ÁDLER & KÜRTÖSI

REIMBURSEMENT AND FUNDING OF MEDICAL DEVICES IN HUNGARY

Overview

ABOUT THE PRESENTATION

This presentation material has been prepared at the joint request of ETOSZ and OSZ.

The Association of Health Technology Suppliers and Medical Device Manufacturers (ETOSZ) is the trade association of the innovative medical technology sector in Hungary. ETOSZ's mission is to make the results of medtech innovation available to Hungarian patients. Its member companies include renowned manufacturers and suppliers of state-of-the-art medical technologies.

The Association of Medical Devices Manufacturers (OSZ) is a recognized and influential lobbying organization in the Hungarian healthcare sector that unites and represents companies that supply inpatient and outpatient care facilities with medical devices, imaging diagnostics, and medical aids, as well as ICT companies that service the medical sector. It has been a member of MedTech Europe since 1998.

FLUENT IN YOUR BUSINESS.

Ádler&Kürtösi provides deep knowledge of local regulatory and business environment at your fingertips.

WHO WE ARE

We at Ádler & Kürtösi are highly committed to ensure legal services of the highest quality for you based on our substantial professional experience with deep knowledge of the local regulatory and business environment. Based on clear understanding of your business strategies and legal needs we combine extensive industry knowledge with sound business advice and skilled legal counsel in our roles as trusted advisors.

OUR BUSINESS IS MINDING YOUR BUSINESS

Focus on tailor-made support and development of proper and feasible solutions for you with effective and cost-efficient guidance to foster your business objectives via due actions that meets even the most sensitive legal challenges.

KEY AREA OF EXPERTISE: LIFE-SCIENCES

Complete legal support for players at the field of pharmaceuticals, biologics, health technologies and wider life sciences from „greenfield" investments, strategic planning to execution of successful business operation:

- development of internal business regulation, licensing and regulatory procedures ; full-scale SOP- integrated compliance services;
- sales and marketing activities in the wider health industry ;
- administrative procedures and investigation of Authorities, advice on clinical trials
- business process optimization; special business concerns of acquisition of rights, infringement cases, enforcement and prevention of sanctions and litigations
- data management

Dora Adler, managing partner

20+ years of special experience at the field of regulated business of pharma and medtech companies, private healthcare providers and health insurers. Solid and comprehensive knowledge on local and international Code of Conducts, practice of Authorities and commercial activities, professional and laic communication of Pharma and MedTech companies, clinical trials, complex patient adherence programs

Emese Kürtösi, senior partner

Two decades of unique experience on regulated markets of health industry, deep and special knowledge on proceedings of the relevant authorities. Former deputy head of the department responsible for HC investigations (Hungarian Competition Authority), senior executive responsible for investigations (Health Insurance Supervision Authority).

GENERAL OVERVIEW OF THE HUNGARIAN HEALTHCARE SYSTEM

Extremely centralized public healthcare system

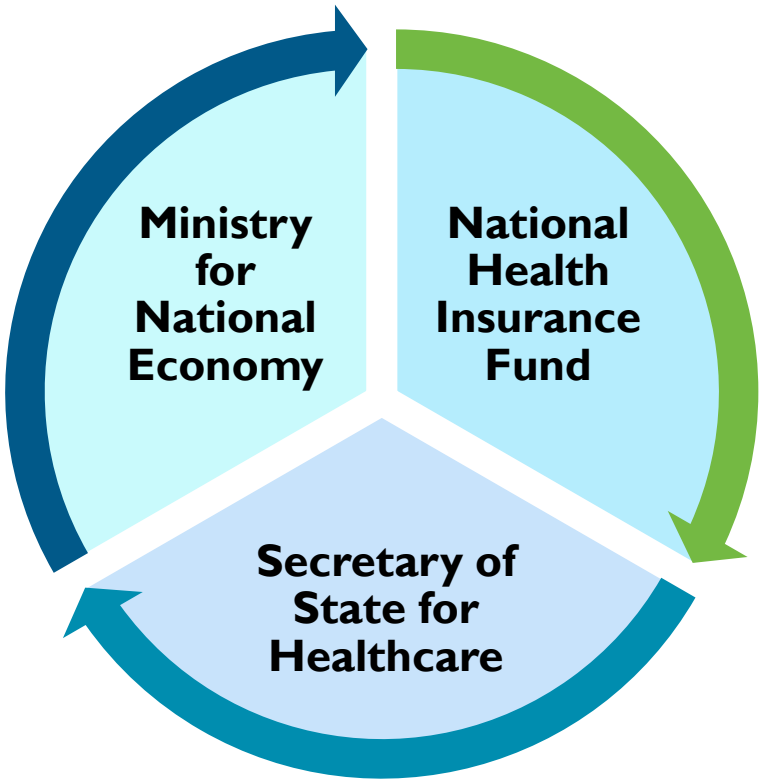
The State is the primary and most dominant entity responsible for operating and funding healthcare

Main source:
social insurance contribution

Hungary's centralized system operates through mandatory social health insurance, with NEAK *(National Health Insurance Fund of Hungary)* as the central payer and multiple ministries controlling the €0.5B medical device budget.

Private healthcare sector plays ever-growing relevancy, but mixing private and public services is not allowed.

MARKET ACCESS



Hospital devices face triangular approval between NEAK, the Secretary of State, and Ministry of Economy, while **medical devices used in outpatient care** require technology assessment and functional group classification.

Market access of medical devices used in outpatient care is subject to a detailed, bureaucratic (and slow) procedure based on MAH request for new products/ price revision or ex officio for de-listing, revision of functional class etc.

REIMBURSED PRICE

Two main channels for health insurance coverage

1. inclusion into reimbursement system *(devices that can be sold directly to consumers)*
   - The contents of the application is prescribed by law.
   - The application may only be submitted to the health insurance authority by a qualified marketer registered at the health insurance authority.

2. centralized public procurement *(supply of medical devices to healthcare institutions)*

Adjudication of application for inclusion: 90 days

KEY REQUIREMENTS FOR SUCCESSFUL APPLICATIONS

Beyond basic CE certification, Hungary demands supplier pre-qualification, quality management verification, and service background documentation.

ADVERTISING

- **Advertising**
  → B2C communication towards patients/consumers
- **Presentation/promotion**
  → B2B communication towards HCP

Rules differ

- for medical devices and medical aids
- for reimbursed (Rx) and non-reimbursed (OTC) products
- B2B and B2C communication

ADVERTISING

Reimbursed devices shall face **strict advertising limitations** with narrow website exceptions, while B2B promotion requires registered representatives with specific qualifications.

REGISTRATION

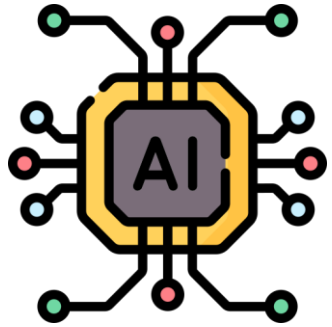
MDR/national medical device registration

Hungarian distributors must submit comprehensive documentation including Hungarian-language instructions, EU declarations of conformity, and detailed product specifications.

THE FUTURE IS AI
THE CHALLENGE IS COMPLIANCE

EU regulations - direct application in the EU

- MDR
- GDPR
- AI Act



AI-based medical devices face dual regulation under both MDR and the AI Act, with specific requirements for risk management, data governance, and human supervision.

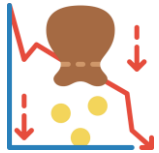
According to the MDR concept, software/AI-based systems can also be medical devices.

CHALLENGES

Slow entry into reimbursement system

Untransparent factors

Diverse accessibility



Poor financial resources

Beyond bureaucratic hurdles and hospital debt challenges lies a growing private healthcare sector and expedited pathways for innovative technologies.

For more information about the training please contact:
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You can contact us with any legal questions you may have at:
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