GLOBAL WAVES: THE RIPPLE EFFECT OF EU JOINT CLINICAL ASSESSMENT ON HEALTHCARE WORLDWIDE

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Interactive question #1

What is your work environment?

a) Academia

b) Government

c) Hospital/clinic

d) Industry/consulting

e) Managed care/payer

f) Patient advocacy group

Interactive question #2

What is the best way to describe your country?

a) EU markets

b) Non-EU Matured HTA markets (UK, Canada, Australia,…etc)

c) Non-EU Emerging HTA markets (Latin America, Asia Pacific,…etc)

d) USA - it’s complicated…

e) Others

Why will there be an EU JCA?

From

- HTA decisions are national, based on varying criteria
- Small countries lack resources for a timely or thorough appraisal
- Appraisal outcomes vary from country to country, resulting in unequal access to medicines across EU member states

Individual Countries
Population size: 0.54 million – 84.4 million

To

- Improved equality of patient access to innovative technologies across member states
- Strengthened quality of HTA across the EU
- Reduced duplication and increased efficiency (eventually…)

EU
Population size: 449.2 million

What does the new HTA Regulation cover?

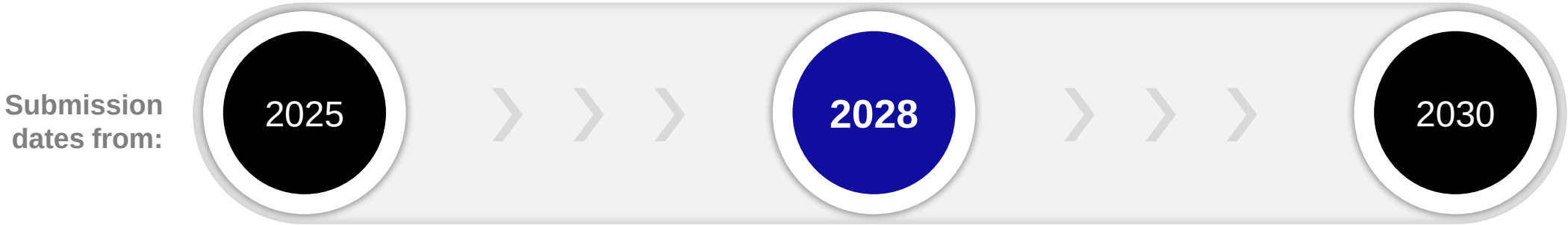
- **The HTA Regulation focuses on clinical aspects of HTA:**
  - relative clinical effectiveness and
  - relative clinical safety
- **of a new health technology as compared with existing technologies through**
  - Joint Clinical Assessments (JCA) and/or
  - Joint Scientific Consultations (JSC)
- **It is MANDATORY**

- **NO conclusions on the relative effectiveness of health technologies**
- **NO EU-level economic analysis or reimbursement decisions**
- **Price and reimbursement decisions remain national**

Which medicines are in scope and by when?

The regulation applies to:

- New drugs submitted via a centralized MA procedure, and claim a **new active substance**
- New **therapeutic indications** granted for these drugs (if a joint clinical assessment has already been made)



12 January 2025

Treatment of **cancer** and medicinal products which are regulated as '**advanced therapy medicinal products (ATMPs)**'*

13 January 2028

orphan medicinal products

13 January 2030

all medicinal products are in scope

*ATMPs are medicines for human use based on genes, tissues or cells.

Leveraging evidence across border for decision making

Impact of EMA decision on Latin America

- EMA and other reputed regulators must be aware that their regulatory decisions may directly impact downstream regulatory decisions in other countries and therefore, patients' lives elsewhere.

Impact of HTA on Asia Pacific

- Taiwan references HTA and reimbursement decisions in UK, Australia, Canada's HTA decisions
- South Korea references UK, Australia, Canada's HTA decisions in their assessment

"When HTA bodies in other markets approve our drug, it doesn't guarantee approval in our own market. However, if they reject it, securing a positive outcome here becomes significantly more challenging." Quote from a market access leader in country affiliate

Durán CE, Cañás M, Urtasun M, Elseviers M, Vander Stichele R, Christiaens T. Potential negative impact of reputed regulators' decisions on the approval status of new cancer drugs in Latin American countries: A descriptive analysis. PLoS One. 2021 Jul 13;16(7)

Liu, Gordon, et al. "The development of health technology assessment in Asia: current status and future trends." *Value in Health Regional Issues* 21 (2020): 39-44.

Global support for affiliate

Global market access

- Global pricing guidance
- Global reimbursement strategy
- Global value dossier
- Global economic models

Affiliate market access

- Alignment with global on pricing and reimbursement strategy
- Local value dossier adaptation
- Local model adaptations
- Local literature review or evidence generation as needed

Why are we here today?

Past: individual HTA

Now: JCA

Future: ?

Established HTA Markets

Emerging HTA markets

and many other countries

Impact of JCA on other countries - ripple, wave, or tsunami?

Panelist

Anouchka Cecilia Vidal, PharmD, MBA, MSc

Roche, Global/EU HTA Pipeline Lead, Switzerland

Global Markets

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Established HTA market

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Emerging HTA market