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The reference price regulation in the AMNOG market - a view from practice

The reference price regulation in the AMNOG market – a view from the field

This article examines for the German market the practical implementation of the interface between two price regulation instruments AMNOG and reference price from 2011 to July 2024. Three typical case constellations of the linking of the price regulation instruments are reviewed and the procedural practices of the self-administration are analyzed on the basis of previous application.
Immediate categorisation of medicinal products without proven additional benefit into the reference price system was intended as a standard pathway. The time-consuming fixed rate reimbursement negotiations should only apply on an interim basis in these cases.
The review shows that in practice however, only a small number of AMNOG medicines have come into contact with the often faster reference price system to date.
Mainly this can be put down to the incompatibility of the two systems with different regulatory logics.
In the future, as the AMNOG 'ages', the reference price regulations for reimbursement-regulated medicinal products will increase after the expiry of data and patent protection, thereby facing regulators and industry.

Keywords

reference price system, AMNOG, medicinal products, Product life cycle, health economics, applied practice

The Pharmaceutical Market Reorganisation Act (AMNOG) was introduced by the legislator in 2010 as a supplement to the reference price system, which had already been in place for a long time. The AMNOG instruments were intended to regulate prices in the 'non-fixed price market'. The AMNOG obliges the National Association of Statutory Health Insurance Funds and the pharmaceutical company, as the explanatory memorandum to the law briefly and succinctly stated at the time, 'to agree a reimbursement amount for non-fixed-price drugs with new active ingredients with effect for all health insurance funds' (Deutscher Bundestag 2010: 31). In reality, however, the exact application and delimitation of both instruments were unclear. The categorisation of drugs without proven additional benefit into the reference price system was considered the standard case in the initial concept: 'Without additional benefit - transfer to the reference price system' was the chapter heading in the explanatory brochure of the Federal Ministry of Health on the AMNOG (BMG 2010: 16). In these cases, the reimbursement amount negotiation should only be necessary on an interim basis. On closer inspection, however, there was a lack of concrete guidelines as to which instrument should be used when and how the different regulatory logics of the two systems should be harmonised. De facto, the self-administration had a great deal of room for manoeuvre here. This article analyses how the reference price regulation has been applied in practice in the AMNOG market since 2011. After a brief explanation of the legal framework (1), different case constellations are presented and the procedural practices of the self-administration are analysed in each case (2). The analysis is based on all benefit assessment procedures published by the Federal Joint Committee (G-BA) up to and including 15 July 2024 in which the reference price regulation has become relevant. These 42 procedures for 27 medicinal products were classified and compared. The review is followed by a discussion of the challenges and problems arising from procedural practice (3). Overall, the present study shows that reference price regulations in the AMNOG market have so far tended to be a 'procedural sidetrack' in practice (4).

Legal framework

>> The AMNOG provides for an allocation to the reference price system for drugs that are not certified as having an additional benefit in the benefit assessment according to § 35a SGB V. This procedural step can be implemented quickly. This procedural step can be implemented quickly if a pharmacologically and therapeutically 'suitable' reference price group already exists at the start of the AMNOG procedure. In this case, the G-BA only examines whether there is a 'therapeutic improvement' according to the rules of the reference price system (Section 35a para. 1 sentence 4 SGB V) that would prevent the pharmaceutical from being categorised. If this is not the case, the product is categorised directly in the reference price system without any further comment procedure.

The procedural step can also be initiated at a later point in time, after the G-BA has newly formed a 'suitable' reference price group in accordance with Section 35a (1) SGB V. In this case, following the benefit assessment, a reimbursement amount is first agreed in accordance with Section 130b para. 3 sentence 2 or sentence 3 SGB V (or determined by the AMNOG arbitration board). When the reference price group is newly formed, the AMNOG active substance is then categorised with an opinion procedure.

In detail, the change from one price regulation system to the other is not specified by law (Stallberg 2021). In recent years, many implementation issues have arisen for self-administration and industry at the AMNOG-fixed price interface: Is there a dossier obligation if the medicinal product is to be allocated directly to the fixed price? Is there a priority rule for the reference price grouping or can the G-BA also group downstream? Under what conditions is a change in the other direction conceivable, i.e. a de-grouping from the reference price and a transfer to the reimbursement system? Does the G-BA also have the option of categorising medicinal products in the reference price system if an additional benefit can be proven? - etc.

A further constellation has been added with the 'ageing' of the AMNOG system: the reference price as a follow-up regulation when the medicinal products are no longer protected by patents and documents and the AMNOG no longer applies. The legislator recognised a regulatory gap here and introduced a complex transitional

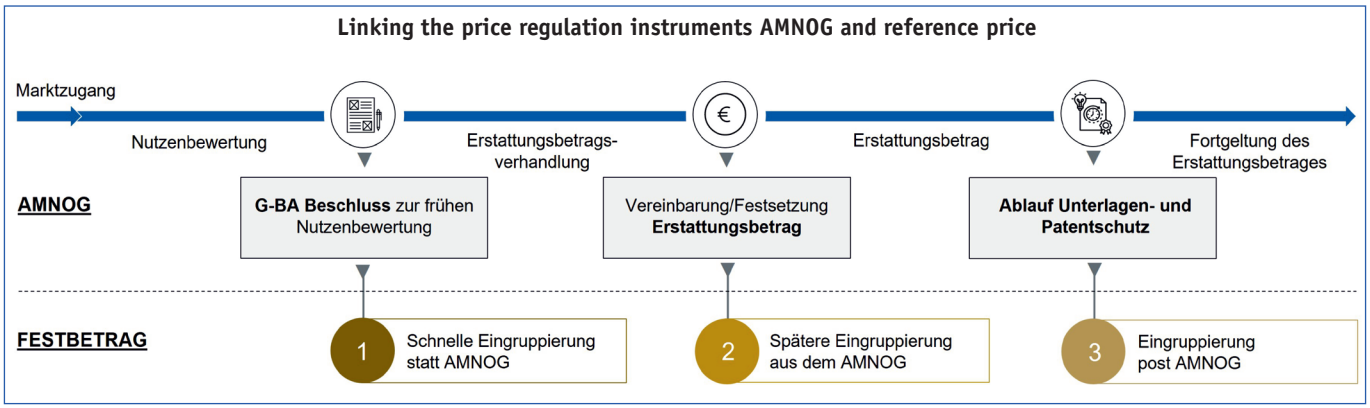


Fig. 1: *Linking the AMNOG and reference price price price regulation instruments. Source: own illustration.*

regime for price regulation in 2020/21 as part of the Fairer Health Insurance Competition Act (GKV-FKG) and the Health Care Further Development Act (GVWG) in Section 130b para. 8a SGB V.

The reimbursement amount or the reimbursement amount agreement will be extended as a statutory maximum price regulation until they are replaced by a reference price. In this transitional regime, the calculation of the reimbursement amount for new launches is based on the individually agreed price structure model published by the GKV-Spitzenverband on its website. Here too, the practical question arises as to when the self-administration will initiate the switch to the reference price system.

To summarise, there are three points of contact between the two price regulation systems:

(1) the initial application of one or the other instrument when the drug enters the market;
(2) the subsequent application of the instruments when the medicinal product is already subject to reimbursement regulation;
(3) the subsequent application when the medicinal product leaves the scope of the AMNOG (see Fig. 1).

Practical application

By 15 July 2024, a total of 1,069 early benefit assessment procedures according to Section 35a SGB V for 469 active substances had been published by the G-BA on its website (excluding the procedures with exemption according to Section 35a para. 1a, 1c SGB V). Initial, retrospective or subsequent grouping into the reference price system was carried out for 42 procedures - a total of only 3.9% of AMNOG procedures with 27 active pharmaceutical ingredients have been affected to date (G-BA website, vfa procedure database).

Rapid grouping instead of AMNOG

There is apparently a clear classification rule for new active pharmaceutical ingredients without identifiable additional benefits that are pharmacologically and therapeutically comparable to reference price drugs and for which a reference price group already exists (or for which the group formation procedure will be completed in time). So far, such a rapid reference price regulation has been carried out in six cases instead of an early benefit assessment procedure. Implementation for a seventh case is planned for the group 'Blood coagulation factors, recombinant, group 1' in stage 2 from 1 October 2024, provided that pharmacological and therapeutic comparability is ensured and the reference price regulation comes into effect.

In all seven cases, the pharmaceutical company, in consultation with the G-BA, did not submit a dossier to prove an additional medical benefit as a therapeutic improvement. When deciding on the added benefit of a medicinal product without a manufacturer's dossier, the pharmaceutical company directly affected, the pharmaceutical companies of the medicinal products in the reference price group and other experts are not given any further opportunity to comment .1 The G-BA's decisions on the classification

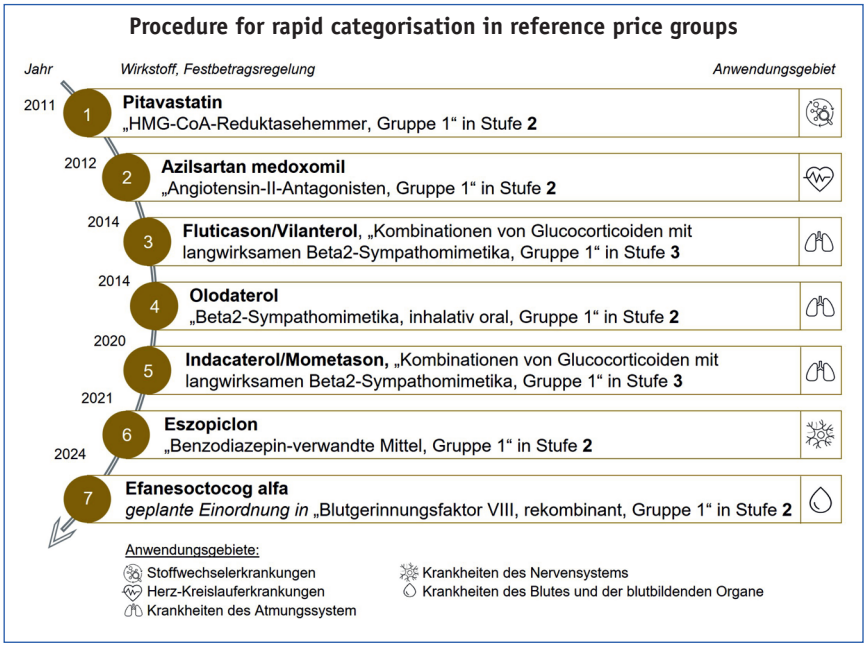


Fig. 2: *Procedure for rapid classification into reference price groups instead of AMNOG between 2011 and July 2024. Source: own illustration.*

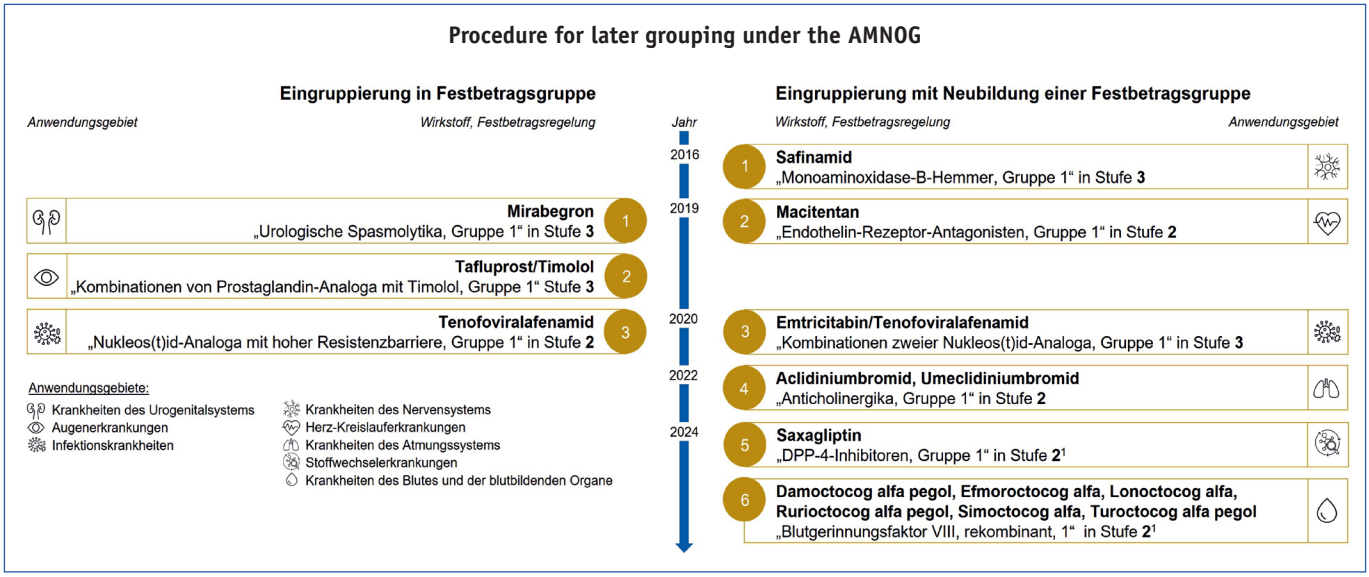


Fig. 3: *Procedure for later grouping under the AMNOG. Legend: 1 = The reference price group includes other active substances with benefit assessments. Source: own illustration. Source: own illustration.*

of AMNOG active pharmaceutical ingredients in a reference price group have been implemented correspondingly quickly in the six cases to date (2.0 to 3.0 months from the market launch of the medicinal product). This has greatly accelerated the reference price procedures in this constellation. It only took around 4.0 to 5.5 months after market launch for the reference price to come into force (with notification to the directory services).

The so-called reference price dossier has actually only been used once in the AMNOG history - in a special constellation for the active substance fluticasone/vilanterol trifenatate. The 'reference price dossier' has therefore not been of great importance in practice to date.

Following an early benefit assessment by the G-BA in June 2014, the medicinal product for the treatment of asthma and COPD was categorised in the reference price group 'Combinations of glucocorticoids with long-acting beta2-sympathomimetics, group 1' in stage 2. In February 2018, the pharmaceutical company submitted a reference price dossier for a new benefit assessment based on new scientific findings. Following an overall assessment of all study results, the G-BA came to the conclusion in August 2018 that there was no therapeutic improvement over the comparable medicinal products (G-BA, supporting reasons 2018). Subsequent removal from a reference price group after classification is difficult to implement for pharmaceutical companies in particular and in general. The requirements for establishing a therapeutic improvement are high. The G-BA requires that proof of therapeutic improvement must be provided for each individual active substance in the reference price group, as can be seen from the G-BA's reasons for its decision on fluticasone/vilanterol trifenatate (G-BA, supporting reasons 2018).

Later grouping from the AMNOG

If there are no suitable reference price groups with pharmacologically and therapeutically comparable medicinal products at the time the decision is taken for medicinal products without additional benefit, the G-BA examines whether it is possible to form a reference price group or to categorise them at a later date, in accordance with the rules of procedure. In total, the G-BA initiated the transfer from the AMNOG to the reference price system for 15 medicinal products between 2011 and July 2024.

In three cases, medicinal products were subsequently classified into an existing group.

In all three cases, there was no additional benefit for the active substances compared to the appropriate comparator therapy after early benefit assessment (in four procedures).

Mirabegron and Tafluprost/Timolol - subsequent categorisation after temporary withdrawal from the market

The later categorisation of Mirabegron (for the symptomatic treatment of an overactive bladder) and Tafluprost/Timolol (for the reduction of intraocular pressure) resulted from the temporary withdrawal of the drugs from the market following the AMNOG benefit assessment. The respective initiation of an opinion procedure for categorisation in a reference price group took place in both cases very promptly within 4 to 6 weeks after reintroduction to the market. The entry into force of the reference prices varied depending on the scope and content of the comments and took approx. 9 months from the initiation of the comments procedure to the entry into force of the reference prices for Tafluprost/Timolol and approx. 24 months for Mirabegron.

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1: *When classifying active pharmaceutical ingredients in reference price procedures, all affected pharmaceutical companies and experts are involved in the question of pharmacological-therapeutic comparability and possible exemptions. An active substance cannot be categorised if it represents a therapeutic improvement within the meaning of Section 35 (1b) SGB V. However, according to the wording of Section 35 para. 1 sentence 6 SGB V, this privilege only applies to patent-protected active ingredients.*

Tenofoviralafenamide - classification after completion of the parallel benefit assessment procedure

In the decision to initiate an opinion procedure for the reference price group 'Nucleos(t)id analogues with a high resistance barrier, group 1' in stage 2 (G-BA, supporting reasons of 6 November 2018), the G-BA pointed out that tenofoviralafenamide would also fit into the group, but that the classification would only be reviewed after completion of the parallel benefit assessment procedure. As a result, the reference price group was originally decided without including the AMNOG active substance. This shows that the G-BA primarily examines the question of whether an additional benefit exists for a new active substance as part of the benefit assessment procedure. This approach is understandable, as the G-BA is legally obliged to implement early benefit assessments, whereas there is no comparable legal obligation to introduce reference prices. However, the G-BA's procedure also means that the new active substances do not remain permanently in the AMNOG regulatory group and can later be allocated to the reference prices even before the expiry of the documentation and patent protection.

The commenting procedure for the classification of tenofoviralafenamide, which is used to treat hepatitis B or HIV infection, was initiated shortly before the reimbursement amount from the second AMNOG benefit assessment was reported. This is in line with the procedural practice for the active substance safinamide (see Fig. 1), for which a commenting procedure on the new formation of the reference price group ('monoamine oxidase B inhibitor, group 1' in stage 2) was initiated during the reimbursement amount negotiation or several months before the reimbursement amount was reported.

The majority of the procedures with subsequent grouping from the AMNOG comprise twelve medicinal products that were included in the follow-up regulations through a new formation of reference price groups. Since 2016, six reference price groups of level 2 or 3 have been formed with the inclusion of AMNOG-assessed active pharmaceutical ingredients. The reference price group 'Blood coagulation factor VIII, recombinant, group 1' in level 2 comprises seven medicinal products, the largest number of active pharmaceutical ingredients with a negotiated or fixed reimbursement amount that have been evaluated in advance in accordance with Section 35a SGB V. In quantitative terms, however, the new formations are small. In the same period, the G-BA decided on a threefold higher number of fixed price groups of level 2 or 3 (eighteen), without the inclusion of medicinal products evaluated for use.

Orphan drugs - no protection from reference price regulation

The authorisation status as a medicinal product for the treatment of a rare condition (orphan drug) generally does not protect against a reference price regulation, although a clinical benefit is even a prerequisite for authorisation. This can be seen in the planned rapid classification of efanesoctocog alfa ('blood coagulation factor VIII, recombinant, group 1' in stage 2) and the new establishment of the reference price group 'endothelin receptor antagonists, group 1' in stage 2 with macitentan in 2018/2019. For the active substance for the treatment of pulmonary arterial hypertension (PAH), evidence of a minor additional benefit was found in the first benefit assessment according to Section 35a SGB V, but not in the reassessment after the sales threshold was exceeded.

Anticholinergics - formation of reference price groups for an active substance with considerable added benefit

The fixed-amount procedure 'Anticholinergics, group 1' in stage 2 was of great significance for the issue of subsequent grouping under the AMNOG for active substances with added benefit. It shows that although the benefit assessment procedure and fixed amounts interact with each other, they are not harmonised.

Aclidinium bromide for long-term therapy in adults with chronic obstructive pulmonary disease (COPD) was the first active substance to be included in a follow-up regulation before the expiry of the dossier and patent protection that had last demonstrated an indication of considerable additional benefit in the benefit assessment procedure in accordance with Section 35a of the German Social Code Book V (SGB V). The additional benefit identified in the G-BA decision of 7 April 2016 in a subpopulation was shown in the therapeutic indication COPD, which was also the relevant joint therapeutic indication in the reference price procedure.

There were no procedural regulations for this retrospective inclusion. It was unclear how to deal with an identified added benefit compared to an appropriate comparator therapy in the benefit assessment procedure for the reference price classification. The extent and probability of the additional benefit 'indication of a considerable additional benefit' reflect a significant improvement in the therapy-relevant benefit that has not yet been achieved. However, the additional benefit identified for the active substance in a subpopulation was compared to an active substance outside the implemented reference price group.

An appropriate comparator therapy that differs from the active pharmaceutical ingredient group makes it more difficult to provide evidence in the subsequent reference price procedure. Pharmaceutical companies are required to conduct studies not only against the appropriate comparator therapy, but also against all possible comparators of a possibly still unknown reference price group.

Delafloxacin, lasmiditan - decisions with exceptions to the reference price regulation

Following a review by the G-BA, two new active substances have so far been exempted from categorisation in existing groups.

In the case of delafloxacin, which is used to treat acute bacterial skin and skin structure infections, the G-BA assessed in its decision of 6 February 2020 that the active substance, as a (reserve) antibiotic, is not pharmacologically and therapeutically comparable to the medicines in the reference price group 'Fluoroquinolones, group 2' in level 2. The resistance situation of the active substance compared to the other reference-priced fluoroquinolones (ciprofloxacin, levofloxacin and ofloxacin) isdifferent. In addition, the provision of Section 35 (1) sentence 4 SGB V on the possible

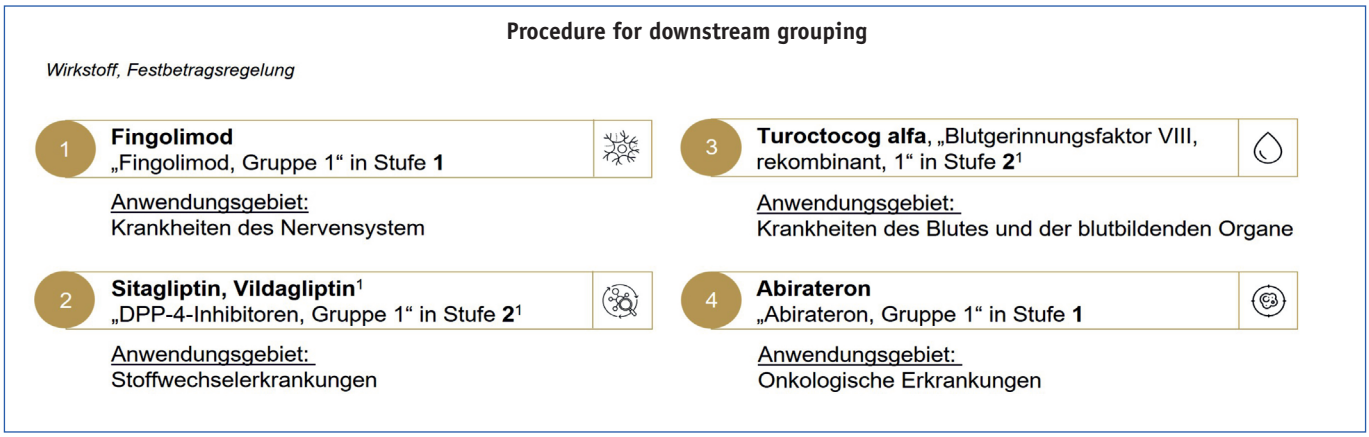


Fig. 4: *Procedure for downstream grouping. Legend: 1 = The reference price group contains other active substances that are evaluated for their usefulness. Source: own simplified illustration. Source: own illustration.*

exemption of reserve antibiotics from the reference price regulation was taken into account For lasmiditan for the acute treatment of migraine with or without aura in adults, the G-BA, in its decision of 17 November 2022, refrained from classification in the reference price group 'Selective serotonin-5HT1 agonists, group 1' in level 2 due to the restriction of treatment options that would otherwise have been possible at the time of the assessment. Certain patient groups are dependent on the product due to contraindications and without other therapy options outside the reference price group. The G-BA assessment implemented with authorisation took place in order to make an assessment regarding the type of dossier to be submitted. From April 2023, a benefit assessment procedure was carried out for the active substance instead.

Classification post AMNOG

In total, there are four newly formed reference price groups with five benefit-assessed active substances in the constellation of the classification of benefit-assessed active substances post AMNOG.

Fingolimod, abiraterone - reference price groups in stage 1

Due to the expiry of documentation and patent protection and the market entry of generic suppliers, two reference price procedures were implemented for the active substances fingolimod (used for the treatment of multiple sclerosis) and abiraterone (treatment of advanced prostate cancer). In several benefit assessment procedures, the G-BA had determined an additional benefit for both active substances compared to a respective appropriate comparative therapy. Following the expiry of the patent and the market entry of generics at a lower list price, an opinion procedure was initiated in each case for the formation of reference price groups in stage 1. In the reference price procedure, it was not assessed whether these drugs are pharmacologically and therapeutically comparable with other active substances or whether they offer a therapeutic improvement.

DPP-4 inhibitors, factor VIII preparations - reference price groups in stage 2

For three active substances, it is known that a follow-up regulation with reference price implementation will take place on 1 October 2024. This concerns the active substances sitagliptin and vildagliptin for the treatment of type 2 diabetes mellitus (reference price group 'DPP-4 inhibitors, group 1' in stage 2) and turoctocog alfa for the treatment and prevention of bleeding in haemophilia A (in reference price group 'Blood coagulation factor VIII, recombinant, group 1' in stage 2).

This raises the fundamental question of how and when a switch to the reference price system will take place. This is particularly important for group formation, as the decision on the timing, status and selection of the reference price group and the suitable comparator is subject to the G-BA's room for manoeuvre. It decides whether to implement the switch to the reference price system in stage 1, 2 or 3.

In the case of the active substances sitagliptin and vildagliptin, a reference price regulation in the group 'DPP-4 inhibitors, group 1' was implemented in stage 2 after generics entered the market. Sitagliptin showed an indication of a minor additional benefit compared to the appropriate comparator therapy in several benefit assessment procedures according to Section 35a SGB V. As with aclidinium bromide and the anticholinergics, the G-BA assessed in the opinion procedure for group formation that there was no evidence of added benefit compared to the active substances in the reference price group. In addition, there was no proof of therapeutic improvement, as the so-called reference price block had been lifted following the expiry of patent protection for sitagliptin.

Price structure model

With the statutory regulation in Section 130b (8a) SGB V, a maximum price regime was introduced until a reference price is set, which requires the publication of the so-called price structure model. This transitional regime leads to seamless price regulation in the German pharmaceutical market.

The existence of a price structure model for eleven active pharmaceutical ingredients is currentlydocumented on the website of the GKV-Spitzenverband.

Two of the active ingredients mentioned are not currently being marketed (albiglutide and simeprevir). The marketing authorisations for both active ingredients have been revoked by the European Medicines Agency (EMA). A reference price grouping pro-

Publication of active pharmaceutical ingredients with a price structure model

Wirkstoff	Handelsname	Therapeutisches Gebiet	Anmerkung
Albiglutid	Eperzan	Diabetes mellitus Typ 2 (Stoffwechselkrankheiten)	Nicht mehr vermarktet Zulassung wurde widerrufen
Cholsäure	Orphacol	Angeborene Störungen der primären Gallensäuresynthese (Stoffwechselkrankheiten)	
Lebende Larven von Lucilia sericata	BioBag und BioMonde Freie Larven	Wundheilung/Debriment (Sonstiges)	
Pomalidomid	Imnovid	Multiples Myelom (onkologische Erkrankungen)	
Simeprevir	Olysio	chronische Hepatitis C (Infektionskrankheiten)	Nicht mehr vermarktet Zulassung wurde widerrufen
Sitagliptin	Januvia/ Xelevia	Diabetes mellitus Typ 2 (Stoffwechselkrankheiten)	**Festbetragsregelung** „DPP-4-Inhibitoren, Gruppe 1“ in Stufe 2
Sitagliptin/ Metformin	Janumet/ Velmetia	Diabetes mellitus Typ 2 (Stoffwechselkrankheiten)	
Teduglutid	Revestive	Kurzdarmsyndrom (Krankheiten des Verdauungssystems)	
Turoctocog alfa	NovoEight	Hämophilie A (Krankheiten des Blutes und der blutbildenden Organe)	**Festbetragsregelung** „Blutgerinnungsfaktoren VIII, rekombinant, Gruppe 1 “ in Stufe 2
Vildagliptin	Galvus/ Jalra/ Xiliarx	Diabetes mellitus Typ 2 (Stoffwechselkrankheiten)	**Festbetragsregelung** „DPP-4-Inhibitoren, Gruppe 1“ in Stufe 2
Vildagliptin/ Metformin	Eucreas/ Icandra/ Zomarist	Diabetes mellitus Typ 2 (Stoffwechselkrankheiten)	

Fig. 5: *Publication of active pharmaceutical ingredients with a price structure model, as of 6 September 2024 Source: own illustration.*

cedure was implemented for three active ingredients (sitagliptin, vildagliptin, turoctocog alfa). For the remaining six active substances, the transitional regime is expected to continue to apply.

Discussion

The review shows that in practice, only a small number of AMNOG medicinal products have (also) come into contact with the reference price system. The application conflicts between the two price regulation instruments currently only affect individual cases, but not the majority of AMNOG procedures - not even in the group of medicinal products without proven additional benefit, as one might have initially expected.

In principle, reference price regulations can play a role in all phases of the product life cycle of medicinal products. For AMNOG products, they become particularly relevant following reimbursement regulation, when generic competition exists and reference price groups can be formed with pharmacologically and therapeutically comparable medicinal products. The number of cases in the constellation 2.3 described above will therefore increase significantly over the next few years as the AMNOG 'ages'. This will be the 'normal case' in the future.

From the manufacturer's point of view, however, there are also distortions in this constellation, which is undisputed in principle. The fact that a negotiated or fixed reimbursement amount is included in the fixed amount calculation as a list price means that there is de facto double regulation. The future reference price is not determined on the basis of freely chosen market prices, as is the case for groups without AMNOG active ingredients, but on the basis of reimbursement amounts that are already price-regulated.

The rapid grouping of medicinal products directly into the reference price system, on the other hand, is a special case that is not very significant in terms of numbers and is unlikely to become so in the future. In special market situations, it is an option for pharmaceutical companies and self-administration to save themselves the great expense of the AMNOG procedure and instead accept or utilise the possibilities of indirect price regulation via the reference price system. However, this option only exists in rare cases

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where a suitable reference price group already exists for the newly marketed medicinal product with a new active pharmaceutical ingredient.

In the AMNOG procedure and for reference pricing, the requirements for demonstrating an additional benefit are operationalised differently. By merging the two systems, the AMNOG logic of 'value-based pricing' is lost. The focus is no longer on the differentiated monetarisation of the established additional benefit for patient populations, but rather products with and without additional benefit are sorted into a common reference price group and assigned a uniform maximum reimbursement amount. This enables the GKV-Spitzenverband, in its dual role as price negotiator in the AMNOG and key decision-maker in the reference price system, to initiate a switch to the other control instrument depending on the market situation.3

The Aclidinium case has particularly highlighted the problem that an additional benefit proven in the AMNOG and thus a special medical significance in healthcare is not recognised in the reference price system. The definition of other comparators in both systems makes it more difficult to prove the additional benefit as a therapeutic improvement.

Conclusion

Overall, the present study reveals that reference price regulations in the AMNOG market are more of a 'procedural sidetrack' in practice. So far, only a small number of medicinal products have been transferred from the reimbursement system to the reference price system. Above all, the follow-up regulation after the expiry of document and patent protection will increase as the AMNOG 'grows older'.

The coexistence of the AMNOG and reference price price price regulation instruments is particularly problematic if it leads to the AMNOG being undermined. The AMNOG is designed as a flexible instrument for the benefit-based price regulation of innovations. The multiple assessment of medicinal products following indication extensions and time limits is the norm today and leads to the permanent adjustment of reimbursement amounts. In contrast, AMNOG active pharmaceutical ingredients that are regulated by fixed amounts fall back on a mathematical algorithm with regression equations. The additional benefit assessment is de facto irrelevant here.

For the pharmaceutical companies concerned, it is important that transparency and predictability are ensured with regard to the price regulation mechanisms. The self-administration is required to apply the instruments not only with a view to economic efficiency, but also with a sense of proportion for the provision of care. <<

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2: *Reference prices are based on a comparative assessment of medicinal products in a common area of application and represent a standardised maximum reimbursement amount of the SHI for the entire group. Reimbursement amounts are based on an additional benefit assessment of medicinal products in all indications compared to an appropriate comparator therapy and are linked to further contractual conditions (cf. in detail e.g. vfa 2014, Giulini-Limbach et al. 2021, Stallberg 2021).*

3: *Cf. the programmatic contribution by Bode et al. 2014.*

Author's statement

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