HTA Reforms in Germany

Implications for Pharmaceutical Pricing and Reimbursement in Germany and the EU

November 14 2023

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Agenda

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1.

Overview of HTA reforms in Germany

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Statutory Health Insurance Finance Stabilisation Act

March 2022

Announcement of the bill

Objections from different stakeholders

November 2022

Cost-containment measures approved by the government

Major changes in drug appraisal going forward

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Note: background picture from www.freepik.com

Most significant changes following the law

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Free pricing period

The free pricing period following marketing authorization has **changed from 12 months to 6 months.**

During this period the additional benefit assessment takes place, and a decision is made by the G-BA and IQWiG.

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Key: G-BA, Gemeinsamer Bundesausschuss; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

Most significant changes following the law

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Free set list price

The free set list price is replaced by the negotiated price. This **new negotiated price is publicly available in the price list.**

For generics and biosimilars, confidential discounts do exist in most cases.

These do not exist for patented drugs, except:

- When manufacturers are in competition on very similar but patented products
- When a new list price comes into effect in January but is not visible as the list price until June/July

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Most significant changes following the law

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New cost-containment law

There have been **major changes to pricing**:

- *Patented comparator, no additional benefit*: price of the new product must be 10% lower than the price of the comparator
- *Patented comparator, non-quantifiable benefit or a minor additional benefit*: price may not be higher than the price of the comparator
- *Patented comparator, considerable and major added benefit*: premium pricing
- *Unpatented comparator, additional benefit*: price should not be higher than the comparator

Unchanged:

Unpatented comparator, considerable and major added benefit: premium pricing

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Most significant changes following the law

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Price-volume agreements

Although price–volume agreements could be made previously, this is **now mandatory**.

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Most significant changes following the law

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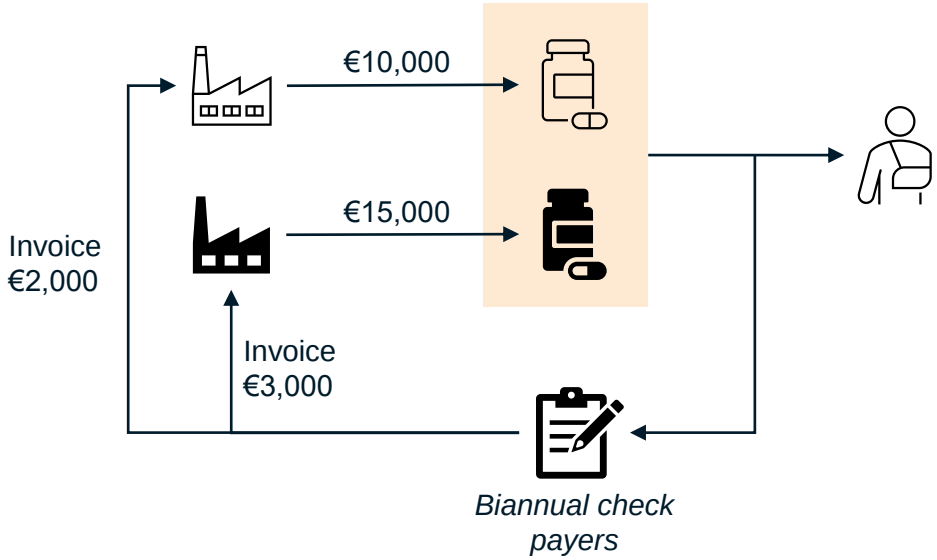
New mandatory regulation for combination products

For products in the G-BA's list of combination products, an additional 20% discount must be applied to all sales that are made in the listed combination.



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Most significant changes following the law

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Wastage

If vial wastage is more than 20% for a given patient, the manufacturer must pay for the wastage.

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Most significant changes following the law

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Orphan drugs

The **threshold for orphan drugs to be exempt from full HTA has decreased from EUR 50 million per year to EUR 30 million**.

This new threshold also applies to existing products.

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2.

Pricing processes

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Factors that influence the price negotiations

Proof and rating on additional clinical benefit	**Indication class**	**Orphan drug status / size of target population**
Cost of comparators	**Price in other European countries**	**Budget impact data are required**
Manufacturer R&D costs *Not mentioned in the law and only very minor impact*	**Severity (health-related quality of life) or frequency of the disease**	**Increased price-volume agreements** *Now mandatory under the new law*

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Key: R&D, research and development

Factors that influence the price negotiations

Proof and rating on additional clinical benefit	• Largest impact on pricing, accounts for approximately 60% of decision making • Based on comparator drug with negotiated premium
Cost of comparators	• Approximately 20% of decision-making algorithm
Price in other European countries	• Approximately 20% of decision-making algorithm • Controversial as law requires the consideration of *net* price

3.

Consequences of the cost-containment law

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Interpretation of mandatory regulation of combination products

G-BA's interpretation changed from very strict to more moderate following backlash

Original interpretation

G-BA considered all products in which it is *not explicitly forbidden to combine* as products for which the mandatory additional 20% discounts to all sales holds to meet the government's savings target

- List of **445** possible combination therapies even included products that have <u>not been tested</u> as a combination in a clinical trial

Revised interpretation 5 October 2023

G-BA has taken a more moderate approach, reducing the list:

- Specialist information must at least contain information about its use as a combination therapy with another drug
- Medicinal product under consideration is approved for use in the area of application assessed

Gemeinsamer Bundesausschuss

Beschluss

des Gemeinsamen Bundesausschusses über die Änderung der Arzneimittel-Richtlinie (AM-RL): Anlage XII/Anlage XIIa – Kombinationen von Arzneimitteln mit neuen Wirkstoffen nach § 35a des Fünften Buch Sozialgesetzbuch (SGB V): Ergänzung der Benennung von Kombinationen gemäß § 35a Absatz 3 Satz 4 SGB V in bereits gefassten Beschlüssen

Vom 5. Oktober 2023

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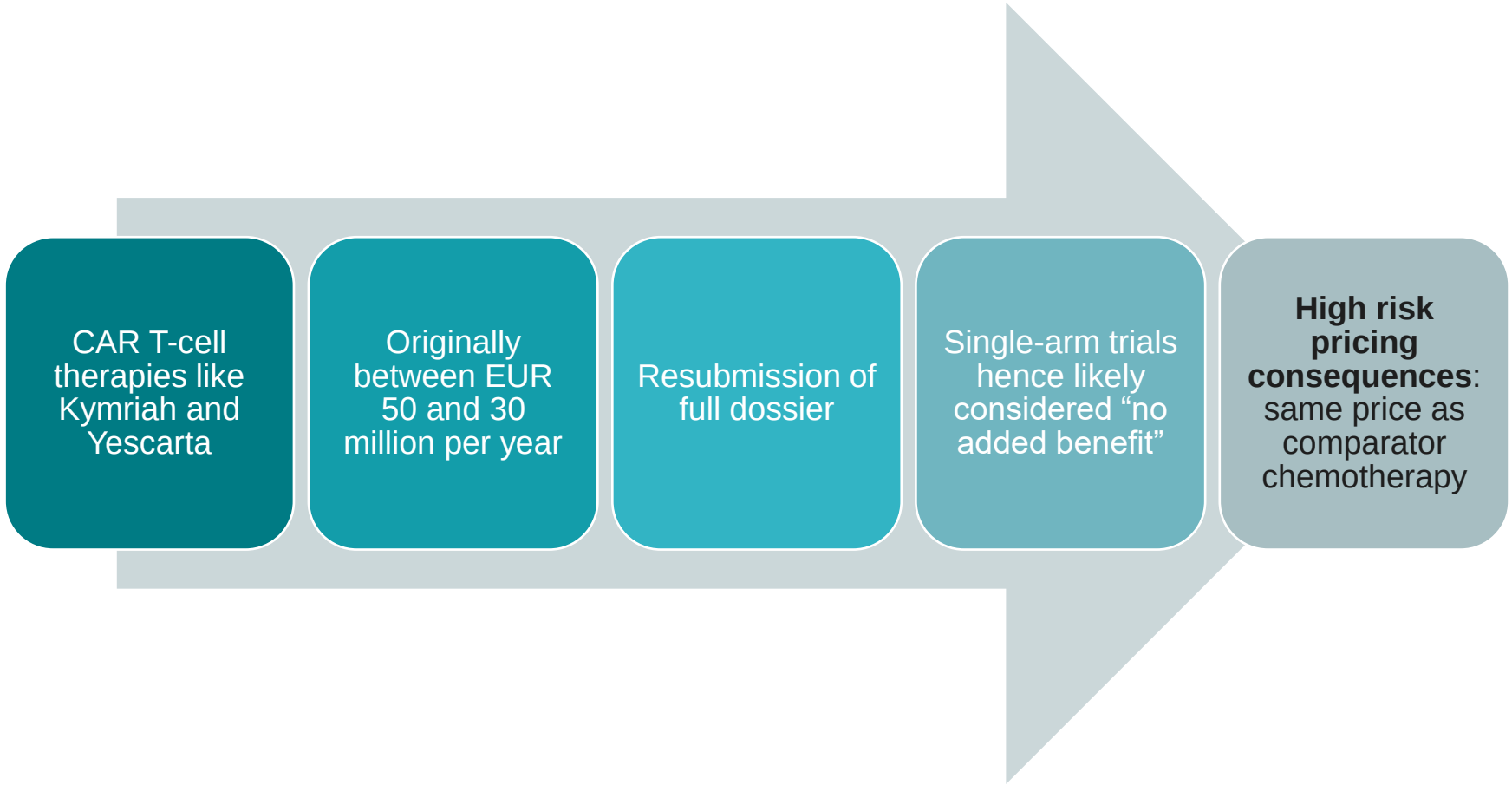
Key: G-BA, Gemeinsamer Bundesausschuss

Reference: https://www.g-ba.de/beschluesse/6067/; https://www.g-ba.de/downloads/40-268-9611/2023-06-27_AM-RL-Anlage-XIIa_SN_Ergaenzung-Benennung-Kombinationen-gefasste-Beschluesse_TrG.pdf; https://www.g-ba.de/presse/pressemitteilungen-meldungen/1134/; https://www.g-ba.de/downloads/39-261-6210/2023-10-05_AM-RL-XII-XIIa_Ergaenzung-Benennung-Kombinationen.pdf

Adjustment orphan diseases' threshold for exemption full HTA

Lower threshold leads to reassessment of products and likely new pricing

Example:



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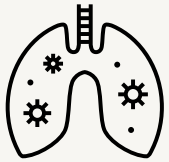
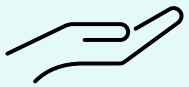
Key: CAR, chimeric antigen receptor; HTA, health technology assessment

Withdrawal or delay in launch of products



Novartis withdrew Talbrecta, due to:

- the assessment by the Federal Joint Committee as part of the early benefit assessment process, concluding ‘additional benefit not proven’
- Lack of agreement with the health insurance companies on an appropriate reimbursement price



Boehringer Ingelheim discontinued sale of Spevigo following G-BA’s criticism on the pivotal trial design and conclusion that there is no evidence of additional benefit

Survey among 48 vfa members: 30 drugs/indications are at risk of being launched later or not at all in Germany as a direct result of the Statutory Health Insurance Finance Stabilisation Act

- Oncology is most heavily affected but treatments for HIV, diabetes and neurological disorders could also be impacted

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Key: G-BA, Gemeinsamer Bundesausschuss; HIV, human immunodeficiency virus; vfa, Verband Forschender Arzneimittelhersteller

4.

Interactions with the EU HTA Regulation and draft EU Pharmaceutical Legislation

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EU Regulation on Health Technology Assessment

Joint Clinical Assessment

EU level from 2025

EUnetHTA 21 methodological guidelines are heavily influenced by Germany

Pricing and reimbursement decisions

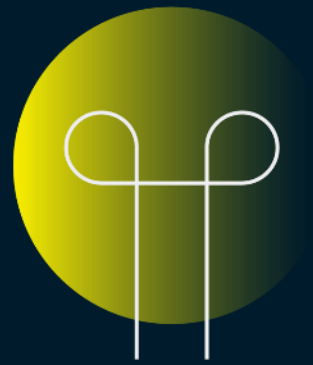
Remains at national level

Though required to give due consideration to the JCA, IQWiG and G-BA could theoretically ignore the outcomes of the joint work

Potential impact

G-BA's historically high rejection rate of ITC could be altered by the outcomes of EU JCAs

- If a submission involving an ITC is positively received at EU level, G-BA might feel pressure to accept this as well



On the other hand, this is exactly why IQWiG and G-BA were so heavily involved in the EUnetHTA 21 deliverables

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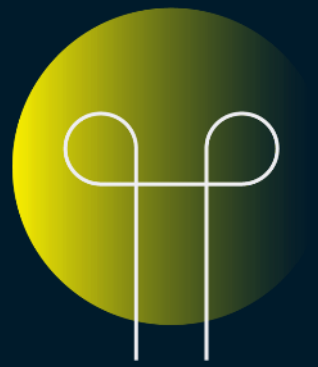
Key: EUnetHTA, European Network for Health Technology Assessment; G-BA, Gemeinsamer Bundesausschuss; ITC, indirect treatment comparison; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; JCA, joint clinical assessment

Draft EU Pharmaceutical Legislation

Potential impact

In the current draft legislation, there is an incentive to launch in all EU countries

- Additional regulatory protection of 2 years



Cost-containing measures could lead to a lower price in Germany which would subsequently be used as reference price in Europe

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Closing remarks

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In conclusion…

01 **The combination of the new rules within the cost-containment law can lead to dramatic pricing outcomes**

02 **Germany is focusing on a law to stimulate research and development; however, the cost-containment law still render the market undesirable when it comes to launching subsequent product**

03 **Likely more products will not come to market in Germany, potentially triggering a public discussion**

Thank you

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