Implications of Germany's 2022 National Association of Statutory Health Insurance Funds Financial Stabilization Act (GKV-FinStG)

Abdullah Noori
Winter 2023
Seminar II
MSc Economics Student
University of Dusseldorf, Germany

Abstract

This paper critically analyzes the implications of the 2022 National Association of Statutory Health Insurance Funds Financial Stabilization Act (GKV-FinStG) on pharmaceutical dynamics in Germany. Delving into reforms within the German Pharmaceutical Market Reorganization Act (AMNOG), it examines adjustments impacting drug pricing, costs, launch times, and incentives for innovation. By dissecting short-term financial measures and long-term impacts on accessibility and innovation, the study unveils a nuanced landscape. The results suggest a balanced approach to cost containment, contingent upon the performance of German pharmaceutical companies in international markets.

Introduction

Germany is one of the countries where health insurance is mandatory. About 90% of citizens in Germany are covered by statutory health insurance, and the remaining 10% by private health insurance companies. The German Social Code - Book V governs statutory health insurance. In Germany, they set a regulatory system through which drugs are assessed, priced, and reimbursed. This system is called the German Pharmaceutical Market Reorganization Act (AMNOG). At the end of the year 2022, some reforms were presented under the name GKV-FinStG, which includes reforms in AMONG. In this paper, I analyze the implications of the National Association of Statutory Health Insurance Funds Financial Stabilization Act (GKV-FinStG) of 2022. Section 1 of the paper covers the new Act in detail. Section 2 digs into how the new reforms would influence drug prices/costs, drug launch times, manufacturers' incentive to invest in the innovation of new drugs, and overall, its positive or negative impacts. Section 3 presents a conclusion of the analysis.

Section 1 - GKV Financial Stabilization Act (GKV-FinStG) 2022

The new GKV Financial Stabilization Act is presented to settle the EURO 17 billion deficit of the Federal government. The pharmaceutical industry compensates for EURO 2.8 billion of this deficit, EURO 1 billion in discounts, and EURO 1.8 billion in the extension of the price moratorium (Verband Forschender Arzneimittelhersteller, 2022). Further motives behind the GKV-FinStG are to facilitate faster specialist appointments and lower prices for medicines without additional benefits. The law encompasses financial reforms in all areas of statutory insurance. These include medicines pricing reforms, doctor remuneration changes, the melting down of health insurance financial reserves, and increased pharmacy discounts (Bundesministerium für Gesundheit, 2022). The components affected by this law are financial reserves, federal subsidy, federal loan, manufacturer's discount, reform in the AMNOG (German Pharmaceutical Market Reorganization Act or Arzneimittelmarktneuordnungsgesetz), pharmacy discount, price moratorium, care budget, new patient rule, dental fee, and additional contribution. In the following, the description of how each component is affected is presented.

Financial Reserves: The current health insurance financial reserves are used for the purpose of contribution rate stabilization with a cross-institutional solidarity equalization. The liquidity reserves' upper limit related to health insurance funds would be divided in half. To close the financial gap even further, the excess funds would be used for higher allocation of health insurance.

Federal Subsidy: The subsidy for GKV is increased for 2023 by EURO 2 billion, accounting for EURO 14.5 billion.

Federal Loan: For the year 2023, a non-interest-bearing loan of EURO 1 billion has been granted to the health funds by the federal government.

Manufacturer's Discount: Pharmaceutical manufacturers offer manufacturer discounts to help with cost-saving purposes. It has been increased by five percentage points for the year 2023. The increase was specially planned for patent-protected medicines. This measure would help with the overall financial burden on the health insurance system through lower prices for patent-protected medicines. The government tries to address medicine's budgetary and affordability issues within the GKV framework.

Reforms in AMNOG: AMNOG is the framework through which the new pharmaceutical assessment, pricing, and reimbursement are performed. The reform in this framework aims to change the pricing structure of medicines that provide no or only added therapeutical value. In addition, new measures are set to mitigate the increased spending on medicines with patent protection.

Pharmacy Discount: This discount refers to the mechanism through which the pharmacies receive price reductions to acquire medicines. The pharmaceutical discount increased for a fixed period of two years from EURO 1.77 to EURO 2 per drug pack. This increase stabilizes the financial situation and possibly cuts the government's budgetary spending.

Price Moratorium: refers to the freeze or limitation of medicine prices on a temporary basis. The new reform imposes a price moratorium on medical products for an extended period until 2026. The price moratorium is often imposed on medical products to control the prices and cost control within the healthcare system.

Care Budget: Only the costs of qualified nurses serving in bed-leading wards in direct patient care would be considered and accounted for in the care budget.

New patient rule: There was some extra-budgetary remuneration previously associated with the contract of medical services related to new patients, which this regulation aims to eliminate. To eliminate this extra-budgetary remuneration, a new remuneration incentive has been introduced, which makes faster treatment appointments for new patients possible through encouraging contract doctors.

Dentist Fees: Limitations on dentist fees are enforced, which means they cannot increase their fees. However, these limitations have some exceptions, including outreach services provided in outreach areas would be exempt. Further, cooperation agreements which cover inpatient facilities and the dentist are also exempt. Finally, periodontitis treatment for insured people with disabilities and care needs is also exempt.

Section 2 – Analysis of GKV-FinStG

The newly added reforms under GKV-FinStG are short-term or permanent (not subject to a specified period). The short-term changes made to the components are mainly to help the government address the deficits left by the previous federal government. On the other hand, the permanent changes in the components are to lower the costs and prices of medicines. Both changes have implications for the pharmaceutical industry. Since the GKV-FinStG was approved in late 2022, we need more data to discover the actual outcomes of the reforms. Getting the industry data and revealing the consequences would take a few years. Here, I take advantage of available literature and my analysis to predict the possible implications in the short and long run. In this section, I will analyze these changes separately, addressing possible implications arising from implementing these reforms. The short-term changes are analyzed first, followed by the analysis of permanent changes.

Section 2.1 – Short-term Changes in Components

These changes are imposed for a limited period to address the deficits and stabilize the finances in the short run. The short-term changes are summarized as changes in federal subsidy, federal loan, manufacturer discount, pharmacy discount, and price moratorium. Since this paper addresses the economic outcomes of the reforms, I dropped the changes in financial reserves, care budget, new patient rule, and dentist fees from my analysis as they are beyond the scope of this paper. This is because these changes are not affecting pharmaceutical products' costs, prices, and supply. Federal subsidies and loans are the most flexible, with little to no negative effects on pharmaceutical manufacturing firms. The federal subsidy increase means injecting more funds into statutory health insurance to overcome the current financial deficit and support the current operations. The Euro 1 billion non-interest-bearing loan from the federal government to statutory health insurance would help stabilize the situation by covering the immediate needs. The federal loan implication is the repayment plan, which is not difficult considering the history of successful repayments.

On the other hand, the manufacturer discount, pharmacy discount, and price moratorium negatively affect the manufacturers' product prices. The manufacturer and pharmacy discounts are increased for one and two years, respectively. Both discounts reduce the prices of products by five percentage points and EURO 17 cents for the specified periods. The price moratorium aims to freeze the pricing of medicine products until 2026, which is a longer

period than manufacturer and pharmacy discounts. One would argue that pharmacy and manufacturer discounts reduce the prices for a limited period of one year, which cannot have considerable adverse consequences for the pharmaceutical industry. In general, this might be the case for most of the pharmaceutical manufacturers. However, only a few firms would face supply problems due to imposed discounts.

On the contrary, the price moratorium lasts for a longer period and prevents the prices from growing. The relationship between price growth and spending in R&D by pharmaceutical manufacturers cannot be ignored. Manufacturers of medical products invest a considerable amount of their profits into their R&D activities to make new medicines available in the market. According to the estimates provided by Statista in 2022, top pharmaceutical companies worldwide have invested 20% of their revenues in R&D activities ("R&D Spending Share of Top Pharmaceutical Companies," 2022). In Germany, the R&D spending in 2018 was 12.5% of revenues on an industry level. In 2020, although the overall production faced a sales growth of over 5%, the investment in R&D was 11.1% of overall revenues. In 2021, the pharmaceutical operation increased by 8.43%, generating EURO 53.3 billion in revenues (Statista, 2022). During this time, the investment in the R&D was recorded to be 16.3%. This increase was motivated by higher revenue growth and the search for the COVID-19 vaccine. The year 2022 was predicted to be difficult for the pharmaceutical industry because of the challenges that arose from Russia's invasion of Ukraine. These challenges are mostly higher energy and raw material prices. The exact statistics for 2022 are not available to see how the spending on R&D is affected. Higher energy and raw material prices and the price moratorium may affect R&D spending. This is because the two forces – freeze of prices and increase in energy and raw material make it difficult for pharmaceutical manufacturing firms to invest the optimal levels in their R&D.

Moreover, spending on R&D increases as the real prices of pharmaceutical products grow when other things are kept constant (See Giaccotto et al., 2005). Giaccotto also found that as estimated elasticity, a 10% increase in real prices of drugs results in a 6% increase in R&D spending. Excluding export revenues from the equation, we can expect the R&D investments to decrease by a few percent for the coming years on a national level limited period price regulation. The lower level of investment in R&D would negatively affect the supply of innovative medicines to the market at national and international levels. Germany's pharmaceutical industry is the biggest pharma industry in Europe and the biggest exporter in the world ("R&D Spending Share of Top Pharmaceutical Companies," 2022). Germany exported EURO 101.6 billion in pharmaceutical goods in 2021, 44.7% of EURO 227.1 billion turnover. The possible implication will change if we consider the exports. The result now depends on how the international market would react to changes in permanent pharmaceutical pricing regulation in Germany. R&D spending also has a direct relationship with the market size. Companies with larger markets tend to be more motivated to spend on their R&D. This relation has been discussed further in section 2.2. Overall, the freeze of prices could negatively affect investment in R&D when excluding the large market reach of

German pharma companies, but considering exports, it would balance the negative effect on R&D.

Section 2.2 – Permanent Changes in Components

The permanent changes in components can be summarized as changes in financial reserves, reforms in AMNOG, new patient rules, and dentist fees. As mentioned before, changes in financial reserves, new patient rules, and dentist fees are beyond the scope of this paper's analysis and will not be analyzed here. One of the significant reforms considerably affecting the pharmaceutical industry is changes in how new medicines are assessed, priced, and reimbursed through the AMNOG system. These reforms have short and long-term implications for the pharmaceutical industry in Germany. I analyze reforms in AMNOG in two sections – the first section describes the AMNOG system and how it has changed, and the second section dives into the implications of the changes to overall medicine prices/costs, supply, and innovation.

Section 2.2.1 - AMNOG and the Recent Changes

In 2011, the federal government of Germany introduced the AMNOG. The AMNOG system aims to assess, price, and reimburse pharmaceutical products in Germany. It evaluates if the drugs have additional benefits through added new substances. In case the drugs are proven to have additional benefits, the maximum reimbursement prices are determined. The entity responsible for assessing whether new drugs have additional new substances and benefits is the German Federal Joint Committee (G-BA). Once a new drug is determined to have added benefits, the maximum reimbursement amount is negotiated between GKV and the manufacturer. An arbitration board sets the maximum reimbursement if the negotiation does not end with an agreement. The GVK also decides on maximum reimbursement for drugs in the reference group. The pharmaceutical pricing through AMNOG comprises six elements (see Rodwin & Gerke, 2021), each of which went through reforms is discussed in detail below with possible implications:

The free pricing strategy is used to ensure rapid access to new drugs in the market. The free pricing allows the manufacturers to set prices without the regulation upon receiving the marketing approval. The free pricing period from 2011 to the presentation of new reforms in 2022 was one year. The drug would be assessed for added benefits during the one-year free pricing period, and the maximum reimbursement would be negotiated. After the G-BA assesses and reports on the new substance and added benefits of the drugs, the GKV negotiates with the manufacturer to reach an agreement on maximum reimbursement. The new reform reduces the free pricing period to 6 months. The new law allows manufacturers to set regulation-free prices upon receiving marketing approval for six months and starting the seventh month; the new reimbursement price would be valid. Since the G-BA value determination assessment and GKV negotiation typically take a year, the manufacturers should pay the difference between the regulation-free lunch price and the reimbursed price

decided and agreed upon in the negotiations after the free pricing period starting the seventh month. Therefore, manufacturers must pay some of their revenues to sick funds after the seventh month, which they usually kept before.
Drugs that can be pharmacologically and therapeutically compared to existing drugs would be evaluated and priced in the same reference price group. To become eligible for maximum reimbursement, drugs should be proven to have additional benefits and new substances that make them superior to the existing drugs in their reference group. When establishing reference group prices, GKV ensures that suppliers are appropriate, sufficient, economical, and of good quality. "A complex formula guarantees that each reference price group will include at least one drug that is fully reimbursed, so the public will not be required to pay more than the token five-to-ten-euro copayment" (Rodwin & Gerke, 2021, p.5). If the patients select the higher-priced drug compared to the reference price, they must pay the difference.

The drugs that cannot be assigned to any reference price group are accessed in relation to appropriate comparator therapy (ACT). G-BA assesses each new drug based on the ACT and ranks it on a scale of 6 added benefits. The added benefits are determined by a committee called IQWiG, which G-BA commissions to evaluate the new drug and make recommendations. Each of the six ranks stands for an added benefit rank, with first to third rank meaning major, considerable, and minor added benefits, respectively. Rank fourth indicates that benefits are not quantifiable with the data limitation, while rank fifth specifies that no evidence supports added benefits. Rank sixth explains that the added benefits are less than ACT. The rank affects reimbursement price during negotiations. If the new drug is found to have additional benefits, G-BA assesses its probability on a three-point scale: hint, indication, and proof. The probability scale is determined based on the reliability of the information. The probability three-point scale is based on the evidence from the manufacturer dossier without using an algorithm (Rodwin & Gerke, 2021, p.8). Before the reforms of 2022, if the drugs have any benefits for any subgroup of patients, then the drugs would be assigned value-added labels (scale 1-4). In this case, the manufacturer is responsible for providing evidence about the safety and effectiveness of drugs. However, the burden of proof might shift in certain cases; for instance, in the case of orphan drugs (which treat rare diseases and conditions), regulatory entities would require further evidence. The new reforms in AMNOG reduce the revenue threshold for orphan drugs from EURO 50 million to EURO 30 million. In case the revenues of the orphan drug surpass a level of EURO 30 million, the drug should undergo a reassessment for added benefit rating. If the orphan drugs fail to provide evidence for additional benefits, the added benefits rating would be retrieved, and significant price cuts would be enforced during the reimbursement price renegotiations.

New drugs are reimbursed more than the ACT if they offer added treatment benefits. The reimbursement price of a new drug considers the ranking assigned by G-BA. The maximum reimbursement for a new drug is set in a confidential negotiation process between GKV and the manufacturer. The negotiation process aligns with the GKV framework and the specific

associations like manufacturers. Drugs that are new and offer added medical benefits and new substances receive a reimbursement higher than ACT. The new drugs that offer no added medical benefits should not cost more than the economic ACT, while the new drugs that offer less added medical benefits than an ACT should also cost less than the economic ACT. The maximum reimbursement for new drugs with added medical benefits is a function of four factors: the scale of added benefits, yearly therapy costs of ACT, reimbursement of drugs in 15 specific European countries, and manufacturer's dossier. The GKV attempts to set maximum reimbursement prices that are, at most, the maximum reimbursement prices in other European countries. A higher maximum reimbursement price than 15 European reference price countries is set by GKV if justified by sales volume and means of economics. In the changes introduced to AMNOG in 2022, the reimbursement prices are still based on the added benefits the new drugs offer; however, with stricter pricing guardrails. If the new drug does not offer additional benefits and the ACT is patent-protected, the new drug should be offered with a 10% discount. In addition, the drugs assigned minor or non-quantifiable added benefits should now cost no more than the most economical ACT. Only new drugs assigned considerable or major added benefits would be reimbursed with a price more than ACT. Also, manufacturers must include the sales volume in the reimbursement price negotiation and contract. Furthermore, a 20% rebate is set to be in action for the combination treatments that were first launched after 2011 and have active new substances. The combination treatments with considerable and major added benefits are exempted. The exact definition of which combination treatments would be eligible for the rebate would be defined in later stages.

Manufacturers should offer manufacturer discounts of 7% on patent-protected drugs and 6% on generic drugs to statutory health insurers. The drugs in the reference price group are exempt from the 6% generic drugs discount. Furthermore, insurers can also negotiate manufacturer further discounts with manufacturers.

Section 2.2.2 – AMNOG Recent Changes Analysis

Reducing the free pricing period from 12 months to six months would reduce the costs and take away false incentives from manufacturers. Previously, the firms could set a regulation-free price for 12 months, during which they could earn all they wanted, and after the free pricing period, the reimbursed price would be enforced. If a drug were recognized to have no additional benefits, then the costs incurred on it in the last year would be just sunk costs. This insurance of prompt market availability costs should be incurred to make the new drugs available without delay. The costs have been halved with the new reforms. There is still one downside to it: free pricing should not be completely free of regulation as it would give the manufacturers a false incentive to set a higher price that would compensate for the reduced six months of free pricing period. A reasonable price should be defined during the free pricing period. Again, the tradeoff between the availability of products on time in the market and determining the price would come into play. For this reason, the definition should be

easy to ensure the on-time availability of medicine in the market. Furthermore, including sales volume before reforms in the price reimbursement contract was optional. The new reforms made it mandatory for manufacturers to include the sales volume in the price reimbursement negotiations and contracts. This brings more clarity to reimbursement negotiation. GKV does not want to set a higher reimbursement price than the highest in price reference countries. Considering this, the GKV would negotiate with more clarity and set a more appropriate reimbursement price with the mandatory existence of sales volumes.

When thinking about strict regulation, the first thing that comes to mind, considering recent reforms in the AMNOG system, is medicine prices. Based on the study by Paneli et al. (2016), prices of medicines are reduced by as much as 15% in a 10-year span in the existence of a reference pricing environment – and discounts, rebates, and price moratoriums. Germany already had these price/cost-reducing components as part of the AMNOG system since 2011. The recent changes increase the regulation even further to ensure a further reduction in prices and costs of medicine. These strict regulations raise the question of how the changes would impact the industry and supply. We can all agree that the industry was intensely regulated before the recent reforms for cost/price reduction purposes compared to northern European countries and the USA. The new reforms make the space even tighter for suppliers of drugs. Local and international firms offering products in highly regulated markets should set their strategies accordingly, which is time-consuming in many instances. In addition, it takes the regulatory authorities in countries with intensive regulatory frameworks more extended periods to assess, price, and reimburse medicines. Manufacturers launch their products faster in less regulated markets. Evidence presented by Kyle (2007) shows that product launches in northern European countries (less price-regulated) are faster compared to southern European countries (more price-regulated). The local and international firms find it difficult to launch their products in heavily price-regulated markets. An excellent example of a heavily regulated country is France, where it takes 497 days for new drugs to be available in the market after receiving approval (Verband Forschender Arzneimittelhersteller, 2022). In Germany, before the recent reforms, it took an average of 133 days to make a new drug available after approval, a relatively shorter period than in France. Furthermore, Kyle (2007) also shows that firms based in countries with intensive price regulations launch new products later than those based in countries with less price regulation. Again, this has to do with the time-consuming process of complying with regulations in the home country jurisdiction. A study by Chuckburn et al. (2016) reveals that regulations that reduce price levels directly contribute to launch delays in regulatory countries. The launch delays in the regulatory country would negatively affect exports and imports. Germany has been ranked the first exporter and second importer of pharmaceuticals worldwide as of 2021 (Observatory of Economic Complexity, 2023). Due to the patent protection of new drugs, the volumes of imports and exports would not be affected; instead, products would be available with delays in the market.

Additionally, the recent reforms in drug reimbursement are possibly affecting the incentives to invest in innovative medicines. Recent developments in AMNOG only qualify drugs with considerable and major added benefits for maximum reimbursement higher than ACT. The drugs with low or non-quantifiable benefits should not cost more than the most economical ACT, and drugs with the same benefits as the most economical patent-protected ACT would be reimbursed with a 10% discount. Previously, the low and non-quantifiable benefits would also fall under the maximum reimbursement category. These new changes reduce the incentives for manufacturers to invest in innovative products. This is because developing a new drug for manufacturing firms is relatively expensive. Nonaka (2018) highlighted the cost of new drug development to be up to EURO 2 billion. These high costs include investment in capital, human resources, and technological expertise. Another critical driver of the high costs of developing new drugs is adherence to strict regulations set on testing and manufacturing before making the drug available in the market (Nonaka, 2018). The exclusion of low-added benefits drugs from maximum reimbursement price eligibility increases firms' risk of investing. The nature of more burdensome regulations in the market that the innovating firms must adhere to and the research uncertainty on adding considerable to major benefits makes it riskier than before to invest. This conclusion might change if we consider the market size for German pharmaceutical products. As mentioned before, Germany was ranked first in export value in 2021. Would that change anything? In their study, Dubois et al. (2015) found that market size and product innovation are directly related – a 1% increase in market size increases products by 0.05% to 0.32%. Considering the reach of German medicine, the pharma companies might find incentives to invest in keeping their external international markets.

On the other hand, in the case of orphan drugs, which are vital for patients with rare diseases, a cap of EURO 30 million would make it unattractive for firms to invest in the innovation of such drugs. There are still many rare diseases for which medicine has yet to be invented, but with the current scheme, most firms and venture capitalists would be less interested in investing in this field. This would negatively affect the progress of drug innovation for treating rare diseases for future generations. In addition, such a revenue cap would give the producer the wrong incentive to lower their supply to avoid the reassessment process and losing the orphan benefits. Hence, the new regulation regarding orphan drugs would fail to accomplish its aim of reassessing orphan drugs for added benefits and reduce innovation in this field. In addition, the 20% rebate on patent-protected combination treatment reduces the supply of such products to the market. Combination therapy is much more effective in treating HIV and cancer, with 3% of cancer patients being cured by combination therapies moratorium (Verband Forschender Arzneimittelhersteller, 2022). This reform would affect the supply of combination therapy products in the market. Again, this makes it unattractive to manufacturers to supply.

Section 3 – Conclusion

To conclude, the price freezing would hinder investment in innovation as the increases in actual prices increase money spent on R&D. Reduction in the free pricing period and inclusion of sales volumes in reimbursement negotiations and contracts is an excellent step to more effective cost reduction and additional clarity during reimbursement negotiations. In addition, the permanent reforms, in general, would delay the availability of new drugs in the market. The effect of new reforms on investment in innovation is unclear due to the vast market reach of German pharma companies. Further, the supply and investment in the innovation of orphan and combination drugs might be reduced as they are no longer attractive to manufacturers.

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