State Institute for Drug Control – Organisational structure valid from 1. 4. 2025

SÚKL

DIRECTOR

- Internal Audit and Control
- Communications and Director Support Unit
- Medicine Shortage and Availability Unit
- Department of the Director´s office
  - Unit of Legal Activities
  - Infractions Unit
  - Unit of International Relations
  - Unit of Civil Service Education and Quality Management

Surveillance Section
- Advertising Surveillance Unit
- Quality Defects Unit
- Surveillance Support Unit
- Inspection Department
  - 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
- Coordinator of Cross-sectional Agendas
- 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
  - 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
  - European Regulatory Affairs manager
  - 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
  - Registration and Notification Unit
  - Expert Opinions Unit
- Market Surveillance Department
  - Medical Devices Market Surveillance Unit
  - Medical Devices Vigilance Unit

Finance and Operations Section
- Section Officer
- Information Security Manager
- Human Resources Unit
- Documentary Service and Mailroom Unit
- Public Contracts and Project Management Unit
- Information Technology Department
  - Assistant
  - Operations Unit
  - IT Management Support Unit
  - ePrescription Unit
  - Business Analysis and Development Unit
- Economic and Operational Department
  - Accounting Unit
  - Budget and Financing Unit
  - Operations and Transport Unit