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18. DGRA Jahreskongress

Adaptiv Pathways – Impact on

- Regulatory Data Protection
- Supplementary Protection Certificate
- Early Benefit Assessment

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EMA - Concept

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2014
EMA/758619/2014

Adaptive pathways to patients: report on the initial experience of the pilot project

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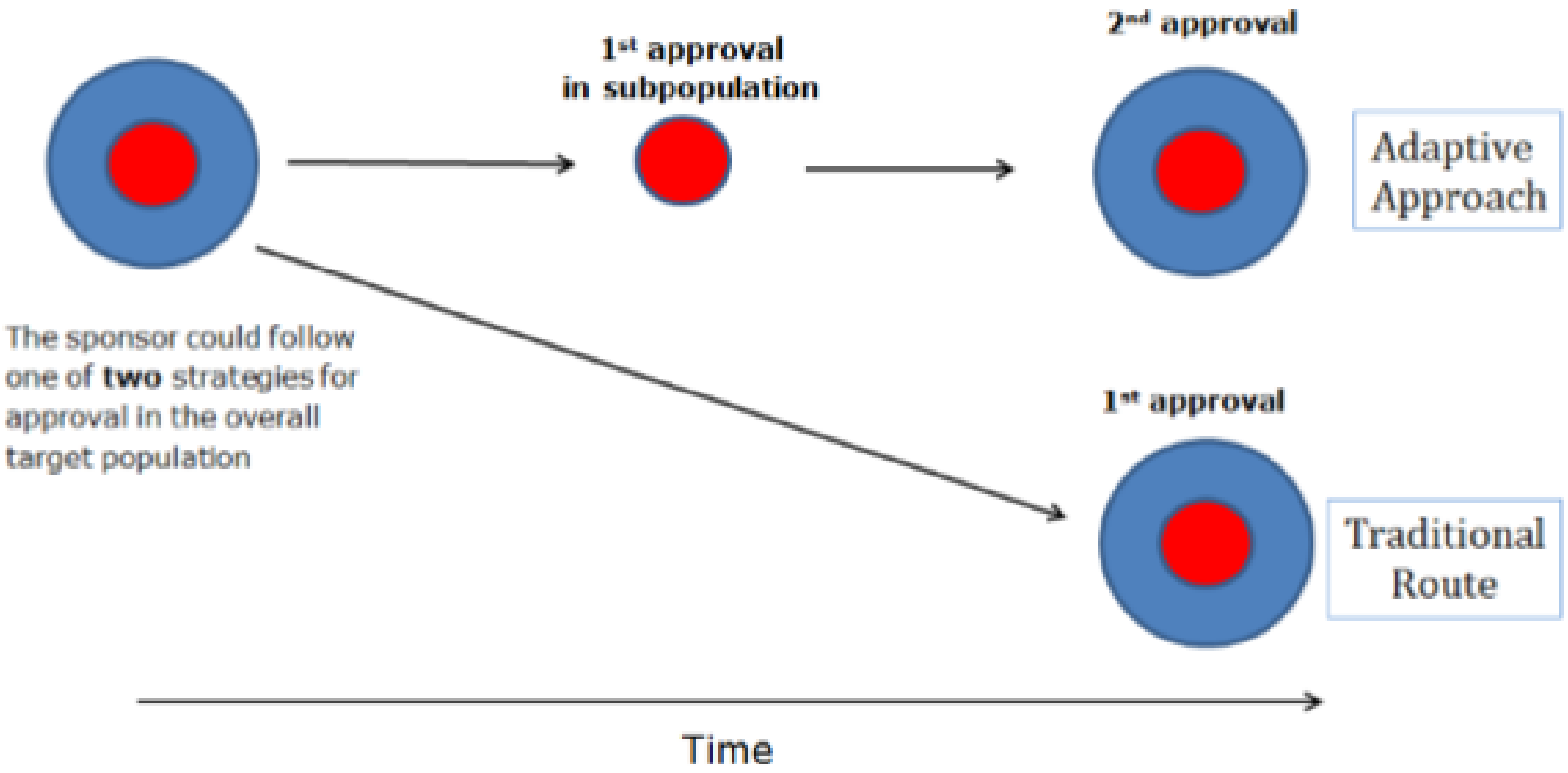
Widening of the indication Scenario
(Final target indication in blue and red)



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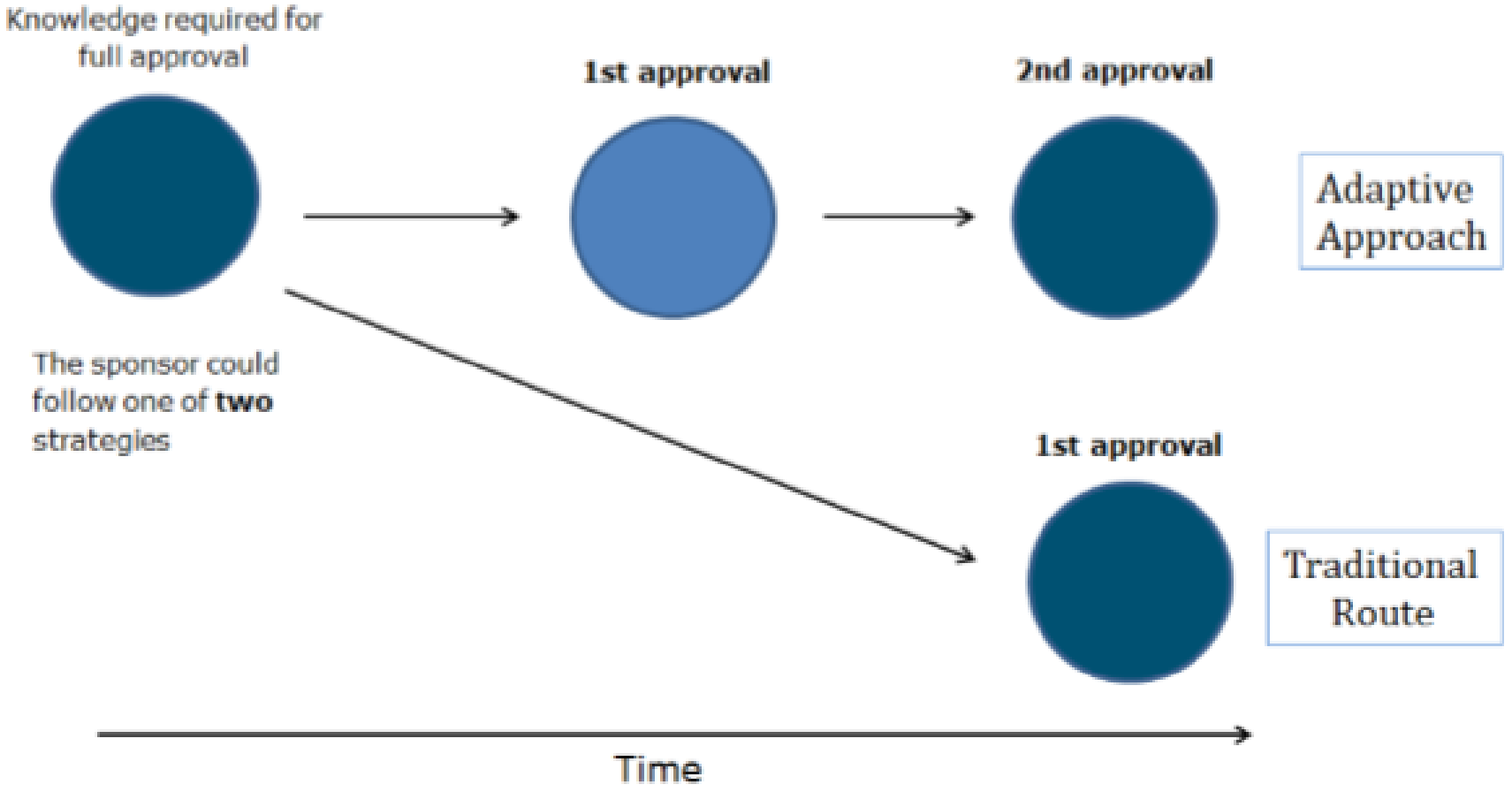
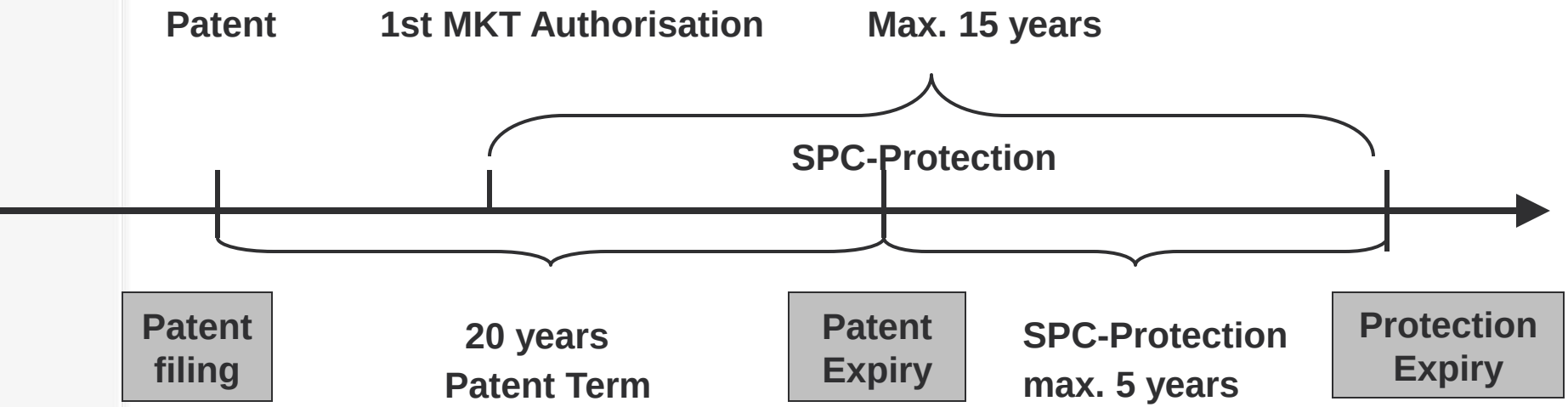
Prospectively planned Reduction of uncertainty Scenario



Supplementary Protection Certificate - SPC - EC Regulation → National Patent Law



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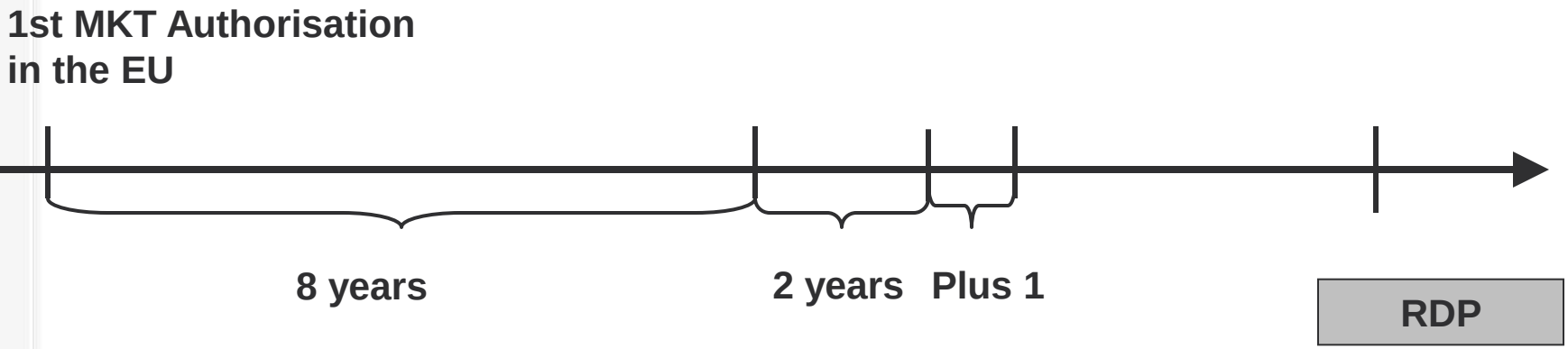
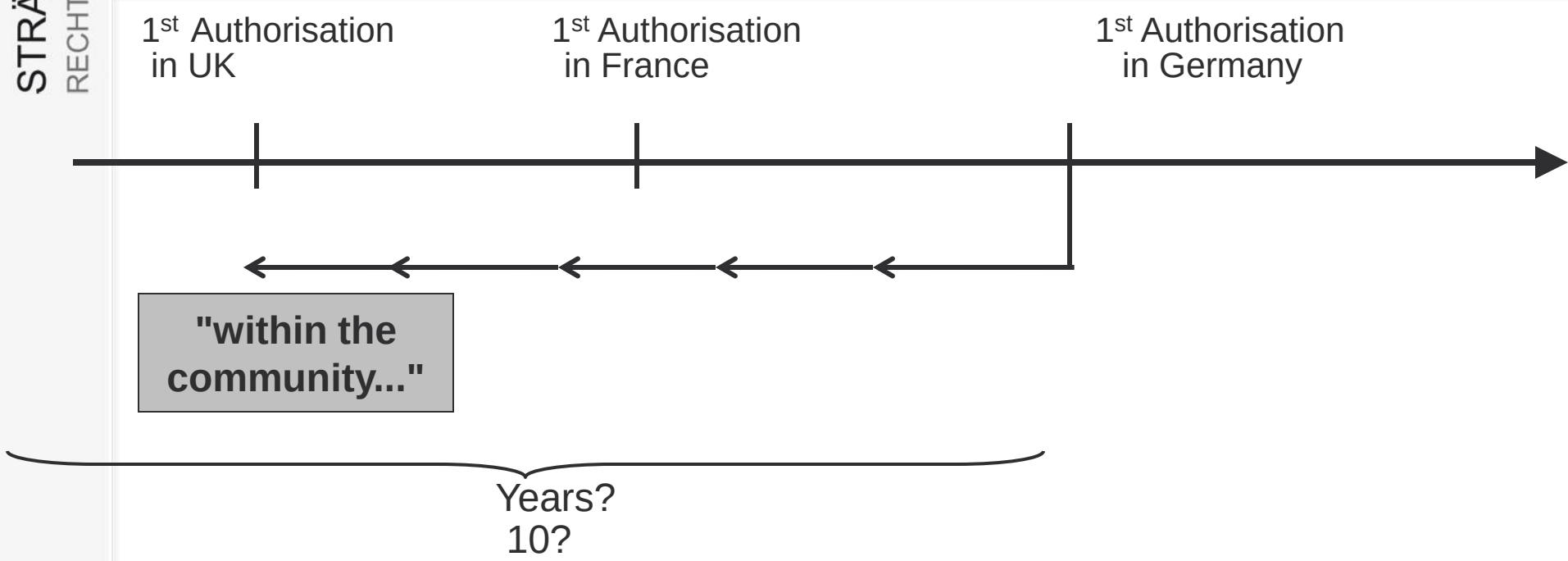
Protection periods for regulatory data protection - RDP



Independent from patent!

loss of protection loss of protection

Start of Protection Term



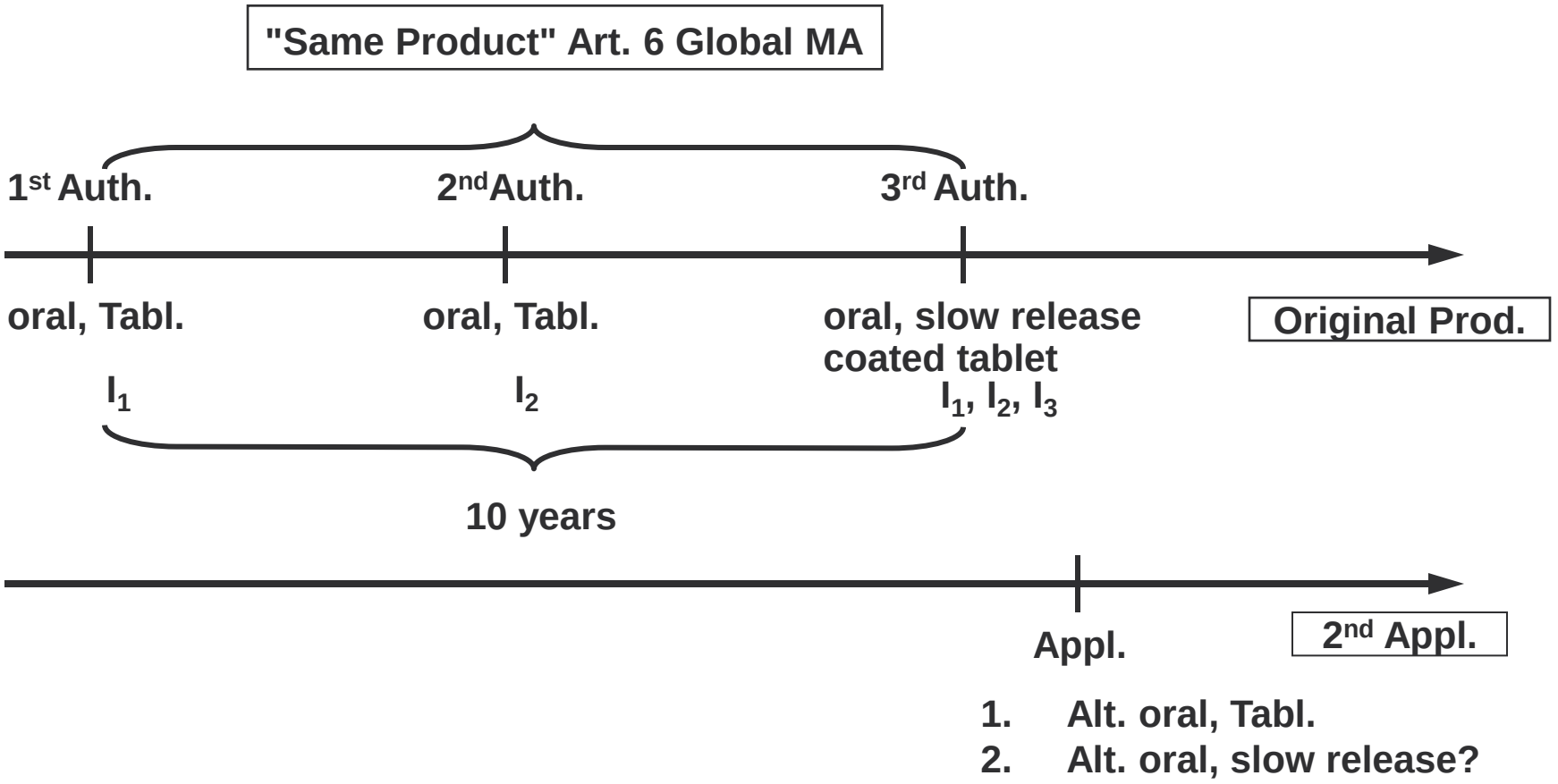
also in Member States other than those in which the application is made

Period of exclusivity will be reduced by the varying duration of MA procedures – EC wide coordination

EC-wide uniform protection term

CP avoids loss of protection

ECJ – Essential Similarity
Line Extensions of the Original MP



1. Alt. oral, Tabl.
2. Alt. oral, slow release?

Concept of Global MA

Art. 6 para. 1

"When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation.

All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10 (1)."

Sec 25 para 9 AMG

Concept of Global MA and „Global SPC“

Principles of Art. 6 apply also for SPC

- **Art. 3 lit b) + c) Reg. (EC) 469/2009**

  <u>one SPC</u> per Medicinal Product only

→ How to define Identicality

→ Concept of global MA applies

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Conclusion

Adaptive Pathways:

early MA on smal subgroups can start protection term for the blockbuster indications (much) to early

→ Risk to loose Billions of Euros

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Adaptive Pathways – Impact on

- **Early Benefit Assessment – EBA –**
- **HTA process in Germany**

→ Impact world wide pricing

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Marketing Authorisation – MA – Impact on Early Benefit Assessment – EBA –

MA

Q

S

E = benefit

3 Hurdles

EBA

✓

✓ can be checked

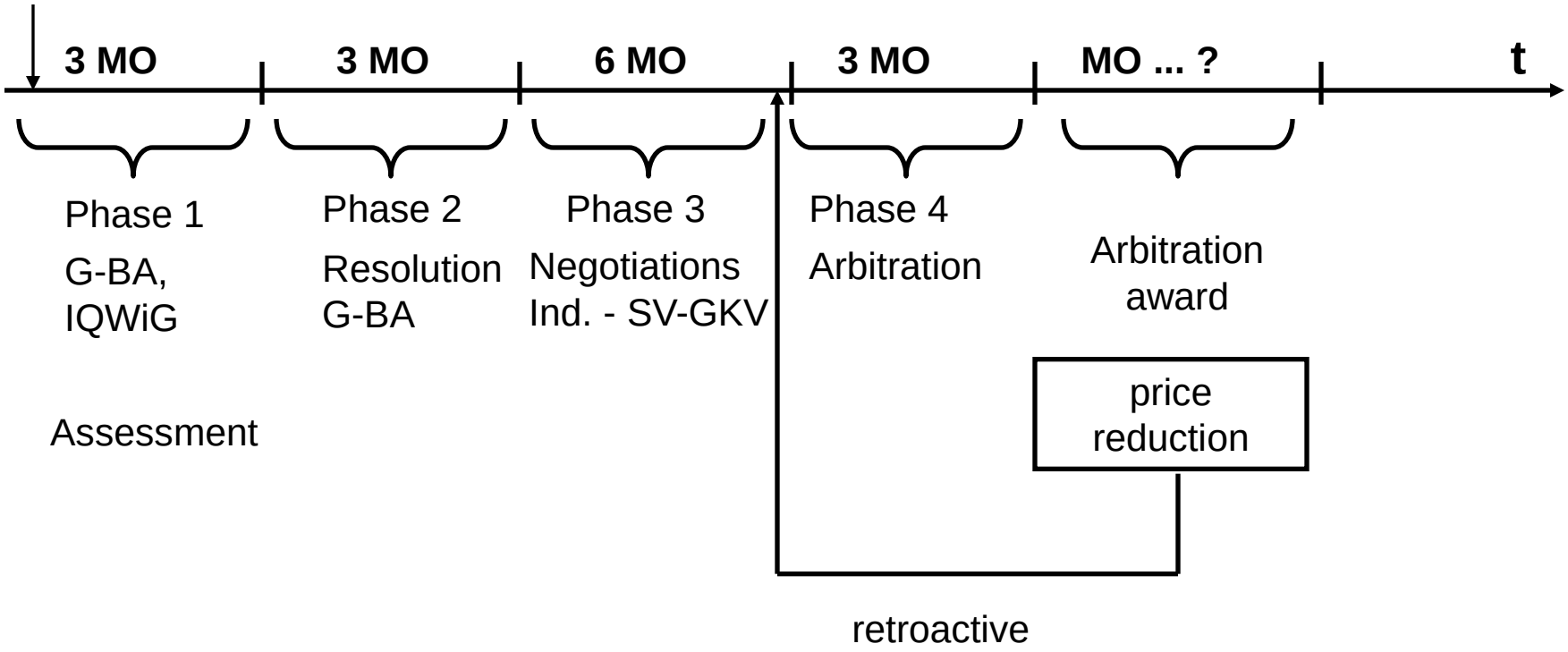
✓ binding

additional benefit

4th Hurdle

EBA-Procedure
MP with new API after 01.01.2011

1. Launch 1st day!



Assessment Principles
Key points

- **What is the additional benefit in relation to the appropriate comparator for which subpopulation of patients?**
- **Extent of additional benefit?**
- **Number of patients and patient groups with therapeutically important additional benefit?**
- **Validity of the endpoints?**
- **Probability or likelihood of the proof of evidence?**

  ➔ Evidence based Medicine - RCT

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Marketing Authorisation – MA – Impact on Early Benefit Assessment – EBA –

- **Adaptive Licencing:**

  → Reducation of Evidence?

  Phase II CTs?

  → No Chance in EBA

  → RDP – Concept of globals MA

  → Loss of protection!

Adaptive Pathways on EBA

AMNOG-Newsletter (01/2016)

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ADAPTIVE PATHWAYS – DIE NEUE HERAUSFORDERUNG FÜR DIE FRÜHE NUT-ZENBEWERTUNG

Adaptive Pathways on EBA

G-BA:

Es bleibt abzuwarten, ob und wie sich das neue Zulassungskonzept der EMA etablieren wird. In seiner derzeitigen Form wird es das deutsche Gesundheitswesen vor schwer zu überwindende Herausforderungen stellen.

→ **Evidence based approval of additional benefit**

→ **Acceptance of surrogate parameters in question**

→ **Risk of a negative or unappropriate benefit assessment**

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Impact on Pricing in Europe

In 50 – 80 countries price negotiations follow the rule:

The German price – X

- **Early pricing in German has a Domino Effect**
- **Adaptive pathways can ruin the success of MPs**

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Many thanks for your attention!

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