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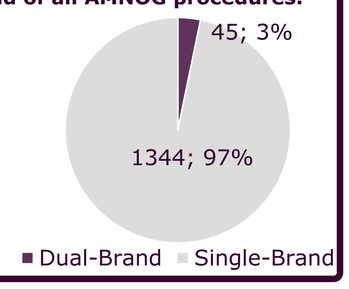
Why Two Brands for One Molecule? Strategic Implications of Dual-Brand Approaches for Orphan Designations, Revenue Thresholds and Pricing in Germany

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Objectives

In certain cases, pharmaceutical companies market the same active substance under two trade names across different indications. This study examines the frequency and health technology assessment (HTA) implications of dual-brand strategies in the German AMNOG (Arzneimittelmarktneuordnungsgesetz) benefit assessment system, with particular focus on orphan designations, the €30 million revenue threshold and pricing dynamics.

Figure 1: Share of dual- vs. single brand of all AMNOG procedures.



Methods

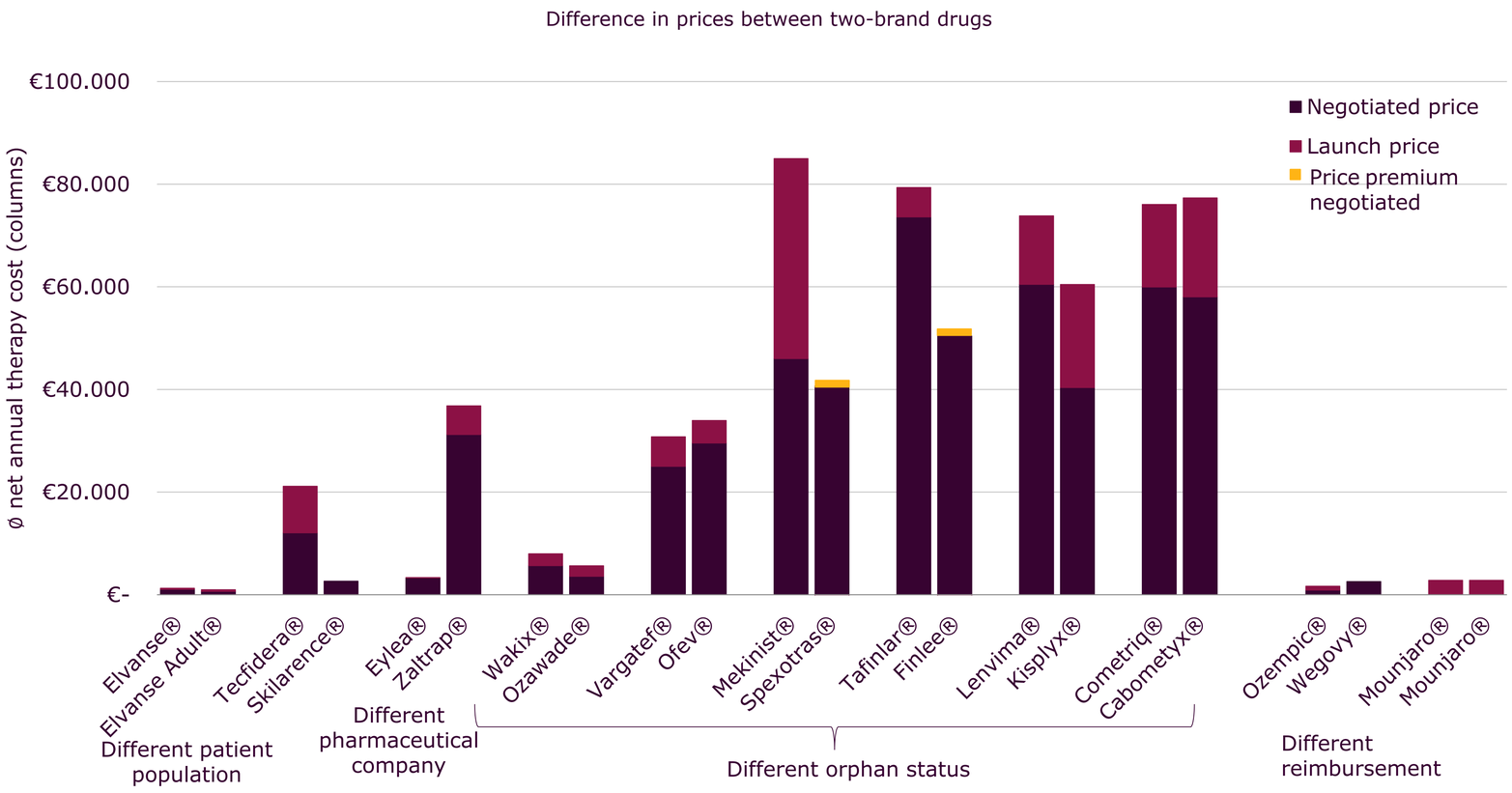
A systematic qualitative analysis of all AMNOG benefit assessment procedures involving active substances marketed under two trade names was conducted using Kintiga's proprietary AMNOG database. GBA (Gemeinsamer Bundesausschuss) benefit assessment decisions and procedural classifications were reviewed. EMA pre-authorisation guidance on naming conventions was analyzed. Pricing and reimbursement implications were assessed, including the role of confidential rebates and anticipated effects of rebate transparency reforms (sunset clause).

Results

Table 1: All procedures with the same active substance but different brand names (first indications, further indication extensions not shown).

Active Substance	Brand	Orphan/ Non-Orphan	Reason for Two Brand Names	Indication	Pharmaceutical Differences
Dabrafenib	Tafinlar®	Non-Orphan	Different orphan/ non-orphan status	Melanoma	✓ Yes, differences in dosage form, strength, and formulation.
	Finlee®	Orphan		Malignant Glioma	
Nintedanib	Vargatef®	Non-Orphan	Different orphan/ non-orphan status	Non-Small Cell Lung Cancer (NSCLC)	✓ Yes, differences in strength.
	Ofev®	Orphan		Idiopathic Pulmonary Fibrosis (IPF)	
Pitolisant	Wakix®	Orphan	Different orphan/ non-orphan status	Narcolepsy	✗ No pharmaceutical differences identified.
	Ozawade®	Non-Orphan		Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea	
Trametinib	Mekinist®	Non-Orphan	Different orphan/ non-orphan status	Melanoma	✓ Yes, differences in dosage form, strength, and formulation identified.
	Spexotras®	Orphan		Malignant Glioma	
Cabozantinib	Cometriq®	Orphan	Different orphan/ non-orphan status	Thyroid Neoplasms	✓ Yes, differences in dosage form and formulation identified.
	Cabometyx®	Non-Orphan		Renal Cell Carcinoma (RCC)	
Dimethyl fumarate	Tecfidera®	Non-Orphan	Different pharmaceutical company	Non-Small Cell Lung Cancer (NSCLC)	✓ Yes, differences in dosage form, strength, and formulation identified.
	Skilarence®			Idiopathic Pulmonary Fibrosis (IPF)	
Lenvatinib	Lenvima®	Orphan	Different orphan/ non-orphan status	Thyroid Carcinoma	✗ No pharmaceutical differences identified.
	Kisplyx®	Non-Orphan		Renal Cell Carcinoma (RCC)	
Lisdexamfetamine dimesylate	Elvanse®	Non-Orphan	Unclear, different patient populations	Attention Deficit Hyperactivity Disorder (ADHD) in Children Aged 6 Years and Older	✗ No pharmaceutical differences identified.
	Elvanse Adult®			Attention Deficit Hyperactivity Disorder (ADHD) in Adults	
Aflibercept	Eylea®	Non-Orphan	Different pharmaceutical company	Retinal diseases (AMD, DME, RVO, mCNV)	✓ Yes, differences in dosage form, strength, and formulation identified.
	Zaltrap®			Metastatic colorectal cancer (mCRC)	

Figure 2: Annual treatment costs (net) of all active substances shown in Table 1 in comparison of the two brands at launch and after negotiation with the GKV-SV. Semaglutide and Tirzepatide are shown additionally for differences in reimbursement status.



Dual-brand strategies represent an exception rather than the rule within the AMNOG landscape. Among all procedures included in the analysis, **only 3% involved active substances marketed under two different brand names** (Figure 1)[1]. The regulatory rationale for such strategies varied across products. While the European regulatory framework generally foresees a single name for a centrally authorised medicinal product, separate marketing authorisations may be permitted for objectively verifiable public-health reasons related to product availability or for co-marketing purposes or when an already authorised medicinal product receives an orphan designation for a previously unapproved indication[2].

Across the nine active substances identified with dual-brand AMNOG procedures, **most brand pairs differed not only in regulatory status but also pharmaceutical characteristics** (Table 1)[1]. Only three cases, dimethyl fumarate, lisdexamfetamine dimesylate, and aflibercept, involved two non-orphan brands. For dimethyl fumarate and aflibercept, the two brands were associated with differences in pharmaceutical characteristics and substantially different therapeutic indications, providing a clear basis for product differentiation. In contrast, the lisdexamfetamine dimesylate case was distinct: Elvanse® and Elvanse Adult® adressed different age groups while the underlying disease and dosing remained comparable. The rationale for maintaining separate brand names in this case could not be conclusively established. Notably, the adult indication was introduced around the time of the transfer from Shire to Takeda, while the previously separate authorisations were subsequently consolidated in 2024.

Dual branding allows distinct pricing outcomes per indication (Figure 2)[1]. In some cases, annual treatment costs of the two brands remained relatively close, as observed for Cometriq®/Cabometyx®, whereas other brand pairs showed substantial differences. For Mekinist®/Spexotras®, for example, the difference in annual treatment costs exceeded €40,000, illustrating that separate branding can be accompanied by materially different pricing positions, depending on indication, formulation and reimbursement context.

Prominent examples outside the identified dual-brand AMNOG cases further illustrate the strategic relevance of brand architecture. In the metabolic market, Novo Nordisk uses separate brands for semaglutide, with Ozempic® positioned in diabetes and Wegovy® in obesity, while Eli Lilly markets tirzepatide as Mounjaro® across both indications. This creates contrasting approaches to navigating the reimbursed diabetes and predominantly self-pay obesity markets in Germany. For Mounjaro®, Lilly chose the option of a confidential rebate (option included 2025 under the Medical Research Act (MFG) by law § 130b Abs. 1c, currently only valid until June 2028), which allows different price levels for the obesity and diabetes market, without publishing the diabetes price. For semaglutide, the different price levels are publicly available (annual therapy costs Ozempic®: 901 €, Wegovy®: 2.569 €) and therefore differ strongly. Another well-known historical example is sildenafil, marketed separately as Viagra® and Revatio® for distinct indications.

Conclusion

Dual-brand strategies can provide substantial strategic flexibility within the German AMNOG framework. In orphan/non-orphan settings, separate brands may allow revenues to be separated with regard to the €30 million orphan-drug threshold while enabling indication-specific pricing. Potential off-label switching between differently priced brands appears less relevant where products differ in formulation, strength or dosage, as observed in most cases.

While several manufacturers established substantially different launch prices across brands, subsequent GKV-SV negotiations narrowed these differences in some cases. The strategic value of dual branding therefore ultimately depends on whether indication-specific price differentiation can be maintained after AMNOG negotiations.

Confidential reimbursement amounts offer an alternative route to price differentiation under a single brand, as illustrated by Mounjaro®, but come with additional financial implications, including the mandatory additional 9% discount and compensation for distribution mark-ups. Under the current framework, this option applies to eligible negotiations concluded through 30 June 2028. Brand architecture and confidential pricing therefore represent distinct strategic approaches to indication-specific pricing, each with different regulatory and financial trade-offs.

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Abbreviations: MFG: German medical research Act; GKV-SV: Spitzenverband Bund der Krankenkassen, National Association of Statutory Health Insurance Funds; HTA: Health Technology Assessment; GBA: Gemeinsamer Bundesauschuss, German Joint Federal Committee

References:
1. Market Acces Intelligence System: Kintigas own database based on the GBA website and Lauer Taxe.
2. https://health.ec.europa.eu/system/files/2016-12/2011_09_duplicates_note_upd_01_0.pdf