swissmedic

# Swissmedic under one roof

Vincenza Trivigno
Executive Director Swissmedic

# Our legal mandate: to protect public health

We ensure the quality, safety and efficacy of therapeutic products in Switzerland.







# Therapeutic products are...

- **Medicinal products**
  Products of chemical or biological origin that have a targeted pharmacological effect on the body (includes blood and blood products)

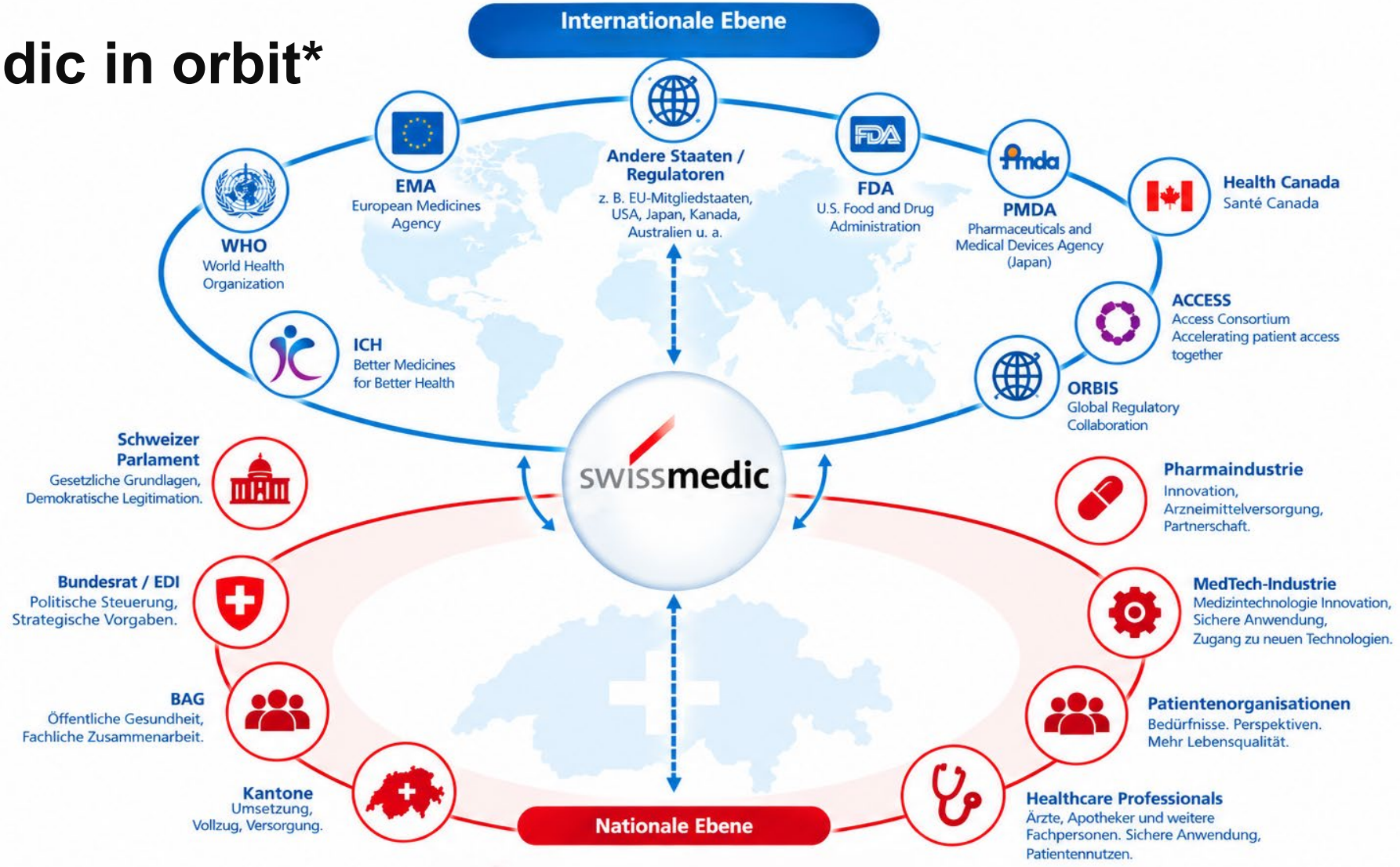
- **Medical devices**
  Products – including instruments, apparatus, implants, in vitro diagnostic medical devices, software and other items or materials – that are intended for medical use.

# Challenges & strategic priorities

## From free skating to compulsory figures

swissmedic

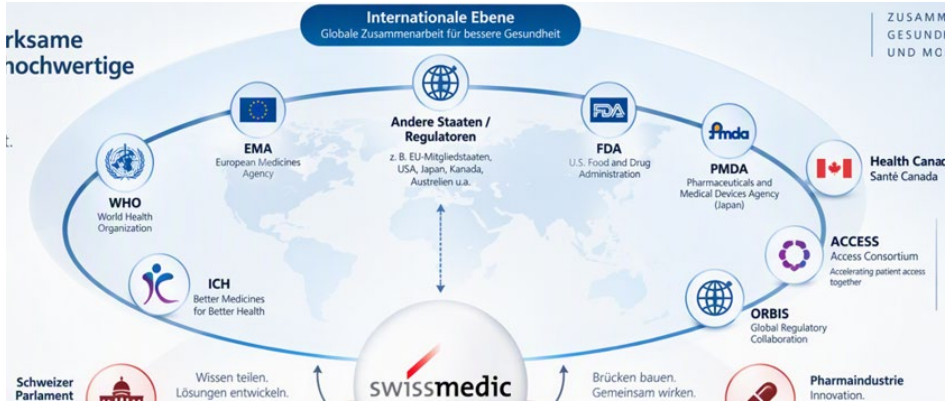
# Swissmedic in orbit*




by Copilot

# Challenges – global view (“up in the sky”)

- Rapid development in science and technology
  → including therapeutic procedures, AI
- Demanding regulatory environment
  → including gap between innovation and regulation
- International networking & cooperation essential
  → harmonisation vs. autonomy
- Changes in society
  → including transparency vs fake news & bubbles

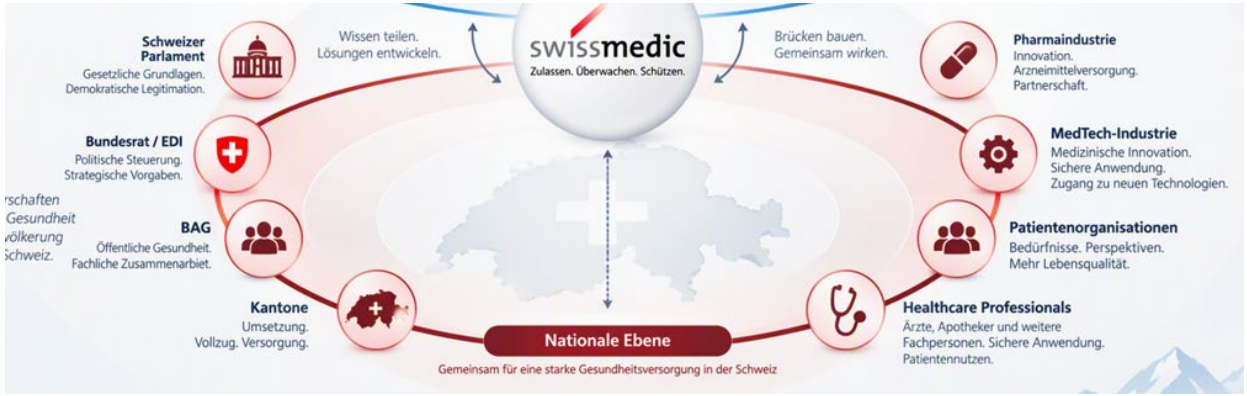


# Challenges – national view (“down to earth”)

- Financial situation
  → reputation has suffered

- Swissmedic’s role
  → Swissmedic’s autonomy in question, political influence

- Replacement of legacy systems not complete
  → costs still high

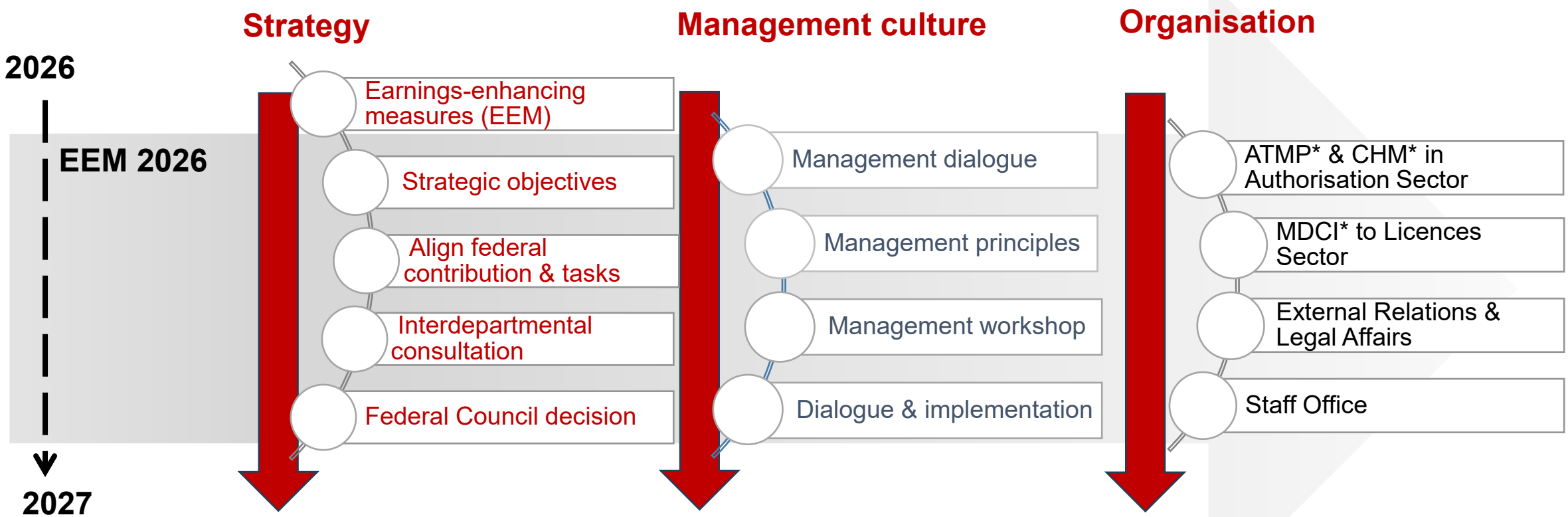


# Opportunities – Swissmedic under one roof

- **New strategy period 2027 – 2030**
  - Review tasks and refine strategic objectives
  - Adjust vision
  - Align federal contribution to assigned tasks
- **Adapt organisation to tasks & resources**
- **Strengthen management and concept of leadership**



# Opportunities – Swissmedic under one roof




**2027 → Focused strategy with clear management principles & adapted organisation**

swissmedic

*ATMP: advanced therapy medicinal products; CHM: complementary and herbal medicines; MDCI: medical devices clinical investigation

# Objectives 2027 – 2030

## Compulsory programme – mandatory strategic objectives

- Ensure sustainable financing including financing legally mandated services
- Provide robust, updated IT landscape for effective performance of tasks

## Free programme – elective strategic objectives (→ core competence)

- Contribute to strengthening Switzerland as a hub for life sciences
  → Promote innovation through prioritised use of resources & smart regulations
- Create trust through dialogue and make impact clearly understandable
  → Communicate in an understandable and audience-appropriate manner

# Management & organisation

- Short channels
- Focus
- Harmonise internal and external perspectives



→ Leadership & management as strengths
→ Expertise serves to focus

swissmedic

# New vision of Swissmedic – Swissmedic as an asset

**Swissmedic**
**For safe therapeutic products and effective innovation – for the benefit of humans and animals.**

# Strategic perspective

## … from a bird's eye view

**Agile access pathways**

for next-generation therapeutic products combined with

**smart post-market surveillance**

To enable faster patient access through proportionate benefit-risk assessments, recognising that risk tolerance varies according to disease severity & unmet medical need