Lukas Maag MSc
Dr. med. Ariane Höer
Stefan Hargesheimer MBA&E
Kathrin Pieloth

Savings through AMNOG rebates

Savings through AMNOG rebates

With the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2011, the German legislator enshrined the principle of benefit-based pricing in law. The aim of the law was to negotiate the price for new medicinal products with patent protection or new document protection following an additional benefit assessment. The resulting price discount on the introductory price is the basis for calculating the AMNOG savings according to § 130b SGB V.

The aim of the study was to calculate the savings from the AMNOG discounts for the years 2018 to 2022 and thus to pursue the question of what volume has been generated so far by the price negotiation within the framework of the AMNOG.

Accordingly, the savings target of 2,000 million euros annually mentioned in the draft law was already achieved in 2018. Since then, the rebate volumes have again increased significantly and amounted to about 6,570 million euros in 2022.

The analysis thus clearly shows that the AMNOG as a price regulation instrument fulfils its function desired by the legislator and makes a considerable contribution to the financial viability of pharmaceutical care.

Keywords

AMNOG, Rebates, Savings, medicinal products, health economics

With the German Medicines Market Reorganisation Act (AMNOG) in 2011, the German legislator enshrined the principle of benefit-based pricing in law. Since then, price negotiations have been largely based on the additional benefit of a drug, in addition to the annual therapy costs of comparable drugs and sales prices in other EU countries. The aim of the law was to negotiate the price of new medicinal products with patent protection or new data protection following an additional benefit assessment. The benefit assessment is carried out against the appropriate comparator therapy (zVT). This determined additional benefit, together with the aforementioned criteria, forms the basis for the reimbursement price negotiation, which is conducted on the basis of the decision of the Joint Federal Committee (G-BA) between the pharmaceutical company and the National Association of Health Insurance Funds (GKV-SV). The resulting price discount on the launch price is the basis for calculating the AMNOG savings according to § 130b SGB V. These are calculated by the difference in turnover of the real turnover considered (price corresponding to the reimbursement amount negotiation x quantity) and a „fictitious" turnover (price without reimbursement amount negotiation x quantity), which would have been reimbursed without the AMNOG price negotiations. The official statistics of the Federal Ministry of Health (BMG) do not show any rebate values resulting from the price negotiations. Therefore, there are currently different figures circulating on the savings achieved so far. There are calculations that assume a volume of 3,900 million euros in 2020 (Maag 2020). Other sources speak of 3,700 million euros in savings in 2020 or 4,900 million euros in savings in 2021 (Ludwig et al. 2022). A recently published report mentions a sum of about 14,000 million euros in savings granted in more than ten years (Techniker Krankenkasse 2023). However, it can be stated with certainty that the savings target of 2,000 million euros annually mentioned in the AMNOG bill (Bundestag 2010) has already been exceeded.

The aim of the study presented in the following was to calculate the savings through the AMNOG discounts for the years 2018 to 2022 and thus to pursue the question of what volume has been generated so far through price negotiation within the framework of the AMNOG. In relation to the rebate levels, these profitability targets are already being achieved (Hammerschmidt 2017).

>> The process of early benefit assessment was again subject to legal adjustments in the recent past, which came into force in particular through the Act on the Financial Stabilisation of Statutory Health Insurance (GKV-FinStG) (Bundestag 2022). In the GKV-FinStG, a number of measures were adopted that have a direct influence on the amount of AMNOG savings, such as the validity of the reimbursement amount from the 7th month after market launch or the manufacturer discount increased by 5 percentage points in 2023. Furthermore, there were structural changes in the pricing of new medicines that have no or only little additional benefit and the lowering of the orphan sales threshold to now 30 million euros.

Methodology

The data basis for the calculation of the savings from the early benefit assessment is the SHI billing data of the National Prescription Information (NVI) from INSIGHT Health as well as information from the IGES ARA® (IGES ARA 2023), the AMNOG database of the IGES Institute, which was linked with the ABDATA (ABDATA Pharmadatenservice 2023) at the level of the pharmaceutical central number (PZN).

The calculation of the AMNOG savings achieved was carried out at the active substance level. This ensured that all subsequent procedures of an active substance could be taken into account in the analysis. Since the discounts achieved in the price negotiations take effect during the course of the year, it was necessary to consider the sales on a monthly basis. The considered turnover referred to the sales price of the pharmaceutical entrepreneur (ApU) and was determined individually for each active substance by linking the PZNs with the respective ATC code, according to the ATC index of the Scientific Institute of the AOK (Fricke et al. 2023).

Since 1 April 2014, the negotiated discounts (§ 130b SGB V) have been applied to the ApU following the early benefit assessment (§ 35a SGB V) and are thus included in the sales by pharmacy sales price (AVP).

The total effect of the AMNOG savings was calculated by three components, which are described in more detail below:

1. discount on the launch price (manufacturer).

In a first step, the savings achieved through the reimbursement amount negotiation in the context of the benefit assessment were determined for all AMNOG active substances. The calculated discount factor results from the price change between the time the active substance was placed on the market and the price that could be observed after the reimbursement amount negotiation had taken place. In order to identify the discounts on the launch price to the exact month, the price change recorded according to IGES ARA® (IGES ARA 2023) after the conclusion of the price negotiation was used. The identical methodology was used for subsequent procedures. Thus, a time series of discount factors could be formed for each active ingredient.

Since 15 November 2022, the negotiated reimbursement amount applies retroactively from the seventh calendar month after market entry and no longer after 12 months (Bundestag 2022). As a reference date for the price calculation of the active substances, the start of the AMNOG procedure was taken into account according to information at the Federal Joint Committee.

In the present study (observation period 2011 to 2022), an average price discount after initial assessment was calculated for the total market of 21.6%. For this purpose, the real turnover was compared with the fictitious turnover that would have been achieved without the discounts from the reimbursement amount negotiations. The resulting difference reflects the savings due to the AMNOG price negotiations in relation to the ApU. This savings volume forms the calculation basis for the trade levels and the statutory discounts.

A value of 26.2% was calculated for the period from 2011 to 2015 (Hammerschmidt 2017). For the years 2011 to 2020, a value of 22.1% was determined (Greiner et al. 2022). Accordingly, the results can be described as robust and are above the savings rate of 16.0% cited in the justification for the AMNOG bill (Bundestag 2010).

2. trade levels (wholesale, pharmacists and VAT)

With the reduction of the ApU due to the price negotiation, the remuneration for wholesalers and pharmacies as well as the VAT to be paid on the pharmacy sales price is automatically reduced, which in turn has an impact on the overall effect of the AMNOG savings.

The amounts used only refer to the difference in turnover that is „lost" due to the calculated rebates. These can only be determined approximately, since only the percentage surcharges could be taken into account. Thus, the emergency service surcharge and the promotion surcharge for pharmaceutical services were not taken into account. The same applies to the fixed values of the wholesale surcharge and the pharmacy surcharge. The values determined for the trade levels are thus slightly underestimated. For the wholesale surcharge, the percentage share is 3.15%, measured against the ApU. If the ApU and the wholesale surcharge are offset, the result is the pharmacy purchase price, which is the basis for the pharmacy surcharge of 3.0%. The next step results in the net pharmacy selling price (net ApU), which is the basis for determining the 19% VAT, although a reduced VAT rate of 16% applied in the second half of 2020 due to the Corona pandemic (BMF 2020).

3. replacing statutory rebates (of which former manufacturer's rebate).

Furthermore, the manufacturer's rebate to be paid according to Section 130a (1a) is reduced, as this is also a percentage of the ApU. For the manufacturer rebates shown in the study, the manufacturer rebate of 7% valid since 2014 still applied, which has increased to 12% in 2023 (Bundestag 2022). Thus, a considerable increase of this item is foreseeable for the year 2023.

The total effect of the AMNOG savings results from the interaction of the described items, whereby the replaced statutory manufacturer discounts were subtracted from the trade levels and the discount on the launch price.

Basic population

Only active substances with a decision date prior to 01.01.2023 were considered in the study. There were also several criteria that led to exclusion from the population. These were: Market withdrawal or opt-out, exemption of the active substance from the benefit assessment or discontinuation of the procedure, active substances without PZN, no or discontinued price negotiation or price negotiation had not yet been concluded as of 31.12.2022. The evaluation also took into account that there may be several products with the same active ingredient.

The aforementioned criteria reduced the basic population of 403 active substances (IGES ARA 2023) in the period from 2011 to 2022 to 365 active substances, which were included in the analysis. Figure 1 shows the number of active ingredients with first-time price negotiation and generic launches for the years 2018 to 2022.

Active ingredients with expired patent protection were removed from the population from the month of the first generic launch. In April 2021, a generic was launched for the first time for an active substance assessed according to AMNOG, namely cabazitaxel („Jevtana"). In 2022, seven further active ingredients as well as two active ingredient combinations with metformin, i.e. in total nine further active ingredients or combinations of generic launches were affected (fingolimod, fampridine, pirfenidone, abiraterone acetate, sitagliptin, sitagliptin/metformin, vildagliptin, vildagliptin/metfor-

Active ingredients with price negotiations concluded for the first time and generic introductions in AMNOG

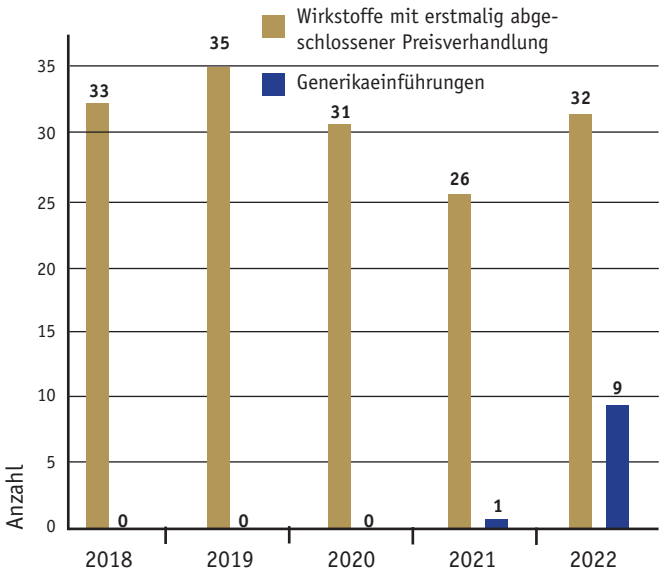


Fig. 1: Active ingredients with price negotiations concluded for the first time and generic introductions in AMNOG (2018–2022). Source: IGES based on own calculations.

min and dimethyl fumarate).

Results

The savings for 2018 to 2022 are detailed below. Discounts on the launch price are the largest item in the calculated savings (see Table 1) and were Euro 5,501 million in 2022, an increase of 18.9% on the previous year. Thus, the growth dynamic was declining, after the savings volume had still increased by 29.2% in 2021 and by 27.9% in 2020.

The decline in the dynamics can be explained in particular by the introduction of generics for former AMNOG active substances. Thus, in 2022, a total of Euro 190 million in calculated savings were no longer taken into account, as active substances lost their patent protection and generics came onto the market. This slowed down the rebate growth by about four percentage points, with the active ingredient combination vildagliptin/metformin accounting for the largest share.

AMNOG savings (§ 130b SGB V) between 2018 and 2022					
Abschläge aus früher Nutzenbewertung (Mio. Euro)	2018	2019	2020	2021	2022
Abschlag auf Einführungspreis	1.919	2.800	3.582	4.627	5.501
Handelsstufen (Großhandel, Apotheker, MwSt.)	507	740	947	1.223	1.454
Ersetzte gesetzliche Herstellerrabatte	- 134	- 196	- 251	- 324	- 385
Gesamteffekt	**2.292**	**3.344**	**4.278**	**5.526**	**6.570**
Veränderung zum Vorjahr (Mio. Euro)	+ 750	+ 1.051	+ 934	+ 1.247	+ 1.044

Tab. 1: AMNOG savings (§ 130b SGB V) between 2018 and 2022. Source: IGES based on our own calculations.

Since the trade levels and the manufacturer rebates refer to the markdowns of the launch price, the rates of increase are identical. In 2022, the calculated volume of trade tiers was 1,454 million euros. The replaced statutory manufacturer discounts were included in the calculation with 385 million euros. With a view to 2023, a considerably higher value is to be expected here, which will be influenced by the manufacturer discount increased by five percentage points.

In total, this results in a total effect of 6,570 million euros for 2022, which corresponds to an absolute increase of 1.044 million euros compared to the previous year. In 2021, AMNOG savings reached a volume of 5,526 million euros.

The increasing number of active substances with savings according to § 130 b SGB V leads in connection with the price discount and the prescription volume to an increasing savings volume, since the inflow (approval of innovative active substance per year) exceeds the outflow (loss of property rights of active substances) of AMNOG active substances.

Conclusion

The AMNOG, which came into force more than 12 years ago, has reached its annual savings target of 2,000 million euros (Bundestag 2010) in 2018, as stated in the draft law. Since then, the rebate volumes have again increased significantly and amounted to about 6,570 million euros in 2022. In the literature, the rebate volume has thus been significantly underestimated so far (Maag 2020 and Ludwig et al. 2022). For comparison, it should be mentioned here that the relief for the SHI through manufacturer discounts, discount contracts, pharmacy surcharges and statutory co-payments was an

Literature

ABDATA Pharmadatenservice (2023): ABDA-Artikelstamm.

Berkemeier, Fabian / Whaley, Christopher / Robinson, C. James. "Increasing Divergence in Drug Prices Between the United States and Germany After Implementation of Comparative Effectiveness Analysis and Collective Price Negotiations" Journal of Managed Care & Specialty Pharmacy. Vol. 25, No. 12, 1310-1317 (2019).

Bundesministerium der Finanzen (BMF) (2020): Befristete Absenkung des allgemeinen und ermäßigten Umsatzsteuersatzes zum 1. Juli 2020. https://www.bundesfinanzministerium.de/Content/DE/Downloads/BMF_Schreiben/Steuerarten/Umsatzsteuer/2020-06-30-befristete-Senkung-umsatzsteuer-juli-2020-final.pdf?__blob=publicationFile&v=7 (zugegriffen am: 29.06.2023).

Bundestag (2010): Entwurf eines Gesetzes zur Neuordnung des Arzneimittelmarktes in der gesetzlichen Krankenversicherung (Arzneimittelmarktneuordnungsgesetz – AMNOG). Gesetzentwurf der Fraktionen der CDU/CSU und FDP https://dserver.bundestag.de/btd/17/024/1702413.pdf (zugegriffen am: 13.06.2023).

Bundestag (2022): Gesetz zur finanziellen Stabilisierung der gesetzlichen Krankenversicherung (GKV-Finanzstabilisierungsgesetz).

Bundesverband der Arzneimittel-Hersteller e.V. (BAH) (2023): Der Arzneimittelmarkt in Deutschland – Zahlen und Fakten aus 2022. https://www.bah-bonn.de/redakteur_filesystem/public/Weitere_oeffentliche_Dateien/20230522_BAH_Zahlenbroschuere_2022_WEB.pdf (zugegriffen am: 28.06.2023).

Fricke, Uwe / Günther, Judith / Niepraschk-von Dollen Katja / Zawinell, Anette. „Methodik der ATC-Klassifikation und DD-Festlegung für den deutschen Arzneimittelmarkt" Wissenschaftliches Institut der AOK (2023).

Greiner, Wolfgang / Gensorowsky, Daniel / Witte, Julian / Batram, Manuel. „AMNOG-Report 2022" https://www.dak.de/dak/download/report-2524570.pdf (zugegriffen am: 13.06.2023).

Hammerschmidt, Thomas. „Analyse der AMNOG-Erstattungsbeträge im europäischen Preisumfeld" Gesundheitsökonomie & Qualitätsmanagement 22.01 (2017): 43-53.

IGES ARA (2023): IGES AMNOG Resolution Analyzer: https://iges-ara.com (zugegriffen am: 13.06.2023).

Ludwig, Wolf-Dieter / Mühlbauer Bernd / Seifert Roland. „Arzneiverordnungs-Report 2022" Springer (2022).

Maag, Gisela. „Arzneimittelmarkt 2020 in Deutschland: Innovationen und Auswirkungen der Pandemie im Fokus." IQVIA (2021) https://www.iqvia.com/-/media/iqvia/pdfs/germany/news/iqvia-arzneimittelmarkt-deutschland-2020-pm-2021-02.pdf?la=de-de&hash=C04933F63B24EAD63FB9067AF424DA0C (zugegriffen am: 13.06.2023).

Maag, Lukas / Höer, Ariane / Berkemeier, Fabian / Müller, Gerrit „Therapiekosten von Orphan Drugs vor und nach Einführung des AMNOG" Monitor Versorgungsforschung. 61-66, 05/2022.

Techniker Krankenkasse. „Arzneimittel-Fokus: Pillen, Preise und Patente" (2023) https://www.tk.de/resource/blob/2149674/efc48cfe2278d949d7943865e0782bed/tk-report-2023-arzneimittel-fokus-pillen--preise-und-patente-data.pdf (zugegriffen am: 15.06.2023).

estimated 10,865 million euros in 2022 (BAH 2023), which corresponds to a share of 19.6% of the gross expenditure on medicines of 55,417 million euros.

For 2023, the total effect of AMNOG savings is estimated to be 8,300 million euros, with a noticeable increase in the item of replaced statutory manufacturer rebates. The calculation is made within the framework of an extrapolation and is thus subject to uncertainties.

Despite their volume, the AMNOG savings are often not sufficiently considered in the discussion about the relief of the SHI. Since these are calculated from the difference between the launch price and the reimbursement amount, the amount of the price at launch, the amount of the rebate and the prescription quantity are decisive for the volume of AMNOG savings.

Different studies show that there has not been a systematic increase in launch prices since the introduction of the AMNOG. This can be seen both when comparing against the average discounted prices in the USA (Berkemeier et al. 2019) and when looking at the calculated population expenditure in Germany for orphan drugs (Maag et al. 2022). Accordingly, the AMNOG savings are real savings, which make a considerable contribution to the financial viability of medicinal products in Germany and will continue to increase in the coming years.

The increase is due to the positive net growth of AMNOG active substances, which is also reflected in 2022, which shows a slightly weaker growth dynamic in AMNOG savings compared to previous years. This is due to nine generic product launches, which slowed down the rebate growth by four percentage points.

The analysis thus clearly shows that the AMNOG as a price regulation instrument fulfils its function as desired by the legislator and makes a considerable contribution to the financial viability of pharmaceutical care. <<

Author's statement

The study was funded by the German Association of Research-based Pharmaceutical Companies (vfa). Conflict of interest: Kathrin Pieloth is employed by INSIGHT Health. Lukas Maag, Dr. Ariane Höer and Stefan Hargesheimer are employed by IGES Institut GmbH, which received financial support for this research project from the German Association of Research-Based Pharmaceutical Companies (vfa).

Citation

Maag et al.: „Savings through AMNOG rebates", in: „Monitor Versorgungsforschung" (05/23), pp. 71–75. http://doi.org/10.24945/MVF.05.23.1866-0533.2549

Lukas Maag MSc ORCID: 0000-0002-6758-9679



studied Public Economics (MSc) at the Free University of Berlin and Political Science (BA) with a focus on economics and political science at the University of Erfurt. He is employed at the IGES Institute and works as a project manager in the area of pharmaceutical markets. His work focuses on theoretical and empirical analysis of health policy issues as well as the scientific evaluation and assessment of market data. Contact: Lukas.Maag@iges.de

Dr. med. Ariane Höer ORCID: 0000-0003-3426-2984



is a doctor of pharmacology and toxicology and has been head of the pharmaceutical market division at the IGES Institute since 2011, where she has worked since 2001. The focus of her scientific work is on analyses of the development of the pharmaceutical market including forecasts, pharmacoepidemiological studies, studies on health services research as well as topics related to the benefit assessment of new medicinal products, which also includes the preparation of benefit dossiers. Contact: Ariane.Hoer@iges.de

Stefan Hargesheimer MBA&E ORCID: 0000-0002-4044-4066



studied Life Science Management in Berlin and works as a team leader in the Value & Access Strategy department of the IGES Institute. His focus is on questions regarding reimbursement pricing instruments of the different sectors of the German health care system with regard to innovative medicines. Furthermore, he is responsible for data analyses and modelling to map patient care structures in the SHI system. Contact: Stefan.Hargesheimer@iges.de

Kathrin Pieloth ORCID: 0009-0002-5665-2852



studied nutritional sciences with a focus on biochemistry at the University of Hohenheim. She works for INSIGHT Health and is responsible for the development of data-based solutions and the analysis of pharmaceutical market data with a focus on pricing and reimbursement as Team Lead in the Market Access department.
Contact: KPieloth@insight-health.de