



## **Innovation Office – Lessons Learned**

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## What's it all about?

*"...and finally, we have to go to Swissmedic so they can destroy our product..."*



# Federal Council decisions



## Master plan

- **Federal measures for the promotion of biomedical research and technology 2022–2026**

## Strategic objectives 2023–2026

- **Swissmedic supports the development of novel therapeutic products and helps ensure swift access to innovative therapies.**



# Innovation Office pilot project

## Objectives

- To be **more accessible** as a regulator
- To provide more regulatory and scientific advice, particularly for **early development phases**
- To spread regulatory **knowledge**
- To identify and prepare for **future trends**

## Approach

- Dare, fail, **learn** and retry
- **Opportunistic** approach – invest in functioning approaches
- **Refine** the Innovation Office model during the introductory phase
- The pilot phase is restricted to cell and gene therapies (**ATMPs**)

# Findings derived from

- **Survey** of regulators
- **Literature** review
- Stakeholder **interviews**
- **Pilot** Innovation Office for ATMPs
- **Stakeholder survey** of ATMP ecosystem



# Survey of regulators

- Generally positive experience (1963 to present)
- Early dialogue is crucial for success
- Highly innovative therapies at the centre
- Focus on clinical trials and development plans
- Very different focus among stakeholders
- Diverse organisational forms



# Literature review



- Small companies benefit most
- Complex therapeutic products benefit more
- Submissions speeded up
- Fewer rejections, conditions and queries
- It helps if stakeholders abide by advice

# Stakeholder interviews



- Undisputed need for advice
- Overall therapeutic product life cycle
- Start-ups, SMEs, researchers and universities
- Desire for scientific, regulatory and business advice
- Teaching events would be very helpful
- Warning against a consumer attitude – "Swissmedic should solve my problem"



# Pilot Innovation Office for ATMPs



- Commenced 1 Jan. 23 – Regular operation 29 May 24
- >140 individual advice sessions
- Undisputed need and very positive reaction from stakeholders
- Start-ups, SMEs, researchers and universities
- Face-to-face greatly appreciated (Geneva, Lausanne, Allschwil and Zurich)
- Cooperation is key



## Stakeholder survey of ATMP ecosystem

- Small and large companies are better catered for than medium-sized ones
- Strong desire for greater and more frequent dialogue
- Visibility is still too low
- International harmonisation of regulations is still not visible enough
- People see the will to promote innovation...  
...but the path is still not clear enough



# Summary and outlook

- **Objectives**

- Maintain leadership position among authorities
- Promote innovation and patient access in Switzerland
- Prepare Swissmedic for the future

- **How**

- Regular operation for ATMPs
- More advice and interaction
- Teaching activity
- Greater visibility (branding)

- **Time horizon**

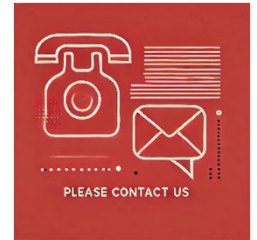
- Implementation over the next two years

# What's it actually all about?



*"...Innovation is not an end in itself, it must always serve the patient..."*

**Please contact us!**

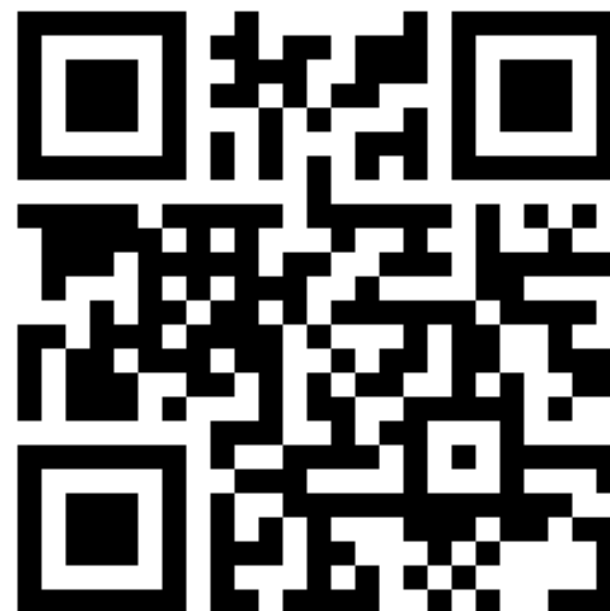


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**Non esitate a contattarci!**

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# Backup

# Objectives and foundations

- Innovation Office pilot project – **Objectives**
  - To be more **accessible** as a regulator
  - To provide **more** regulatory and scientific **advice** for **early development phases**
  - To spread **regulatory knowledge**
  - To identify **future trends** and prepare Swissmedic for them
- **Federal Council decisions**
  - Federal measures for the **promotion of biomedical research** and technology 2022–2026
  - Strategic objectives of Swissmedic: **Swissmedic supports the development** of novel therapeutic products and helps ensure swift access to **innovative** therapies.



## Results of survey of ATMP stakeholders



# Achievements



## TOR

- Established and practised since 24 May 23
- Good experience

## On-the-spot advice

- Lausanne, Station R
- Lausanne, Biopôle
- Geneva, Campus Biotech
- Wyss Zurich
- CSEM Allschwil

## Interaction

- UK-Swiss Cell & Gene Therapy Exchange
- Netherlands Innovation Network
- Centre for Future Affordable & Sustainable Therapy development (FAST), NL
- MHRA
- Catapult, UK
- Medicine Zurich, Uni Zurich
- Life Sciences, EPFL Lausanne

# Achievements

## Events

- Swiss Biotech Day Basel
- BioInnovation Day Lausanne
- DIA Basel
- SPARK Night University Zurich (3x)
- Lectures at Universities of Bern and Zurich, EPFL
- Biopôle Expert Advice

## ATMP survey

- What do stakeholders need?

## IO presentation

- Interpharma
- vips
- CSEM
- EPFL
- University of Zurich
- Innosuisse

## Publications

- Visible (3x)
- Swiss Biotech Report



# Learnings I

- Scientific and regulatory advice are key
  - Strong need
  - Effective promotion
- Offering adapted to stakeholder needs
  - Big Pharma blockbuster vs start-up with one orphan drug
- More is always better or "the broader the merrier"
  - From researcher to Big Pharma
  - Across the entire life cycle
  - Training and teaching



## Learnings II

- Promotion
  - Partner-up
  - Branding
  - Other activities (teaching, industry events)
- Need
  - Strong need beyond ATMPs
  - Resource-intensive



## Scientific advice – a balance sheet (as at November)

- > 33 meetings @WyssZurich
- > 10 meetings @CSEM in Allschwil
- > 30 meetings in Lausanne and Geneva
- > 4 remote
- 65 Scientific Advice Meetings
- 4 Scientific Advice Meetings were a direct result of dialogue with the Innovation Office

# Current priorities

- Presence
  - Bern and Ticino
  - Reduction in Geneva (focus on medtech)
- Reinforce external impact (other than directly affected stakeholders)
  - Swiss biotech (events and publications)
  - Regulatory news
  - Stakeholder survey on ATMPs
  - Involve associations (location promotion discussion/leading agency)
  - Media event
- Transition to regular operation
  - Clarify expectations and priorities with the SHs