The
Life Sciences
Law Review

EDITOR
Richard Kingham

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THE RESTRUCTURING REVIEW

THE PRIVATE COMPETITION ENFORCEMENT REVIEW

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THE CARTELS AND LENIENCY REVIEW

THE TAX DISPUTES AND LITIGATION REVIEW

THE LIFE SCIENCES LAW REVIEW

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ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following law firms for their learned assistance throughout the preparation of this book:

ADVOKATFIRMAET BA-HR DA
BAE, KIM & LEE LLC
BÄR & KARRER AG
CORPORATE LAW GROUP
COVINGTON & BURLING LLP
DIERKS + BOHLE
FAUS & MOLINER
FIEBINGER POLAK LEON & PARTNER RECHTSANWÄLTE
HOGAN LOVELLS
KHURSHEED KHAN & ASSOCIATES
LEE AND LI, ATTORNEYS-AT-LAW
MAPLES AND CALDER
MATTOS MURIEL KESTENER ADVOGADOS
NAGASHIMA OHNO & TSUNEMATSU
NORTON ROSE
NSN LAW FIRM
PLESNER LAW FIRM
ROSCHIER
SÁNCHEZ DEVANNY
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It is a pleasure to serve as the editor of the first edition of *The Life Sciences Law Review*, which aims to provide an overview of legal issues of special interest to pharmaceutical, biotechnology and medical device companies in 27 jurisdictions. The life sciences sector is of vital importance to the health and well-being of persons around the world. Innovative manufacturers play a key role in the discovery and development of new therapies, while generic manufacturers serve an equally important function by ensuring availability of inexpensive products once patents and regulatory exclusivity periods expire. Throughout the lifespan of a drug or device – from the earliest discovery stage, through non-clinical tests and clinical trials, the governmental approval process, and after entry to the market – lawyers play a central role as advisers to the industry.

We have sought to organise the regulatory discussion in each national entry to correspond roughly to the key stages of product development: the regulatory classification of the product, which determines requirements for approval; non-clinical studies and clinical trials; compassionate use prior to approval; product pre-clearance; regulatory incentives for investment in drug development; post-approval controls; manufacturing; promotion; distribution; legal status; imports and exports; special rules on controlled substances; and enforcement.

In addition to product pre-clearance procedures, many jurisdictions impose requirements for approval of pricing or reimbursement of pharmaceuticals and, to a lesser extent, devices. These are addressed in the entry for each country. We also set out basic information on administrative and judicial remedies, controls on financial relationships with prescribers and payors, special liability systems, and transactional and competition issues that are specific to pharmaceuticals and medical devices.

Finally, each chapter identifies issues of current interest in the jurisdiction. These include, for example, plans to increase transparency in the regulatory process without undermining protection of intellectual and industry property; efforts to adapt traditional regulatory systems to new and emerging technologies, such as companion diagnostics, gene therapy and cell processing; and implementation of regulatory pathways for
‘biosimilars’ as patents expire for the first generation of biotechnology-derived medicinal properties. As these and other issues develop, we expect to devote additional attention to them in future editions.

I wish to thank all of the contributors who have made this publication possible. They are an impressive group, and it is a privilege to be associated with them in this enterprise.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2013
I  INTRODUCTION

The life sciences sector is and has traditionally been very important in Sweden. However, the number of employees within this sector has declined in the last few years. This decline can be seen from the number of employees within R&D and clinical research. The reasons for this are linked to the fact that innovative medicine companies conduct fewer clinical trials in Sweden than they used to, but the number of companies has increased, probably due to some large companies decreasing their presence in Sweden.

Most Swedish regulations within this area emanate from the European Union. The Swedish authority responsible for approving medicines as well as supervising medicines and medical devices is the Medical Products Agency. The most important legislation in this area is the Medical Products Act as well as the Medical Products Ordinance for medicines, the Medical Devices Act and the Medical Devices Ordinance.

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1 Håkan Sterner is an IP counsel at Roschier.
2 With companies such as AstraZeneca, Swedish Orphan Biovitrum, Karo Bio, Elekta and Getinge.
3 Läkemedelsverket.
5 Läkemedelsförordning (SFS 2006:272).
6 Lag om medicintekniska produkter (SFS 1993:584).
7 Förordning om medicintekniska produkter (SFS 1993:876).
II THE REGULATORY REGIME

i Classification
A medicine is defined as every substance or combination of substances that is supplied with an indication that it has properties that prevent or medicate diseases in humans or animals, or that can be used on or applied to humans in order to restore, correct or modify physiological functions through pharmacological, immunological or metabolical effect or in order to set a diagnosis.8

A medical device is a product that, according to the manufacturer’s information, is to be used, alone or in combination with other things, to identify, prevent, monitor, treat or ease an illness, or identify, monitor, treat, ease or compensate for an injury or a disability, or investigate, modify or replace a part of a person’s anatomy or a physiological process, or control fertilisation.9

Food is defined as all substances or products, whether processed, partially processed or unprocessed, that is intended to be or could reasonably be expected to be ingested by humans. Food includes beverages, water, chewing gum and any substance, including water, intentionally incorporated into the food during its production, preparation or treatment. Food does not include feed, live animals, plants, medicines, cosmetics, narcotics or psychotropic substances or residues and contaminants.10

Cosmetic and hygienic products are defined as substances or preparations intended to be applied to the outer parts of the human body, the teeth or mucous membranes in the mouth exclusively or with the main purpose of cleaning or perfuming them, changing their appearance, protecting them, preserving them in good condition or correcting body odour.11

A chemical product is defined as substances and preparations. A substance, in turn, is defined as a chemical element and its compounds in natural or produced form (including possible additives necessary in order to preserve the stability of the substance and possible contaminations that are derived from the manufacturing process, but excluding possible solvents that can be separated without any effect on the stability of the product and without changing the composition of the product).

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8 Läkemedelslagen Section 1.
9 Lagen om medicintekniska produkter Section 2.
11 Förordningen om kosmetiska och hygieniska produkter (SFS 1993:1283) Section 1.
Preparations in turn are defined as mixtures or solutions that consist of two or more substances.\(^\text{12}\)

### ii Non-clinical studies

The Animal Welfare Act\(^\text{13}\) and the Animal Welfare Ordinance\(^\text{14}\) regulates some aspects of studies in animal models. As a general rule animals shall be treated well and be protected from unnecessary suffering and illness.\(^\text{15}\) However, animals being studied shall not be seen as being exposed to unnecessary suffering or illness if the study has been approved by an Animal Study Committee.\(^\text{16}\) Animal studies are only permitted if the activity's aim cannot be accomplished through any other satisfactory method without using animals. As few animals as possible should be used in animal studies. Animal studies shall be designed in such a manner that the animals are not exposed to more suffering than what is absolutely necessary. No animals other than those that have been bred for that explicit purpose can, as a general rule, be used in animal studies. Permission is necessary to use, breed, store or supply study animals. Permission can be given by the Swedish Board of Agriculture.\(^\text{17}\) Medical devices do not have to go through non-clinical studies to be sold. However, as part of the manufacturers post-launch monitoring of their product the manufacturers of medical devices have to monitor how their product functions in practical use.

### iii Clinical trials

Clinical studies on humans are only allowed to be carried out by registered medical doctors or registered dentists. Persons intended to be part of a clinical study as study objects shall be sufficiently informed about the study to be able to decide whether or not to take part.\(^\text{18}\) These study objects should be informed about the possibility to withdraw their consent to take part. It is mandatory to get consent from each study object in a clinical study. Clinical studies are only allowed once they have been approved by the Medical Products Agency. Approval should, as a general rule, be considered as given if the Medical Product Agency has not given its decision within 60 days of a complete

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14 Djurskyddsförordningen (SFS 1988:539).

15 Djurförsöksstätsk namnd.

16 Djurskyddslagen Section 2. Djurförsöksstätsk namnd. There are seven Animal Study Committees in Sweden (Northern Stockholm, Southern Stockholm, Uppsala, Linköping, Malmö/Lund, Göteborg and Umeå).

17 Jordbruksverket.

18 Läkemedelslagen Section 13a.
application has been filed. In order to conduct a clinical study in Sweden approval from a research ethics committee is mandatory. Research is only allowed if it can be conducted while maintaining respect for human values. Human rights, basic freedoms and basic rights are to be considered during the approval procedure. Further, research is to be allowed only if the risk the study can carry is outweighed by the value it has from a scientific point of view. A study is not to be allowed if the same result can be accomplished in some other way that does not involve the same risk regarding the health, safety and personal integrity of the study objects involved.

Medical devices do not have to go through clinical studies to be marketed. However, as part of the manufacturer’s post-launch monitoring of its product manufacturers of medical devices must monitor how their product functions in practical use and report any accidents and incidents to the Medical Product Agency.

iv Named-patient and compassionate use procedures

According to the Medical Products Act sale of non-approved medicines is permitted if the sale is for a named patient and the medicine is manufactured at a pharmacy (ex tempore medicine). The medicine has to be delivered directly to the patient. The Dental and Pharmaceutical Benefits Agency can approve a price for ex tempore medicines if they are manufactured with some frequency. If a price is approved these ex tempore medicines can also be reimbursed. However, if the ex tempore medicine is manufactured more rarely, no price will be approved. The price will, under such circumstances, be set according to a fixed pricelist, mainly based on ingredients, type of formulation and process for manufacturing. Substitution is for natural reasons not an issue with such medicines. Another possibility to sell non-approved medicines is so-called ‘licensed medicines’, which can be sold even without ordinary authorisation. Such licence is to be given by the Medical Product Agency, if the need for a medicine cannot be fulfilled with authorised medicines. Whenever the Medical Product Agency approves a clinical study this automatically means that the medicine to be studied can be given to the objects of the study within the clinical study. Due to the common European Union rules patients can get access to unauthorised medicines also in compassionate use cases, see Regulation (EC) No. 726/2004 of the European Parliament and of the Council. This is applicable in cases where the patient is suffering from a chronic, seriously debilitating or life-threatening illness that cannot be treated satisfactorily with an authorised medicine. The medicine in question has to be in the process of being granted an authorisation via the centralised procedure or be undergoing clinical studies. A customised medical device for a certain patient can be manufactured based on a prescription by a medical doctor.

19 Läkemedelslagen Section 14.
20 Lagen om etikprövning av forskning som avser människor (SFS 2003:460).
21 Läkemedelslagen Section 5.
22 Tandvårds- och Läkemedelsförmånsverket.
v Pre-market clearance

A medicine can be sold in Sweden only once it has been authorised for sale or has been registered (registration concerns homeopathic medicines or herbal medicines) by the Medical Product Agency.23 Only one established in the European Economic Area (EEA) can apply for authorisation, registration or recognition.24 Medicines that has been authorised or registered in another state within EEA can be recognised and can be sold in Sweden.25 In order to be authorised it is required that a medicine shall be effective and of good quality.26 A medicine is considered to be effective if it is active for its purpose and does not have side effects that are disproportionate to the intended effect during normal use. It is up to the applicant to show that these requirements are fulfilled.27 The Medical Product Agency shall accept that the requirement for pre-clinical and clinical studies is fulfilled if the applicant (of the authorisation for a generic medicine) refers to the same documentation for the reference medicine. However, the reference medicine must have been authorised for 10 years or more in a member state of the EEA.28 Biosimilars have to be applied for via the centralised procedure within the European Union.

Medical devices do not need to be pre-approved in order to be sold.29 Instead it is the manufacturers that must make sure the medical device meets all requirements. Medical devices shall bear a CE mark to show that they meet the requirements. In many cases the manufacturer can conduct the testing verifying the fulfilment of the requirements themselves. In some cases a certified agency shall be used. The Medical Product Agency supervises this afterwards.

vi Regulatory incentives

Sweden has no linkage system (i.e., the Medical Product Agency takes no consideration of patents when assessing whether to grant marketing authorisations or not).

Sweden has supplementary protection certificates30 for medicine products that can extend the protection for a maximum period of five years.31 Furthermore, a system of paediatric term extension also exists that can extend the protection for a period of six years.

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23 Läkemedelslagen Section 5 Section and Section 7.
24 Läkemedelsförordningen 3:1.
25 Läkemedelslagen Section 6a.
26 Läkemedelslagen Section 4.
27 Läkemedelslagen Section 4.
28 Läkemedelslagen Section 8a.
29 Lagen om medicintekniska produkter.
30 TilläggsSkydd.
months. Sweden has no special legislation (beyond Regulation (EC) No. 141/2000 of the European Council on Orphan Medicinal Products) regarding orphan drugs besides a stipulation that the sponsor of clinical studies regarding orphan drugs may not have to supply the patients and study objects medicine free of charge. This is the case if the approval to conduct the clinical study has been combined with the condition that follow-up investigations should be carried out. The EU rules cover, among other issues, a sole right to market the medicine for 10 years. Similar medicines will not be authorised for the same therapeutic indication, unless the inventor of the orphan drug accepts this, they cannot supply the market with enough of the drug or the new applicant shows that the new product, though similar, is clinically superior to the original.

In Sweden data protection is valid for pre-clinical studies and clinical studies filed as part of the regulatory file when applying for marketing approval. This protection protects the data filed by the original filer for up to 10 years. New filers can sell their product (if authorised) at the earliest 10 years after the original product was authorised.

No special incentives exist for medical devices.

vii Post-approval controls

The holder of a marketing approval shall keep a record containing information on all suspected side effects that have occurred within the EEA or within a third country that has come to the attention of the holder of the marketing authorisation. Such side effects should be reported to the Medical Products Agency. If the holder of a marketing authorisation acquires knowledge about circumstances that give him or her reason to believe that information or documents on which the authorisation has been based are incorrect or need to be supplemented, he or she is obligated to notify the Medical Products Agency immediately. The holder of a marketing authorisation has to report any new risks, changed risks or any changes in the relationship between the benefit and the risk of the medicine to the Medicinal Products Agency and to the European Medicines Agency. The holder of a marketing authorisation shall maintain a detailed description of the system for safety monitoring used by the holder. The Medical Product Agency can order a medicine to be recalled. The Medical Product Agency can also withdraw

34 Läkemedelslagen Section 8c.
35 Läkemedelsförordningen 4:2.
36 Läkemedelsförordningen 4:2a.
37 Läkemedelslagen Section 11.
the marketing authorisation temporarily or definitely.\textsuperscript{38} The authorisation can also be altered.\textsuperscript{39}

The manufacturers of medical devices shall continually monitor how their products work in practical use. The manufacturers must report all accidents and incidents. If the Medical Product Agency is notified about any accident or incident regarding the medical devices or notes any such accidents or incidents during their own supervision they can demand that the problem be fixed. The Agency can also order a sale ban for the medical device in question as well as order a product recall. The Agency can combine these orders with a fine to be paid if the manufacturer does not fulfil the order. Anyone in breach of the Medical Devices Act or the Instructions of the Medical Product Agency can be sentenced to a fine or imprisonment for up to one year.

viii Manufacturing controls

Production, packaging and repackaging of medicines or intermediates\textsuperscript{40} are considered to be manufacturing.\textsuperscript{41} Approval from the Medical Products Agency is required for professional manufacturing.\textsuperscript{42} There is a common good manufacturing practice standard within the European Union. This requires, for instance, that a quality management system is set up. This should contain self-managed inspections. It is mandatory to keep certain types of documentation available, such as documentation covering specifications and testing methods, manufacturing methods, instructions for manufacturing and packaging as well as protocols from manufacturing processes. The documentation shall make it possible to reconstruct the manufacturing process for each manufacturing batch. Manufacturing should be done in accordance with instructions and methods set up in advance. Manufacturers shall have a quality control system. Reference samples from every manufacturing batch should be kept for at least one year post-expiry. Manufacturers shall set up a system for the registration and handling of complaints. Manufacturers shall set up an effective system for withdrawals of medicines. Such withdrawal should be possible at any given moment.\textsuperscript{43}

ix Advertising and promotion

Both the Medical Products Act and the Marketing Act\textsuperscript{44} is applicable to the marketing of medicines. Marketing to the public of prescription medicines and of non-authorised medicines is prohibited. Marketing towards children is prohibited.\textsuperscript{45} Marketing of medicines shall promote an appropriate use of the product through a presentation that

\textsuperscript{38} Läkemedelslagen Section 12.
\textsuperscript{39} Läkemedelslagen Section 12.
\textsuperscript{40} Material that has been worked on but still needs to be worked on further before it is a finished product.
\textsuperscript{41} Läkemedelslagen Section 15.
\textsuperscript{42} Läkemedelslagen Section 16.
\textsuperscript{43} Läkemedelsverkets föreskrifter om god tillverkningssed för läkemedel (LVFS 2004:6).
\textsuperscript{44} Marknadsföringslagen (SFS 2008:486).
\textsuperscript{45} Läkemedelslagen Section 21a.
is current, factual and balanced. The marketing cannot be misleading and should be in line with good practice for such marketing. Marketing of medicines towards the general public shall be designed in such manner that it clearly shows that the message is an advertisement and that the product is a medicine. The content of such advertising cannot be designed so that it can lead to use of the medicine that results in injury or that is in any other way inappropriate or leads to people not seeking relevant medical treatment.46 No special regulation exists for advertising and promoting medical devices. The common regulation in the Marketing Act applies.

Distributors and wholesalers

In order to be able to operate a wholesale business regarding medicines (distribution of medicines is considered to be a wholesale business)47 an approval from the Medical Products Agency is required.48 Anybody having such approval shall make sure that the premises in which the business is to be carried out is suitable, leave the information necessary to a specific legal entity49 in order for that entity to be able to keep statistics regarding the wholesale business, document the handling of medicines in such manner that the medicines are traceable, conduct self-managed controls and make sure that a programme for self-managed controls exists.50

No licensing is necessary for the distribution and wholesale of medical devices.

Classification of products

Authorised medical products shall be classified as either prescription medicines or over-the-counter medicines. The Medical Product Agency can also specify if other special conditions shall exist for the prescription of medicines (it can, for instance, be necessary to restrict the prescription of certain medicines).51 Medical products are also classified as to whether they will be substitutable or not.52 If they are substitutable, pharmacists have to substitute medical products prescribed with the cheapest substitutable product if a comparable package is available.53 Medical products are substitutable only against such medical products that can be considered as equivalent.54 The assessment of whether products are substitutable should be based on medical criteria. Medically equivalent products usually mean products with the same active substance, strength and formulation in a corresponding packet size. They can, however, differ regarding additives, appearance and product information in the packet insert. Biosimilars are, currently, not assessed to be substitutable according to the Medical Product Agency.

46 Läkemedelslagen Section 21b.
48 Lagen om handel med läkemedel 3:1.
49 Apotekens Service Aktiebolag.
50 Lagen om handel med läkemedel 3:3.
51 Läkemedelslagen Section 8g.
52 Läkemedelslagen Section 8i.
53 Lagen om läkemedelsförmåner m.m. (SFS 2002:160) Section 21.
54 Läkemedelslagen Section 8i.
Medical devices are classified into four different classes (class I, IIa, IIb or III). This relates to which procedure manufacturers shall use to verify that the device complies with applicable requirements.\textsuperscript{55}

xii Imports and exports

Medicines and intermediates can be imported from a country outside the EEA only by those with approval to manufacture medicines or special approval to import medicines. Medicines and intermediates can be exported to a country outside the EEA only by those with approval to manufacture medicines.\textsuperscript{56}

No special regulation of the import and export of medical devices exists.

xiii Controlled substances

The Medical Products Agency is obliged to set up and promulgate lists covering what constitutes narcotics. These lists shall contain both narcotics according to Exhibit 1 in the Ordinance on Control of Narcotics and such substances that are subject to control according to international agreements entered into by Sweden.\textsuperscript{57} Some psychotropics are listed as narcotics due to them being part of the Convention on Psychotropic Substances from 1971.\textsuperscript{58} It is notable that plants containing the very same substances (the substances listed by the Medical Product Agency) might not be considered narcotics according to a ruling in the Supreme Court, see NJA 1995 page 219. According to the Control of Narcotics Act the import, export, manufacture, offering for sale, sale or possession of narcotics is permitted only for medical purposes, for scientific purposes, for other purposes that are especially urgent or for industrial purposes.\textsuperscript{59} For these purposes authorisation can be given by the Medical Products Agency.\textsuperscript{60} The Medical Products Agency is responsible for supervising these rules.\textsuperscript{61} Anybody importing, exporting, transitting, manufacturing or trading with narcotics shall keep notes that are necessary for the Medical Products Agency to be able to check that these rules are complied with.\textsuperscript{62}

Anyone selling, manufacturing, purchasing, offering or possessing such narcotics in any other case than the ones listed is liable for narcotics violation according to the Narcotics Penalty Act.\textsuperscript{63} However, travellers are permitted to carry narcotic medicines with them if they are intended for medical purposes and the traveller’s personal use. Narcotic medicines can, however, only be carried with the traveller in an amount equivalent to up

\textsuperscript{55} Läkemedelsverkets föreskrifter om medicintekniska produkter (LVFS 2003:11) Section 6 och Section 7.

\textsuperscript{56} Läkemedelslagen Section 17.

\textsuperscript{57} Förordningen om kontroll av narkotika (SFS 1992:1554) Section 3.

\textsuperscript{58} Convention on Psychotropic Substances (Vienna, 1971).

\textsuperscript{59} Lagen om kontroll av narkotika (SFS1992:860) Section 2.

\textsuperscript{60} Lagen om kontroll av narkotika Section 3.

\textsuperscript{61} Lagen om kontroll av narkotika Section 10.

\textsuperscript{62} Lagen om kontroll av narkotika Section 9.

\textsuperscript{63} Narkotikastrafflagen (SFS1968:64).
to five days’ personal consumption.\textsuperscript{64} Narcotic medicines can only be dispensed after an order by a medical doctor.

xiv Enforcement

The Medical Products Agency is to supervise compliance with the Medical Products Act and the Medical Devices Act.\textsuperscript{65} In that supervision the Agency has the right to get the information and documents it so requests. The Agency can also impart the injunctions and prohibitions deemed necessary for compliance with the Medical Products Act and the Medical Devices Act. The Agency has the right to inspections at premises and other spaces used for manufacturing of medicines, intermediates or packaging material as well as to premises where testing of the properties of medicines is carried out as well as where medical devices are handled. The Agency also has the right to investigate and take samples at such premises. Refusal to allow the Agency access can be charged with a penalty.\textsuperscript{66}

III PRICING AND REIMBURSEMENT

The Swedish system for subsidising covers medicines for human use that have been included into the system (if a price for the product has been approved by the Dental and Pharmaceutical Benefits Agency).\textsuperscript{67} The level of subsidising depends on the total amount purchased by the patient per year.

Sweden also practises the substitution of medicines (however, as a general rule not for medical devices). The Dental and Pharmaceutical Benefits Agency puts together a list of products that are the products to substitute with (the cheapest products if they can be delivered to all pharmacies).

A medical device can be reimbursed if it is classified as a consumable.\textsuperscript{68} Consumables needed by a patient in order to take a medicine or consumables needed by a patient in order to control his or her medication are reimbursed. Consumables needed for stoma patients are reimbursed. Consumables have to be included into the system in the same manner as for medicines (i.e., a price has to have been set). A further requirement for the reimbursement of consumables is that it has been prescribed by a medical doctor or someone else especially authorised to do so by the National Board of Health and Welfare.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Decisions by administrative authorities are as a general rule appealable to administrative courts. For instance, decisions by the Medical Products Agency are appealable to the Administrative Court in Uppsala while decisions by the Dental and Pharmaceutical

\textsuperscript{64} Förordningen om kontroll av narkotika (SFS1992:1554) Section 5a.
\textsuperscript{65} Läkemedelslagen Section 23 and Förordningen om medicintekniska produkter Section 11.
\textsuperscript{66} Läkemedelslagen Section 24 and Lagen om medicintekniska produkter Sections 12, 13 and 14.
\textsuperscript{67} Lagen om läkemedelsförmåner m.m. Section 7.
\textsuperscript{68} Lagen om läkemedelsförmåner m.m. Section 18.
Benefits Agency are appealable to the Administrative Court in Stockholm. General procedural rules applicable in administrative courts apply. Generally speaking the proceedings are in writing, even though oral hearings can take place if the non-administrative party so requests as long as the hearing is not deemed to be unnecessary or there are specific reasons against the hearing. Leave to appeal is necessary in order to be able to further appeal to the Administrative Court of Appeal in Stockholm and also to the Supreme Administrative Court.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

Besides the regular bribery rules that can be found in the Penal Code chapter 10, the Swedish Association of the Pharmaceutical Industry has set up several different ethical regulations. Besides the obligation for the Association's members to follow these regulations, they might also have influence over, for instance, when bribery should be assessed according to the Penal Code or when marketing should be assessed according to the Marketing Act. These ethical regulations have been set up in agreement with the Swedish Association of Local Authorities and Regions, the Swedish Medical Association, some pharmacies, the Swedish Disability Federation and others. In essence they regulate what contacts are deemed appropriate between the different actors within this field.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

In Sweden there is no special regulation of damages due to personal injury or adverse effects caused by medicines or medical devices. Instead the general rules on damages apply, which means that causation must be shown. However, a voluntary insurance scheme, the Pharmaceutical Insurance, has been set up where many medicine companies active in Sweden take part. The insurance is aimed at those that suffer adverse effects due to medicine treatment. The scheme is set up in order for everyone who has been treated with prescribed medicines purchased from a legitimate dealer in Sweden. The insurance also covers patients who received their medicines at a hospital or who are suffering adverse reactions or effects owing to participation in clinical trials. The scheme means that each patient does not have to show causation. Instead it is enough that there is a preponderant probability that the injury was caused by a medicine.

The scheme described briefly above does not cover medical devices. This means that ordinary rules on damages apply (i.e., the Damages Act and the Product Liability

70 Förvaltningsprocesslagen Section 33.
71 Brotnsbalken (SFS1962:700).
72 Läkemedelsbranschens etiska regelverk.
73 Läkemedelsförsäkringen.
74 www.lff.se.
75 Skadeståndslagen (SFS1972:207).
The Product Liability Act regulates liability for personal injury caused by a product due to a security deficiency.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law
The famous AstraZeneca case originated in Sweden (among other countries) although it related to the European Union. In this case AstraZeneca was fined for having abused its dominant position in relation to one of its medicines (Losec). The first abuse consisted of having provided misleading information to national patent offices and thereby having been unjustly granted supplementary protection certificates. The second abuse consisted of having deregistered marketing authorisations in relation to Losec. This had the effect of preventing the generic companies from using a simplified procedure to obtain their respective marketing authorisations.

ii Transactional issues
One of the pieces of legislation most often considered in cases of licensing, strategic collaborations, joint ventures, and mergers and acquisitions is that regarding competition. As for all other member states of the European Union the European Commission has been and still is very active in enforcing these rules, one sign of this is the sector inquiry carried out at a number of medicine companies throughout Europe.

VIII CURRENT DEVELOPMENTS

As a comment on the European Medicines Agency’s consultation process regarding the access to pre-clinical and clinical data filed with the Agency, it can be noted that the Administrative Court of Appeal in Stockholm has confirmed that most of the information regarding applications for marketing authorisation is confidential and will not be released following a freedom of information request. The information requested in a recent case in the Court, was whether any applications for marketing authorisation regarding two different active substances or any combination including either substance existed, and if so how many were there and from how many companies. The request also included the legal basis for the applications for marketing authorisation, what kind of procedure the applications used (mutual recognition, decentralised procedure or national procedure), the identity of the reference member state and that of the concerned Member States, whether the applications had been validated, and whether any pre-clinical or clinical data had been filed. The request also looked for whether any application had been either withdrawn (if so, the name of the applicant, when it was withdrawn and the

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76 Produktansvarslagen (SFS1992:18).
77 CJEU case C-457/10P.
79 Kammarrätten i Stockholm, mål nr 7536-12.
reasons for withdrawal) or whether any procedure had been ended (if so, the legal basis for this, the approved product résumé and the assessment report). The Medical Product Agency refused to disclose anything other than to confirm that applications had been made, that no applications had been withdrawn and that no any procedures had ended. All other information was considered to be confidential for business reasons. The Court upheld the Agency’s decision.
Appendix 1

ABOUT THE AUTHORS

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Håkan Sterner is a member of Roschier’s intellectual property practice in Stockholm. He regularly advises clients, especially in the pharmaceutical industry, in relation to intellectual property issues with focus on complex global patent litigation and patent strategies. Håkan Sterner has extensive experience also in licensing and pharmaceutical regulation.

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