

# MARS Webinar: The Alpes, cheese, banks – and early paid access for drugs! Wonderland, Switzerland?!

25<sup>th</sup> February 2021

Dr. Stefan Walzer

Lutz Vollmer

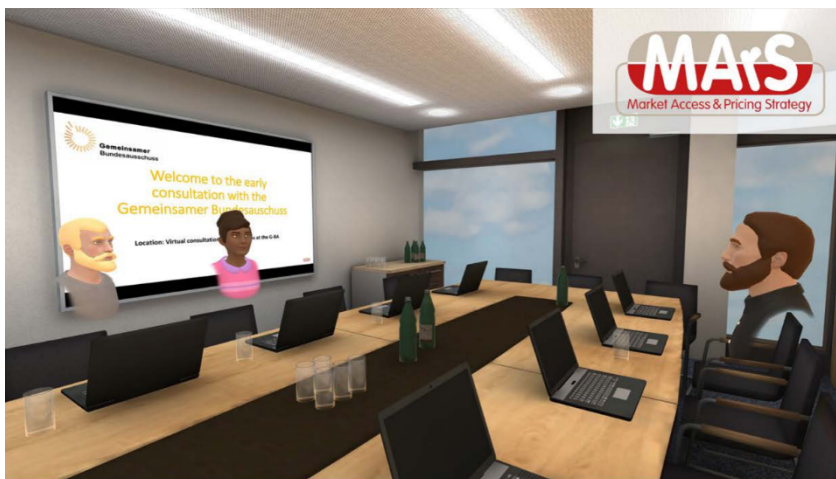
MARS Market Access & Pricing Strategy GmbH, Germany

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### Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill

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Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg

# Questions welcome!






- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
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# Webinar




**Digital health in Germany**  
– start of a rocket or just a big bluff?

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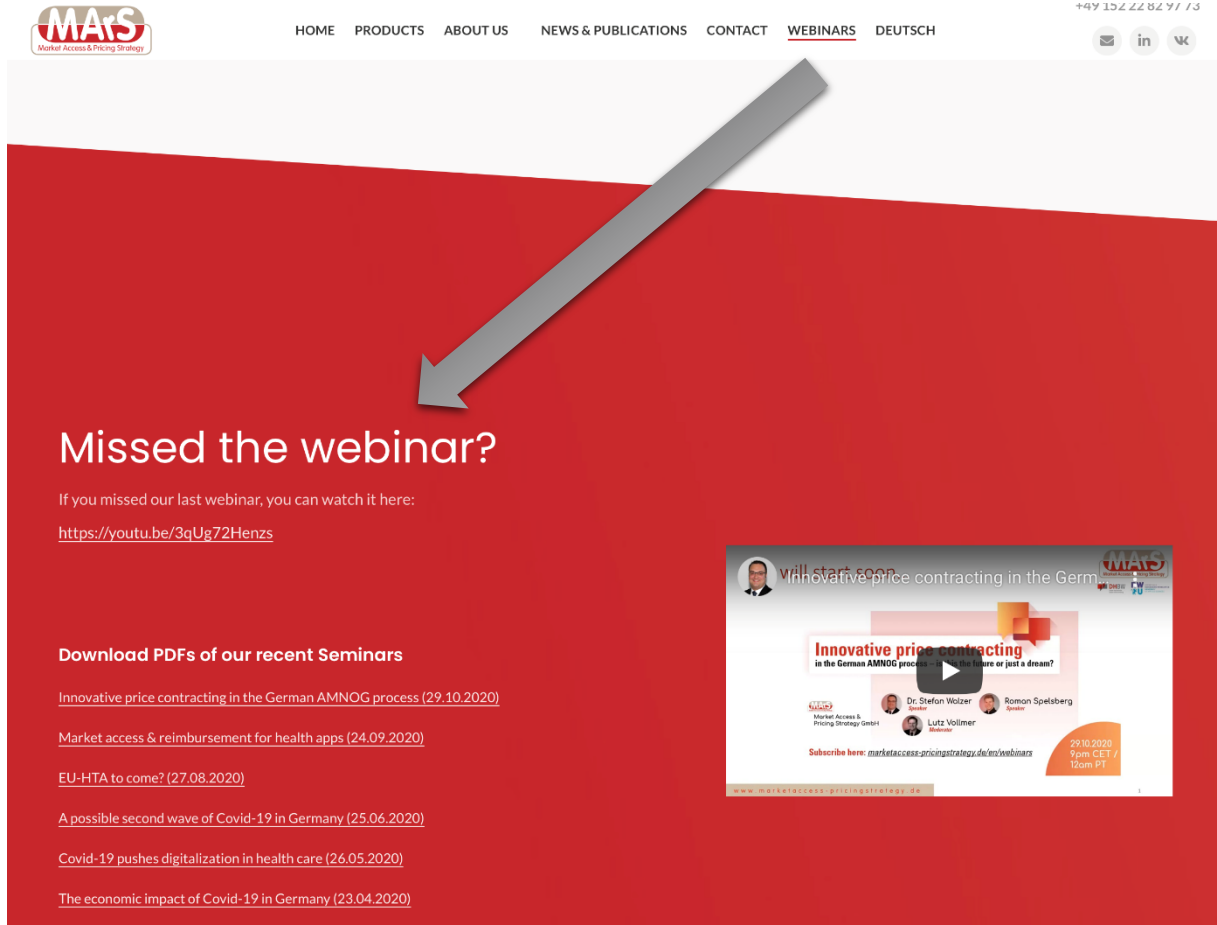
 **Dr. Stefan Walzer**  
*Speaker*

 **Lutz Vollmer**  
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- [A possible second wave of Covid-19 in Germany \(25.06.2020\)](#)
- [Covid-19 pushes digitalization in health care \(26.05.2020\)](#)
- [The economic impact of Covid-19 in Germany \(23.04.2020\)](#)



# Our presenters and discussants today



Dr. Stefan Walzer  
*Speaker*



Lutz Vollmer  
*Moderator*



Remo Christen  
*Roche*

# MArS Webinar: The Alpes, cheese, banks – and early paid access for drugs! Wonderland, Switzerland?!

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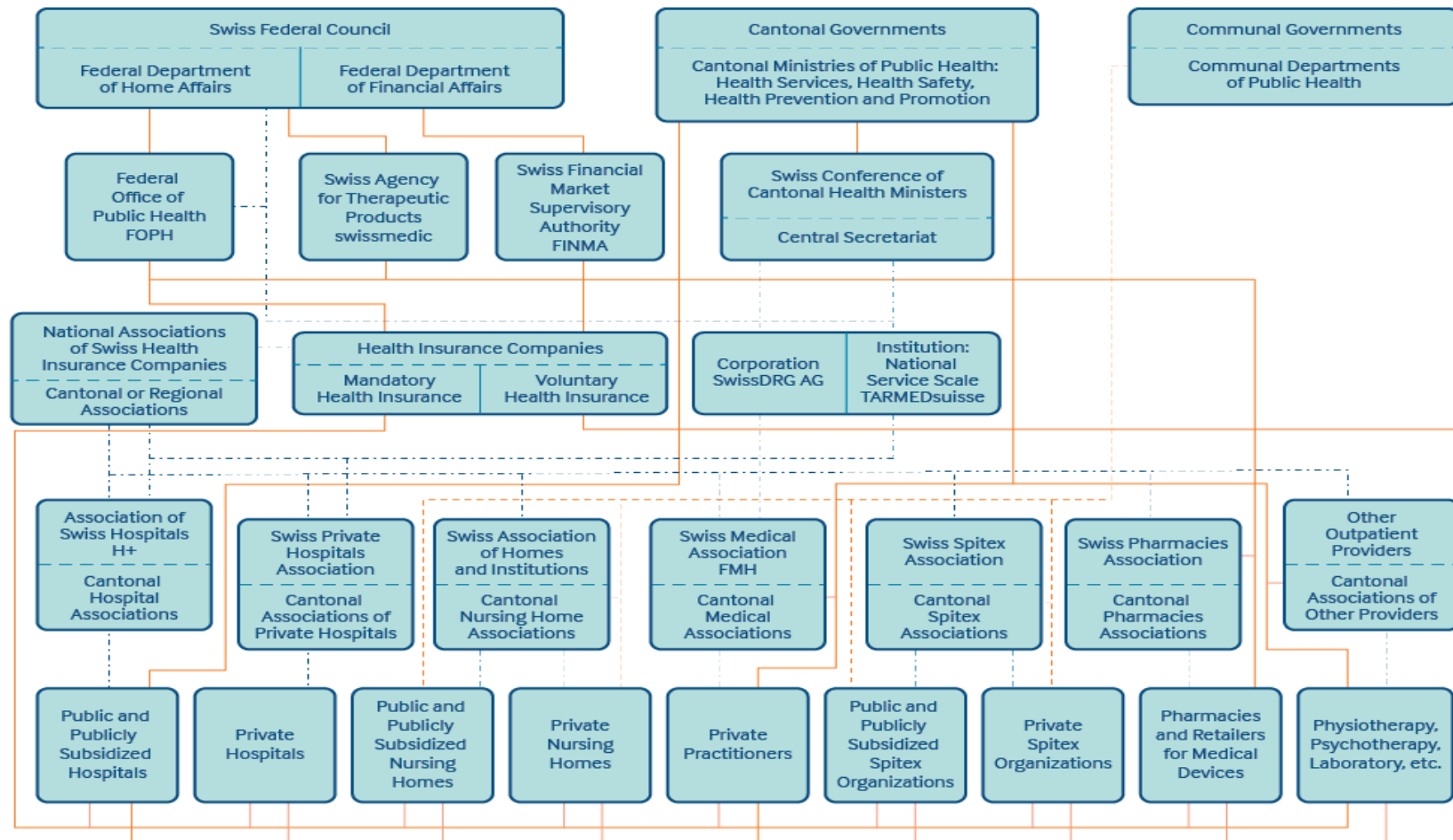
State University Baden-Wuerttemberg, Germany

University of Applied Sciences Ravensburg-Weingarten, Germany

# The Swiss Health system is good but comparatively expensive

- Population size – Switzerland 8.7 Mio (41.290 km<sup>2</sup>)
- According to OECD, Switzerland has one of the world's best AND most expensive health care systems
- 11.1% - Switzerland's health expenditures per gross domestic product (GDP) with significantly higher private expenditures than elsewhere
- Subject to criticism by experts are the high health costs, the strongly regulated competition and the high proportion of out of pocket payments that Swiss patients have to afford.

# Organization of the Health System of Switzerland



Source: P. Camenzind, Swiss Health Observatory, 2015.

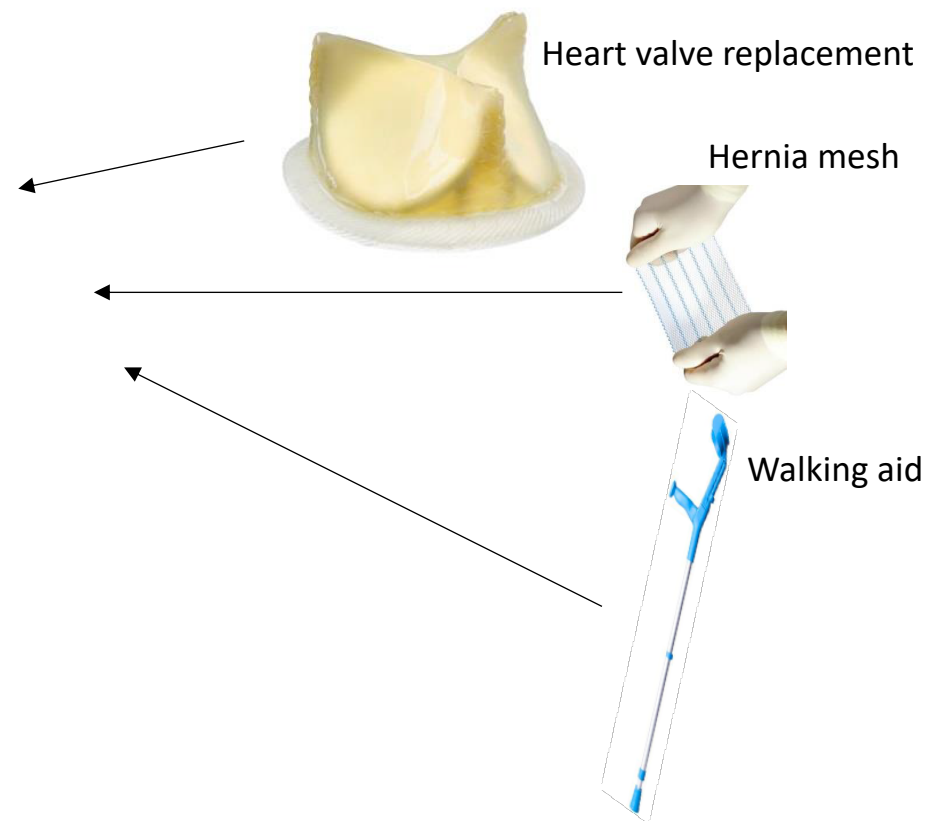
# Various tariff systems available in Switzerland

- **Overview**

- Inpatient cases: SwissDRG
- Outpatient cases: TARMED
- Remedies and devices: MiGeL

- **Others:**

- Analyses: List of Analyses (AL)
- Drugs: Specialty List (SL)
- Rehabilitation
- Psychiatry



# SwissDRG for Swissmedic approved procedures

Applications can only be submitted online using the respective form (in H+) and **only for Swissmedic approved therapies / procedures.**



Applications submitted via H+ must be agreed with the respective hospital management and can be accepted with the email sender of the Hospital Directorate or the person responsible for the tariff service.



Applications from the FMH organizations will only be accepted with the email sender of the president or collective delegate of the professional associations or umbrella organizations.



Complex applications which require the verification of superordinate dependencies as well as intensive inquiries with the applicant and the medical societies concerned may delay the processing.



If the content of the application also covers other subject areas, then the content of the interdisciplinary application must be agreed with all subject areas concerned. The final result of the consolidation must be confirmed in writing by the respective professional society. Only applications in which a consensual agreement has been reached with the subject areas concerned will be dealt with.

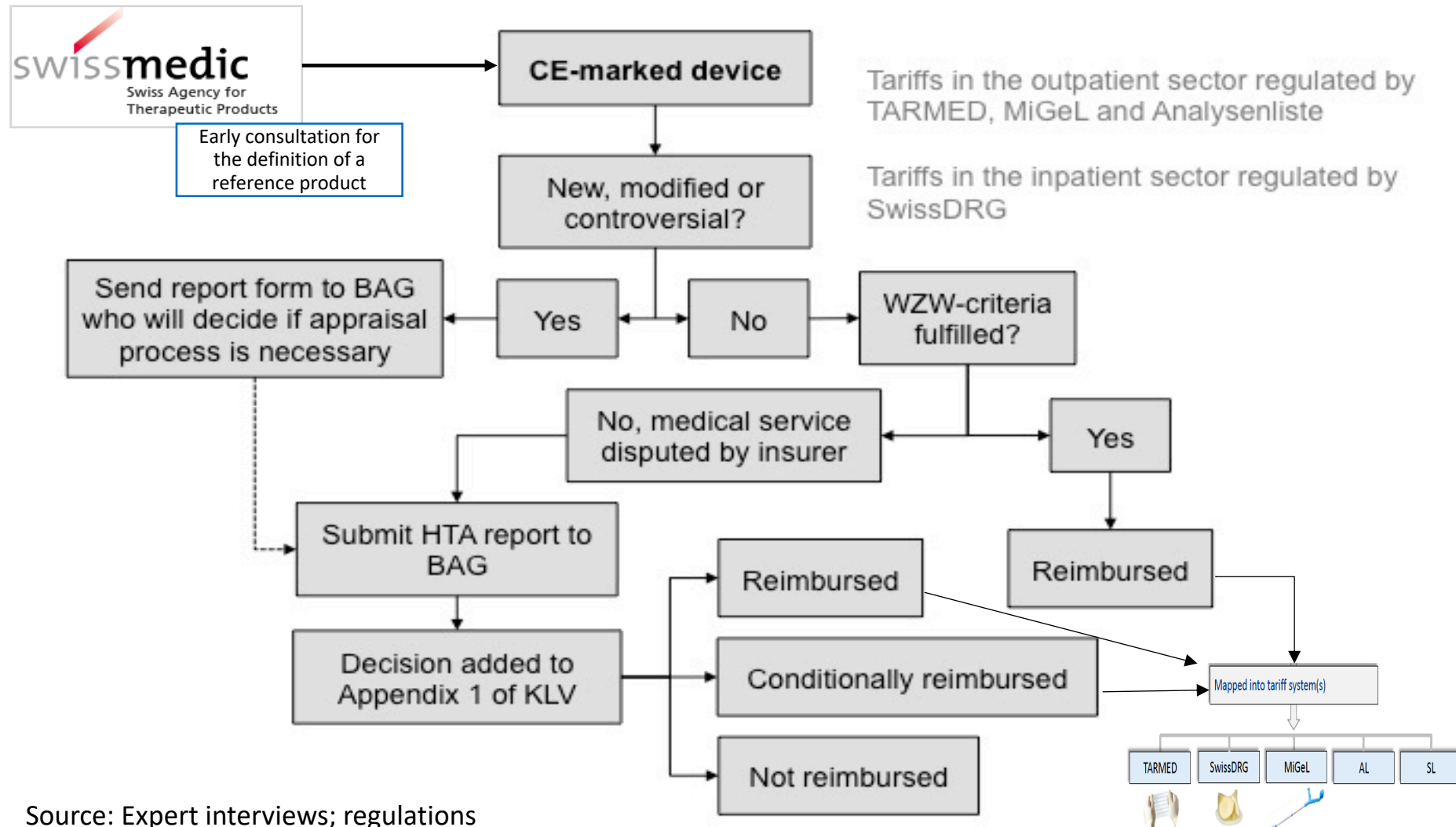


The applications submitted will be published in abbreviated form on the website of SwissDRG AG, naming the applicant institution on the Internet. The fields that are published on the homepage of SwissDRG AG as part of the compilation of the application process are marked with the corresponding information in the application form.



# Medical device reimbursement

BAG = Federal Office of Public Health (FOPH/BAG)



Source: Expert interviews; regulations

# ... and digital health?

- According to Article 25 KVG, means and objects that serve the treatment or examination of a disease and its consequences are among the compulsory benefits of the compulsory health care insurance.
- The examination of a disease in the area of the means and objects list (MiGeL) thereby refers to the monitoring of the disease and the treatment of the same.

**-> MiGeL List**

# MiGeL List of Remedies and Devices

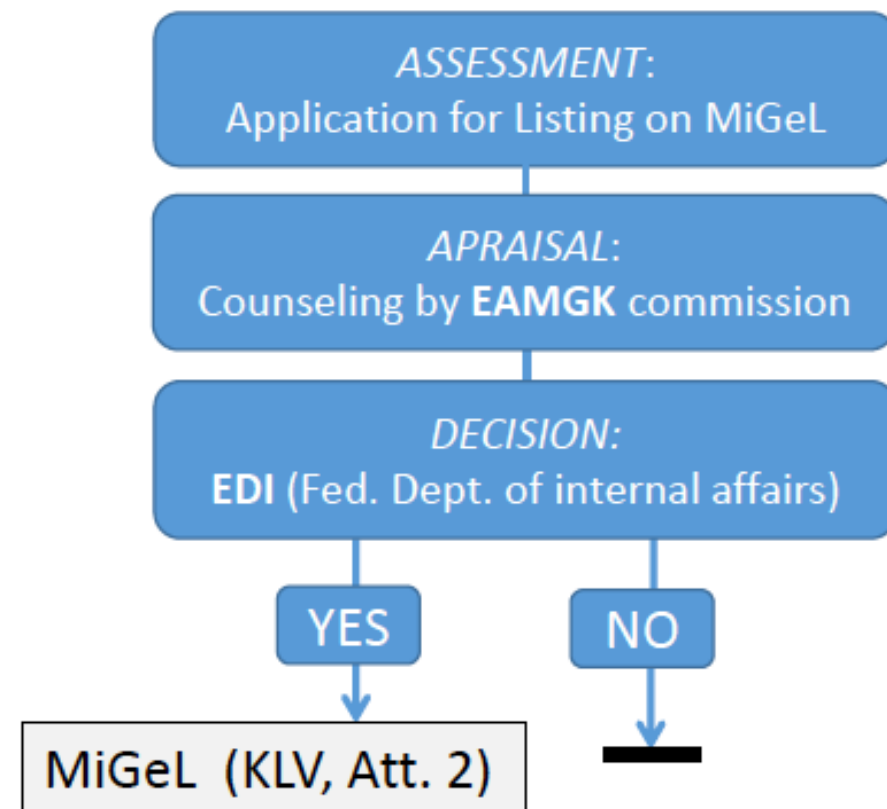
- **Patient care service act** (*Krankenpflege-Leistungsverordnung (KLV)* )
- **Art. 2 MiGeL** (List of Remedies and Devices)  
*Liste der Mittel und Gegenstände (MiGeL-> KLV Anh. 2)*  
Remedies and devices, which are handed out on medical prescription and are applied by the patient himself or another person who is not professionally involved.
- **Art. 24 MiGeL**  
Defines maximum amounts reimbursed by social insurance  
(*Höchstvergütungsbeträge HVB*)



Walking aid

# MiGeL innovation uptake

- The only positive list for MedTech products in Switzerland, covering estimated 55'000 products in non-branded product groups
- Participation of all stakeholders, incl. industry (FASMED)

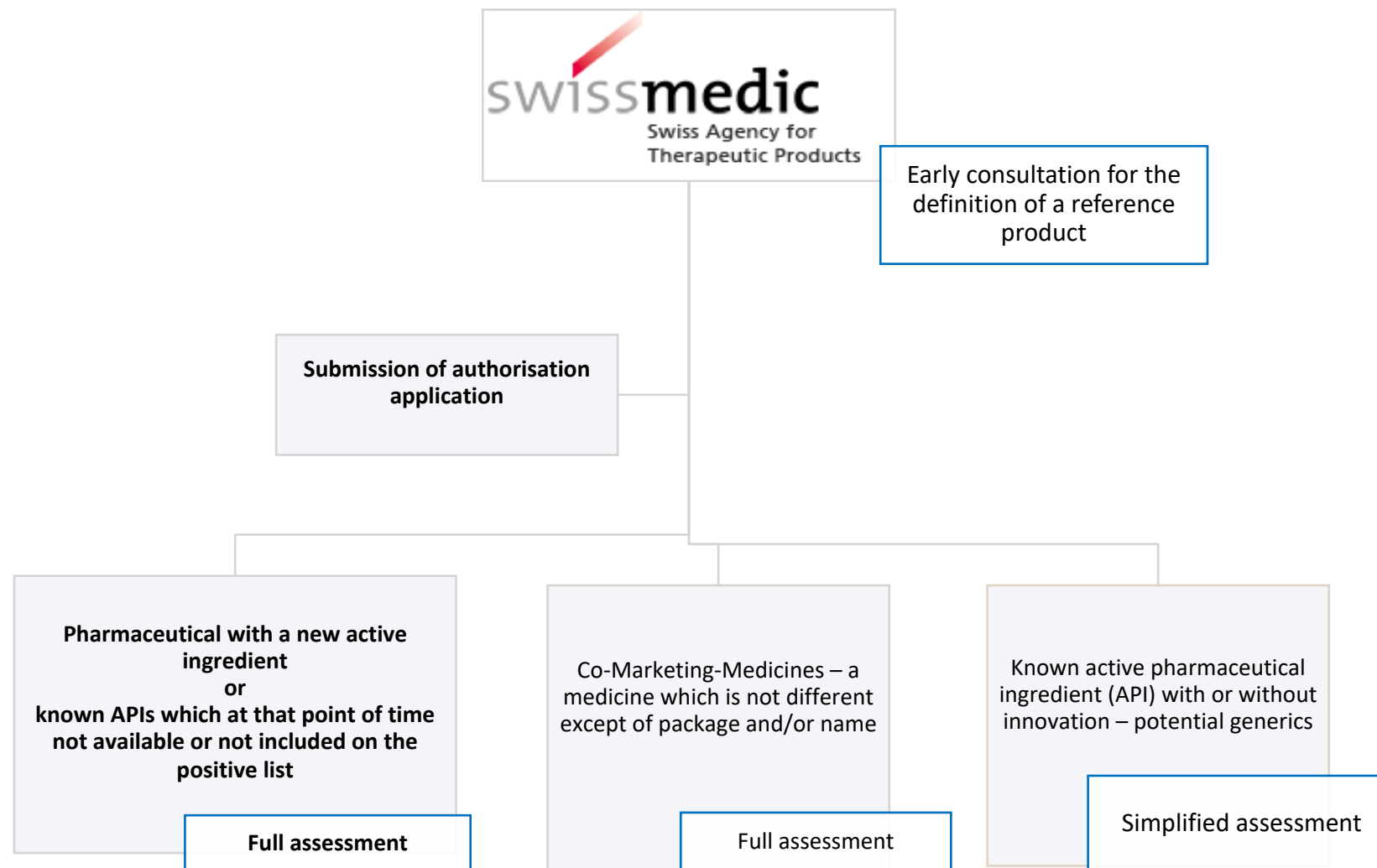


# Back to Pharma...

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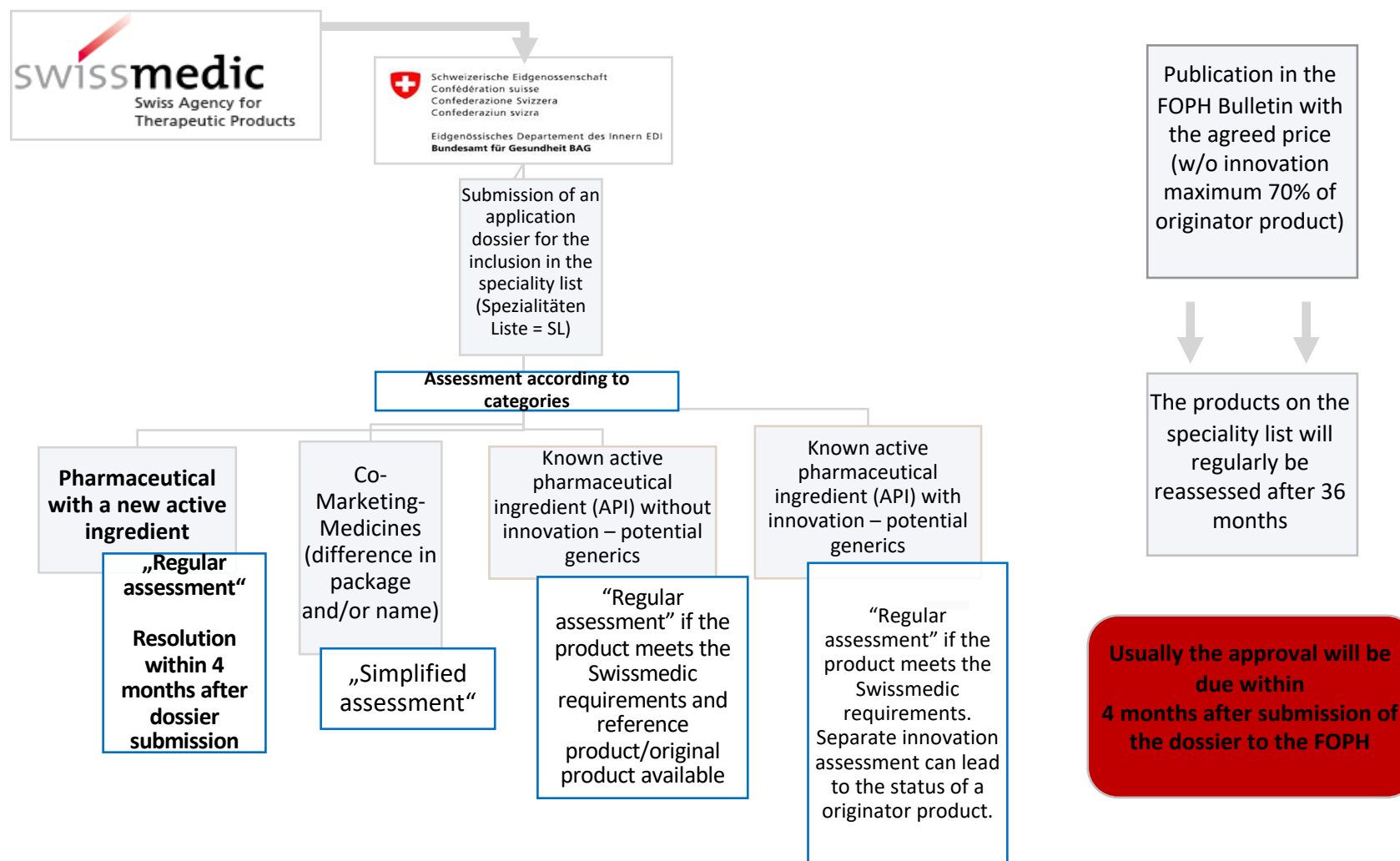
# Regulatory approval process by Swissmedic



# Regulatory approval process for medicinal products



# Standard market access pathway in Switzerland





# So, wonderland, Switzerland?!

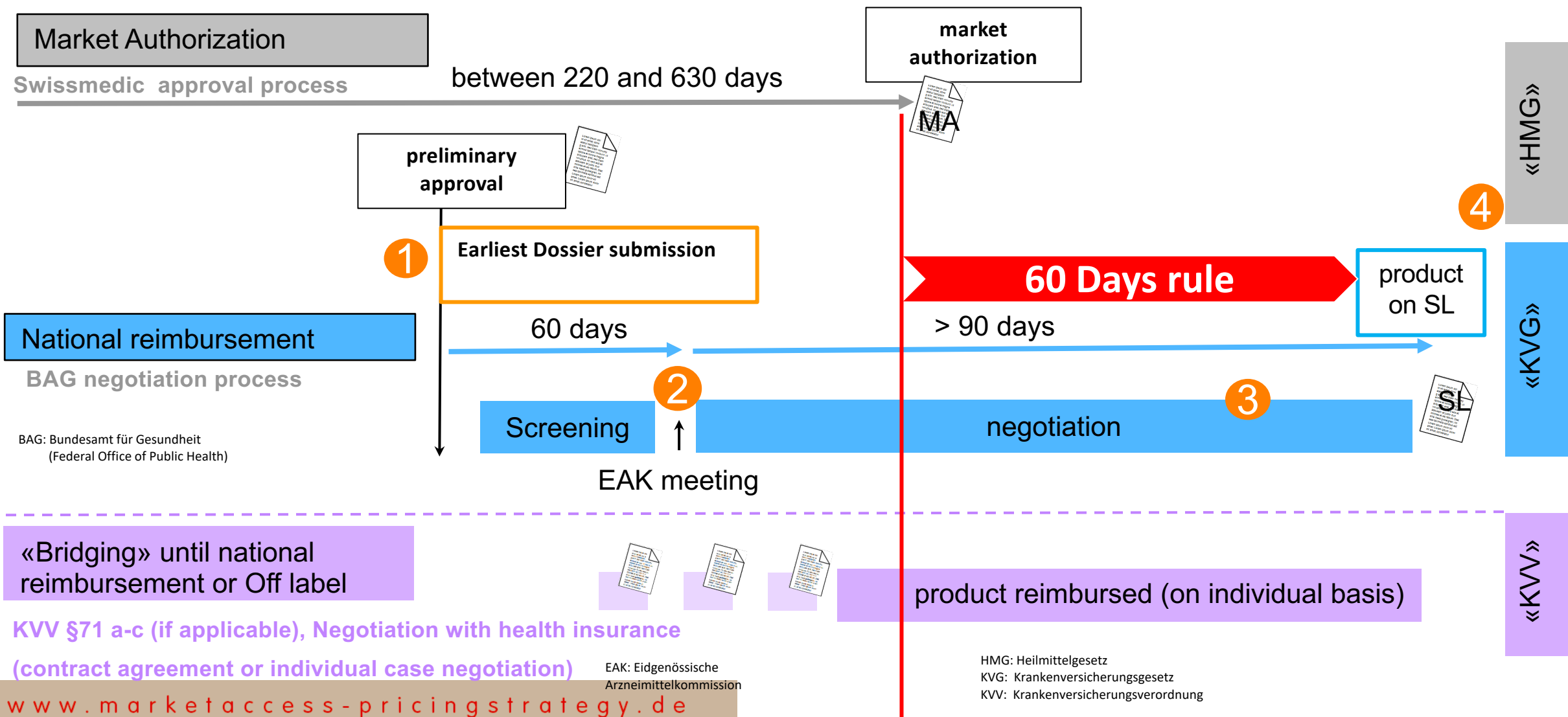
## The alpes, cheese, banks Access in Switzerland




***Remo Christen, Director Market Access & Health Care Affairs  
Roche Pharma (Switzerland) Ltd***



# Price negotiation timelines in Switzerland



# Price negotiation for national reimbursement (speciality list) based on “WZW” (“EAE” criteria)

<b>Efficacy ("E")</b>	Clinical evidence based 1) Swissmedic approval 2) Efficacy in everyday clinical practice
<b>Appropriateness ("A")</b>	All aspects of pharmacology and drug formulation (e.g. package sizes) Recently also inclusion of benefit assessments from abroad
<b>Economic Efficiency ("EE")</b>	<div>Therapeutic cross comparison (TC)</div> <div>Foreign price comparison (FPC)</div> <div></div> <div>Innovation surcharge (IS)</div> <div>Price: <math display="block">\frac{FPC + (TC + IS)}{2}</math></div>
<b>Limitation</b>	Restriction of the field of application (e.g. "only in severe cases", special clinics) Mapping of pricing models (co-financing of pharmaceutical companies)

**Regular  
renegotiation**

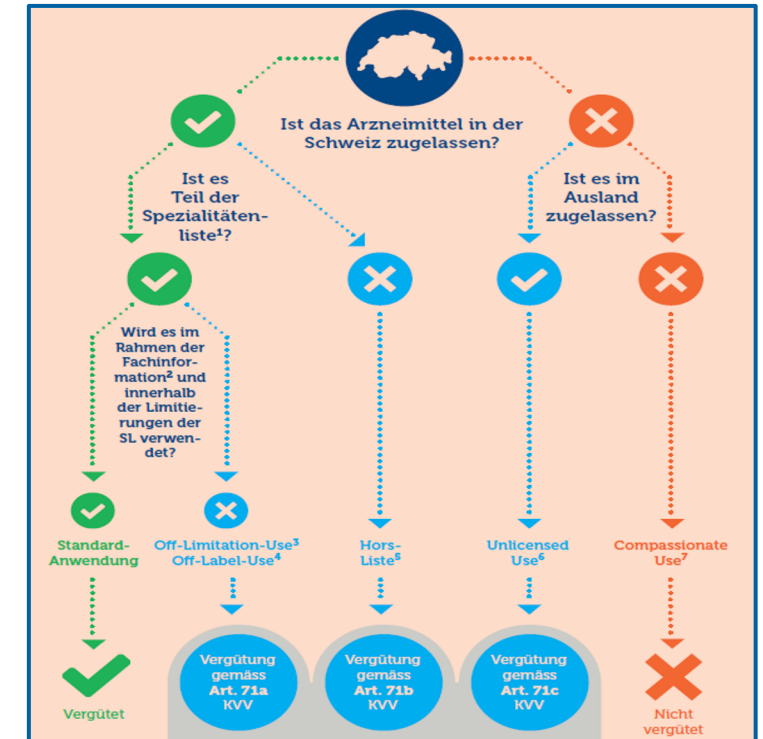
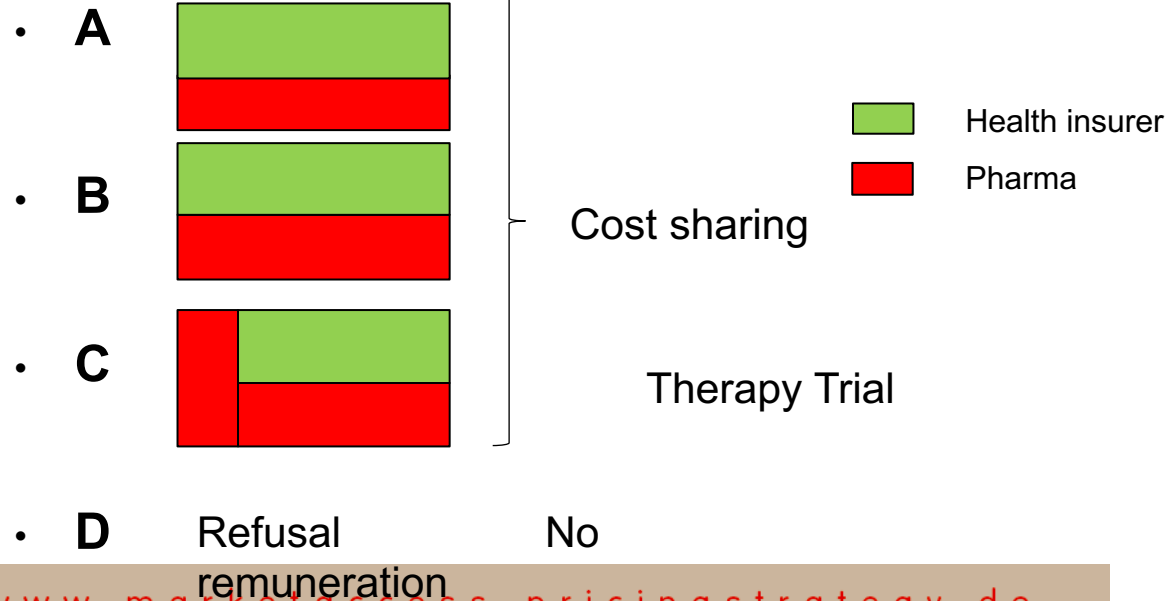
- new indications,
- modifications of limitations
- new dosing
- new packages
- patent expiry
- 3 year revision

# Article 71a - 71d KVV

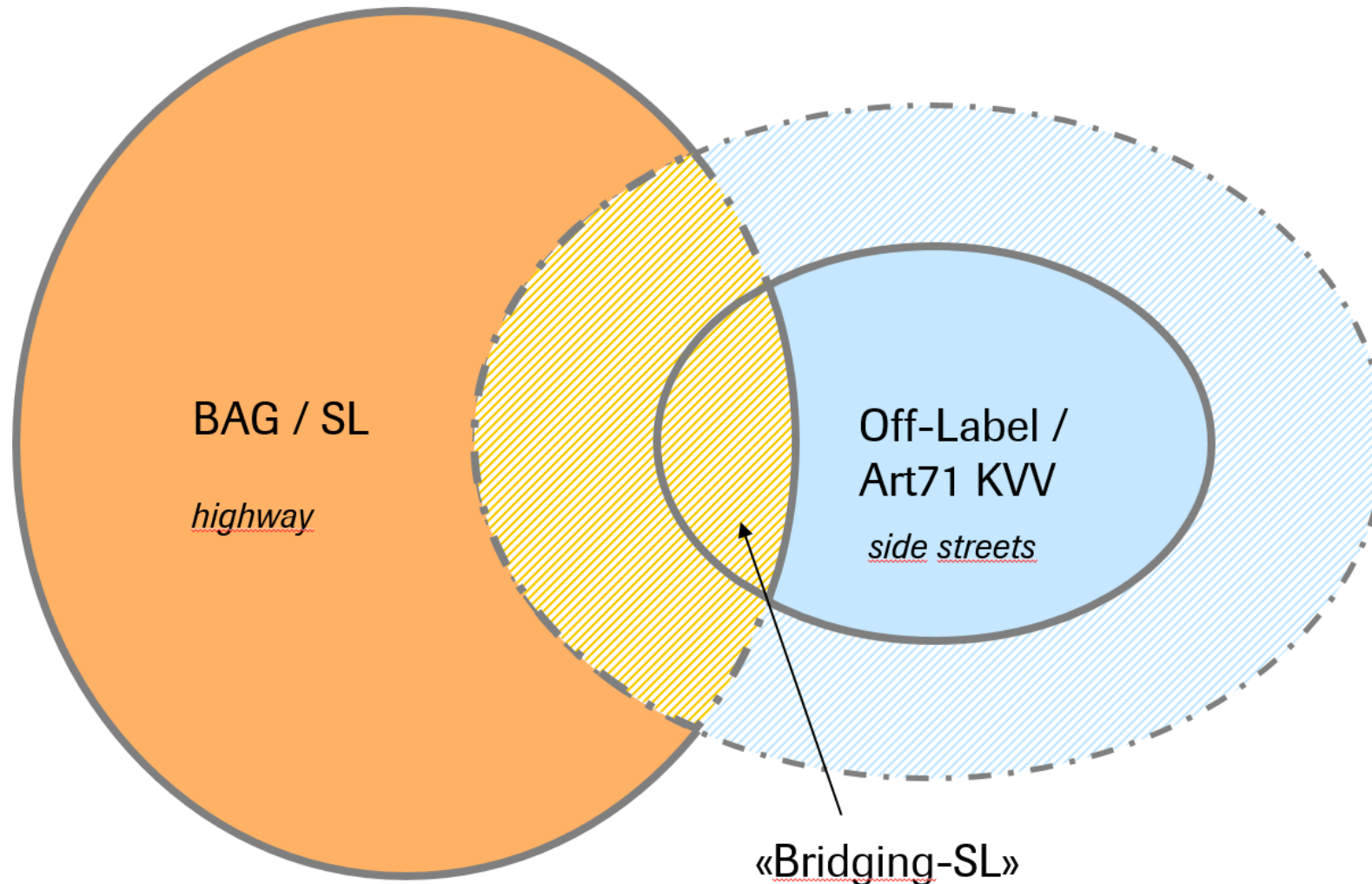
## Conditions

- no alternative
- life-threatening disease
- high therapeutic benefit expected

## Benefit categories/cost sharing

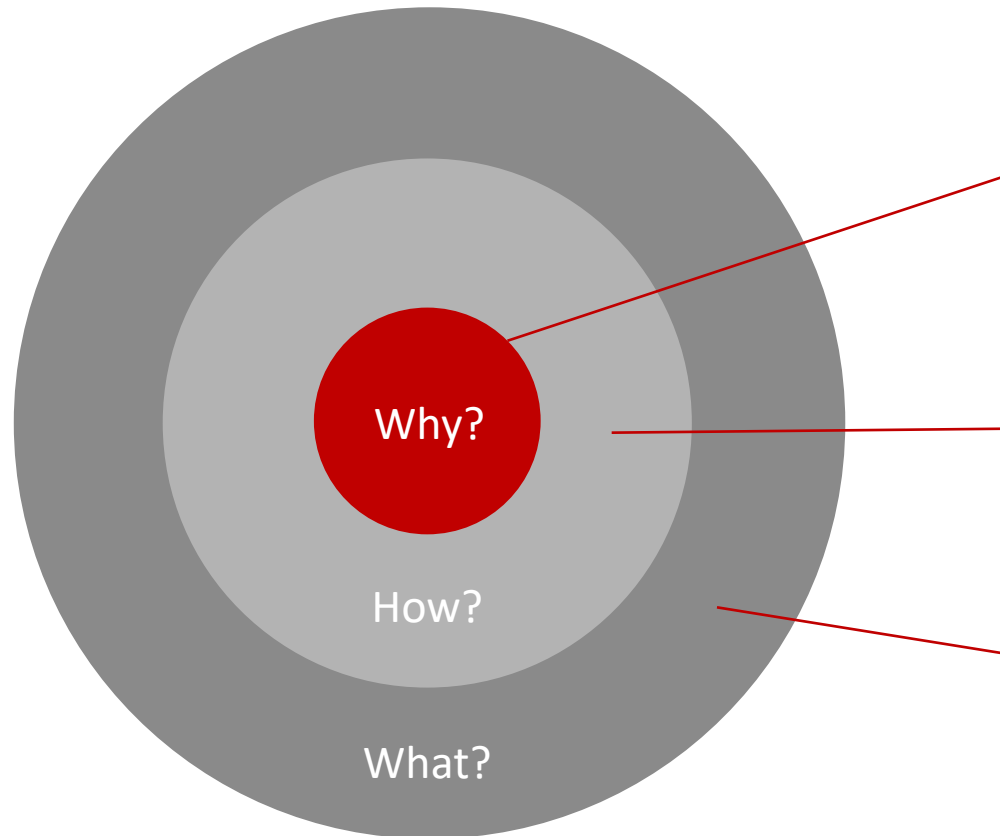


# Summary – BAG and KVV 71

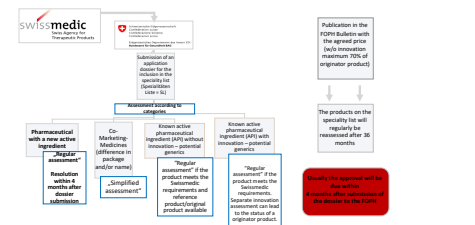


# Conclusions

The Swiss market access process is pragmatic, but...



Standard market access pathway in Switzerland



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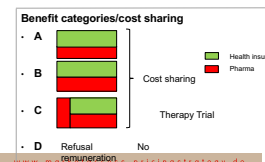
Price negotiation for national reimbursement (speciality list) based on "WZW" ("EAE" criteria)

Efficacy ("E")	Clinical evidence based 1) Swissmedic approval 2) Efficacy in everyday clinical practice
Appropriateness ("A")	All aspects of pharmacology and drug formulation (e.g. package sizes) Recently also inclusion of benefit assessments from abroad
Economic Efficiency ("EE")	Therapeutic cross comparison (TC) Parallel price comparison (PPC) Innovation surcharge (IS) $\text{Price} = \frac{\text{FPC} + (\text{TC} + \text{IS})}{2}$
Limitation	Restriction of the field of application (e.g. "only in severe cases", special clinics) Mapping of pricing models (co-financing of pharmaceutical companies)

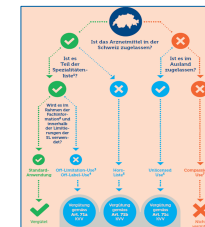
<b>Regular renegotiation</b>	<ul style="list-style-type: none"> <li>- new indications,</li> <li>- new packages</li> <li>- modifications of limitations</li> <li>- patent expiry</li> <li>- new dosing</li> <li>- 3 year revision</li> </ul>
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Article 71a - 71d KVV

- Conditions**
- no alternative
  - life-threatening disease
  - high therapeutic benefit expected



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## 10 years AMNOG

what have we learnt for drug development and pricing?



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*University of Applied Sciences Rosenheim*

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