The Pharma Legal Handbook

Baltics

ESTONIA · LATVIA · LITHUANIA

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms

PHARMA BOARDROOM

Baltics

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Estonia, Latvia and Lithuania. It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with TGS Baltic, a leading law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN AUGUST 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

TGS BALTIC
VARUL GRUNTE SUTKIENE

TGS Baltic is a top-tier commercial law firm with offices in all the Baltic countries. We believe lawyers should not only be experts in law – the real added value for our clients comes from our understanding of their business objectives and specifics as well as innovative solutions provided by our professionals. TGS Baltic is recognised as the No. 1 law firm in Lithuania according client ranking by the latest independent research KANTAR Sifo Prospera Tier 1 Law Firm Review 2018.

TGS Baltic has been advising international and domestic business organisations and the public sector, including the European Central Bank, the European Investment Bank, various European Union institutions, as well as collaborating with top-tier international law firms since the Baltic countries returned to a market economy in the early 1990s. Since then, the firm has been involved in almost all of the major transactions, landmark disputes and legislative developments in the region.

The firm employs more than 135 lawyers covering over 25 practice areas. Our Baltic team provides solutions to complex legal problems, advises on strategic decisions and gives day-to-day assistance on a wide range of legal issues. TGS Baltic is listed as a top-tier law firm in Corporate, M&A, Banking & Finance, Competition, Energy, Dispute Resolution, Tax and other practice areas by the most reputable international legal directories. TGS Baltic has offices in Tallinn, Tartu (Estonia), Riga (Latvia) and Vilnius (Lithuania).

We are in strategic cooperation with the law firm Vlasova Mikhel & Partners in Minsk (Belarus) and a member of Terra-Lex, a global network of independent law firms, and all mayor international law professionals' organisations such as IBA, AEL, ILN, EWLA. We work in English, German, Russian, French, Polish and Finnish.

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We believe that true team work happens only when you really understand what you are doing. For us, the value of a team lies in the deep knowledge of the client's business and the ability to think differently from others in order to find the most innovative legal solutions.

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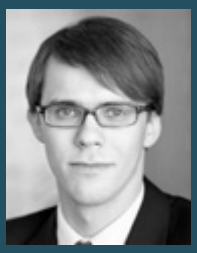
Estonia

THE AUTHORS - ESTONIA



SANDER KÄRSON

Sander joined TGS Baltic in 2013 and became a partner in 2018. Co-heading the M&A practice, he is involved in most of the firm's transactional work, while his special focus is on pharmaceuticals and IT. His recent M&A work highlights include advising Euroapteek, part of the Nordic and Central and Eastern Europe's leading pharmacy group Euroapotheca, on the acquisition of Ülikooli Apteek pharmacy chain in Estonia and advising pharmaceuticals producer Kevelt, a subsidiary of MSE listed company, in selling its IP rights to oncologic drug candidate Virexxa to a listed US biopharmaceuticals company Xenetic Biosciences in the first and only transaction of its kind in Estonia.

Sander has a long track-record experience in the pharmaceuticals industry, including advertising and clinical trials. His clients include international pharmaceutical companies Merck Sharp & Dohme and Oribalt whom he advises on daily basis in various legal fields including promotion and marketing of medicinal products, corporate/commercial, M&A, data protection and other regulatory matters.

Sander is a member of the Ministry of Justice's corporate law audit committee that has been set up to review all legislation regulating the corporate/commercial field. Also, he co-authored the suretyship and guarantee sections' commentaries on the General Part of the Law of Obligations Act He teaches contract law, company law and M&A in the University of Tartu, the main legal education provider in Estonia.

LANGUAGES
- Estonian
- English
- German

INGERI LUIK-TAMME

Ingeri joined TGS Baltic in 2004. She is one of the few Estonian lawyers specialising in healthcare and pharmaceuticals. Ingeri has focused on healthcare sector projects advising clients in drafting terms and conditions, reorganising and funding healthcare services, bringing innovative medical services to market, and other related issues. She also has extensive experience in representing healthcare providers in extrajudicial negotiations and litigation regarding patient compensation claims.

In the field of pharmaceuticals, her work includes collaborative projects between pharmaceutical companies and research institutions for the development of advanced pharmaceuticals, pharmaceutical clinical trials, as well as daily advice for several international pharmaceutical companies in various legal matters, including applications for permits, pharmaceutical advertising, marketing and pricing policies. Her most recent work in the pharmaceuticals sector has focused on due diligence for pharmacies, the establishment of an online pharmacy and the development of cross-border pharmacy services.

Ingeri has published numerous articles on medical law and held seminars in Estonia and abroad to workers in various healthcare sectors, as well as to judges. Her training activities cover both public and healthcare provider internal staff-training regarding the quality of medical care and healthcare services; patient safety and the rights, obligations and responsibilities of doctors and healthcare providers.

LANGUAGES
- Estonian
- English
- German

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The authority with jurisdiction over medicines and biologicals is the State Agency of Medicines (SAM). The authority responsible for applying and enforcing the regulatory framework in relation to medical devices is the Health Board.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The primary national legislation for the authorization and pricing of medicines and biologicals is the Medicinal Products Act (MPA) and its regulations. Authorization of medical devices is primarily regulated by the Medical Devices Act (MDA) and its regulations. Pricing of medical devices is not regulated. Reimbursement of medicines, biologicals and medical devices is mainly regulated by the Health Insurance Act (HIA) and its regulations.

3. What are the steps to obtaining authorization to develop, test, and market a product?

a) MEDICINES:

For manufacture of medicinal products, an activity license for the manufacture of medicinal products must be obtained.

For every specific medicinal product, marketing authorization valid in Estonia is required. Marketing authorization is not required for:

- medicinal products prepared as magistral and officinal formulae and medicinal products divided up into retail packaging by pharmacies;
- medicinal products imported based on a single import authorization and a single distribution permit granted by the State Agency of Medicines;
- whole blood and blood components;
- herbal substances;
- medicinal products prescribed for use on aquarium fish, cage birds, terrarium animals, small rodents as well as ferrets and rabbits kept as pets provided that the use of such medicinal products on any other animal species is precluded;
- advanced therapy medicinal products that have been, by way of exception, made on the basis of a doctor's prescription and subject to doctor's professional liability for the purpose of use by a specific patient upon provision of in-patient health services in Estonia.

Please see chapter 3 question 22 for details on different procedures for obtaining a marketing authorization in Estonia.