

## FOPI Impulses for a Strong Life Science and Pharma Strategy

Austria is increasingly under pressure in the global competition for research and innovation. While the U.S. and China view health technologies as strategic future assets and scale up investments massively, Europe risks falling further behind. Without an innovation-friendly environment, Austria risks losing clinical trials, research activities and product launches – with consequences for patient access, jobs and competitiveness.

At the same time, Austria benefits from strong talent, scientific excellence and established structures that can serve as a launching pad. An ambitious Life Science Strategy that covers the full innovation cycle – from research to reimbursement – is therefore essential to strengthen Austria as an attractive, resilient and competitive location.

### Areas of action for a strong strategy

#### 1. Accelerating Market Access Pathways

A fast and innovation-friendly market access system is essential to ensure timely availability of modern therapies and to strengthen Austria as a competitive location.

- **Modernization of the reimbursement code (EKO)**
  - Recognizing the value of innovative medicines across the entire lifecycle
  - Increased and sustained investment in innovative medicines recognizing them as a strategic investment in health, an overall catalyst for economic growth, and a pillar of health security
  - Introducing a value-based pricing framework with clear and transparent assessment criteria reflecting benefits to patients, the health system and the economy
  - Modern definition of innovation: considering incremental improvements, including indication extensions of existing medicines
  - Removal of the additional discount applied to the EU average price in the No-Box
  - Replacing the EU average price mechanism with a basket of countries with comparable purchasing power
  - Introduction of a reimbursement bonus reflecting supply security, quality and economic value creation
  - Submission for pricing and reimbursement based on the CHMP opinion to ensure immediate access upon marketing authorization
- **Reform of the hospital evaluation board**
  - Immediate availability following EU marketing authorization, without delays caused by fragmented evaluation processes
  - Involvement of marketing authorization holders, scientific expertise and patient representatives in evaluation process

## 2. Strengthening Clinical Research

The number of newly initiated clinical trials has decreased by 28% within just three years—clear evidence of urgent need for reform <sup>1</sup>.

- **Establishing a central ethics committee** to accelerate and harmonize clinical trial approvals
- **Expanding existing funding programs** and opening them to pharmaceutical research and international studies
- **Sustainable financing:** permanent research staff positions, adequate remuneration of physicians' research time, structured project coordination, expansion of hospital research infrastructure
- **Expanding the role of the “principal investigator”** to other professional groups to relieve medical staff
- **Standardized contract clauses, fast processes and digital approval procedures** to reduce administrative burden on study centers
- **Promoting decentralized study models:** video consultations, wearables, satellite centers, digital signatures
- **Allowing direct-to-patient distribution of investigational medicinal products** – already common practice in numerous EU countries
- **Recognizing clinical trials** conducted in Austria as tax-deductible research expenditure

## 3. Securing Applied Research, Development and Production

The recently presented national industrial strategy is a positive signal. To secure Austria as a long-term production and development hub, strong industrial policy measures are required.

- **Tax exemptions** and investment incentives without caps – including for large enterprises
- **Accelerated and transparent funding procedures** with reliable planning security
- **Increasing and adjusting existing research funding** (FFG, aws, targeted programs) for inflation
- **Technology funding** in key areas such as biotechnology, automated production and sustainable energy systems
- **Simplifying and accelerating regulatory approval processes** (e.g., import licenses, certificates of marketability)

## 4. Using Health Data Effectively and Securely

A modern health system requires contemporary, secure and interoperable data use that supports care and scientific progress.

- **Establishing a national health data platform** enabling controlled, pseudonymized secondary use for research and public health
- **Reducing data silos** through mandatory, harmonized national registries and improved connectivity between hospitals, social insurance institutions and research organizations
- **Enabling research access to ELGA and expanding access to the Austrian Microdata Center (AMDC)** - also for private-sector research organizations

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<sup>1</sup> PHARMIG-„Daten & Fakten 2025“