LEGAL, ETHICAL, AND COMPLIANCE ASSESSMENT AND LEGAL PATH

Project: *AI-Driven OTC Medicine Vending Machine System in Latvia*
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1. Purpose of This Document

This document aims to evaluate the legal and regulatory framework for selling over-the-counter (OTC) medicines in Latvia and to determine whether the use of an automated vending machine model is currently allowed. It also discusses compliance requirements, ethical issues, and potential future regulatory developments.

2. Regulatory Framework Overview

The sale, storage, distribution, and advertising of medicinal products in Latvia are regulated by several legal instruments. Core regulations include:

Regulation	Source	Scope
Pharmaceutical Law	https://likumi.lv/ta/en/en/id/43127-pharmaceutical-law	Governs classification, registration, distribution, and pharmacy licensing
Procedures Regarding the Distribution and Quality Control of Medicinal Products	https://likumi.lv/ta/en/en/id/159645-procedures-regarding-the-distribution-and-quality-control-of-medicinal-products	Defines legal distribution channels and restricts vending machine sales
Regulations Regarding Operating of Pharmacies	https://likumi.lv/ta/en/en/id/207397-regulations-regarding-operating-of-pharmacies	Specifies pharmacy staffing, licensing, and operational obligations
Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Distribute Free Samples of Medicinal Products to Physicians	https://likumi.lv/ta/en/en/id/230392-procedures-for-advertising-medicinal-products-and-procedures-by-which-a-medicinal-product-manufacturer-is-entitled-to-distribute-free-samples-of-medicinal-products-to-physicians	Regulates how OTC medicines may be presented and promoted

3. Key Legal Barriers Identified

Area	Regulation	Chapter/Paragraph	Status Impact
Automated retail of medicines prohibited	Procedures Regarding the Distribution and Quality Control of Medicinal Products	Chapter 77	The distribution of medicinal products in vending (sales) machines is prohibited.
Only pharmacies may sell medicines	Pharmaceutical Law	Section 25. (1)	Preparation of medicinal products, manufacture, importation, and distribution of medicinal products in the Republic of Latvia shall only be permitted if the special permit (license) has been obtained for the relevant type of commercial activity
Pharmacist supervision required	Regulations Regarding Operating of Pharmacies	Sectios 3,7,10,17	According to Sections 3, 7, 10, and 17 of the Regulations Regarding Operating of Pharmacies, medicines may only be dispensed by a licensed pharmacy with a supervising pharmacist, making unsupervised vending machines legally prohibited.
Storage & safety requirements	Procedures Regarding the Distribution and Quality Control of Medicinal Products	Sections 18,21,26,27,33	Medicinal products must be stored under regulated environmental, traceability, and safety conditions that traditionally require controlled premises and pharmacist oversight. A standalone vending machine does not yet meet the required storage, monitoring, or quality-control obligations.
Advertising restrictions	Procedures for Advertising Medicinal Products and Procedures by Which a Medicinal Product Manufacturer is Entitled to Distribute Free Samples of Medicinal Products to Physicians	Sections: 2, 4, 5.1.-5.5, 7.1-7.3, 11.1-11.3, 16, 18.1-18.12	Under Cabinet Regulation the vending machine interface and chatbot legally count as advertising. Therefore, messaging must remain strictly factual, non-promotional, and compliant with section 7, 16, and 18. The prototype cannot provide treatment suggestions, promote brands, display discounts, or encourage use, and must include the mandatory warning: "Zāļu nepamatota lietošana ir kaitīga veselībai", "Unreasonable use of medicines is harmful to health".

4. Compliance Risks

Risk Type	Description	Risk level	Mitigation Strategy	Owner
Legal Risk	Deployment would violate Regulation No. 416 (vending prohibition) and Pharmaceutical Law licensing requirements.	High	Treat project as a research prototype only; include legal compliance review and clearly label as non-deployable under current regulation.	Product & Domain Lead
Safety Risk	Unsupervised access may lead to inappropriate medicine choice, incorrect dosing, or unsafe use (especially with children's medicines).	High	Implement mandatory safety warnings, usage limits (1 product per 24h), age separation logic, and disclaimers; require confirmation before dispensing.	App & Chatbot Developer
Ethical Risk	Lack of pharmacist oversight may negatively impact vulnerable users (children, elderly, low health literacy).	Medium	Use symptom-based chatbot guidance with conservative safety rules (e.g., “consult a pharmacist/doctor if unsure”); avoid medical diagnosis.	Ethics Lead / Product Owner
Data Protection Risk	Facial recognition triggers GDPR obligations (consent, retention limits, user rights, privacy safeguards).	Medium	Implement explicit consent screen, temporary storage (max 24 hours), anonymisation techniques, and “withdraw / delete data” option.	Data Engineer & Privacy Compliance

5. Ethical Controls (Prototype Phase)

For this university prototype, the following safeguards are implemented:

- No real medicine is dispensed.
- Only simulated or anonymised data is used.
- Safety disclaimers included in chatbot interaction.

- Facial recognition data stored only temporarily (max. 24 hours) and deleted automatically.
- The system does not diagnose health conditions.

6. Future Legal Pathway (For Real-World Deployment)

To enable lawful deployment of OTC vending machines in Latvia, the following regulatory changes would be needed:

Required Change	Relevant Law / Authority	Proposed Action
Legalise the sale of OTC medicines via automated vending machines	**Cabinet Regulation No. 416 — *Procedures for the Distribution and Quality Control of Medicinal Products*** (currently prohibits vending machine sale)	Amend the regulation or introduce a legal exception explicitly allowing certified automated dispensing devices for OTC medicines.
Create a licensing and compliance category for automated medicine retail	**Pharmaceutical Law of the Republic of Latvia and Cabinet Regulation No. 288 — *Regulations Regarding Operating of Pharmacies***	Establish a new legally recognised class: Automated Pharmacy Outlet, defining licensing requirements, operating conditions, and pharmacist supervision obligations.
Define technical storage, safety, and monitoring standards for automated dispensing	**Cabinet Regulation No. 416 — Procedures for the Distribution and Quality Control of Medicinal Products**	Specify requirements for: temperature-controlled storage, expiry tracking, automated logs, controlled access, and product traceability compatible with State Agency of Medicines requirements.
Establish remote supervision, audit, and safety control framework	**Ministry of Health (MoH)** + **State Agency of Medicines (ZVA)** regulatory authority	Introduce rules requiring remote pharmacist validation, AI-assisted symptom warnings, age verification, restricted purchasing limits, and compliance audits.
Support legal reform using demonstrated public demand	**Public Civic Initiative** — *ManaBalss.lv Petition (2018–present)*: "Allow OTC medicines in supermarkets and vending machines"	Use petition data as a policy justification mechanism in government proposals and stakeholder discussions to demonstrate national demand and access gap. Link: https://manabalss.lv/i/3732"

7. Conclusion

Under Latvia's current legal framework, OTC medicine vending machines cannot be deployed because pharmaceutical regulations explicitly ban automated distribution. They also mandate pharmacy licensing, controlled storage, and pharmacist involvement in dispensing. Consequently, this work functions solely as a research prototype and simulation, not as a deployable real-world solution.

Despite these limitations, the project shows how this kind of solution could be safely used in the future. It integrates AI-driven demand forecasting, regulated OTC product choices, ethical safeguards, stock monitoring, purchase caps, remote oversight, and GDPR-compliant identity verification. The system acts as a model for how automated access can enhance healthcare access, especially in underserved or rural areas.

If future regulatory changes occur, the proposed system can enable secure, compliant, and fair public access to OTC medicines, all while safeguarding patient safety and ensuring legal accountability.