# The Pharma Legal Handbook

# Baltics

## ESTONIA · LATVIA · LITHUANIA

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labelling 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.**
**** LAST UPDATE: NOVEMBER 2021**

TGS BALTIC
VARUL GRUNTE SUTKIENE

TGS Baltic is a top-tier commercial law firm with offices in all three Baltic countries. The firm is continuously ranked high in the following prestigious international legal directories: Chambers Europe, Chambers Global, Legal 500 and IFLR1000.

TGS Baltic also is a leading law firm for the life sciences practice in the Baltics, covering health care, pharma, food safety regulation, and biotech industries, among others. Additionally, TGS Baltic was the top shortlisted Baltic law firm in the 2020 and 2021 European LMG Life Sciences Awards.

Our life science practice has unique experience in national and international healthcare regulation. The TGS Baltic team has helped healthcare providers in the Baltic region, Great Britain and Northern Europe implement new organizational models ensuring top international standards of care.

The firm's reputation for excellence in life sciences has made us the law firm of choice for the world's leading companies such as Boehringer Ingelheim, GlaxoSmithKline, BauschHealth, AstraZeneca, Coca-Cola and Mars Inc.

Key regional players, including Euroaphoteca, an international group of companies in the Baltics and the CEE region managing pharmacy retail chains in Lithuania, Latvia, Estonia, Sweden, and Poland, as well as Biotechpharma, a leading contract development and manufacturing organization (CDMO) for biopharmaceuticals all rely upon TGS Baltic.

It should be noted that TGS Baltic also represented the 8 largest producers of food supplements in the Baltics, Eastern Europe, and Nordic countries with a combined 70% share of the Baltic food supplement market.

www.tgsbaltic.com

www.tgsbaltic.com

# TRUSTED LEGAL AND STRATEGIC ADVISOR

TGS BALTIC
VARUL GRUNTE SUTKIENE

A top-tier commercial law firm with offices in all the Baltic countries

## 30 YEARS OF EXPERIENCE

| 30 | 150+ | 28 | 2000+ | 3000+ | 41+b |
|---|---|---|---|---|---|
| partners | lawyers | practices | local and international clients | projects handled last year | value of major projects |

# 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. He assists on everyday basis a multinational pharmaceutical company.

Sander has a long track-record experience in the pharmaceuticals industry, including advertising and clinical trials. His clients include international pharmaceutical company Merck Sharp & Dohme (Merck & Co., Inc. in US and Canada) whom he advises on daily basis in various legal fields including promotion and marketing of medicinal products, corporate/commercial, 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 several commentaries in the field of civil law (sales contracts, suretyship, guarantees, contracts for services etc). He teaches contract law and company law 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 life sciences and data protection. She advises a wide spectrum of local and international clients from start-ups to well-known corporations in the healthcare, pharmaceutical, medical devices and biotechnology sectors. Her practice focuses on EU and national regulatory issues. In pharma industry, this includes scientific research, clinical trials, marketing authorisations, licensing, pricing and reimbursement, marketing and advertising, and related matters. Most recent projects in other life science sectors include advising on several COVID-19 related products and services (vaccine, tests etc), the use of RWD in HealthTech & MedTech; healthcare and pharma apps; conducting due diligence of healthcare providers. In the field of data protection, she has led comprehensive GDPR compliance audits and helped develop internal data protection systems for several large companies in Estonia.

In addition, Ingeri has extensive experience in representing parties in extrajudicial negotiations and litigation regarding highly delicate and complex matters, such as patient compensation claims, funding treatment of rare and severe diseases and use of prohibited substances in sports (Ingeri advises and represents Estonian national antidoping organisation) etc.

Ingeri is an active speaker on improvement of the quality of healthcare services, processes, and technologies in Estonia. She trains healthcare professionals on various topics, such as data protection, quality standards, patient involvement, and safety and liability of healthcare providers.

As of 2019, Ingeri is a member of the Estonian Committee on Bioethics and Human Research.

LANGUAGES
- Estonian
- English
- German

# CONTENTS - ESTONIA

# 01

# REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

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

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

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

4. What are the approximate fees for each authorisation?

5. For how long are marketing authorisations/registrations valid? How are marketing authorisations/registrations renewed?

6. How does the authorisation process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

# 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 authorisation, pricing, and reimbursement of drugs, biologicals, and medical devices?**

The primary national legislation for the authorisation and pricing of medicines and biologicals is the Medicinal Products Act (MPA) and its regulations. Authorisation of medical devices is primarily regulated on EU level by the directly applicable regulations - the Regulation on Medical Devices (Regulation (EU) 2017/745) and the Regulation on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746). On national level, Medical Devices Act (MDA) and regulations thereof are applicable in extent not regulated in EU 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 authorisation 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 authorisation valid in Estonia is required. Marketing authorisation 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 authorisation 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.