State Institute for Drug Control – Organisational structure valid from 1. 1. 2024

DIRECTOR

- Internal Audit and Control
- Information Security Manager
- Quality Manager

- Press and Information Unit
- Human Resources and Education Unit
- Director's Support Unit

- Coordinator of Professional Agendas

Surveillance Section
- Expert Support
- Lawyer
- Advertising Surveillance Unit
- Quality Defects Unit
- Data Analysis Unit
- **Inspection Department**
  - Assistant
  - Good Manufacturing Practice Unit
  - Surveillance over Biological Materials Unit
  - Clinical Practices Unit
- **Pharmacy and Distribution Department**
  - Regional Pharmaceutical Control Units 31210-31280
  - Good Distribution Practice Unit
- **Laboratory Control Department**
  - Analytical Chemistry Unit
  - Biological Methods Unit

Marketing Authorisation Section
- Assistant
- Lawyer
- **Pharmaceutical Documentation Assessment Department**
  - Assistant
  - Chemical and Herbal Products Assessment Unit
  - Chemical Products in Clinical Trials Assessment Unit
  - Unit of Biological Products Assessment, Incl. Clinical Trials
  - Variation Assessment and Parallel Import Unit
- **Clinical Trials of Medicinal Products Department**
  - Assistant
  - Clinical Trials of Pharmaceuticals Unit
  - Coordination and Administrative Unit
- **Administrative and Procedural Support Department**
  - Assistant
  - Implementation and Assessment of Product Names and Mock-ups Unit
  - MRP Applications Unit
  - MA Section Validation Unit
  - MA Data Support Unit
  - National Applications Unit
- **Coordination and Regulation Department**
  - Assistant
  - MA Procedures Coordination Unit
  - National Regulation Unit
- **Pharmacovigilance Department**
  - Pharmacovigilance Assessment Unit
  - Pharmacovigilance Inspection and Data Support Unit
- **Non-Clinical and Clinical Assessment Department**
  - Regulatory Manager
  - Centralised Procedures Coordinator
  - Non-clinical and Bioanalysis Assessment Unit
  - Clinical Assessment Unit

Section of Pricing and Reimbursement Regulation
- Validation and Administrative Support Unit
- Technical Support Unit
- **Pricing and Legal Support Department**
  - Data and Analytics Unit
  - Legal Support Unit for Price and Reimbursement Regulation
  - Unit of Selected Types of Administrative Proceedings
- **Health Technology Assessment Department**
  - Medicines Evaluation Unit
  - Health Economics Unit

Medical Devices Section
- Assistant
- Unit of Systems
- Legal Support Unit
- Medical Devices Reimbursement Unit
- **Expert Activities Department**
  - Medical Devices Clinical Evaluation Unit
  - Expert Opinions Unit
  - Registration and Notification Unit
- **Market Surveillance Department**
  - Medical Devices Advertising Surveillance Unit
  - Medical Devices Market Surveillance Unit
  - Medical Devices Vigilance Unit

Director and Management Support Section
- Section Officer
- Medicine Shortage and Availability Unit
- Unit of International Relations
- **Legal Department**
  - Legislation Lawyer
    - Infractions Unit
    - Public Contracts and Project Management Unit
  - Unit of Legal Activities
- **Information Technology Department**
  - Assistant
    - IT Management Support Unit
  - Lawyer
    - ePrescription Unit
  - Operations Unit
    - Business Analysis and Development Unit
- **Economic and Operational Department**
  - Accounting Unit
    - Documentary Service and Mailroom Unit
  - Budget and Financing Unit
    - Operations and Transport Unit