PIF members regarding appropriate interaction.

In general, the PIF Code prohibits giving promotional gifts related to prescription-only medicines. The distribution and offer of promotional gifts related to the marketing of self-care medicines must also be reasonable. The promotional gifts must have only minor economic significance for the recipient, and they must have a bearing on their professional operations. The company must also document and publish all the economic benefits targeted at health-care organisations or professions according to the PIF Code. The provisions of the Sailab Code are much like the PIF Code.

According to the Medicines Act, the MA holder or other party engaging in marketing must also keep available for public review an up-to-date list of all direct and indirect financial and comparable support that they have given to associations in the fields of medicine and health care and to patient organisations.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

A statutory obligation to compensate for pharmaceutical-related injuries can be based on the Finnish Product Liability Act (694/1990), Patients Insurance Act (585/1986) and the Damages Act (412/1974). No special legislation on damages caused by medicines or medical devices, thus, exist. According to the Product Liability Act, a prerequisite for the compensation is that the injury or damage was sustained or incurred because the product was not as safe as could have been expected at the time when the product was put on the market. The injured party shall prove the injury or damage, the defect in the product as well as the causal relationship between the defect and the injury or damage. The legislation is based on Directive 85/374/EEC on liability for defective products. General principles of tort law may also be applicable to pharmaceuticals-related injuries, mainly liability due to negligence.

Finnish Pharmaceutical Injury Insurance is a voluntary and additional insurance policy system founded by members of the pharmaceutical industry and pharmaceutical importers to cover damages caused by pharmaceutical products under the Medicines Act. According to the general insurance terms and conditions, pharmaceutical injury refers to any bodily illness or injury or a psychic disease likely to have resulted from a pharmaceutical taken by the injured party. However, pharmaceutical injuries do not include illnesses or injuries resulting from a pharmaceutical failing to produce the intended effect or occurring in connection with measures that should not have been taken in view of the intended or recognised effect of the pharmaceutical concerned. Additionally, pharmaceutical injuries do not include illnesses or injuries resulting from an error in the prescription, and further, compensation is not paid for known side effects of the medication if these were in proportion to the illness being treated in case of a necessary risk taken in treatment of a serious illness. Minor damages are not compensated.

The Patient Insurance Act requires that hospitals and clinics acting in Finland have a mandatory patient insurance that covers bodily injuries that have been caused to patients due to health-care treatment.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

General European competition law principles and legislation are applicable in Finland. There are no recent and relevant enforcement actions or case law regarding the life sciences sector. Patent settlements are conducted in accordance with general EU policies. Patent litigation in pharmaceutical industry has been active in Finland, and EU level guidelines and decisions are closely monitored by the local industry.

The Finnish pharmacy system has been a topic of conversation recently in Finland. The system is not open to free competition because under the Medicines Act, the operation of a pharmacy business requires a pharmacy licence issued by Fimea. The granting of a licence is subject to a means test based on population number in the pharmacy's location area, and there are also other competition-restricting aspects. The Finnish Competition Authority (FCA) drafted a report in 2012 regarding the functionality and competition aspects of the system, but no measures have been taken so far. At the same time, releasing prescription-free medicines to the retail trade has been discussed.

ii Transactional issues

No major transactions have been conducted recently in the pharma sector in Finland. From a legal point of view, competition law must be taken into account regarding possible M&A activities of major players in the market, and a decision of the FCA may be required. The tax law and practical aspects are also important when planning an M&A transaction.

VIII CURRENT DEVELOPMENTS

The costs of medication have been under constant review in Finland, and the state authorities aim to reduce overall costs. An extensive organisational change in health-care services is also currently in progress. Responsibility for organising social welfare and health-care services will be, most likely, moved from municipalities to social welfare and health-care regions (SOTE regions). This will have an effect on the life sciences sector as well. The role of research activities, for example, has been under discussion. According to the draft law, a research committee will be established for each SOTE region, and the committee will define focus areas of academic research, the allocation of funds and the monitoring of research together with the Ministry of Social Affairs and Health for a period of four years.

The wholesale of medicines is conducted via a single-channel system, in which the distribution of medicines from manufacturer to pharmacies is generally run by wholesale traders based on exclusive agreements between the manufacturers and the wholesale traders. In practice, two major wholesale trade players exist in Finland, and they both have a nearly 50 per cent market share. Naturally, this arrangement is constantly under examination by the FCA, but so far, the FCA has not found it necessary to intervene in the single-channel system.

Appendix 1

ABOUT THE AUTHORS

HANNA PALOHEIMO

Castrén & Snellman Attorneys Ltd

Hanna Paloheimo is head of the life sciences practice at Castrén & Snellman and she specialises in life sciences, IP and technology, and dispute resolution with a particular emphasis on industrial property rights and patent litigation. She advises life science companies in various matters including transactions and regulatory issues. Besides her law degree, she holds a master of sciences degree in genetics, and this combination provides useful insight in meeting the special needs of life science, pharmaceutical, and biotechnology companies. *Chambers Europe*, *Chambers Global*, *Best Lawyers* and *Intellectual Asset Management* rank Hanna Paloheimo among Finland's leading legal experts.

HILMA-KAROLIINA MARKKANEN

Castrén & Snellman Attorneys Ltd

Hilma-Karoliina Markkanen specialises in intellectual property law and advises clients in various industrial property rights and copyright related matters. Her main practice areas also include life sciences, consumer protection and advertising law and technology.

CASTRÉN & SNELLMAN ATTORNEYS LTD
PO Box 233 (Eteläesplanadi 14)
00131 Helsinki
Finland
Tel: +358 20 7765 214
Fax: +358 20 7761 214
hanna.paloheimo@castren.fi
hilma-karoliina.markkanen@castren.fi
www.castren.fi