EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

From Adaptive Licensing To Adaptive Pathways

Paris, ANSM, September 2014

Hans-Georg Eichler
Senior Medical Officer

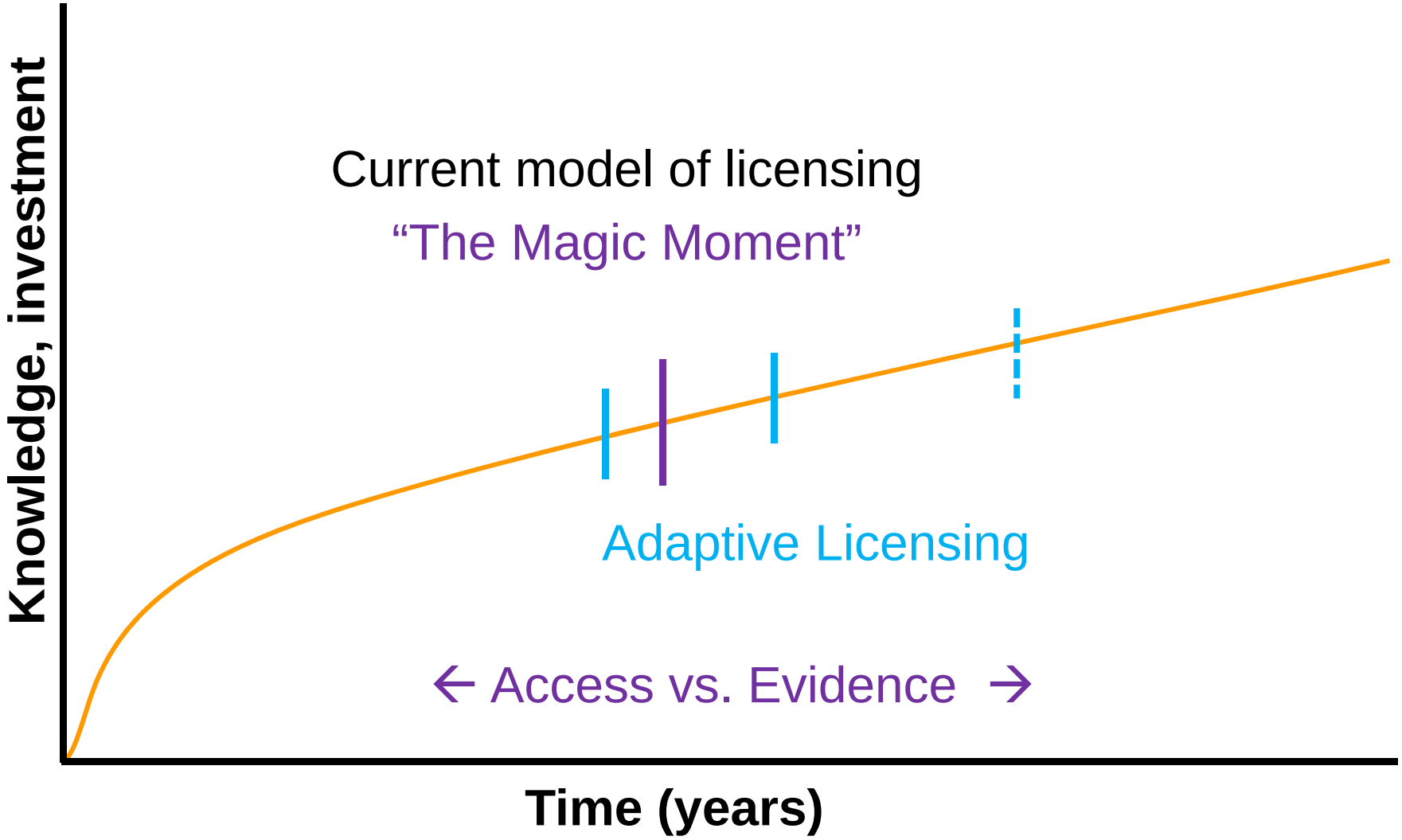
An agency of the European Union

How can we address the access vs. evidence trade-off?

Competing objectives

- Allow timely access for patients to address unmet medical need: “the safest drug that arrives too late is of no benefit to a patient”
- Provide an environment supportive of innovation
- Provide ‘complete’ information on benefits, risks, relative effectiveness

From magic moment to life-span management

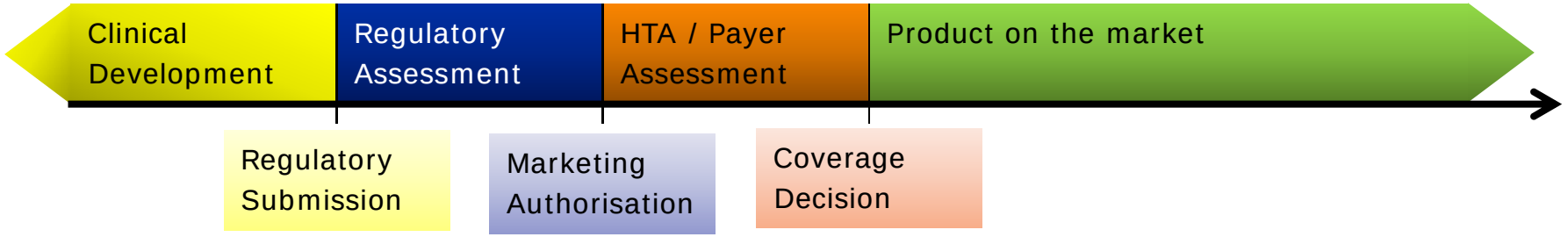


A systems approach

Comprises the entire life-span:

Development → licensing → coverage → utilization → monitoring

- Adaptive Licensing
- Adaptive Pathways



What needs to be in place to enable adaptive pathways? 1/2

- Culture of collaboration with patients and physicians to agree on level of unmet need and acceptable uncertainty

- Collaboration of sponsor, regulators, payers/HTA bodies throughout the life-span of a product

What needs to be in place to enable adaptive pathways? 2/2

- Rapid learning systems for data generation across whole life-span → to minimise *realised* risk (as opposed to *inherent* risk)

- Tools to provide reasonable assurance of appropriate Rx

Conclusion

- We are on a trajectory to more adaptive pathways
- The speed of change will depend on how fast preconditions can be met
- Adaptive pathways are likely the best (only?) way to address the access versus evidence trade-off
- EMA is currently running the ‘Adaptive Licensing Pilots Project’; to date: 26 products submitted, 7 selected for pilot – watch this space!

Thank you

European Medicines Agency

30 Churchill Place

London E14 5EU

www.ema.europa.eu

info@ema.europa.eu