



SORAINEN

Fresh legal news from
the Life Sciences &
Healthcare sector –
what's hot in the Baltics

Lise-Lotte Lääne, Marika Grunte, Erika Žigutė
Estonia, Latvia, Lithuania

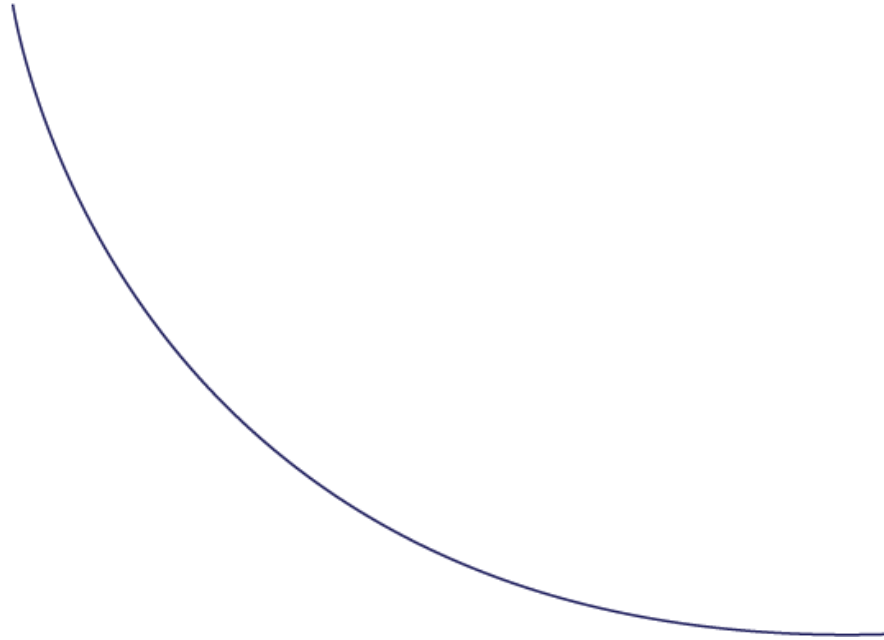
12 September 2024

Estonia

SORAINEN



Liability insurance for healthcare providers



- Patient insurance act will enter into force on 1 November 2024 (*„Tervishoiuteenuse osutaja kohustusliku vastutuskindlustuse seadus“*)
- A breach of the healthcare service provider's duty if bodily injury, health damage or death of the patient is caused by the provision of health care services
- Creation of the new database collecting patient safety incidents

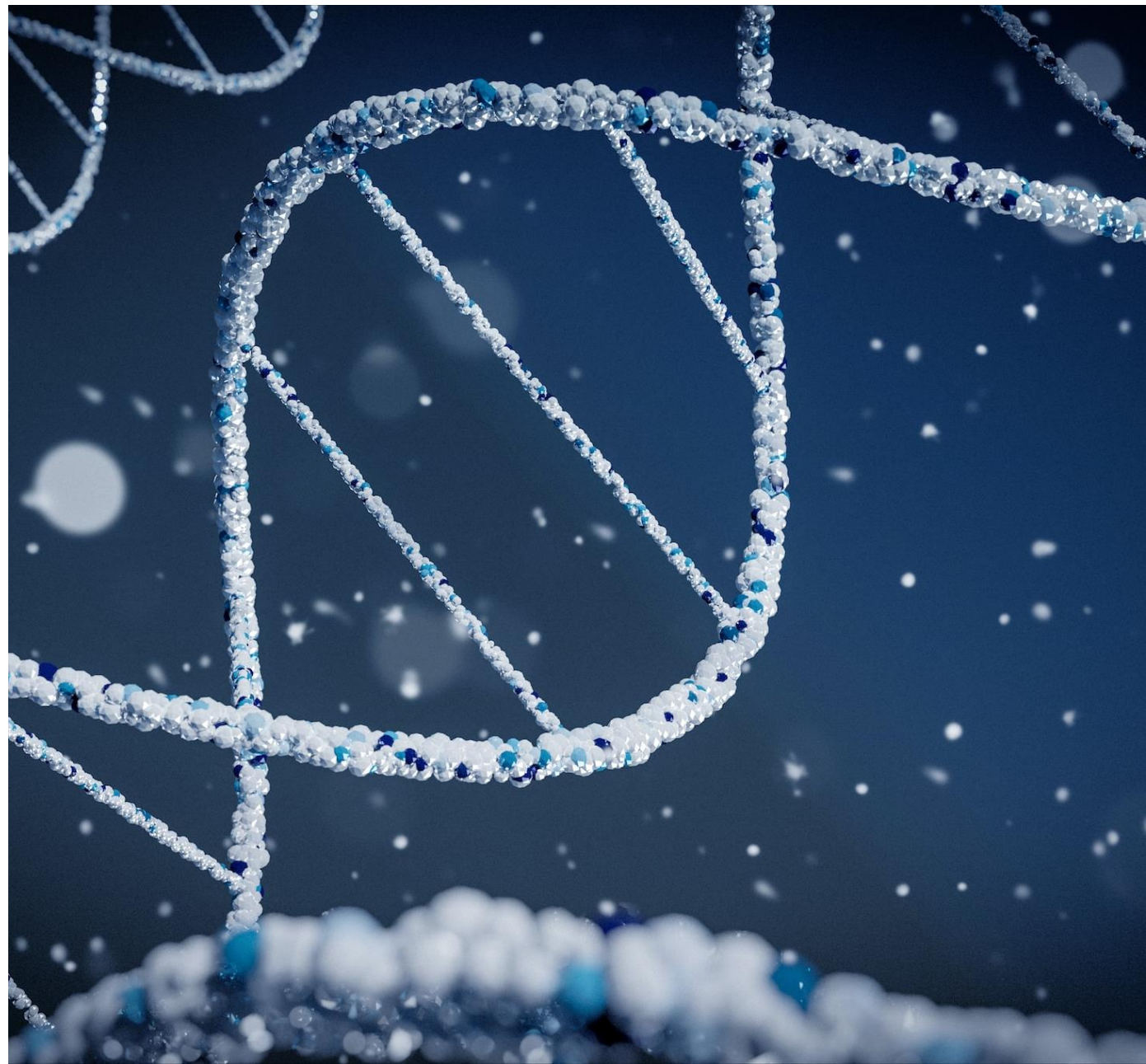
Medical devices in focus

- Increased number of market surveillance inspections
- Special provision in the Estonian Medical Devices Act:
 - Subsection 26(4) of the Estonian Medical Devices Act;
 - Every undertaking
 - who distributes on the market of Estonia
 - *[class IIa, IIb or III medical device / [...] / class B, C or D in vitro diagnostic medical devices],*
 - shall notify the Health Board thereof within 10 days after distribution of the relevant medical device for the first time.
- **Points to remember:**
 - Art 14 of MDR/IVDR
 - Register of complaints
 - Identification within the supply chain



Latvia

SORAINEN



New pricing model for prescription medicines in Latvia enforceable from 1 January 2025

- The new pricing model for prescription medicines developed by the MoH anticipates a 15-20% decrease in prescription medicines' prices:
 - A new wholesaler and pharmacy mark-up model for prescription drugs and reimbursable medicines.
 - **No changes** in respect of wholesale and pharmacy mark-ups for over-the-counter and unregistered medicines.
- In addition to the price of the medicine, the pharmacy will charge a fee for the pharmacist's service.



Wholesale and pharmacy mark-up for prescription drugs and reimbursable medicines per pack

- **Manufacturer's** price will not exceed the price in Lithuania and Estonia, manufacturer will only be able to make price changes once every 12 months.
- **Wholesale** - one fixed mark-up, regardless of price, adding to the manufacturer's price the correction amount of 0.50 euros and the VAT value.
- **Pharmacies** - fixed mark-ups in three price groups, i.e.:
 - price at which the pharmacy buys medicines from the manufacturer or wholesaler, excluding VAT (purchase price), plus adjustment amount and VAT value.
 - The amount of the adjustment is determined based on the purchase price: purchase price up to 2 euros – 0.50 euros; for the purchase price from 2.01 to 100 euros – 1.20 euros; for the purchase price over 100 euros – 2 euros.
- Both wholesalers and pharmacies will apply the maximum permitted price.

Fee for pharmacy service fee will be introduced

- A pharmacy fee for the pharmacist's service for the prescription at the first dispensing if the pharmacy (pharmacy branch) is the only pharmacy (pharmacy branch) in the given settlement.
- Fee amount 1.50 EUR per prescription served for large pharmacies and 2.50 EUR for small rural pharmacies.
- 0.75 euros of the said fee collected from the buyer, the rest covered from the state budget.
- Some purchaser groups exempted from the fee payment (for prescriptions issued for children under 18 years of age and needy persons, asylum seekers and Ukrainian civilians defined by the Law on the Support of Civilians of Ukraine).



Lithuania

SORAINEN



Political Background in Lithuania

- State Medicines Control Agency (VVKT) → No head for half a year. New head – Dovilė Marcinkė appointed in August 2024
- National Health Insurance Fund (VLK) → New head – Gytis Bendorius appointed in June 2024
- Ministry of Health (MoH) → MoH Arūnas Dulkys – dismissed from the office in August 2024 (Vice Minister Aurimas Pečkauskas appointed as MoH)
- The Parliament (Seimas) → New elections for Parliament in October 2024

(1) Disruptions in the supply of the reimbursed medicines

- Reported as major issue by the State Audit Office (Dec 2023): Adjustments to the list of reimbursed medicines (LRM) are not properly managed

Impact:

- Frequent changes in the LRM
- Uncertain availability of medicines

(2) Instructions for use (IFUs) for medical devices – may also be in English language (as of June 2024)

- 2 criteria must be met:
 - For professional use medical devices only
 - Only if the healthcare institutions/specialists agree
- Impact: better access of innovative devices at HCO
- Challenges: mindset of HCO personnel

(3) Medicines with Lithuanian e-prescriptions are now available in pharmacies in Latvia, Poland, Spain, Portugal, Greece And Estonia

- Impact: measurable benefits for patients in combination with remote healthcare services

(4) Competition Council updates Guidelines on “Activities of Associations: how not to infringe competition law”

- Inspired by famous “Pharmacies case”
- What’s new: if entities in association provide *false* information to the institution, it could be deemed as infringement of the Competition Law
- Impact: Even greater risk/more cases where lobbying activities could lead to a breach of the Competition law (risks: a fine of 10% of the global group’s revenue)

(5) New EU Health Technology Assessment Regulation (HTAR) – pharmaceuticals and medical devices

- Aims to make innovative health technologies more available to EU patients, reduce duplication of efforts by national HTA bodies
- EU → Clinical Assessment (benefits compared to existing treatments); National HTA → non-clinical assessment (economic, social and ethic)
- Entered into force in January 2022 and begins to apply as of January 2025 with full implementation in 2030



Lise-Lotte Lääne

Regional co-head of Life Sciences
& Healthcare sector group,
Counsel (Estonia)

lise-lotte.laane@sorainen.com



Marika Grunte

Senior Associate (Latvia)
marika.grunte@sorainen.com



Erika Žigutė

Lead of Life Sciences & Healthcare
sector group in Lithuania,
Senior Associate

erika.zigute@sorainen.com