DOLON

Pulling back the curtain on Joint Clinical Assessment

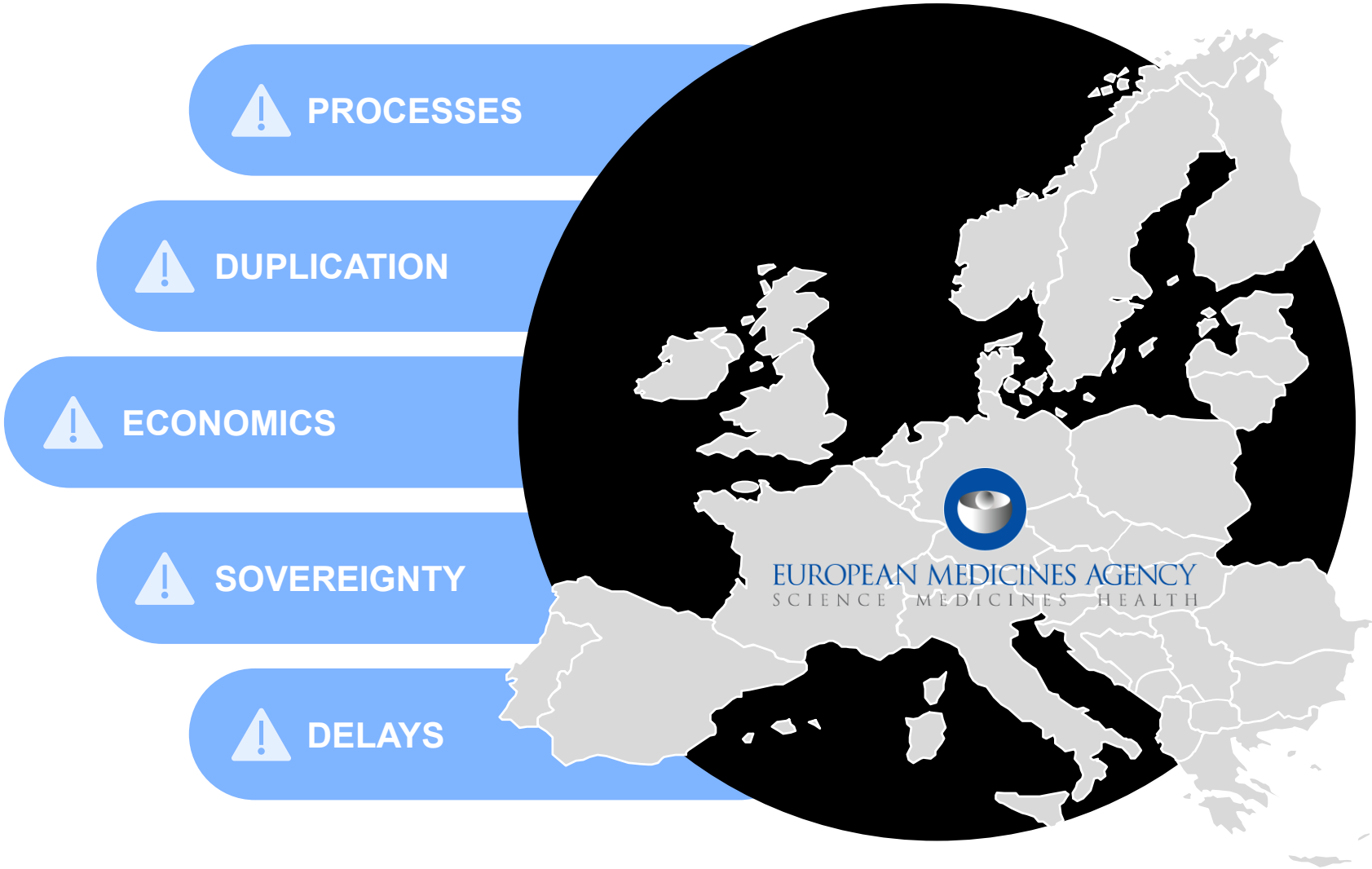
Emilie Neez

All opinions my own!

Confidential

WODC Europe | Barcelona | 24 October 2024

Same script, different cast



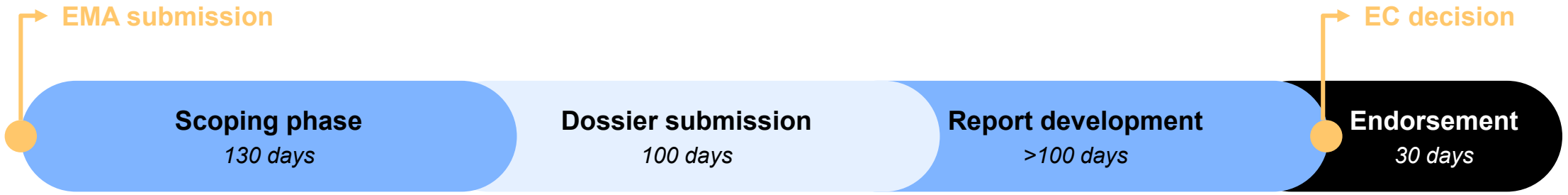
Waiting for the final (Implementing) Act

Practical questions	
EU-LEVEL IMPLEMENTATION	• What will the JCA process be? • What will the report cover vs. not cover? • How will stakeholders be involved?
COUNTRY-LEVEL IMPLEMENTATION	• How might countries adapt their national HTA/P&R processes in the short/medium term? • What systems will be established to monitor the implementation of JCA recommendations at country level?
EVIDENCE & PICOs	• What type of evidence does the JCA require and favour? • What is the process for PICO selection?

DOLON

Stage directions are generally clear

Topline JCA timelines



Knowns

- ✓ **JCA timelines**
- ✓ **JCA dossier & report content**
- ✓ **Governance & stakeholder interactions**

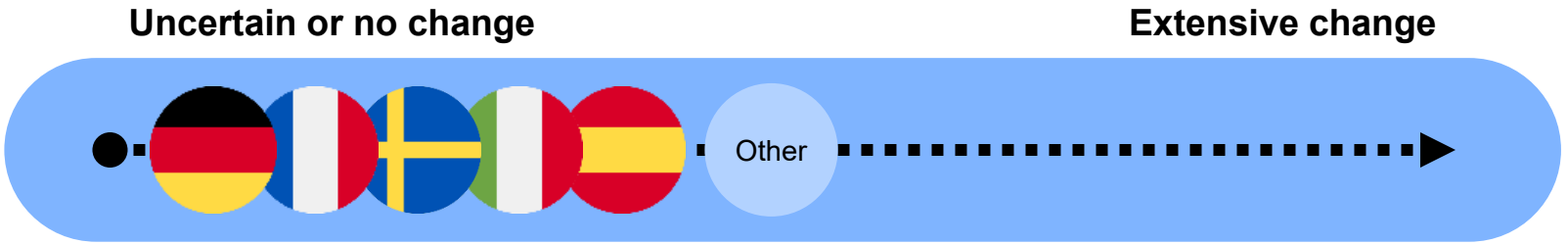
Uncertainties

- ? **Interactions with EMA**
- ? **Conflict of interest management**
- ? **Impact of patients and clinical experts**

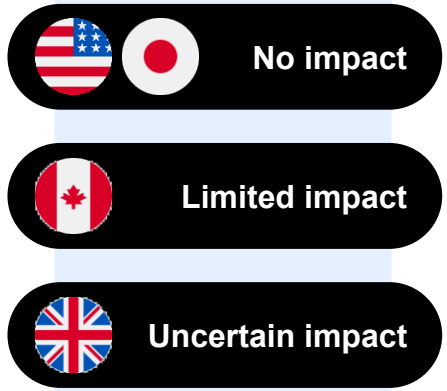
Sources: Commission Implementing Act on the JCA; Implementation rolling plan

How actors might play remains to be seen

Hypothesised extent of change in national processes vs status quo within ~3 years



Ex-EU hypotheses



Knowns

- ✓ **Implementation by *some* countries**
- ✓ **Requirement for "due consideration"**
- ✓ **Data requests restrictions**

Uncertainties

- ? **Implementation by *all* countries & resourcing**
- ? **Justification of deviations**
- ? **Impact of limited use of JCA reports**

Sources: Spanish Ministry of Health; Dolon hypotheses

The thorny drama: PICOs and evidence requirements

Need for PICO consolidation

1L NSCLC

10 PICOs

50% requested by single country

280 analyses requested

50% indirect analyses

3L MM

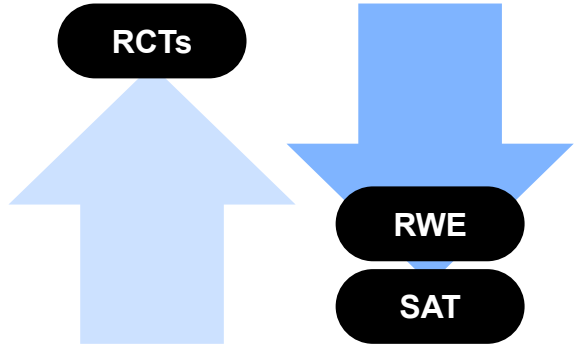
16 PICOs

75% requested by single country

720 analyses requested

69% indirect analyses

JCA evidence hierarchy



Knowns

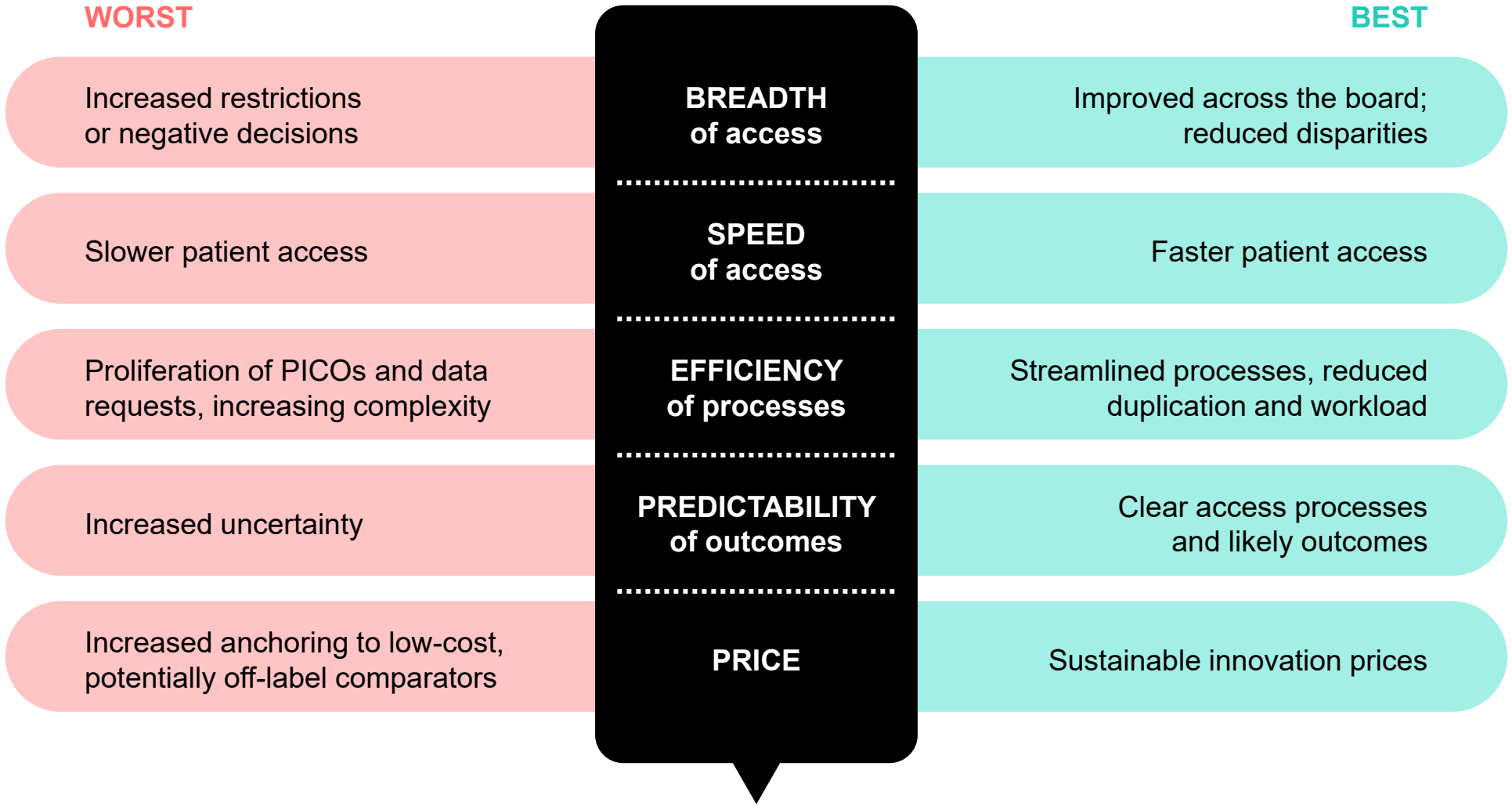
- ✓ **Evidence reporting requirements**
- ✓ **Process for PICO selection**
- ✓ **Strict evidence hierarchy**

Uncertainties

- ? **Integration of additional evidence**
- ? **Approach to PICO consolidation**
- ? **Adaptations to orphan specificities**

Sources: Guidance on outcomes for joint clinical assessments; Practical guideline for quantitative evidence synthesis: direct and indirect comparisons; Guidance on validity of clinical studies; Van Engen et al. The Impact of Additive Population(s), Intervention, Comparator(s), and Outcomes in a European Joint Clinical Health Technology Assessment

How the plot might twist



Critical factors in launch and innovation decisions

Could JCA be the hero?

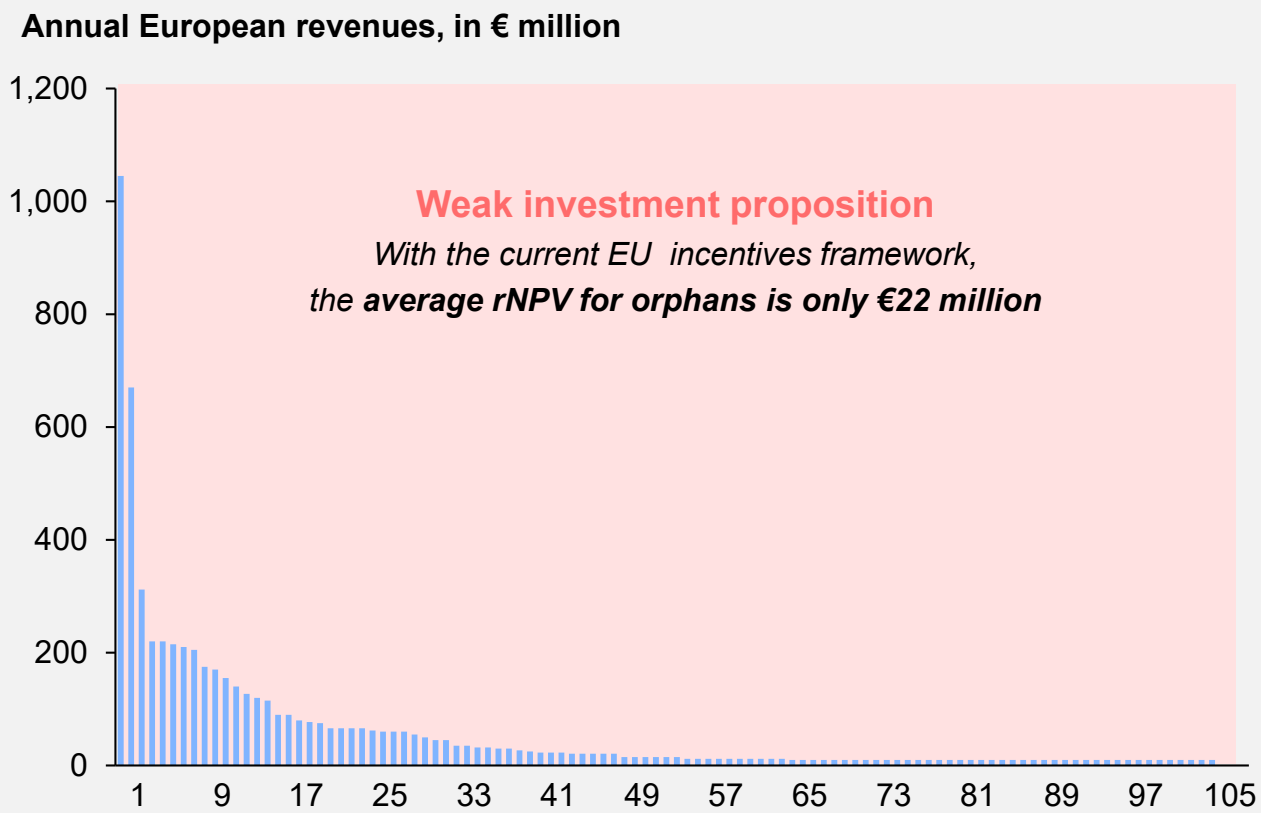
BREADTH
of access

SPEED
of access

EFFICIENCY
of processes

PREDICTABILITY
of outcomes

PRICE



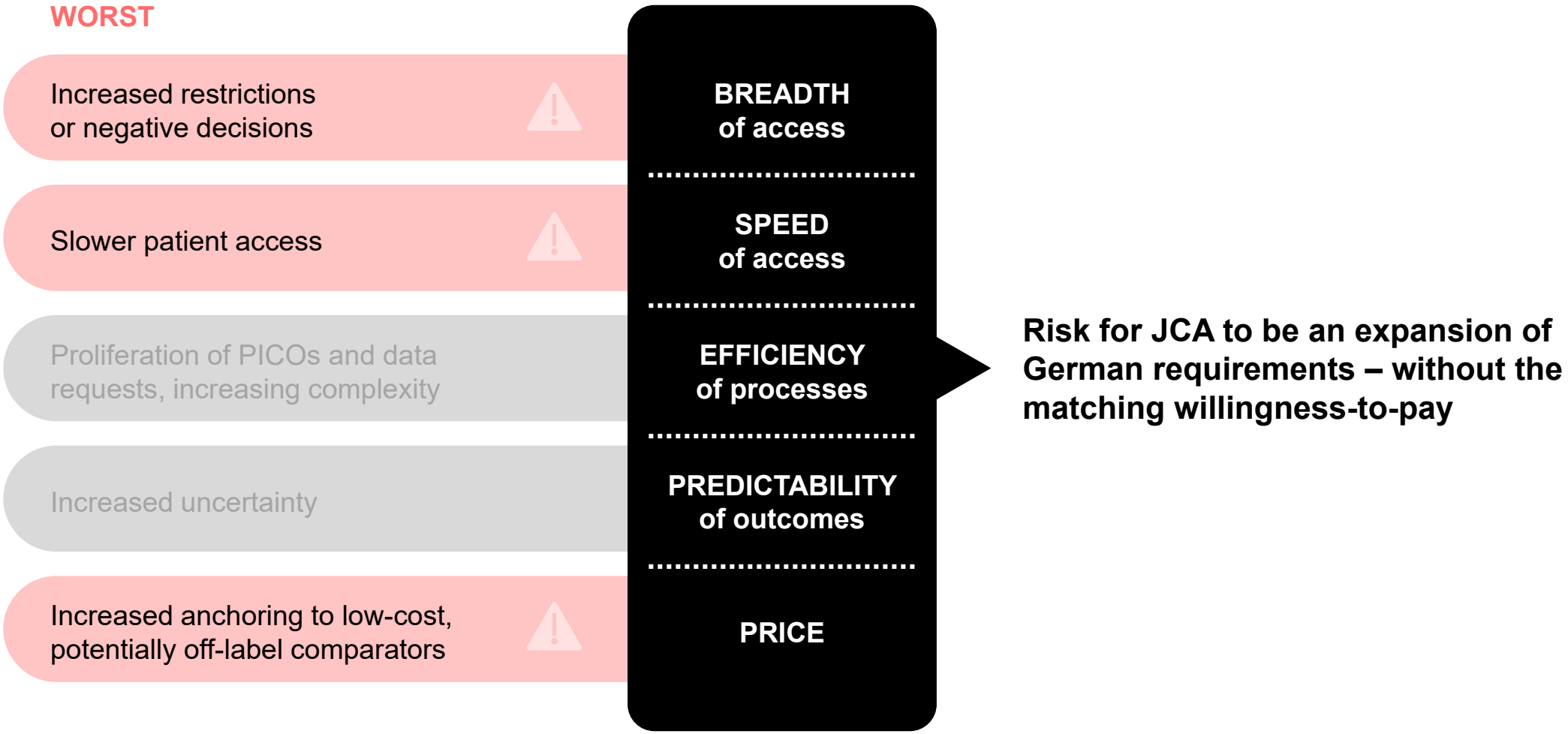
Sources: European Commission Staff Working Document on Orphan and Paediatric Regulations; Dolon Impact Assessment on the Orphan Regulation

Mario Draghi thinks so

	Summary of pharma proposals	Time horizon: Short term	Medium term	Long term
1	Maximise the impact of the EU Health Data Space	✓	✓	
2	Streamline the set-up and management of multi-country trials		✓	
3	Expedite access through coordinated action by medicines agencies, HTA authorities and payers on guidance to industry, P&R as well as procurement		✓	
4	Provide clear and timely guidance on the use of AI		✓	
5	Rapidly and fully implement the HTA regulation and ensure the required resources are allocated to ensure the delivery of JCA as of 2025, with the aim of establishing an EU agency in the long term	✓		✓
6	Improve business predictability through a continuous evidence-based dialogue with stakeholders to underpin EU policy-making on protection mechanisms for novel medicines		✓	✓
7	Increase and focus public R&D investment in the EU		✓	
8	Mobilise private R&D investment in the EU		✓	
9	Develop strategic international partnerships		✓	✓

Sources: The future of European competitiveness. Part B | In-depth analysis and recommendations

But the risk is real



How to avoid a tragedy

Some pending questions

1. County-level changes
2. PICO consolidation methodology
3. Rules for patient and KOL involvement
4. Adaptations to orphan specificities
5. Evolution of JCA over time

Recommendations for manufacturers

1. Anticipate PICO requests
2. Rethink pre-launch timelines & processes
3. Build capacity in stat & HEOR teams
4. Consider JCA evidence requirements
5. Engage with stakeholders where possible