International reference pricing and joint clinical assessments

How will European-level HTA evaluations impact international reference pricing and launch sequencing?

International Society for Pharmacoeconomics and Outcomes Research, Inc.

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Today’s agenda

AGENDA

- Background
- Objectives
- Methodology
- Results
- Key takeaway

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Joint clinical assessments are intended to decrease time to access, particularly in clinical-effectiveness markets

	WEIGHT OF CLINICAL ASSESSMENTS ON PATIENT ACCESS TIMELINES		IMPACT OF JCA ON PATIENT ACCESS TIMELINES
Clinical-effectiveness markets e.g., 	FULL WEIGHT 	*Clinical assessments are the **sole driver** of decision-making*	 *Timelines for HTA assessment will be **shortened** as the clinical assessments will be expedited*
Cost-effectiveness markets e.g., 	MEDIUM WEIGHT 	*Additional **economic evidence** will also be assessed*	 *While the expedited clinical assessments will **reduce timelines** for HTA, additional time will be required for the economic assessment*
Budget-impact markets e.g., 			

HTA: Health technology assessment; JCA: Joint clinical assessment

We analyzed the current influence of IRP on time to access and the expected impact of joint clinical assessments

Historically, **IRP** has been used by manufacturers to **inform launch sequence**, connecting national strategies with international revenue targets

In the future, **JCA** is expected to **expedite clinical assessment** timelines, putting pressure to also **expedite P&MA discussions** at the national level, which could impact **launch sequence**

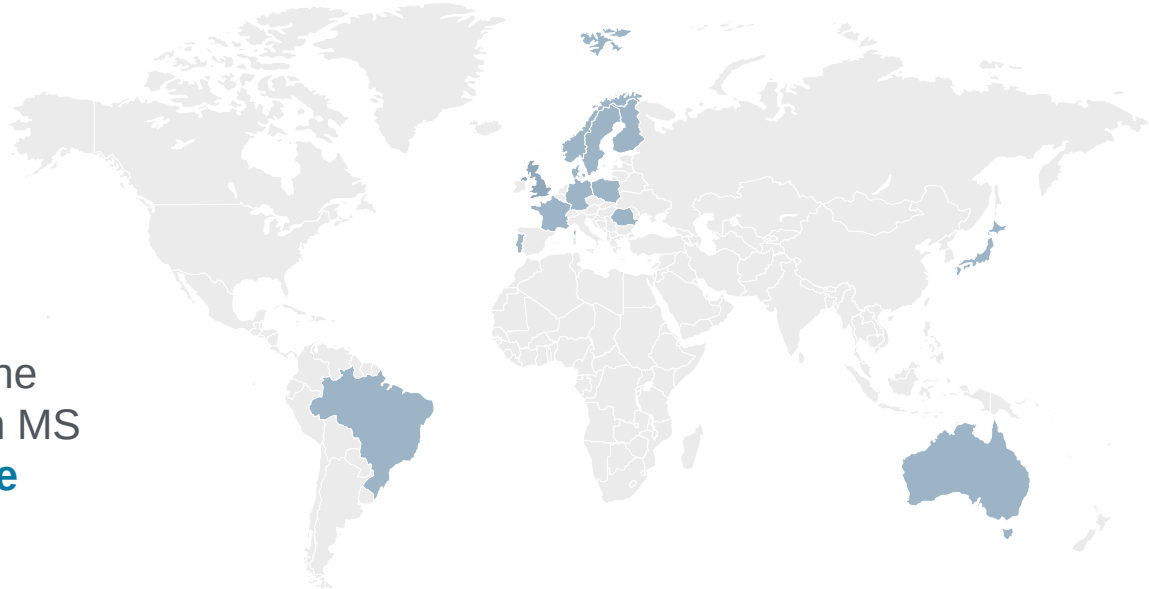
This research aimed to analyze the extent to which **IRP policies** are guiding **time to access**, and the **potential impact** that **JCAs** may have on **time to access** globally

IRP: International reference pricing; JCA: Joint clinical assessments; P&MA: Pricing and market access

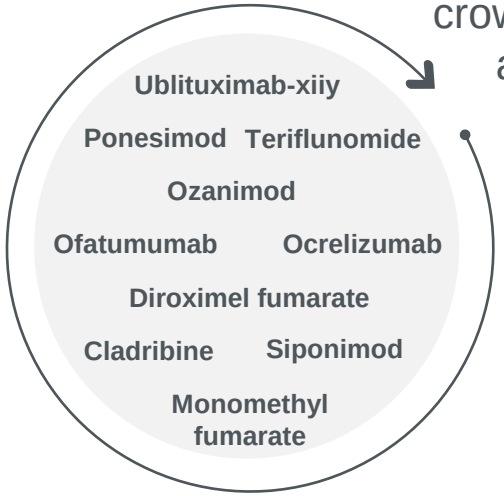
We analyzed 10 drugs in 13 countries to determine if IRP policies were still influencing the timing for access

RESEARCH METHODOLOGY

We selected **13 countries** with established HTA entities that either have **IRP policies** or act as **IRP referenced countries**, and reviewed their **IRP policies**



We selected **10 MS drugs** as the crowded competitive landscape in MS allowed a **robust drug sample**



We defined the **timing for access** based on HTA submission dates, excluding submissions **pre-2019***

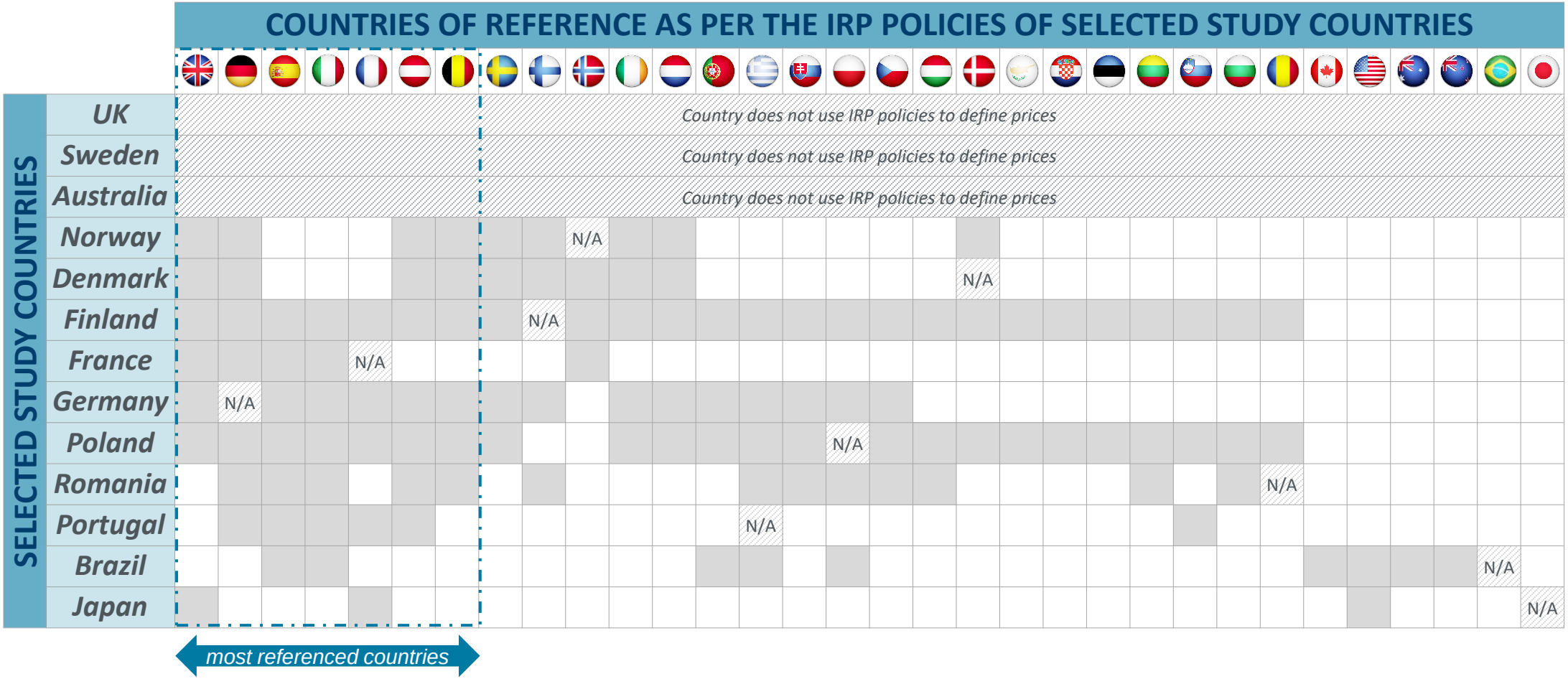
We analyzed time to access and IRPs to determine if **IRPs** may have **informed time to access**

* Time to access based on HTA submission dates considered the average HTA process duration

HTA: Health technology assessment; IRP: International reference pricing; MS: Multiple sclerosis

While, based on IRP policies, most of the select countries reference prices in the UK, EU-4, Austria, and Belgium…

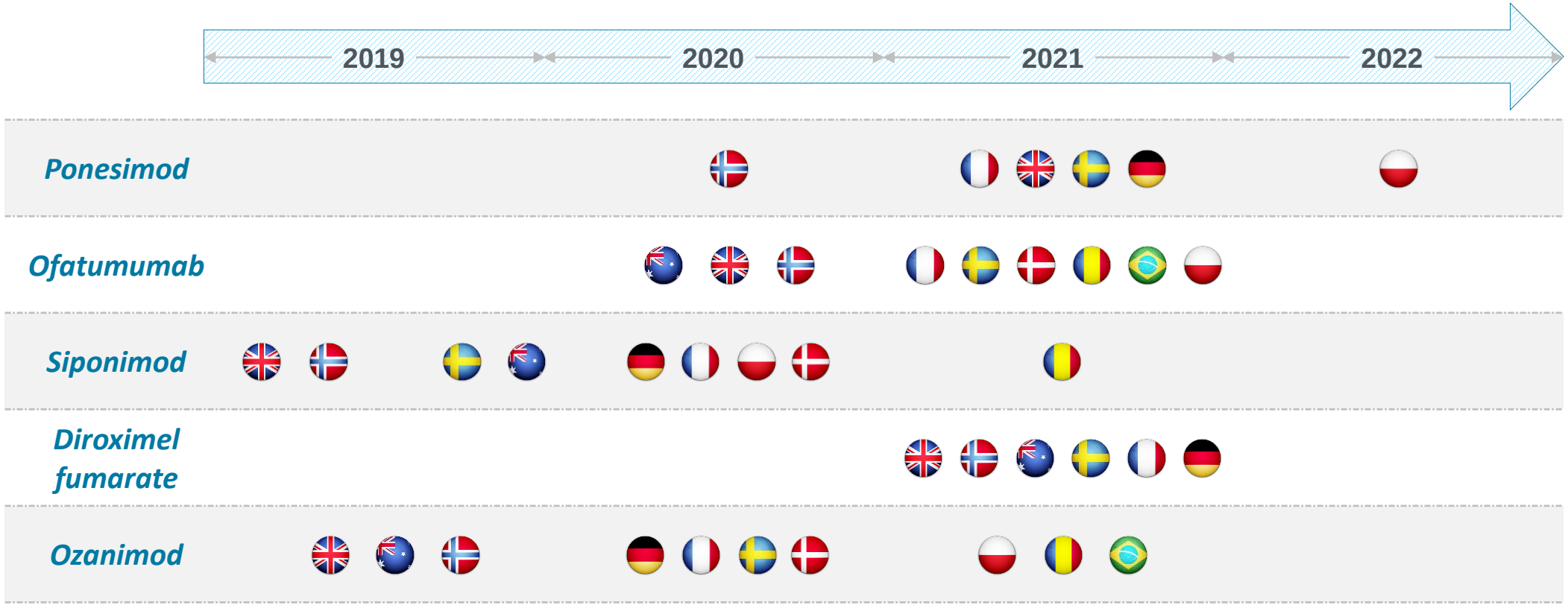
IRP POLICIES



IRP: International reference pricing; N/A: not applicable; UK: United Kingdom

... our research showed that time to access was early in the UK, Australia, and Norway compared to other countries

TIME TO ACCESS*



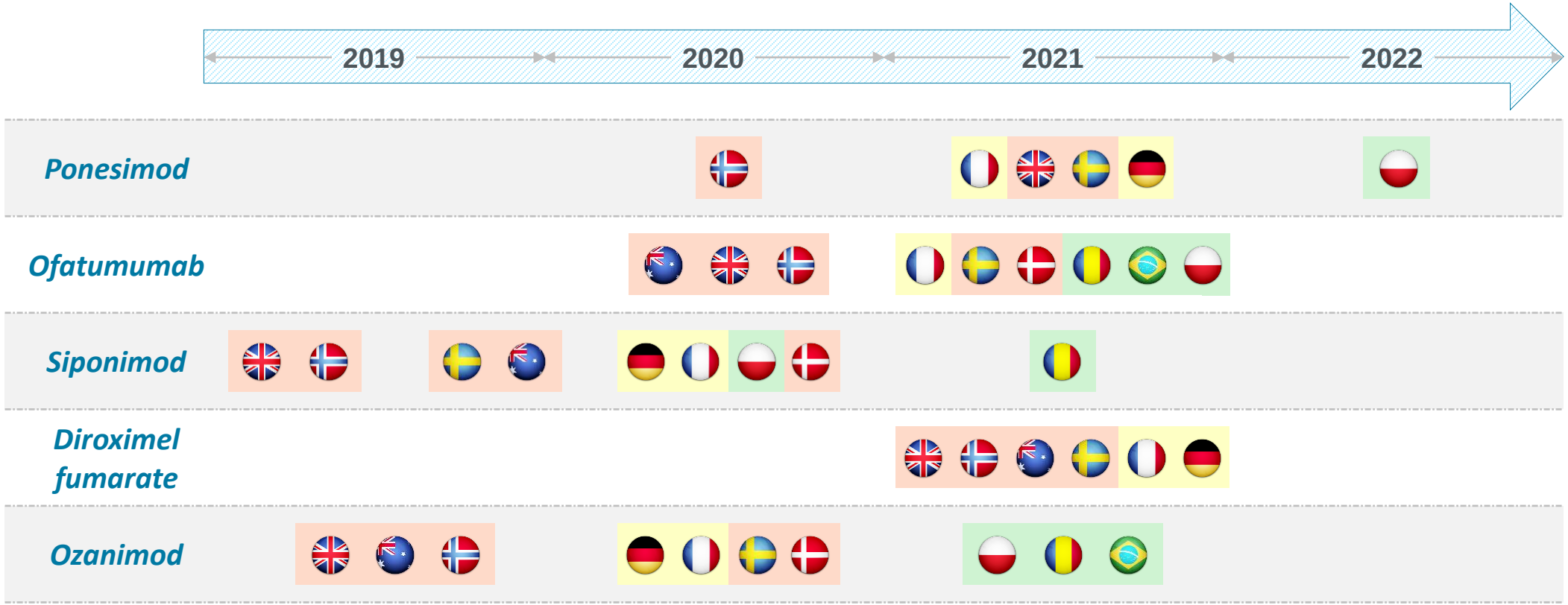
MOST REFERENCED COUNTRIES AS PER IRP POLICIES

* Time to access based on HTA submission dates considered the average HTA process duration

HTA: Health technology assessment; IRP: International reference pricing; UK: United Kingdom

Our research also showed earlier time to access in cost-effectiveness markets against other market archetypes

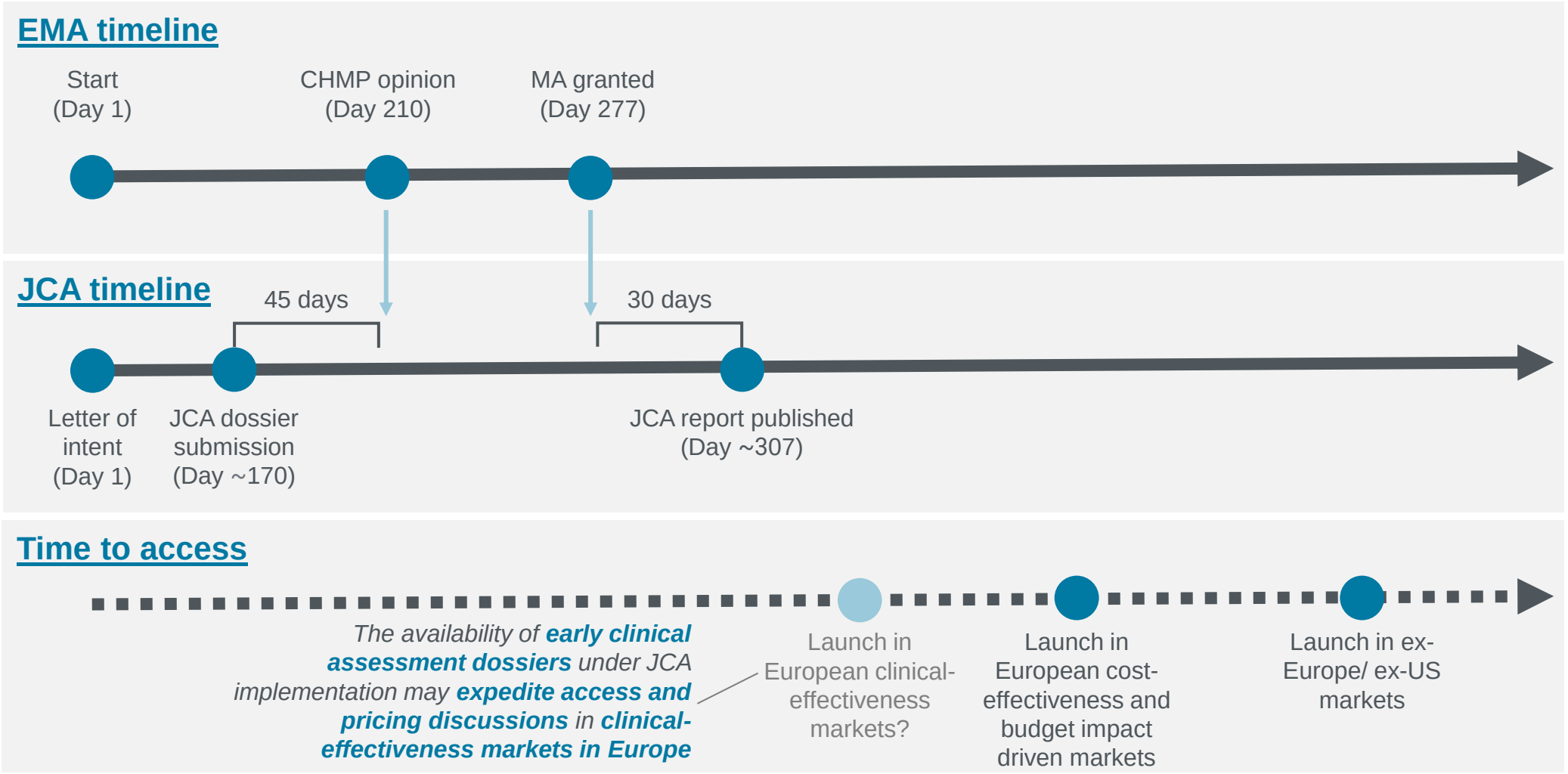
TIME TO ACCESS*



* Time to access based on HTA submission dates considered the average HTA process duration

HTA: Health technology assessment; IRP: International reference pricing

Joint clinical assessments may unify time to access in Europe, and expedite it in clinical-effectiveness markets



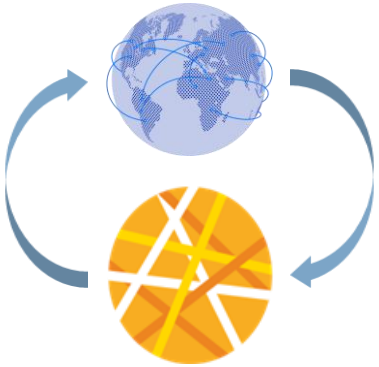
CHMP: Committee for Medicinal Products for Human Use; EMA: European Medicine Agency; EU: European Union; JCA: Joint clinical assessment; MA: Marketing authorization; US: United States

Despite being defined to streamline access, joint clinical assessments may increase the complexity of launch strategy

✓ Based on the current state of evidence, **time to access** is driven by **manufacturers´ freedom** to define their **launch sequence**, which **connects decision-makers** across the world due to the establishment of **IRP policies**

✓ JCA may **increase pressure** to trigger **early pricing discussions**, and **interfere** with the traditional **launch strategies**, including the additional need to consider launch in EU markets based on **payer archetype** and **timelines for the economic assessment**

Manufacturer-guided launch strategy



JCA-integrated launch strategy

✓ In global scale, **non-European countries** with less established HTA agencies that find IRP as an easier approach may regularly **revisit their basket of referenced countries** based on **JCA´s impact** on **launch sequencing**

Manufacturers need to fine-tune their launch strategies to account for the uncertainties and ramifications of the JCA, including the uneven influence of IRPs across geographic regions

JCA: Joint clinical assessment; HTA: Health technology assessment; IRP: International reference pricing

Thank you