**Cabinet of Ministers Regulation No 537**
In Riga, 31 July 2012 (prot. No 42 50.§)

**By-laws of the State Agency of Medicines**

*Issued pursuant to Section 4, Paragraph 2 of the Public Agencies Law*

**I. General Provisions**

1. The State Agency of Medicines (hereinafter – Agency) is a state institution which is under the supervision of the Minister for Health. The Minister for Health shall implement the supervision through the Ministry of Health.

2. The aim of Agency’s operation is to provide qualitative and justified services in evaluation of medicinal products used in healthcare, procurement and utilisation sites of human blood, tissues, cells and organs, as well as pharmaceutical activity companies according to state and public interests in the field of healthcare.

**II. Functions, Tasks and Rights of the Agency**

3. By providing services to private persons, state and municipal institutions and foreign institutions, the Agency performs the functions laid down by the Pharmaceutical Law, Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors and other normative acts.

 (As amended by CM [05.07.2022.](https://likumi.lv/ta/id/333812-grozijumi-ministru-kabineta-2012-gada-31-julija-noteikumos-nr-537-zalu-valsts-agenturas-nolikums-) Regulation No 404)

4. The Agency shall perform the following tasks:

4.1. Evaluation and registration of medicines, expertise on the quality of medicines, establishment and updating of the Medicinal Product Register of Latvia;

4.2. Pharmacovigilance;

4.2.1 Assessment of compensation claims for established severe or moderate harm to health or life caused by an confirmed adverse drug reaction to a COVID-19 vaccine, determining the amount of compensation, granting and payment of compensation;

4.3. Issuance of authorisation for conduct of clinical studies with medicines, clinical trial compliance evaluation with the requirements of good clinical practice, as well as evaluation of applications for non‑interventional studies;

4.4. Issuance of permits for import, export, transit, distribution and acquisition (to ensure own operation) of medicines, as well as permits for use of herbs, substances and medicines included in the lists of narcotic substances, psychotropic substances and precursors controlled in Latvia for medical and veterinary medical scientific studies, testing of physical and chemical properties and for training;

4.5. Regular collection and distribution of information on consumption of medicines;

4.5.1 Assessment of the cost-effectiveness of health technologies;

4.6. Registration of precursor operators and users, and issuance of special permits (licences) for work with precursors;

4.7. Registration of medical devices manufactured in Latvia, issuance of permits for release of specially supplied medical devices in circulation, as well as vigilance of medical devices;

4.7.1 Approval of health technologies utilised in healthcare, registration of approved health technologies, establishment and maintenance of approved health technology records and database of health technologies financed from the state budget;

4.8. Issuance of authorisation for clinical trials with medical devices;

4.9. Issuance of compliance certificates to procurement (utilisation) sites for tissues, cells and organs, blood transfusion rooms of medical treatment institutions, blood preparation divisions and the State Blood Donor Centre;

4.10. Issuance of special permits (licences) for pharmaceutical activity;

4.11. Issuance of certificates for compliance with good manufacturing practice;

4.12. Participation in the unified systems of medicines agencies and medical device agencies of European Economic Area countries, collaboration with European institutions and international organisations by participating in work‑sharing and complying with unified standards and procedures;

4.13. Cooperation with professional organisations of doctors and pharmacists, non‑governmental organisations in this field, foreign and international institutions, as well as ensuring mutual exchange of information related to the areas of Agency’s operation;

4.14. Performance of the tasks of a competent authority in accordance to the requirements laid down by:

4.14.1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

4.14.2. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004;

4.14.3. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004;

4.14.4. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products;

4.14.5. Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products;

4.14.6. Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council;

4.15. Performance of other tasks laid down by normative acts.

 *(As amended by CM* [*02.07.2019.*](https://likumi.lv/ta/id/307996-grozijumi-ministru-kabineta-2012-gada-31-julija-noteikumos-nr-537-zalu-valsts-agenturas-nolikums-) *Regulation No 301; CM* [*05.07.2022.*](https://likumi.lv/ta/id/333812-grozijumi-ministru-kabineta-2012-gada-31-julija-noteikumos-nr-537-zalu-valsts-agenturas-nolikums-) *Regulation No 404)*

5. The Agency shall have the following rights:

5.1. Request and receive without any fee the information required for performance of Agency’s functions and tasks from state and municipal institutions, as well as from private persons and legal entities according to the procedure laid down by normative acts;

5.2. Receive a fee for the public services provided by the Agency in the amount laid down by the Cabinet of Ministers;

5.3. Invite experts, as well as establish expert councils and commissions in order to perform Agency’s functions;

5.4. Organise conferences, seminars, courses, training and other educational and informative events according to the area of operation;

5.5. According to Agency’s competence, sign contracts with state and municipal institutions, non‑governmental organisations, private persons and legal entities, as well as foreign institutions and international organisations.

**III. Administration, Assurance of Operational Lawfulness and Oversight of the Agency**

6. Director of the Agency is a state civil servant who is appointed and whose appointment is terminated by the Minister for Health.

7. Director of the Agency may have deputies – state civil servants.

8. Decisions and actual action of the officials of the Agency’s structural units may be contested by submitting an appropriate application to the director of the Agency. Decisions adopted by the director of the Agency may be appealed in administrative court.

9. Administrative acts (except the decision mentioned in Article 8 of this Regulation) issued by the director of the Agency and actual action may be contested at the Ministry of Health. Decisions adopted by the Ministry of Health may be appealed in administrative court.

10. The Agency shall prepare and submit to the Ministry of Health a regular and annual report on its operation and use of financial resources.

11. Upon request from the Ministry of Health, the Agency shall provide information on Agency’s operation and use of financial resources.

**IV. Closing Provisions**

12. Repeal Cabinet of Ministers Regulation No 1006 of 7 December 2004 “The Statutes of the State Agency of Medicines” (Official Publisher of the Republic of Latvia, 2004, 196.no; 2005, 172.no; 2009, 157.no).

13. This Regulation shall come into effect on 1 January 2013.

Prime Minister V.Dombrovskis

Minister for Health I.Circene