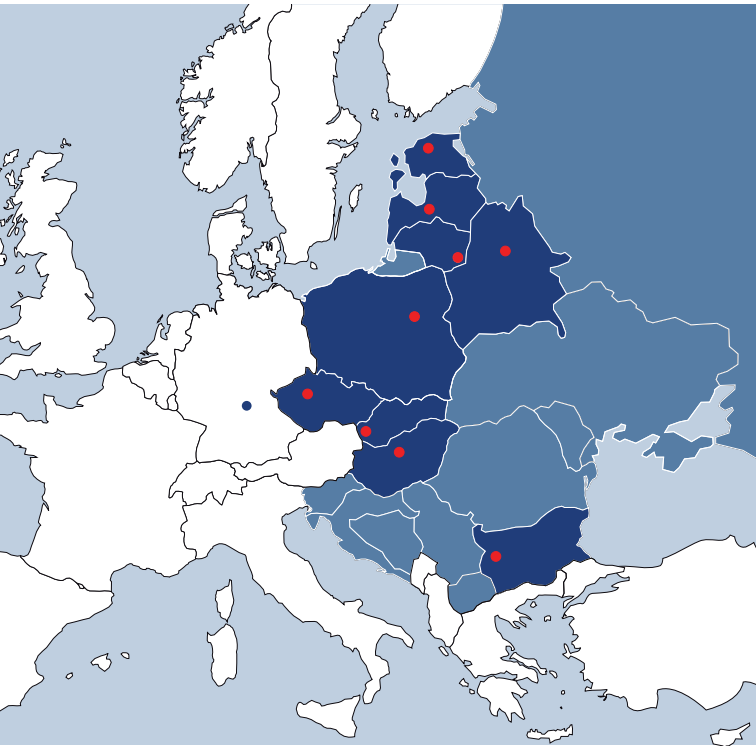

Pharma Law Survey 2015: The Baltic States

Latvia
Lithuania
Estonia

bnt
attorneys-at-law

Contents

Introduction

bnt attorneys-at-law: a leading group of law firms for Central and Eastern Europe

bnt attorneys-at-law is based in ten Central and East European countries, offering legal advice in all core areas of commercial law. Our clients come from Western Europe, Scandinavia and overseas, as well as from Central and East European countries. Discerning businesses, which our 120 + lawyers, tax counsel, and accountants advise on transactions in their homeland or internationally. Further afield – in Russia or Ukraine – bnt attorneys-at-law works alongside long-standing partners of proven worth.

In the Baltic States – Latvia, Lithuania and Estonia – bnt attorneys-at-law advises many international corporate clients, including from Sweden, Finland, Germany, Austria, Denmark, Turkey, Norway, France, Great Britain, and the USA. Business sectors represented cover many areas including life science, IT, energy, banking and finance, transport, logistics, the automotive industry, real estate, building and architecture, consumer law, and insurance.

In bnt offices in the Baltics, 45 lawyers plus staff work in close collaboration to form consulting teams, developing solutions for cross-border transactions and legal issues typical of the Baltic States. All lawyers in the ten bnt attorneys-at-law offices cooperate through international expert practice groups, of which one explicitly focuses on pharma law.

The working language is determined by the client, according to whose wishes cases are handled in German, English, Swedish, Finnish, Russian as well as in local languages.

Our mission is to ensure that the client's business decisions are implemented promptly and with legal certainty. As experienced specialists in Central and Eastern Europe, the signature characteristic of bnt attorneys-at-law is a high level of local expertise and close all-round co-operation between partners and colleagues. In this way, we offer all our clients the one-stop quality that we owe them.

bnt attorneys-at-law is a leading commercial law firm in the countries where it operates. This gives you the assurance of optimal advice for your business aims in Central and Eastern Europe – right from the very outset. That way, you see clearly ahead.

bnt Pharma Law Survey 2015

bnt Baltic Law Surveys offer a practical insight into the areas of law which are most valuable for doing business in the Baltic States. The surveys are written by leading legal experts in their fields and cover relevant issues from the perspective of all three countries. The straightforward language chosen for bnt Law Surveys ensures a better understanding of complicated and intricate aspects of the laws of these countries.

Pharma law is a classic interdisciplinary domain: Legal disputes may arise in IP issues such as patent or trademark law as well as in all fields of competition law, while often company, tax or labour law aspects may be involved as well. As the pharmaceutical sector is one of the world's most globalized markets, professional resolution of these disputes will also often require a sound command of international law including a wide range of specific international regulations.

The best way of dealing with disputes is always dispute prevention. By keeping in mind the most essential peculiarities of Latvian, Lithuanian and Estonian pharma law regulations when doing business in the Baltics, this can be assured. However, in spite of all efforts to unify European and international pharma law, Baltic national pharma law systems still differ considerably among each other, mainly due to divergent national health regulations, while the complexity of this branch of law even further impedes a clear view on the issue.

That clear view is what this brochure provides: It summarizes in a nutshell the legal essence from each Baltic State on the four most important aspects of pharmaceutical law in practice:

- general regulatory law,
- competition law,
- marketing regulations and
- a joint last chapter covering:
  - pricing mechanisms,
  - reimbursement schemes for drugs by national

health insurance systems
- national rules on disclosure of transfers of value
- recent developments, e.g. status of implementation of the EFPIA Disclosure Code.

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1. Chapter 1: Pharmaceutical regulatory law

1.1 Latvia

The Pharmaceutical Act (1997) and governmental regulations comprise the regulatory framework for marketing, distribution, pricing and import of pharmaceuticals in Latvia.
The major relevant by-laws are set out in

- Regulation No. 334 on the Import and Distribution of Active Substances (2013);
- Regulation No. 800 on the Licensing of Pharmaceutical Activities (2011);
- Regulation No. 289 on Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and Procedures for Assessing Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice (2010);
- Regulation No. 288 on the Operating of Pharmacies (2010);
- Regulation No. 378 on the Advertising Procedure for Medicinal Products and the Procedure Entitling a Manufacturer of Medicinal Products to Provide Free Samples of Medicinal Products to Physicians (2011);
- Regulation No. 416 on Procedures for Distribution and Quality Control of Medicinal Products (2007);
- Regulation No. 436 on Procedures for Import and Export of Medicinal Products (2007);
- Regulation No. 376 on Registration of Medicinal Products (2006) and
- Regulation No. 803 on Medicinal Product Pricing Principles (2005).

Competition law issues in the pharmaceutical sector are regulated by the Competition Act (2001). This is the framework law in the area of merger regulation and trust control. These are primarily regulated by the Law on Competition in conjunction with the Law on Pharmacy, which are applied in practice in line with EU competition law guidelines and regulations for the pharmaceutical sector. Apart from the Competition Act, a number of by-laws also provide the regulatory framework for competition regulation (e.g. on notifying agreements between market participants, on merger notifications, on exemption applications to particular vertical and horizontal agreements).

1.2 Lithuania

Lithuanian pharmaceutical regulatory law is at first glance quite complicated as it comprises a large set of rules, regulations and ministerial orders. Some main laws and legal acts provide the basis for pharmaceutical activities and products as well as marketing, authorization and pricing.

Among these are the Law on Pharmacy (2006); the Law on the Health System (1994); the Government Decision of 10 March 2010 setting the highest wholesale and retail Mark-ups of uncompensated medicines and the Order of the Minister of Health of 28 December 2006 dealing with marketing of medicinal products.

Also worth a mention are the Order of the Minister of Health of 13 September 2005 on calculating the base prices and the Order of the Minister of Health of 6 April 2010, which deals with lists of reimbursable medicinal products and aid equipment (also found in the sections below).

Execution and surveillance of compliance with these laws and orders is the task of the State Medicines Control Agency at the Ministry of Health, which acts on the basis of Article 61 of the Law on Pharmacy.

1.3 Estonia

In Estonia, marketing, authorization and pricing of pharmaceutical products (including generic drugs) is mainly regulated by three acts: the Medicine Act (2005), the Health Insurance Act (2002) and the Estonian Health Insurance Fund Act (2001). These acts are further supplemented by ministerial and government regulations dating from 2005-2010, which impose special conditions and procedures for various kinds of classification, documentation, pricing and other sales or marketing issues. These rules are enforced by the State Agency for Medicines, as stated in Article 100 Para 1 of the Medicine Act, including state supervision over compliance with the act and subordinate legislation. Additionally, the Health Board, the Veterinary and Food Board, the Competition Authority, and the Tax and Customs Board supervise compliance with these regulations within the scope of their competences.

Competition law issues in the pharmaceutical sector are primarily regulated by the Medicine Act, in conjunction with the Competition Act (2001) as well as the Advertising Act (2008). Additionally in force as of 2006 are government regulations on granting a permit for concluding R&D, specialization or vertical agreements that harm or are likely to harm competition, or on mergers.

2. Chapter 2: Pharmaceutical competition law

2.1 Control Authorities

2.1.1 Latvia

The Competition Council of Latvia is the authority in charge of examining any potentially prohibited agreement or antitrust violation, as well as reviewing mergers in the pharmaceutical market.
In the case of a competition violation, the Competition Council can impose obligations and duties to eliminate the violation, as well as penalties.

In turn, the State Agency for Medicines as regulatory authority is in charge of enforcing pharmaceutical laws. Aside from that, the Health Inspectorate is responsible for market surveillance and controls pricing issues. Finally, the National Health Service provides a financial assessment of medicinal products and technologies and maintains a List of State Reimbursed Medicines. These three authorities are subject to the direct jurisdiction of the Ministry of Health, which bears general responsibility for implementation of pharmaceutical laws.

2.1.2 Lithuania

The Competition Council of Lithuania is the state authority tasked with implementing state competition policy and supervising compliance of competition law (Law on Competition).

No specific guidelines are available on application of competition law to the pharmaceutical sector. However, general principles adopted by the Competition Council and EU-level legislation and guidelines (including case law) are of direct relevance to pharmaceutical matters.

The Competition Council may react in various ways to infringements or conduct prohibited under competition law. It can require companies to cease illegal activity, compel controlling persons to perform certain activities (e.g. sale of assets or parts of the company) and impose fines up to 10 % of the turnover of the previous year. The Council may also impose restrictions on the economic activity of companies in default of penalties imposed, such as suspension of export-import operations, a freeze on bank operations or revocation of permits. The Competition Council may also seize or destroy goods directly related to competition law infringements and require the individual concerned to cover resulting damages (which would, however, be subject to different laws e.g. the Lithuanian Civil Code). Both entities and individuals must comply with competition regulations.

So far, the Competition Council has placed no special focus in applying competition law to the pharmaceutical sector, so that only very few practical case examples exist.

2.1.3 Estonia

Apart from advisory services, the main task of the competition division of the Estonian Competition Authority is to analyse the competitive situation of businesses. Under Article 62 Para 1 of the Competition Act, the Competition Authority may issue a precept requiring performance of an act, refraining from a prohibited act, terminating or suspending anti-competitive practices, or restoring the situation prior to the offence.

Under Article 55 Para 2 of the Competition Act, the Estonian Competition Authority can require disclosure of information from all natural and legal persons and their representatives as well as state institutions and local authorities and their officials. However, in the pharmaceutical sector this has not been necessary so far, as all relevant information has generally been publicly available on the internet. This availability also enables non-governmental groups to proceed against an alleged competition law violation: According to Article 63 of the Competition Act, natural persons, legal entities and persons authorized on behalf of organizations that are not legal entities may apply to the Competition Authority to institute administrative proceedings.

As to non-compliance with the above-mentioned precept, under Article 62 Para 1 of the Competition Act the Competition Authority may impose a penalty of up to 3 200 EUR on individuals and up to 6 400 EUR on legal entities that fail to comply. Additionally, private parties may themselves be entitled to remedies: If civil proceedings have not proved the absence of unfair competition (Article 53 Competition Act) but following proceedings provide evidence of a violation, then money or other losses may be compensated either on the basis of the Law of Obligations Act or the Consumer Protection Act.

2.2 Control issue: Mergers

2.2.1 Latvia

Under the Competition Law, market participants that are party to a planned merger must file notification with the Competition Council if: (i) the combined turnover of the merging parties in the previous financial year in Latvia exceeded 35.572 million EUR; or (ii) the total market share of the merging partiers exceeds 40 % of the relevant market. Notification is not required if the turnover of each of the merging parties in the previous financial year in Latvia did not exceed 2.134 million EUR.

A detailed list of documents to be filed with the Competition Council is laid down in the Governmental Regulation on merger control. Once notification has been filed, the Competition Council must decide within one month whether an in-depth assessment of the merger is required. If the assessment procedure is initiated, the Competition Council has three months to complete its assessment and to adopt a formal decision.

Although the Competition Council has considered several mergers within the pharmaceutical sector, its main concerns have been similar to those in cases in other markets and sectors, including:

- delimiting the relevant market and the particular geographic market;
- assessing whether the merger will create a new dominant position or strengthen an existing dominant position; and
- determining to what extent a merger will have an impact on competition in the relevant market,

especially as to consumer issues (e.g., price).

Each proposed merger is assessed on the basis of the relevant market that it affects. The product and geographic markets in each case must be determined separately. The product market is determined mainly by considering distribution levels.

At manufacturer level, substitutability of products is important. The availability of equivalent generic or original products and medicines of different composition in the same ATC classification code level must be reviewed to determine market boundaries. Other criteria (e.g. price, habits of use, whether prescription or non-prescription medicines) may also be considered. The geographic market for this level is Latvia.

From the customer's viewpoint, the possibility of product or service substitutability is highly relevant. Mainly, the particular type of activity will be considered as the product market, for example wholesale pharmacies or retail pharmacies. According to case law, a distinction must be made between types of pharmacy; for example, the public (ordinary) pharmacies market is separate from that of closed (limited access) pharmacies, as closed pharmacies do not serve individuals but only specific health entities. This issue must be evaluated taking the view of the consumer.

The same approach applies to the geographic market. On the assumption that locations of accessible pharmacies are not replaceable from the customer's perspective because customers use outlets close to where they live, a particular town or city is defined as a single geographical market. The potential effects on competition because of a planned merger are therefore reviewed by way of considering the situation between competitors in each particular town or city.

At the wholesale level, a separate product market is usually determined for each named medicine on the basis of demand. Customers (pharmacies) require drugs with a specific name to be supplied by a wholesaler, and they are not substitutable by other medicines. The geographic market at this level is also Latvia.

At the retail level, the geographic market is the administrative area of the respective towns. Additionally,

for determining market power, other criteria, such as siting a pharmacy at strategic locations where there is a large flow of people (e.g. supermarkets, railway stations) may be considered.

2.2.2 Lithuania

A “concentration” or a “merger” under Lithuanian law is understood as the acquisition of control over another company on the basis of a contract or other means. This form of control can derive from contracts for sale of assets or consist in acquisition of one or more patents or licences.

To fall under national merger control, the combined aggregate income of the companies concerned has to be more than ca. 14.5 million EUR and the aggregate income of each of at least two companies concerned has to be more than ca 1.45 million EUR for the financial year preceding the concentration. Under Lithuanian law, a concentration also means acquisition of control due to a contract or other factual circumstances. Thus, acquisition of one or more patents or licences might establish a concentration and fall under respective control mechanisms.

So far, no sector-specific definition of the relevant market in the pharmaceutical sector has been formed and no merger investigations have been undertaken.

The Competition Council must decide on clearance or prohibition of a merger within four months after receiving complete notification documents. In a non-complicated situation a clearance decision will usually be made within one month after receiving the complete notification documents.

A fine up to 10 % of the turnover of the previous year may be imposed for an illegal concentration. Until now, no negative decision has been adopted on a concentration in the pharmaceutical sector.

2.2.3 Estonia

Under Article 21 Para 1 of the Competition Act, the Competition Authority reviews a merger if the parties’ annual turnover in Estonia prior to the merger exceeded 6.3912 million EUR, and the individual turnover in Estonia

of at least two parties exceeds 1.91735 million EUR.

Apart from general preconditions for mergers stipulated by law, other criteria to be taken into account include e.g. the future market share of the merger parties, the number of competitors and their economic and financial situation or the absence of legal barriers to market entry: According to Article 22 Para 1 of the Competition Act, the structure of the given market as well as actual and potential competition are taken into account in the merger assessment. This includes assessing the market position of the merger parties, their economic and financial power, access to the market by competitors, market-entry barriers, product supply and demand, as well as the interests of buyers, suppliers and consumers. In cases of potential competition, one factor considered is possible pressure on incumbent companies from expansion by other companies, imports and market entry by new operators.

Market definitions are essential for analysing a merger. In the Estonian pharmaceutical sector, the "relevant market" according to Article 3 Para 1 of the Competition Act is an "area covering ... the whole ... or a part of Estonia where products regarded as interchangeable or substitutable by the buyer due to their price, quality, technical characteristics, sales or use conditions, consumption or other characteristics, are circulated." "Geographic market" is an "area where competitive conditions related to certain products or services are similar enough and differ significantly from neighbouring territories".

2.3 Control issue: Cartels

2.3.1 Latvia

Under the Competition Law, agreements restricting competition as well as acts of unfair competition are prohibited. This includes agreements that involve prevention, restriction or distortion of competition within the common market, and in particular those that:

- directly or indirectly fix purchase or selling prices or any other trading conditions or exchange of respective information;
- limit or control production, markets, technical development or investment;
- share markets or sources of supply;

- apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; or
- make conclusion of contracts subject to acceptance by other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the subject of those contracts;
- lead other market participants to leave the market or impede potential entrants in a given market.

Price agreements between competitors constitute one of the most serious breaches of competition rules. Price cooperation (including agreeing or using pricing principles, guidelines and recommendations, calculation models or coefficients) between competitors is presumed to be illegal. This prohibition concerns both sales and purchase prices. In addition, cooperation in discounts, delivery terms, and sanctions for undue delivery or guarantee periods etc. is prohibited. Under case law, such cooperation is prohibited even if it took place within a trade association between members according to the rules of that association.

Cooperation between competitors in competitive bidding has also been considered a prohibited practice. The prohibited cooperation in that sense can consist of agreeing on purchase or sales prices, submitting similar tenders; agreeing on a higher sales price or lower purchase price than the competitor, or cancelling a tender because of cooperation with a competitor. However, no cartel investigations have been commenced in the pharmaceutical sector in Latvia as yet.

2.3.2 Lithuania

Article 5 of the Lithuanian Law on Competition prohibits conclusion of agreements restricting competition. The Competition Council usually assumes such a restriction to be present in often-occurring “classic cases”. These apply to agreements between competitors that directly or indirectly fix prices or sales conditions for, or the production of, certain goods. The same would hold true for agreements sharing a product market on a territorial basis.

Co-promotion and co-marketing agreements may be considered unlawfully anti-competitive mainly if concluded by companies competing with products

covered by such agreements, too, as well as any other agreement between competitors, if the intention is to limit competition or even potentially limit concentration.
The same regulations apply to vertical agreements. Here again, provisions restricting the buyer from setting resale prices, provisions allocating territories or clients or restrictions on active and passive sales either to the end-user or to the members of a distribution network engaged in retail may be considered wrongfully anti-competitive – though some exceptions exist.
Apart from the national Law on Competition, EU-level practice and guidelines are usually taken into account and referred to even in purely national cases.
To avoid circumvention of these provisions by secret agreements or other collusive practices, the Competition Council can seize documents, enter premises, question company employees, and so on.

2.3.3 Estonia

Article 4 Para 1 of the Competition Act generally prohibits anticompetitive agreements between companies and concerted practices and decisions by associations of companies. However, the EU has granted block exemptions to agreements on technology transfer (patents, know-how, software copyrights), as far as this applies to information received as a result of research and development protected as intellectual property or is know-how, is necessary for production of goods that are subject to the agreement or for implementing processes and substantially contributes to technical or economic progress.

Additionally, general cooperation agreements will not be seen as anti-competitive if cooperation takes place between non-competitors, between competing companies that cannot independently carry out projects or activities covered by cooperation or if cooperation does not affect the parameters of competition. Full-function joint ventures, which are assessed on the basis of merger control rules, are permitted.

Moreover, vertical agreements may be seen as anti-competitive. These agreements between companies operating on different levels of the supply chain are most likely to raise antitrust concerns if they refer to resale price maintenance or to restriction of resale territories or customers, of active or passive sale to end-users by

the members of a selective distribution system operating at the retail level or of cross-supplies between suppliers in a selective distribution system. In the pharmaceutical sector, however, no cartel investigations have been undertaken in Estonia to date.

2.4 Control issue: Dominance

2.4.1 Latvia

The Competition Law prohibits abuse of a dominant position.

A company is considered to be in a dominant position if its activities can substantially impede, limit or distort competition in a given market for a sufficiently long period, regardless of competitors, suppliers, customers or consumers.

Market share is not formally a factor indicating dominance. Previously, a company with a market share of at least 40 per cent was assumed to be in a dominant position. In turn, a company with a market share of less than 25 % was presumed not to be in a dominant position. Beyond the market share level, other criteria used to indicate dominance include division and stability of market shares. If the market is fragmented and the market share of the closest competitor is very low, a dominant position may be established even by passing the 40 % mark. Alternatively, significant and rapid changes in market shares generally speak against a dominant position. If barriers to market entry are high or a company has significant economic resources and valuable brands, a dominant position is expected to be more easily achieved.
The scope of the new definition is rather wide, allowing the Competition Council to ascertain in each particular case whether a market participant has a dominant position or not, without referring to strict criteria (relating to market share percentage).

In general, acquiring and further strengthening a dominant position is allowed. However, companies in a dominant position are legally bound to stricter competition rules than non-dominant companies. Thus, a business activity may be legal for non-dominant companies but clearly constitute a prohibited abuse if practised by a dominant undertaking. Actions that

without justification restrict or might restrict competition and limit the possibilities of other undertakings to operate on the market, or violate the interests of consumers, are considered abusive actions. Abusive actions may occur as:

- refusal to enter into transactions with other market participants or to amend the provisions of a transaction without justifiable reason, including unfair and unjustified refusal to supply goods or services;
- restrictions as to the amount of manufacture or sale of goods, or to market or technical development without justifiable reason, causing detriment to consumers;
- application of dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- making conclusion of contracts subject to acceptance by other parties of supplementary obligations that, by their nature or according to commercial usage, have no connection with the subject of such contracts;
- directly or indirectly imposing or applying unfair purchase or selling prices or other unfair trading provisions.

A single case establishing significant abuse of a dominant position in the life sciences industry has been examined so far. In 2007, the Competition Council imposed a fine of 167 300 EUR on a Latvian company based on a finding of abuse of its dominant position in distributing oxygen for medical use in Latvia; the company was also required to draw up a new pricing and accountancy method, as well as new price calculations.

2.4.2 Lithuania

Article 7 of the Lithuanian Law on Competition prohibits abuse of a dominant position.

The Competition Council has issued explanations on the definition of the relevant market and has developed principles for establishing a dominant position.

A market player would be considered dominant in the pharmaceutical sector (and in general) that either does not face competition or whose position in the market enables it to exert unilateral decisive influence by effectively restricting competition. It is thus necessary to look at the correlation of all active market players to

determine the influence of any one of them.

Under Lithuanian competition law, a company with a market share of more than 40 % is assumed to have a dominant position. A group of companies jointly holding 70 % or more of a given market will also be considered as having a dominant position under competition law. With regard to the retail trade, a retailer is deemed to dominate a given market if it holds more than 30 % of it and 55 % in the case of a group of retailers.

As to the national sector, there have so far been no significant cases of abuse of monopoly positions by pharmaceutical companies.

2.4.3 Estonia

Under the Estonian Competition Act, a company is presumed to have a dominant position if it can operate on the market to an appreciable extent independently of competitors, suppliers and buyers and if it holds at least 40 per cent of the turnover on the given market. Additionally, companies with special or exclusive rights as well as companies in control of essential facilities are also considered to have a dominant position.

In the pharmaceutical sector, patent law in particular may raise anti-competitive issues in the field of anti-monopoly law. Generally, a patent owner's efforts to achieve long-term protection are a justifiable interest. However, refusal to grant a patent may still be considered as conduct that is abusive to competition if the product or service is essential for operating on another market, if it eliminates competition on the given market; and if it prevents the emergence of new products with potential consumer demand, or if refusal is not objectively justified.

Moreover, enforcement of a patent does not generally constitute a patent owner's liability for antitrust violations. In the same way, line extension strategies such as new indications, new formulas, next-generation medicines and combination products and other lifecycle management strategies, such as strategic pricing, authorized generics, paediatric exclusivity and so on do not generally expose the patent owner to liability for antitrust violations. Nevertheless, if these strategies are intended to harm competition or aim for exclusionary abuses, they may be considered anti-competitive and

thus prohibited conduct.

Restrictions imposed through patents that prevent new companies from entering the market or which reduce that likelihood may also incur liability. Estonian patent law – especially in the field of authorised generics – deserves a closer look against an anti-competitive background: Under Article 37 Para 1 of the Estonian Patent Act, original medicines are patent-protected for 20 years from the grant of the patent. During the term of the patent, the manufacturer of the original medicine can license use of the rights of the patent proprietor in part or in full to one or more persons under Article 46 of the Patents Act. Whether a patent owner's decision to launch a generic or licensed generic before the patent expires to allow 'early entry' raises competition issues depends on the content of the specific licence agreement. All principles of fair competition – first and foremost prohibition of anti-competitive agreements between companies and concerted practices and decisions by associations of companies under Article 4 of the Competition Act – are applicable and have to be complied with.

In addition to proceedings before the Competition Authority, antitrust matters may also be subject to administrative, civil, misdemeanour or criminal proceedings. However, no follow-on litigation related to pharmaceutical antitrust in Estonia is known of.

3. Chapter 3: Advertising

3.1 Latvia

Advertising of medicinal products is regulated by the Pharmacy Law and Governmental Regulations No.167 (2007). In addition, the general provisions of the Advertising Law and the Consumer Protection Law apply. These laws and by-laws transpose directive 2001/83/EC of the European Parliament and of the Council.

By law, pharmaceutical NGOs may develop a joint code of ethics for advertising medicinal products that conforms to these laws as well as international ethical norms for advertising medicinal products. Therefore market practices are also covered by the Latvian Code of Practice for Advertising Medicines (legally non-

binding). In addition, members of Latvian pharmaceutical professional organizations follow the codes of ethics regarding promotion of prescription-only medicines adopted by the EFPIA and the AFA.

Prior notification or approval of the authorities for advertising materials is not required as of 2011, although these must still comply with statutory requirements. The Health Inspection may still provide surveillance on the content and form of advertising in the scope of general market control (conducting inspections upon complaints from third parties or on its own initiative).

The main principles applying to advertising intended for healthcare organizations (HCOs) and healthcare professionals (HCPs) are as follows: advertising must include at least the following information:

- the most essential summary information of product characteristics;
- whether the product is a prescription or non-prescription product;
- the date of last approval of the advertisement by the State Agency for Medicines (until the above amendments enter into force).

Information must be (i) accurate, up-to-date, verifiable and complete so that the recipient may judge the therapeutic value of the product, and (ii) quoted precisely from medical journals or other scientific publications with references to the source of quotations, tables and other illustrative material. An advertisement may only indicate the name of the product if the advertising is intended as a reminder of a previously disseminated advertisement.

An advertisement may be placed only in scientific and informative press publications for specialists or in specially prepared advertising materials, which might not be distributed to the rest of the public.

Concerning advertising aimed at the general public, a prohibition exists on advertising the following medicinal products (except vaccines) to the general public: prescription products, products containing psychotropic or narcotic substances or analogues thereof; and products whose purchase price is partly or fully covered from State budget resources. Manufacturers must not distribute medicinal products to the general public for

promotional purposes.

Advertising must be designed so that there could be no doubt that the information distributed is an advertisement and the product being advertised is a medicinal product.

If products prohibited from being advertised to the general public are advertised on the internet, the advertiser or disseminator of the advertising must ensure accessibility of information only to specialists.

Advertising must include at least the following information:

- the name of the medicinal product, as well as the common name specified in laws regarding labelling of medicinal products and the requirements to be met for the instructions for use of medicinal products, if the medicinal product contains only one active substance;
- information required for correct use of the medicinal product;
- a clear and legible invitation to carefully read the instructions for use or the relevant information on the packaging;
- an invitation to consult with a physician or pharmacist regarding use of the medicinal product; and
- the warning „unreasonable use of medicinal products is harmful to health".

Using mail services or providing advice in another similar manner and giving the impression that a physician's consultation is not necessary for determining a diagnosis are also prohibited.

Advertising (both to professionals and the general public) of products not authorized in Latvia or lacking a valid marketing authorization or not authorized according to the centralized authorization procedure of the European Medicines Agency is prohibited. Also prohibited is advertising medicinal products offered as a gift or compensation for the purchase of goods or receipt of a service or where a gift is offered for purchase of medicinal products (including an offer associated with the purchase of medicinal products to purchase medicinal products, other goods or services at a discount).

In respect to collaboration by the pharmaceutical industry with HCP and HCO, it must be noted that an advertiser or disseminator of advertising of a medicinal product may not supply, offer or promise any material or other kind of benefit regarding the prescription or distribution of medicinal products, except for cases where it is to be used in the practice of medicine or pharmacy and its material value is insignificant.

The law requires that representation (entertainment) expenses at events with a professional and scientific orientation must be subordinated to the main purpose of the event, and they may be applied only to specialists. Health care specialists must not solicit, request or accept any material or other kind of benefits as prohibited above.
Free samples of products may be distributed by medical sales representatives only to persons having the right to prescribe medicinal products.

The most common infringements of the advertising rules relate to non-compliance of the contents of an advertisement with the above mandatory rules or code of ethics. There have also been several instances of advertising prescription medicinal products through the internet, which is prohibited in Latvia.

Regarding collaboration rules, the most common violations relate to illegal sponsorship of physicians and to organization of activities for physicians with a disproportionate allotment between the scientific and recreational (entertainment) parts.

3.2 Lithuania

According to the Lithuanian Law on Pharmacy (the "Law") and Rules for Advertising Medicinal Products, advertising medicinal products must be objective and not misleading. The information and terms used in advertising must comply with the particulars listed in a summary of product characteristics, objectively present the properties of the product and promote rational use of the medicinal product.

Only registered medicinal products may be advertised in Lithuania. Additionally, specific requirements apply to advertising medicinal products subject to prescription and OTC medicinal products. Products that require a

prescription may only be advertised in publications / on specialised web sites meant for health care professionals and pharmaceutical specialists. These publications / web sites must not be publicly accessible. OTC medicinal products may be advertised publicly. However, advertisements must follow specific information requirements (including but not limited to pharmaceutical form and strength of product, therapeutic indications).

The Law entirely prohibits public advertising of medicinal products containing psychotropic and/or narcotic substances and medicinal products included in a list of drugs subject to reimbursement as approved by the Government.

For violation of general requirements, prohibitions or restrictions on advertising, sanctions might include e.g. a requirement for immediate discontinuation and/or public withdrawal of advertisements. Violations may also result in a fine from 290 EUR to 2 900 EUR, depending on the infringement committed.

3.3 Estonia

Under the Estonian Advertising Act (2008), advertising must be designed and presented so that it is recognised as such, must comply with prevailing customs and public order, must not be discriminatory and must not contain false or misleading information. Direct or indirect comparison of products or services provided by different competitors is generally allowed if comparison is based on material and verifiable features (including e.g. price) and does not infringe intellectual property rights or harm a competitor's reputation.

However, many specific goods and services require more restrictions when being advertised: This may either be because of the group of consumers targeted (in particular, advertising directed at children is further regulated), or because of their specific characteristics. Looking at technically complex goods, items that contain hazardous substances or products which require special operating skills must include an invitation to read the operating instructions and to consult a specialist if necessary. This goes especially for medical products such as antidepressants, headache pills or soporifics.

Entirely prohibited under the Act is promotion of narcotic

drugs or psychotropic substances – to name but a few.

Those violating general requirements, prohibitions or restrictions for advertising goods and services can be fined up to 300 EUR for individuals and up to 3 200 EUR for legal entities.

4. Chapter 4: Pricing, reimbursement and disclosure of transfers of value

4.1 Pricing

4.1.1 Latvia

Latvia restricts its price regulation policy to the distribution level, keeping the manufacturing level basically without restrictions.

Those medicines outside (i) the reimbursement system (below Chapter 4.2) or (ii) other public funding systems are subject to a specific price notification procedure. A manufacturer intending to launch certain medicines in Latvia must notify the selling price to the State Agency for Medicine („Agency") in advance.

Restrictions apply to the sale price of wholesalers and retail pharmacies. The law provides formulas with the correction rate of the manufacturer's price used to calculate the maximum permitted wholesale or retail price. Additionally, the Agency publishes on its website the maximal price of medicine permitted for retail in pharmacies.
A manufacturer must inform the Agency and wholesalers of planned changes in the manufacturer's price not later than 30 days before the new price is to be applied. Although the manufacturer must justify the increase of the price within 15 days upon inquiry by the Agency, justification has only an informative purpose, as it could not actually be examined by the authorities - manufacturers do not disclose formation of the price of a particular medicine, as well as profit earned.

These pricing requirements do not apply to supplies to publicly funded medical entities (state or municipally funded hospitals, out-patient clinics), or, (for centralized supplies) to the National Health Service (NHS). Instead, the public procurement procedure must be provided.

Upon public procurement, one of two selection criteria may be used to choose the best tender: (i) the lowest price; or (ii) the economically most advantageous tender, where factors other than price may be considered (e.g. terms of supply, operational and other costs and their effectiveness, quality of medicines).

In addition, medicines intended for state-funded in-patient treatment (i) must have the lowest costs of treatment compared to other medicines with equal therapeutic efficacy and side effects, or (ii) if costs of treatment are higher, the advantages of the medicines in the sense of therapeutic efficacy and side effects have been proved for a specific group of patients. The list of these medicines including their price is determined by the NHS. Hospitals requiring a broader or more specific range of medicines must elaborate a list of additionally usable medicines to be examined by the NHS. Medicines may be included in the Additional List if they have costs of treatment (i) commensurable with state budget funding for in-patient services of the hospital; and (ii) that are lowest compared to other medicines with equal therapeutic efficacy and side effects.

4.1.2 Lithuania

Pricing rules in Lithuania differ basically between reimbursable and non-reimbursable medicinal products.

Retail price limits of reimbursable products are officially approved every year on the basis of certain calculations.

The price declared by the registrant or the manufacturer or laid down in the parallel import permit serves as a basis to which Government-determined wholesale and retail overcharges and VAT are added.

However, this basis is not freely determined but has to bear comparison with the lowest and highest drug prices in the group of drugs with the same generic name. Products in groups of branded drugs or interchangeable drugs are furthermore bound by products with the same generic name in their respective groups.

The idea behind the base-price system is to force manufacturers to reduce prices and to promote competition.

Registrants or parallel import permit holders of non-reimbursable products must declare the price to be paid in reference to prices in certain other indicated States, which usually includes Latvia and Estonia. The final retail price limit would then be that reference-price adding Government-determined wholesale and retail overcharges and VAT.

4.1.3 Estonia

For specified reimbursable pharmaceuticals and free pricing for non-reimbursable pharmaceuticals, Estonia has a system of statutory pricing, where only statutory markups are applied. The system is based on negotiations between manufacturers and the Ministry of Social Affairs, (MoSA) who will try to cooperate on price policy issues.

The statutory price itself depends on the prices of the given product in other EU Member States with comparable economic conditions (for Estonia, most often Latvia, Lithuania and Hungary are used as references).

A price agreement can be induced either by the manufacturer or MoSA. In cases of expensive medicines, the Estonian Health Insurance Fund (EHIF) will be asked for an opinion on a proposal which will be provided within ten days. In the case of a positive answer from EHIF, an agreement is drafted and negotiated between MoSA and the manufacturer. How long this takes to complete depends on the complexity of the case. Once an agreement is achieved, MoSA will make the information publicly available on its website and also informs all stakeholders individually via a mailing list.

4.2 Reimbursement

4.2.1 Latvia

Only medicines conforming to certain criteria applied to the Reimbursement List and selected by the NHS are subject to reimbursement.

Reimbursement List A includes medicines with equivalent efficiency. Reimbursement List B includes medicines which have no alternatives with equivalent efficiency within the Reimbursement Lists.

Reimbursement List C includes medicines where the cost of treatment for one patient yearly exceeds 4 268,62 EUR and whose costs will be partly covered by the manufacturer itself for a certain number of patients. The number is set by the Authority according to several criteria but must not be less than 10% of the expected patients to be reimbursed by the state or 10% of the expected turnover of medicines to be reimbursed by the state.

Medicines under Reimbursement Lists A, B or C are reimbursed 100%, 75% or 50% depending on the diagnosis, according to Latvian Government Regulation. In turn, reimbursement List M includes medicines for children up to the age of 24 months (50% covered) and for women who are pregnant or within 42 days after child-birth (25% covered).
International reference pricing is one of the criteria for determining the price of reimbursable medicine. The price of medicine to be included in the Latvian Reimbursement List must not exceed the price in Estonia, Lithuania, and the third lowest price among Denmark, the Czech Republic, Romania, Slovakia and Hungary.

The NHS must decide on assigning reimbursement status to a medicine 180 days from receipt of application.

4.2.2 Lithuania

100 %, 90 %, 80 % or 50 % of base price of medicinal products included in one of the following lists may be reimbursed in Lithuania:

- List of diseases and reimbursable medicines for treatment thereof (list “A”);
- List of reimbursable medicines (list “B”);
- Reimbursable aid equipment (list “C”)
- List of centrally paid medicinal products.

The base price of the products included in the above lists are reimbursed for persons insured by compulsory health insurance from the budget of Compulsory Health Insurance Fund (the CHIF), part income of which consists of the insurance contributions. As mentioned above, the cost of the product is reimbursed in part, i.e. only the so-called base price of the product is reimbursed. Base price is a part of the retail price at which the medicinal products are sold in pharmacies. Therefore, difference between the retail and the base

price of the product has to be paid by the patient. Depending on the disease and social group (e.g. pensioners, children), 100 %, 90 %, 80 % or 50 % of the base price of medicinal products can be reimbursed. Medicinal products may also be included in the List of Reserve Medicines. These products are not actually reimbursed. However, they may later be moved to either list A or list of centrally paid medicinal products and thus reimbursed.

4.2.3 Estonia

General restrictions exist on issuance of medical prescriptions in Estonia: A doctor must indicate only the non-proprietary name of a medicine in the prescription, unless a replacement in the same amount and with the same active substance does not medically suit the patient. In that case, the doctor may use the brand name as well.

In general, only medicines on the Reimbursement List can be compensated. The degree of reimbursement depends on the purpose of the medicine: While 100% or 75% of the price of a medicine intended to cure severe or chronic illnesses will be compensated, all other medicines will generally be compensated only at 50 %.

These rules have exceptions: In the first group, 95% instead of 75% is compensated for children between four and sixteen years old as well as for the disabled, pensioners or persons older than 63 years. In the second group, 100% instead of 50% or 75% will be compensated for medicines for children under four years old. In all cases, an application has to be filed, including pharmaco-economical and cost / benefit analyses

The procedure for obtaining reimbursement status of a medicine generally takes 90 days. The reimbursement decision enters into force with the next quarterly amendments in the Reimbursement List, which is generally effected within one-two months after the board's decision.

4.3 Disclosure of transfers of value

4.3.1 Latvia

The EFPIA (European Federation of Pharmaceutical

Industries and Associations) has developed a set of regulations on disclosure of transfers of value – the so called "EFPIA Code". Based on that code the Latvian professional associations- SIFFA (Association of International Research-based Pharmaceutical Manufacturers) and PMA (Latvian Generic Medicines Association) have agreed on the disclosure code providing the criteria for disclosure of transfers of value. This code is binding on members of these associations.

Transfers of value must be disclosed on an individual basis for each recipient. Each member company must disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to transfers of value to the recipient in each reporting period which can be reasonably allocated to one of the categories in the code. Transfers of value may be aggregated on a category-by-category basis, but itemized disclosure must be made available upon request to (i) the relevant recipient, and/or (ii) the relevant authorities.

Transfers of value that (i) are solely related to OTC medicines; or (ii) are part of ordinary course purchases and sales of medicinal products by and between a Member Company and a healthcare professionals (HCPs) or a healthcare organizations (HCOs) do not fall within the scope of the disclosure obligation.

4.3.2 Lithuania

Lithuania has implemented the EFPIA Code into national law, imposing obligations to disclose direct or indirect transfers of value to the HCOs and the HCPs.

As for the former, the disclosure obligation arises for transfers such as donations or grants to those organizations and their respective institutions that support health care, contributing to the cost of events (e.g. sponsorship, registration fees) and fees for services and consultancy of various kinds.

As for the latter, transfers of value to HCPs in the form of contributions to costs for related events or fees for services and consultancy may also bear the obligation to disclose.

However, transfers that are not listed above such as

items of medical utility, meals and drinks, medical samples and are part of ordinary course purchases and sales of Medicinal Products by and between a Member Company and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation.

4.3.3 Estonia

In Estonia, disclosure of Transfers of Value is still so far only covered by the Code of the Association of Pharmaceutical Manufacturers in Estonia on the Promotion of Prescription Medicines and Cooperation with Healthcare Professionals adapted and adopted by APME (the association of Pharmaceutical Manufacturers in Estonia).

According to Article 12 Clause 1.02, "service or consulting fees of the previous year paid either directly or indirectly to health care professionals, pharmacists or health care providers shall be disclosed according to the procedure laid down by the law or by the marketing authorization holder each year. The first disclosure of transfers of value is made in 2016 based on 2015 data."

Article 12 of that code is so far all that is available on disclosure of transfers of value in Estonia. According to information directly provided to us by the association of Pharmaceutical Manufacturers in Estonia, more detailed regulation is currently at the drafting stage and will be presented to the public in June 2015, when it will also be available on the association's website.

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