Co přinesl ISPOR Europe 2018
postřehy mé a mých kolegů

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a technology assessment

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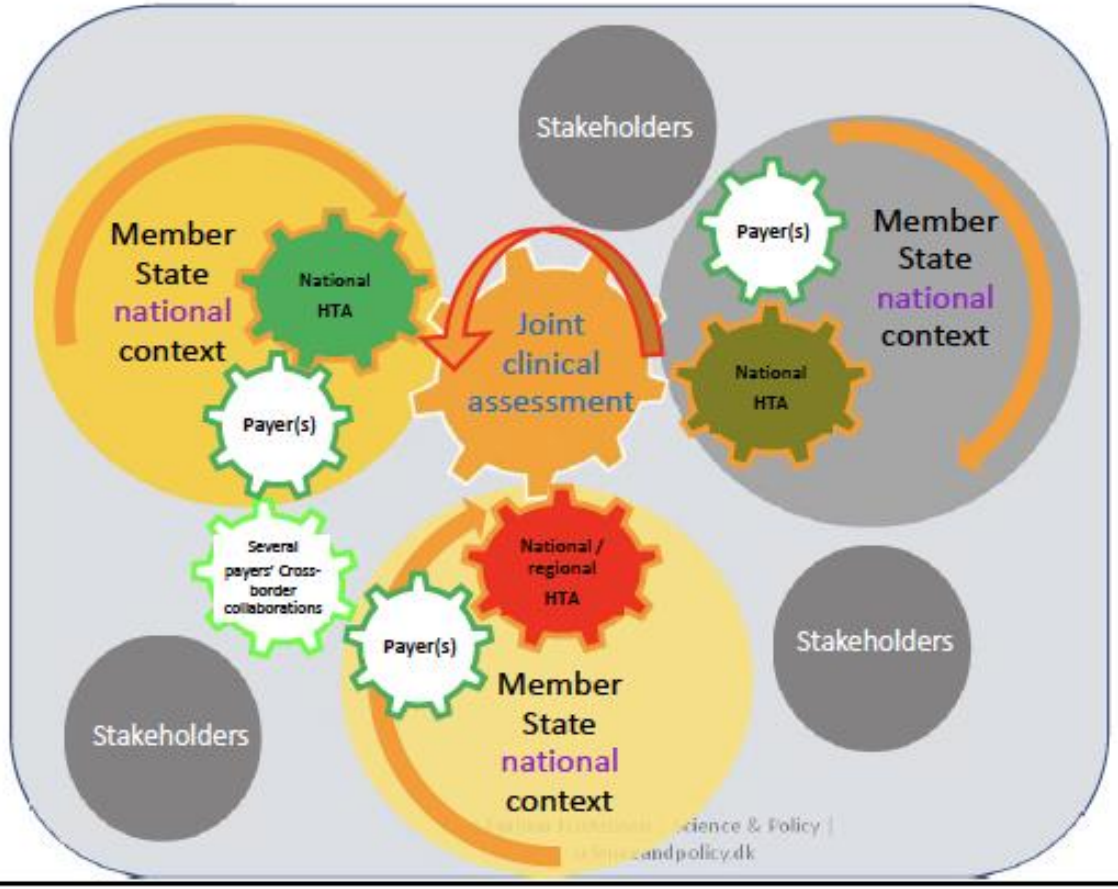
FIRST PLENARY SESSION: JOINT ASSESSMENT OF RELATIVE EFFECTIVENESS: "TRICK OR TREAT" FOR DECISION MAKERS IN EU MEMBER STATES

Member states **own scientific and technical** mechanisms and **joint** mechanisms



Finn Børlum Kristensen, MD, PhD

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VARIANTY POSTUPU

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of common tools and data	Option 4 Cooperation on the production of joint REA reports	Option 5 Cooperation on the production of joint full HTA reports
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget Ending 2020	Largely depending on EU budget Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓

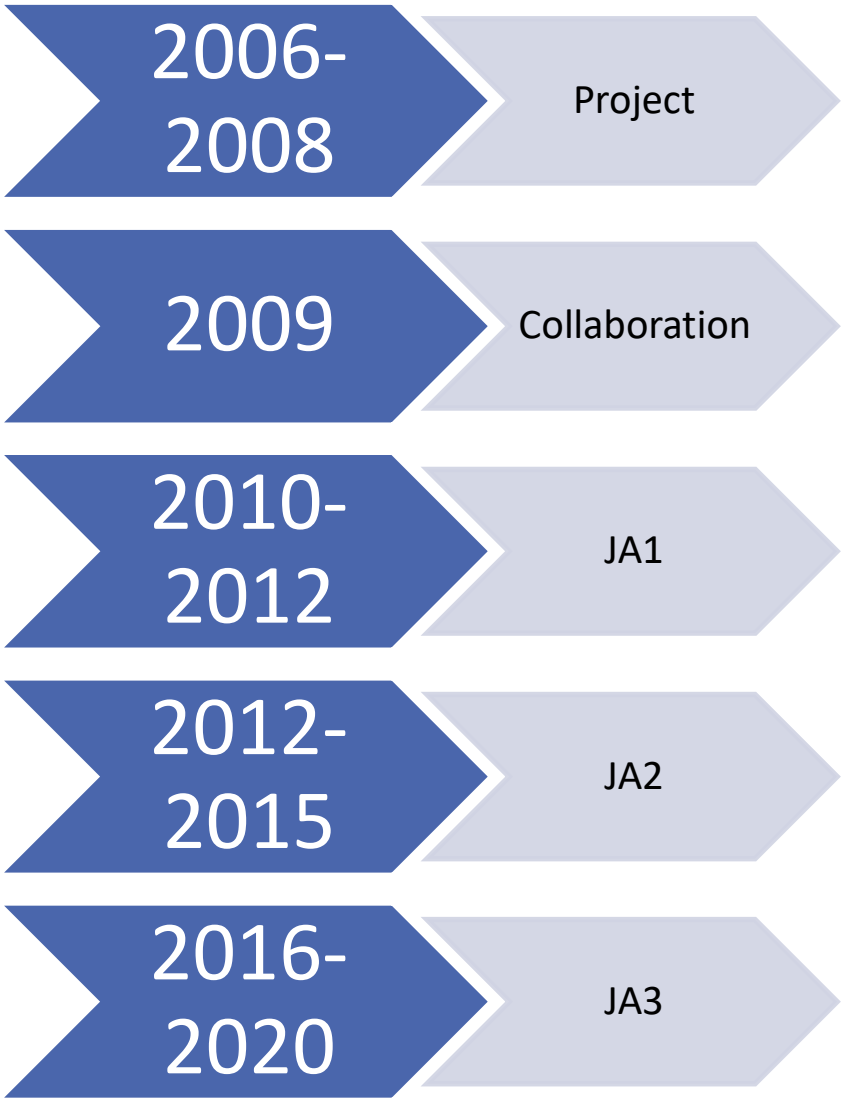
PROPOSAL

Key elements (1)

- **Provides support framework** and procedures for EU cooperation on HTA
- **Well defined scope** — Article 5
- Focus on **clinical** aspects
- **Member States** driven approach — Articles 3-7,13
- **High quality** – Member States experts
- **Timely output** — Recitals 17-18
- **Transparency and independence** — Article 22.1.
- Pragmatic **phase-in** approach — Articles 33, 36

Flora Giorgio
Directorate General for Health and Food Safety (DG SANTE)
European Commission
Brussels, Belgium

EVOLUCE EUNETHTA



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- World Health Organization (WHO) convened - Fair Pricing
  - Ceny léků nastaveny podle výkonosti ekonomiky
- Realita = IRP
  - Výsledkem je zpomalený vstup/až nedostupnost v chudších zemích EU
  - (Ne)viditelnost reálných cen + paralelní export
- Zvyšující se vliv value-based pricing = HTA
  - WTP dle HDP je vlastně take princip fair pricing

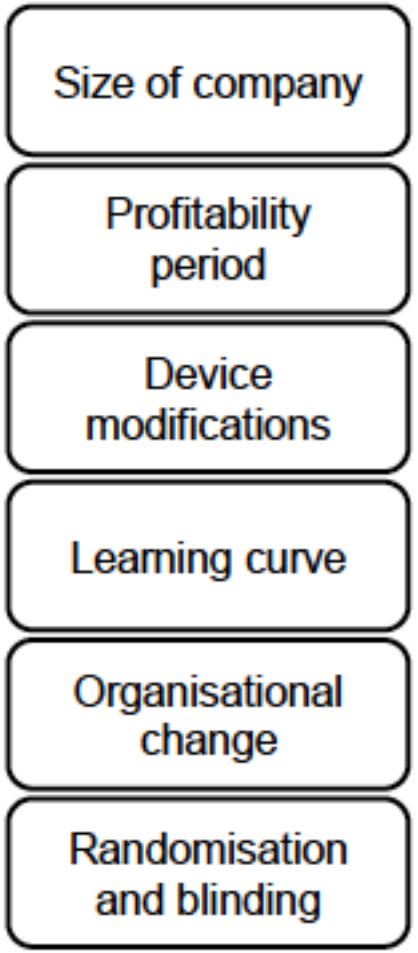
PLENARY 3:
BUDGET IMPACT AND EXPENDITURE CAPS: POTENTIAL OR PITFALL?

- There will never be enough money. That is the whole point of economics – limited resources and efficient choices
- We need to optimise:
  - Decisions about how much health care expenditure
  - How to spend the health money
- Still need to allocate resources efficiently across service
- Apply HTA / value assessment to care pathways, measuring and paying for outcomes across boundaries
  - Episode based payments?
  - With outcomes-based or evidence-based payments?
- Expenditure caps an inevitable requirement for regulating a complex sector of the economy, predominantly funded by the public sector

Adrian Towse, MA, Mphil
Director, Office of Health Economics
London, UK

MEDICAL DEVICES HTA

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- **Medical Devices and Diagnostics**
  - **ISPOR: Special Interest Group**



KDE SE PROVÁDÍ HTA V EU

Yellow – data for pharma and non-pharma; Blue – data for pharma only; Red – No HTA process (in development)

Number of topics considered per year

Darker colour = more topics considered

European network for Health Technology Assessment | JA3 2016 – 2020 | www.eunethta.eu

JA3-WP7: An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: final report

Další zajímavá témata

- Jak prezentovat výsledky HE analýz publiku? Plátcům, regulátorům, pacientům – grafické zjednodušení, infografika, apod.
- Kde je všude role pacientů v HTA procesech (assessment/appraisal)?
- Jak hradit vzácné a ultravzácné terapie?
  - Výsledky HST NICE
- Jak hradit netradiční terapeutická schémata? – genová terapie, buněčná terapie – vysoký náklad na úvod a dlouhotrvající remise – risk-sharingové modely založené na roční splátce („annual fee“)
- AUtomatizace a robotizace HTA – AI/ML – farmakoekonomové nebudou nahrazeni, ale výrazně se jim usnadní rutinní práce, pokud se naučí používat moderní technologie

AUTOMATIZACE V HTA

- Automatizace a robotizace HTA – AI/ML – farmakoekonomové nebudou nahrazeni, ale výrazně se jim usnadní rutinní práce, pokud se naučí používat moderní technologie
- Drummond:
  - Pokud nám technologie umožní zrychlit/zautomatizovat naši analýzu, měli bychom strávit více času na „interface between the analysis and the decision, modeling the impact of managed entry agreements“, protože „decision makers will not want to talk to machines“

…A DALŠÍ….

- Metodická symposia:
  - Očišťování dat o cross-over
  - Pokroky v analýze přežití – cure/mixture cure modely – odlišné křivky pro respondéry/non-respondéry
  - Validace extrapolovaných křivek přežití dle RWE
  - Bayesian Estimation křivek přežití
  - Využitelnost jednoramenných studií
  - Chybějící data z RWE
- Indication-based pricing (IBP) – A.Towse (OHE)
  - IBP expands patient access and maximises quality-adjusted life years (QALYs) gained from a given budget, as well as encouraging the development of new indications. This provides the right signals for R&D

HE VTIP NA ZÁVĚR

- Andrew Briggs tweetuje AHE blog:

- “saying that CEA is insufficient so we should use MCDA instead is like saying I find it hard to put IKEA furniture together so I will make my own furniture from scratch”