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Blitzkrieg on Pharma: Germany targets spend on medicines with sweeping reforms on drug pricing and reimbursement

- Despite heavy criticism from industry players, the recently passed Act for Financial Stability of the Public Health Insurance (GKV- Finanzstabilisierungsgesetz or "GKV-FinStG") introduces several new cost-cutting measures to Germany's pharmaceutical industry, namely:
- The free pricing period for new drugs has been reduced from 12 months to 6 months, with a provision of clawbacks enabling sickness funds to retrieve the differential between the free price and the final reimbursement price retrospectively
- The orphan drug spend limit which triggers a price adjustment is reduced by over 50%. Any orphan drug resulting in an annual revenue of over €30m will be subject to price adjustment
- Changes to the AMNOG process will also give more powers to the sickness funds to negotiate AMNOG rebates, including for the first time, price-volume agreements
- Other measures include: extension of current drug-price freezes for another 4 years, increases to mandatory discounts and new mandatory discounts on combination drugs
- While the new rules will certainly make market access more challenging for most new drugs, particularly orphan drugs, careful understanding of the new regulatory environment can help players to continue benefit from this large European platform

Introduction

Since 2011, German Medicines Market Reorganization Act (AMNOG) allows pharmaceutical companies launching in Germany to benefit from a 12-month period of free pricing before a decision is reached on a reimbursed price, via a formal evaluation of the "added therapeutic benefit".

Benefit assessments are run jointly between the Federal Joint Committee (G-BA) and the Institute for Quality and Efficiency in Health Care (IQWiG). Drugs must demonstrate an Additional Benefit (AB) over existing therapies in order to receive a higher price over existing drugs. If no additional benefit is demonstrated, the new drug is included in a reference price cluster (Festbetrag) where possible, or a price is negotiated no higher than the price of the appropriate comparator.

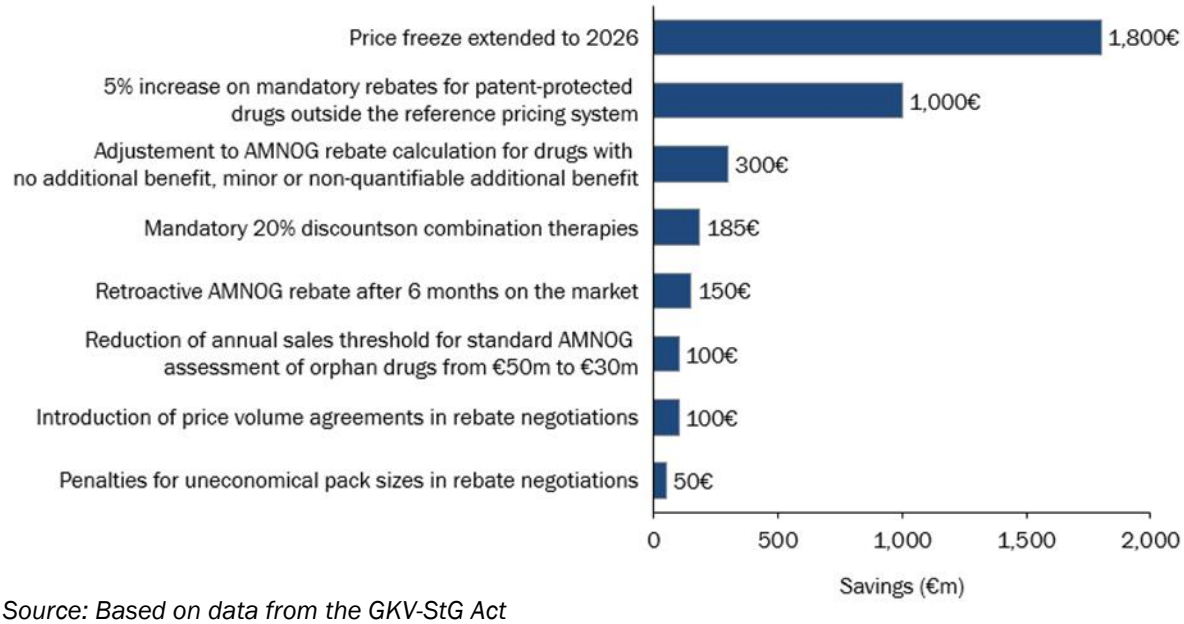
Orphan medicines are considered a special case and benefit from preferential treatment as they are automatically assumed to have an AB in Germany and can therefore be placed on the market at free pricing. A formal benefit evaluation is only required once the financial impact threshold in annual revenue is triggered. This threshold was €50m until recently. New legislation has already revised it down to €30m and established a host of other measures to curb pharmaceutical spending.

All in all, the AMNOG legislation introduced a decade ago has made Germany a preferred destination for the first launch of a new drug, with strong revenues guaranteed in the first year. Now, since the replacement of Angela Merkel's government in December 2021, the new traffic light coalition (made up of SDP/FDP) has vowed to significantly cut down and take back control of pharmaceutical expenditure. To achieve this, a draft Act for the Financial Stabilization of the German Statutory Health Insurance System (GKV-FinStG) was introduced in July 2022. Following months of negotiations, and despite strong backlash from the pharmaceutical industry, the controversial law has now been adopted in October 2022, enforcing a host of new cost-cutting measures over the

pharmaceutical sector. Could this be the end of Pharma's German honeymoon? Read on to find out what the latest cost-saving measures mean for the German pharma industry.

Figure 1 looks at the potential savings that can be obtained through the new Act.

Figure 1: Estimated savings made by the statutory health insurances (sickness funds) as a result of the Act for Financial Stability of the Public Health Insurance main cost-cutting measures



Source: Based on data from the GKV-StG Act

New drug free pricing period reduced from 12 to 6 months

Global pharmaceutical companies have long regarded Germany as the best European country in which to launch new products thanks to its 12-month long "honeymoon" period of free pricing before establishing a negotiated reimbursement price.

Now, not only is the GKV-FinStG Act slashing this free-pricing period to just 6 months, but companies will also need to payback the difference in revenue from sales incurred during those first 6 months of free pricing in the event of a lower negotiated reimbursed price later. This new AMNOG rebate process is expected to generate savings of around €150m per year. Clever and strategic pricing and volume control of drugs during this period will now more than ever become increasingly crucial and challenging if companies want to avoid claw backs.

Orphan drug annual spend threshold triggering formal price adjustment reduced from €50m to €30m

Under the current AMNOG regulations, any drug granted orphan status by the EMA is automatically assumed to have an Additional Benefit and therefore made immediately available on the market. In addition, orphan drugs are exempted from compulsory AMNOG price adjustments, meaning manufacturers are able to freely set their prices, provided annual revenue realized with the German statutory health insurance falls below €50 million. Only when this threshold is exceeded is a regular benefit assessment by IQWiG and the G-BA is conducted, which may bring the price down.

The new GKV-FinStG Act now reduces this threshold down to €30 million. Although an improvement over the initially proposed €20 million threshold, this measure will force orphan drug manufacturers

to carefully consider their pricing decisions to avoid a price review and potential claw backs. For future products, the real challenge will be in optimize earnings from the free pricing period against a risk of downward revision early into the process. Around 10 existing orphan drug products are expected to be affected by this threshold reduction and be required to undergo re-assessment, potentially leading to downward price negotiations and revenue claw backs.

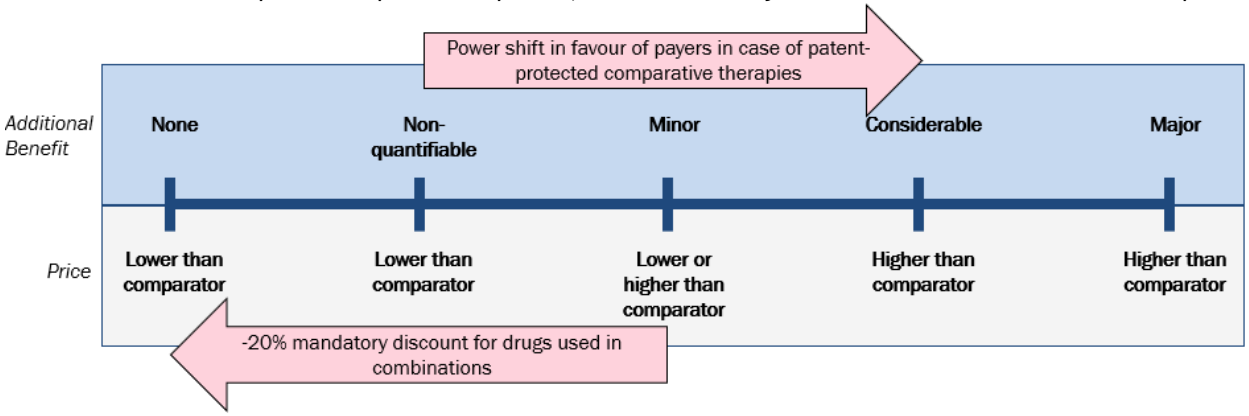
Companies should also be prepared to submit stronger evidence in their benefit assessment to demonstrate true added benefit if they wish to receive higher reimbursement prices. This comes as the German Health Technology Assessment body IQWIG has started to push back on what it claims are 'fictitious' orphan drug additional benefit.

A recent IQWIG study highlighted that more than half (54%) of orphan drugs having undergone both an orphan drug designation evaluation and a regular benefit assessment procedure (e.g., due to annual expenditure exceeding the €50m threshold) could not actually prove an additional benefit during the regular benefit assessment. With both the 12 months free pricing period and the annual revenue threshold limit now reduced to almost half by the GKV-FinStG Act, orphan drug companies are therefore facing severe pricing pressures in Germany, the country which was once hailed as the best pharmaceutical launching platform.

Increased powers for the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) to negotiate price caps and AMNOG rebates

In Germany, drugs with no proven additional benefit have a higher rebate applied to them than comparators if these are patent protected. Medicines deemed to have a Considerable or Major Benefit on the other hand are exempt from this rule. With the implementation of the new GKV-FinStG Act, the AMNOG price rebate calculation will be modified so that all patent-protected drugs that have not yet undergone a benefit assessment will receive a now discounted formula, lowering the overall price. This change is expected to generate savings of around €300m per year.

Figure 2: The Act for Financial Stability of the Public Health Insurance means a considerable benefit is now required for premium prices, with mandatory discounts for combination therapies



Source: Inspired from WS Value & Dossier

In addition, for the first time, AMNOG rebate negotiations will introduce price-volume agreements such as annual prescription volume caps, estimated to generate yearly savings of around €50-100mn. There will also provisions to sanction uneconomic package sizes included in the new rules

around the AMNOG reimbursement price agreements, potentially generating savings of around €50m per year.

Increased mandatory discounts on drugs sold to sickness funds, increased discounts on Rx-drugs sold in pharmacies increased, and brand-new mandatory discounts for listed combination therapies

Germany's reimbursement law establishes a global mandatory discount from all pharmaceutical companies selling to the statutory health insurances. Initially, the draft GKV-FinStG law an extraordinary "solidarity contribution" of €2 billion to be paid by the pharmaceutical industry. This measure was eventually dropped, settling instead on a 5% increase to the mandatory discount, previously set at 7% of the company's total sale price starting in 2023.

Mandatory pharmacy discounts to the statutory health insurers are also being increased from €1.77 to €2.00 (13% increase) per prescription medicine, but only for a period of two years. This measure comes as the new law requires pharmacies to equally contribute to the overall financial stability of the healthcare system.

Finally, new mandatory discounts will now also apply to combination therapies, named a "combination mark-down". The new measure involves changes to the GBA's Additional Benefit evaluation which will now also establish the list of medicines that can be used in combination with the newly approved drug. Drugs listed as combination therapies will receive the new combination markdown payment of 20% of the company's sale price. Only active substances that have been through a benefits assessment and awarded a minimum of 'Significant Benefit' can be exempt.

Medicine retail prices frozen for another 4 years

Price freezes on medicines (known as price moratorium) were introduced back in 2010, this has meant that drug companies have not been allowed to increase prices for prescription only reimbursable drugs. Only inflation related adjustments could be claimed retroactively. The most recent price freeze was implemented in 2017 and was due to be lifted at the end of 2022. The Act now extends the freeze for another 4 years, until the end of 2026. The price freeze applies to drugs reimbursed by the statutory health insurances but not included in reference-pricing groups (i.e. via the AMNOG procedure). Exemptions to the price freeze may be possible for medicines receiving a new market authorization (e.g. in the event of a new indication or a new patient group), however, companies will need to demonstrate clear improvement in the patient's care.

This measure is estimated to generate around €1.8bn in savings per year. With inflation currently at around 8% in Germany, pharmaceutical companies may still benefit from small inflationary adjusted price increases like they did in July 2017 and 2018,

Conclusion

Industry experts have warned that such drastic changes to the German drug pricing and reimbursement system will hinder the country's pace of pharmaceutical innovation, as well as seriously impact patient access, particularly for orphan drugs. The German Association of Research-Based Pharmaceutical Companies (VFA) responded to the government's announcement citing that "the rapid availability of new drugs is unnecessarily jeopardized" by the decision. Han Steutel, President of the German Association of Research-Based Pharmaceutical Companies (VFA) stated that the law "fundamentally changes the business foundation of the pharmaceutical industry in Germany".

While the law has passed despite the warnings, by the end of 2023, Parliament will review the impact of the reduction in the AMNOG sales threshold for orphan drugs, changes to the process for negotiating AMNOG rebates and the 20% discount on combination therapies to determine if these measures are in fact harming patients' access to medicines, the security of supply and the position of the pharmaceutical industry in Germany and the EU. If undesired consequences are uncovered, cost-cutting measures introduced by the Act could therefore be lowered or even reversed.

Even so, the new Act for Financial Stability will undoubtedly leave pharmaceutical companies and investors worried about their prospects in Germany. And although the future may not be as rosy as the past, Germany is still probably one of the more advantageous places to launch a drug in the pharmaceutical industry with the free pricing mechanism likely to persist, albeit for a shorter period. Marwood can assist investors in making sense of what the proposed cost-containment mean for the future of pharma in Germany, and how investors can best place themselves to continue to benefit from the country's thriving life sciences sector.

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