The Ripple Effects of Healthcare Reforms in Germany: A Reduced Free Pricing Period

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INTRODUCTION

Following the 2011 AMNOG act, **Germany has been a top priority market** for launch in the EU, known for **rapid patient access to novel medicine.**

Recently, however, news of the "Statutory Health Insurance Financial Stabilization Bill", which aims to **reduce the free pricing period** from **12 to 6 months,** has cast **uncertainty over the future of this status**.
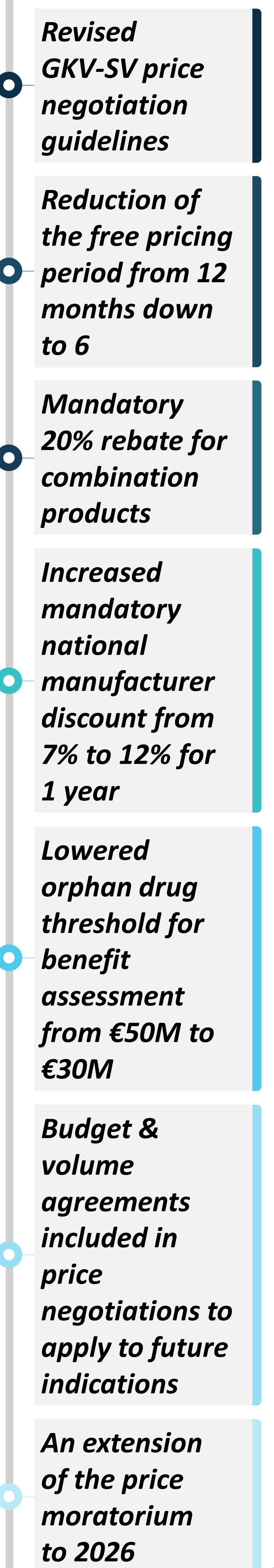
Changes to the German HTA process are aimed at **offsetting rising healthcare costs** and establishing a more sustainable system but are also anticipated to **threaten manufacturers and potentially even patients.**

The impact of the reduced free pricing period is likely to have a **ripple effect for pharma launch strategies** within Germany, across Europe, and beyond.

Objective:

This research aims to understand potential impacts of **reducing the free pricing period for pharma products** from 12 to 6 months on:
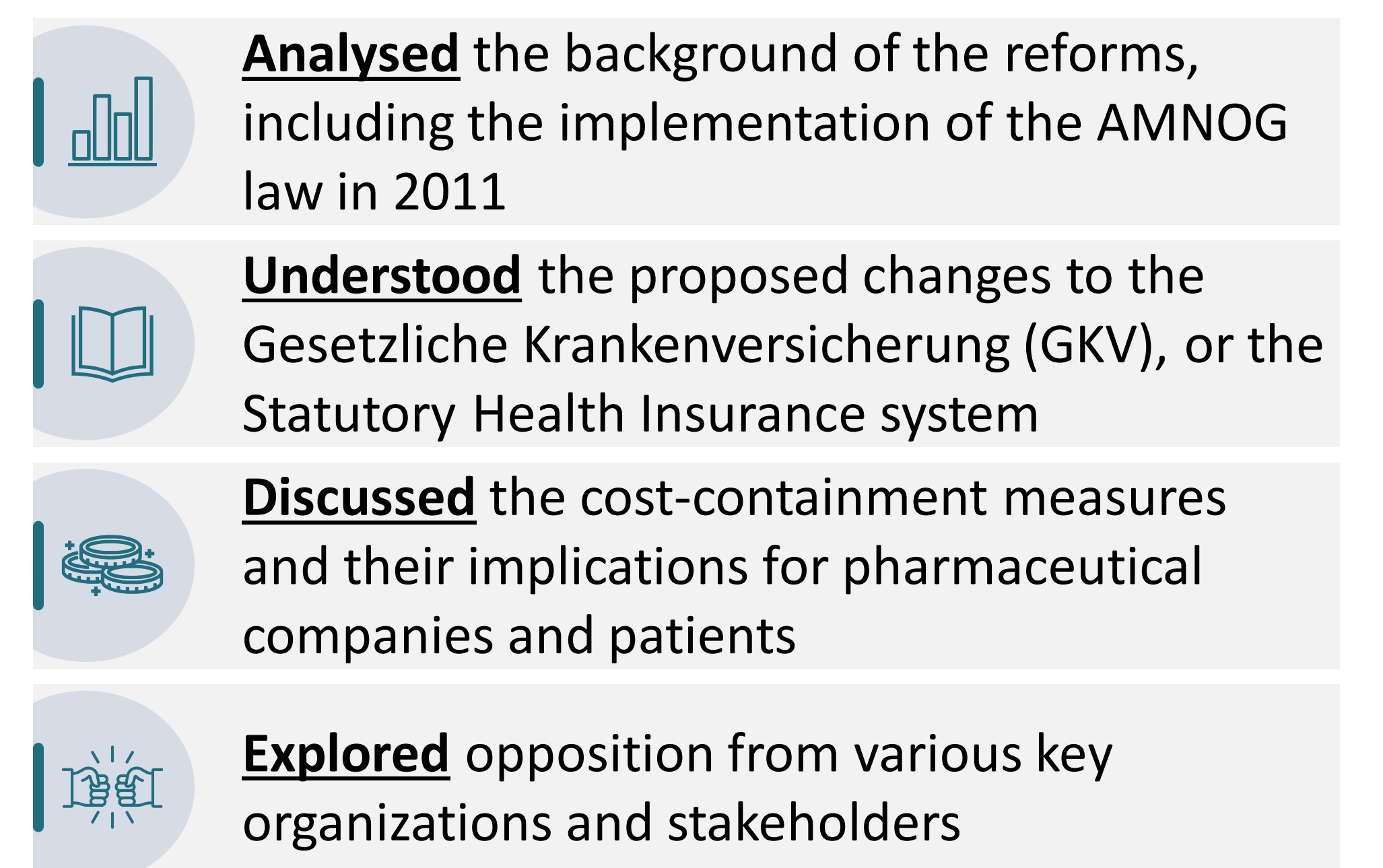
- Pharma **launch strategies**
- **Patient access** to innovative treatments

Figure 1: Cost-containment reforms[1]

- Revised GKV-SV price negotiation guidelines
- **Reduction of the free pricing period from 12 months down to 6**
- Mandatory 20% rebate for combination products
- Increased mandatory national manufacturer discount from 7% to 12% for 1 year
- Lowered orphan drug threshold for benefit assessment from €50M to €30M
- Budget & volume agreements included in price negotiations to apply to future indications
- An extension of the price moratorium to 2026

METHODOLOGY

Figure 2: Methodology overview

- **Analysed** the background of the reforms, including the implementation of the AMNOG law in 2011
- **Understood** the proposed changes to the Gesetzliche Krankenversicherung (GKV), or the Statutory Health Insurance system
- **Discussed** the cost-containment measures and their implications for pharmaceutical companies and patients
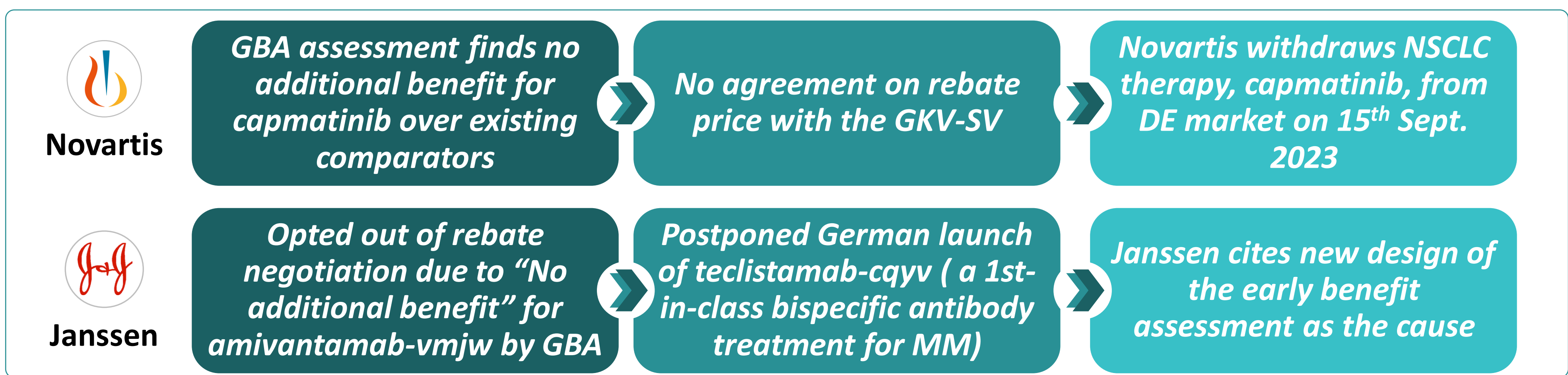- **Explored** opposition from various key organizations and stakeholders

RESULTS

Germany was perceived as the optimal 1st-launch market for oncology treatments & costly medicines

- Germany's previous 12-month free pricing **enables a high, visible list price** across the EU & world
- Other markets would **use Germany as a reference market** for expensive treatments across indications
- Germany became known for their **rapid patient access to innovative treatments**, esp. in oncology

Consequently, the new changes to the free pricing period have been negatively received by pharmaceutical companies, causing them to **rethink their German launch strategy** (Fig. 3)**.**

Figure 3: The effects of the reduced free pricing period are already being seen by major pharma companies

Novartis
- GBA assessment finds no additional benefit for capmatinib over existing comparators
- No agreement on rebate price with the GKV-SV
- Novartis withdraws NSCLC therapy, capmatinib, from DE market on 15th Sept. 2023

Janssen
- Opted out of rebate negotiation due to "No additional benefit" for amivantamab-vmjw by GBA
- Postponed German launch of teclistamab-cqyv (a 1st-in-class bispecific antibody treatment for MM)
- Janssen cites new design of the early benefit assessment as the cause

A reduction to the free pricing period could deter pharmaceutical companies from launching in Germany first, which may have knock-on effects on list prices and potential revenue
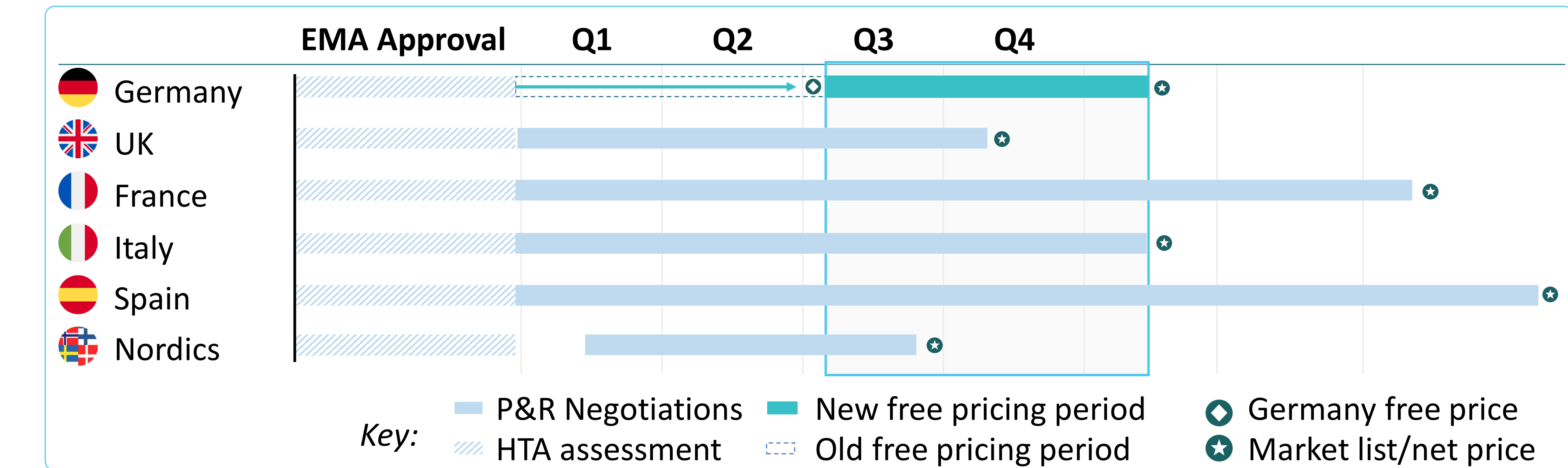
- A reduced free pricing period will likely continue to **disrupt both 'classic' launch-sequencing and first-year revenue forecasting in the EU**
- **Diminished negotiated list-price is likely to be used in external reference pricing (ERP)**, and similarly reduced prices may soon be seen across the EU & the rest of the world
- **Lower-than-forecasted revenue for pharmaceutical companies** within Germany in the first year of launch, and reduced prices in other countries **could lead to a more significant revenue loss**

DISCUSSION

Pharma companies may consider early negotiations in other key EU markets, delaying product launch, and subsequently the free pricing period in Germany to better align with other EU HTA timelines

- A 6-month delay (Fig. 4) **would result in the conclusion of pricing negotiations and list price publishing aligning with respect to other HTA timelines** across the EU
- The risks associated with ERP could be partially mitigated with prudent timing, but this does not come without a **potential ethical dilemma**, with **delayed patient access to novel treatments**
- This may **destabilize Germany's status as front-runner for rapid access and innovation in Europe**

Figure 4: Potential new approval timelines in non-exhaustive list of key markets in the EU

Key: P&R Negotiations / HTA assessment / New free pricing period / Old free pricing period / Germany free price / Market list/net price

Concluding remarks:

- PRMA strategies will need to be continually developed to **minimize the potential negative impacts of a truncated free pricing period on global patient access and pharma revenue**
- This may involve **reallocation of resources** to mitigate potential revenue losses, leading to **increased usage of AI**, or increased **applications to EUnetHTA** to **accelerate** the **HTA process**, among others
- The extent of impact of the new AMNOG reforms are **yet unclear**, but it will **be crucial for pharma companies to be proactive rather than reactive** as we navigate through the uncertainty

References

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