

CONNECTED THROUGH SUCCESS

# THE LIFE CYCLE OF THE MEDICINAL PRODUCT "HAVELEX"



Our Czech-Slovak team focusing on pharmaceutical and health law is the largest on the market, offering a unique, long-established expertise. As we know both the law and the market practice, we are ready to assist you at any stage. With the support of the largest independent law firm in the CEE region, we can provide comprehensive assistance in any legal area, such as regulation, competition law, public procurement, IP/IT, personal data, taxes, etc. We advise the world's leading pharmaceutical companies on a daily basis. We successfully set up new distribution models as well as business and communication strategies. In the health law category, we were awarded Czechia's Law Firm of the Year in 2021 and 2023 and Slovakia's Law Firm of the Year in 2023.



### New drug (molecule)

- Patent application
- Technology transfer & licensing
- Pre-clinical trials



#### **Clinical trials**

- Contractual relationships: hospitals & investigators
- Clinical research organisations
- Informed patient consent
- Provision of the drug after the end of the clinical trial (post-trial access)
- Regulatory aspects: personal data
- Indemnity for injury to health

#### **Unauthorized medicine** supply & use

- Compassionate use programmes
- Special permit
- Reimbursement

#### Marketing authorization

Variation to and transfer of the marketing authorization

# Reimbursement

- Reimbursement procedures
- Contracts with payors (risk-sharing)
- Price regulation
- Orphans & advanced therapy

### **Distribution model**

- Traditional distribution model
- Direct distribution (direct-to-pharmacy / direct-to-hospital)
- Agency model
- Competition law and tax assessment
- Contract with a logistics partner
- Contracts with distributors
- Good distribution practice
- Waste management

#### Incidents along the road

- Recalls
- Product liability
- Proceedings initiated by regulators
- Borderline cases
- Relationships with competitors, regulators and payors

# App for patients

- Software development contracting
- Regulatory aspects
- Personal data

#### **Data collection** and purchase

- Non-intervention study
- Health registries
- Market research

# Compliance

- Interactions with HCPs - provision of services. attendance to events
- Sponsorships and grants
- Patient support programmes
- Codes of conduct local industry associations
- Whistleblowing
- Personal data
- Compliance audit & due diligence

## Communication strategies

- Advertisement & marketing campaigns
- Consumer competitions
- Awareness campaigns

# **Business strategies**

- Contracts with customers
- General terms and conditions
- Public procurement
- Pricina schemes
- rebates and discounts
- E-shop setup
- Consumer protection



- New indication
- Investigator-initiated study



#### **Expiry of patent protection**

- Market entry of generics and biosimilars
- Infringement of a patent or supplementary protection certificate
- New business strategy
- Marketing authorization transfer











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