

MArS Webinar: Price negotiations in Germany — live and let die or die hard?!

26th August 2021

Dr. Stefan Walzer Lutz Vollmer

MArS Market Access & Pricing Strategy GmbH, Germany
State University Baden-Wuerttemberg, Germany
University of Applied Sciences Ravensburg-Weingarten, Germany

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Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill

Joost Broekens¹, Maaike Harbers¹, Willem-Paul Brinkman¹, Catholijn M. Jonker¹, Karel Van den Bosch³, and John-Jules Mever²

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Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg

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Webinar Calendar



Dr. Thorsten Peske Sana Solutions

30.09.2021

There is more

than Mozart, Sissi and Sacher cake! The pragmatic reimbursement pathways in Austria?!



Dr. Mathias Perleth G-BA

27.10.2021

The good, the bad, the ugly!? – Experimental

– experimenta coverage in Germany

at 9pm CET / 12am PT





Dr. Mathias Flume KV Westfalen-Lippe

18.11.2021

Regional drug budgets

– KVs as the the

KVs as the the hidden watch dogs in Germany

Questions welcome!



- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards, and the video will be published on our website.

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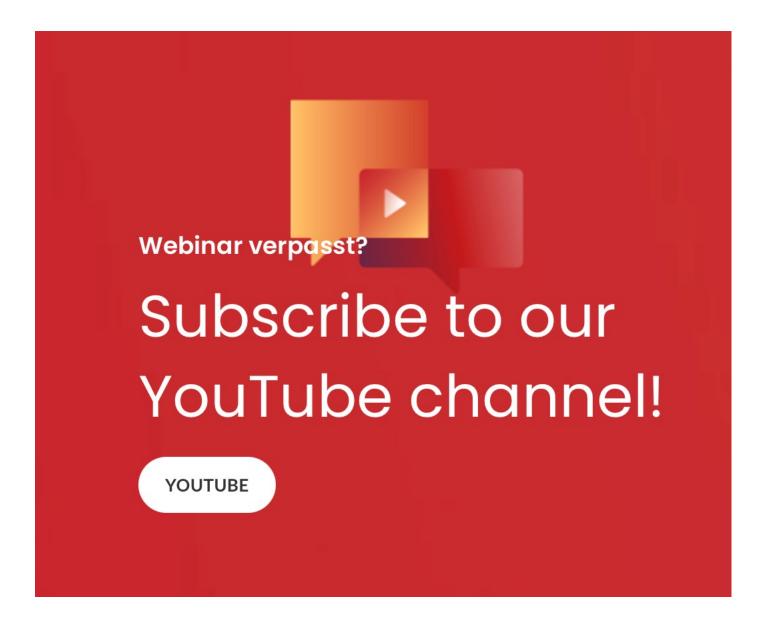




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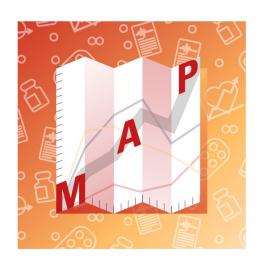
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Our presenters and discussants today





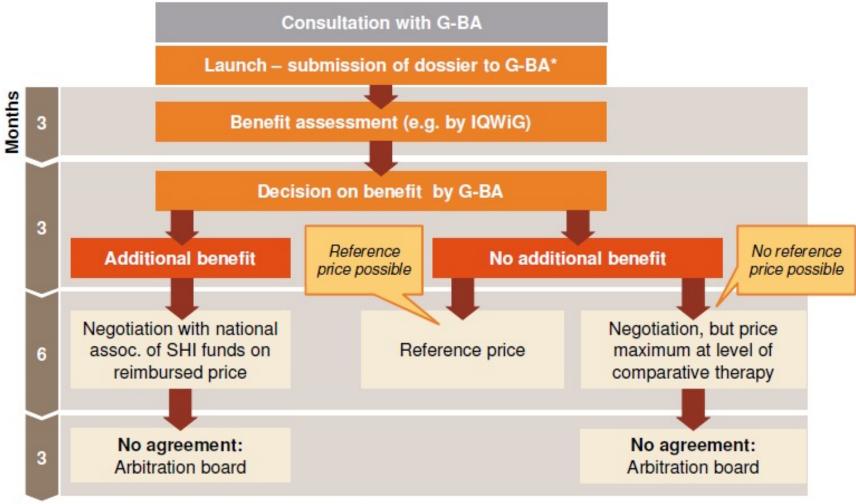




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How does the AMNOG process look like?





^{*}G-BA Gemeinsamer Bundesausschuss - Federal joint committee

Aim: Establish Evidence for Added Benefit Rating



| Note / Score | Decision Category | Definition | Price negotiation | Implication for pricing | EU prices considered |
|-----------------|---|---|--|---|-------------------------|
| 1 | Significant or Major added benefit (erheblich) | Sustainable and not yet achieved significant improvement of the relevant therapeutic benefit | Yes | | Yes |
| 2 | Considerable added benefit (beträchtlich) | Not yet achieved considerable improvement of the relevant therapeutic benefit | Yes | Adjusted premium vs. the appropriate comparator therapy in pricing negotiation. Important: Potential price anchors (other | Yes |
| 3 | Minor/Marginal added benefit (gering) | Not yet achieved moderate and not only marginal improvement of the relevant therapeutic benefit | Yes | therapies) could be discussed. Key negotiation driver is especially the certainty on the added benefit. | Yes |
| 4 | Non-quantifiable added benefit (nicht quantifizierbar) | Added benefit exists, but the scientific data basis does not allow for quantification | Yes | | Yes |
| 5 | No added benefit | | No, if a product can be put into a reference price group | Reference price or as a maximum the price of the appropriate comparator | No |
| 6 | Lesser benefit (geringerer Nutzen) | Benefit is lower then the appropriate comparator | No | Discount on the appropriate comparator | No |

Added benefit granted for orphan drugs



| Note / Score | Decision Category | Definition | Price negotiation | Implication for pricing | EU prices considered | |
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| 4 | Non-quantifiable added benefit (nicht quantifizierbar) | Added benefit exists, but the scientific data basis does not allow for quantification | Yes | | Yes | |
| 5 6 | For Orphan Drugs there are only four potential additional benefit levels! | | | | | |

The price negotiation





- GKV-SV Berlin
- Negotiation room
- Preparation room

Pre- and post-Covid-19

Since Covid-19 pandemic

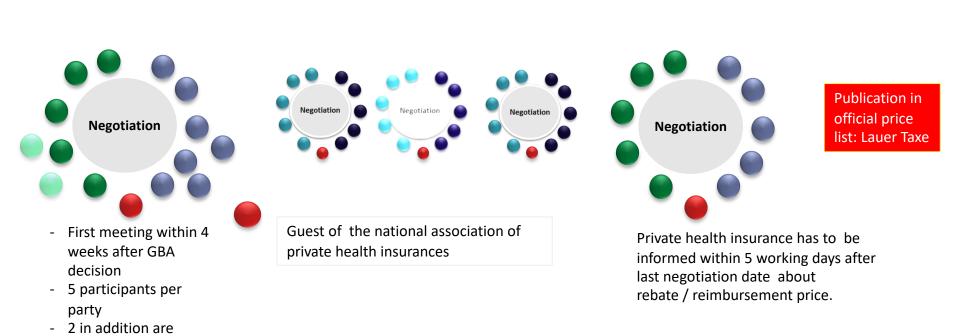
- Web-conferences
- Negotiation team communication (messenger, meetings, separate telephone line, ...)

Structure of the negotiation process at the GKV-SV





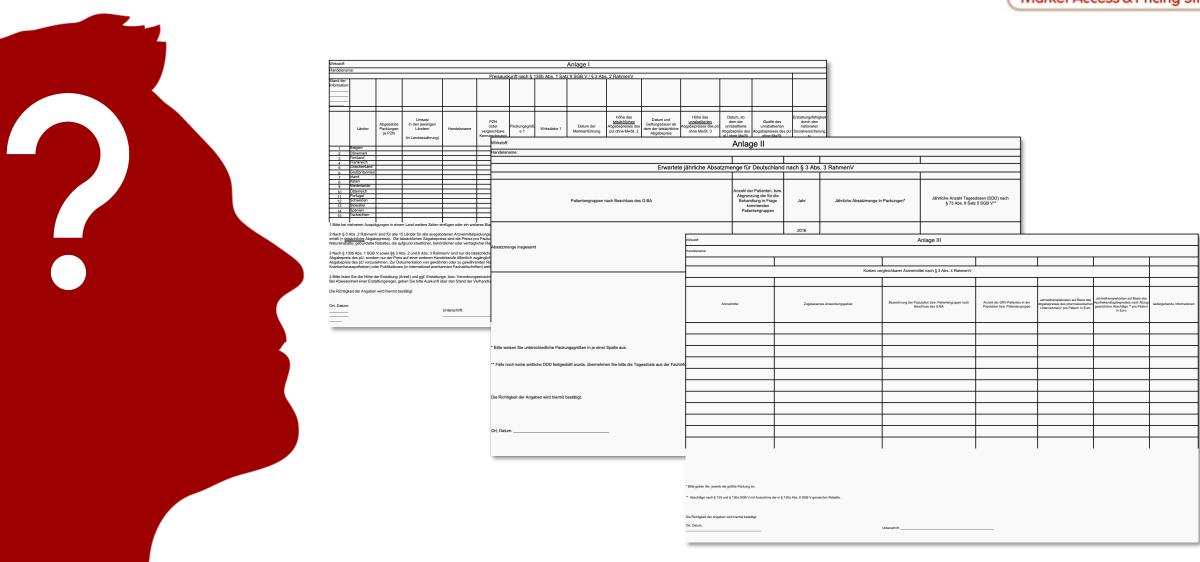
- Two further meetings planned, between first and last meeting
- Upon agreement of parties another meeting is possible
- Last meeting max. 3 weeks prior to price publication



allowed upon agreement.

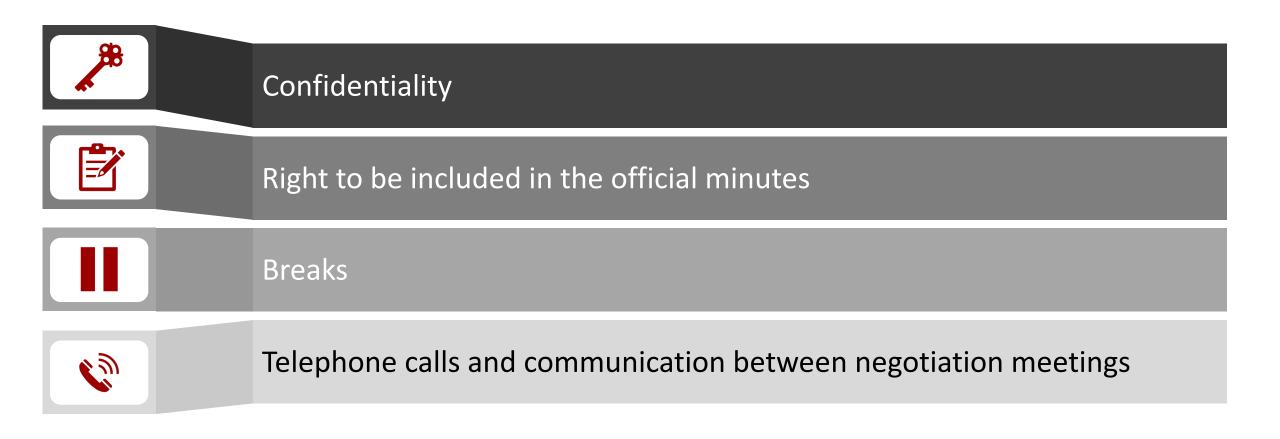
Negotiations...





Some negotiation rules...





Drivers in the price negotiations with the GKV-SV

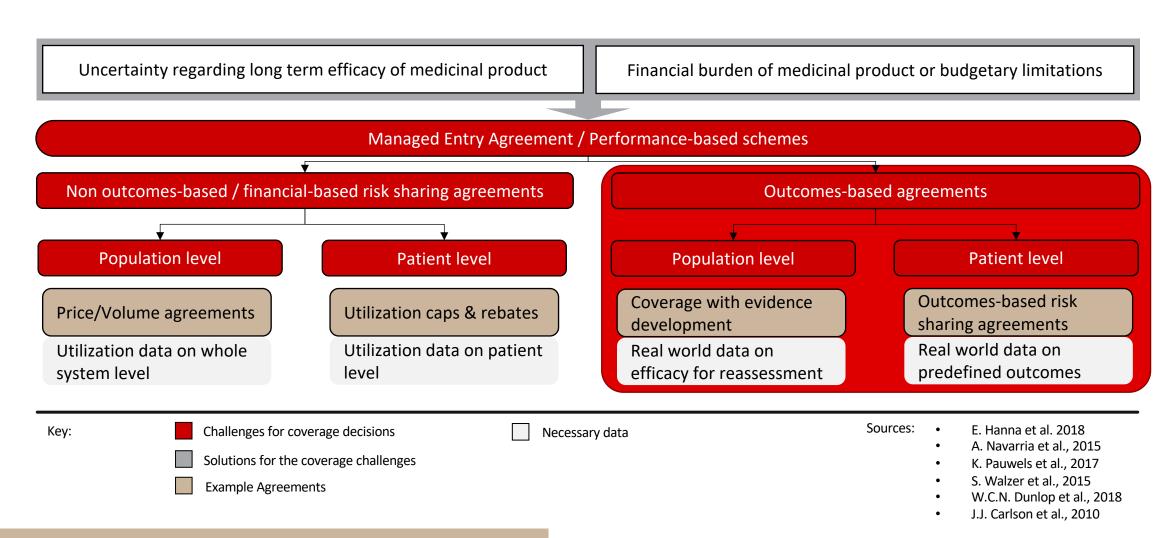




Extract of Managed Entry Agreements



Opportunity within the AMNOG?!



Price impact foreseeable?

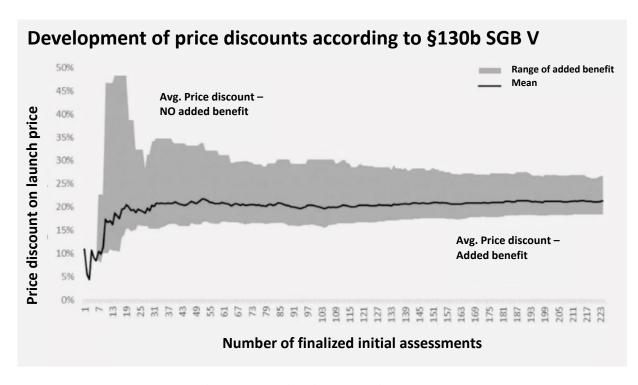


| RESEARCH Open Access | | | | | | |
|---|--|-------|-------|-------|-------|--|
| Benefit assessment in Germany: implications for price discounts | | | | | | |
| Overall | Ulrike Theidel ¹ o and J-Matthias Graf von der Schulenburg ² Overall | | | | | |
| Size of target population | n | Mean | Min | Max | SD | |
| 0-< 1000 | 34 | 20.84 | 1.00 | 53.71 | 12.15 | |
| 1000-< 2500 | 38 | 21.28 | 0.00 | 42.54 | 11.53 | |
| 2500-< 7500 | 31 | 19.79 | 4.74 | 39.44 | 9.00 | |
| 7500-< 25000 | 32 | 21.61 | 2.01 | 46.44 | 11.43 | |
| 25000-< 150000 | 34 | 23.88 | 3.16 | 67.30 | 15.12 | |
| 150000+ | 24 | 25.18 | 2.01 | 78.02 | 19.50 | |
| Orphan drugs | | | | | | |
| Size of target population | n | Mean | Min | Max | SD | |
| 0-< 300 | 10 | 13.70 | 1.00 | 24.50 | 8.15 | |
| 300-< 1500 | 10 | 20.66 | 9.00 | 29.78 | 6.52 | |
| 1500+ | 9 | 20.81 | 10.96 | 25.54 | 4.66 | |

All discounts presented in %

Abbreviations: Min minimum, Max maximum, SD standard deviation

Source: Theidel U. Health Economics Review. 2016



AMNOG report 2020 - https://www.dak.de/dak/download/report-2335144.pdf

Our guest today





Bibiane Schulte-Bosse

Bibiane Schulte-Bosse is specialised in medical law and has been with the Law Firm since 2003.

Her practical training included periods with the panel physician association of Lower Saxony and with the Medical Chamber of Lower Saxony. Before commencing work as a lawyer she was an advisor for panel physician and panel dentist legislation with the regional association of a health insurance fund.

Mrs. Schulte-Bosse advises and represents doctors and pharmacists in disputes with the panel doctor associations, medical chambers, supervisory authorities and health insurance companies. She also advises companies of the pharmaceutical and medical device industry in matters of reimbursement and health policy. Bibiane Schulte-Bosse draws on a wealth of practical experience in the area of advising and accompanying pharmaceutical companies in early benefit assessment and during negotiations on reimbursement amounts.

AMNOG webinar

26.08.2021

Attorney

Bibiane Schulte-Bosse
- Specialist lawyer for medical law -

Sträter Attorneys at Law

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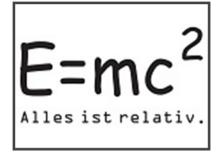
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How do I get to the reimbursement amount?

Basis of the Agreement:

Decision of the G-BA according to § 35a para. 3 SGB V (early benefit assessment)

Influencing variable: (costs of) comparative therapy



Weighting of the criteria

- 1. No explicit weighting in § 130b SGB V or in the Framework agreement (= Rahmenvereinbarung)
- 2. Consideration of additional criteria?
- 3. Room to negotiate?
- 4. Obligation to overweight the additional benefit (LSG B.-B., B. v. 01.03.2017, L 9 KR 437/16 KL ER).

Calculation algorithm for the reimbursement amount?

§ 130b para. 4 sentence 2 SGB V:

The Arbitration Board decides on the basis of a free assessment of all circumstances of the individual case, taking into account the special features of the respective therapeutic area (BT-Drs. 17/13770, p. 24).

Note:

Contrary development in the current arbitration board practice under Chair Prof. Dr. Huster and current case law on drugs without benefit:

"The broard scope granted to the arbitration board by § 130b para. 4 sentence 2 SGB V is limited by § 130b para. 3 sentence 2 SGB V (= annual treatment costs of comparator as max-price) as lex specialis."

Regional Social Court of B.-B., ruling of 29.04.2021, L 14 KR 281/18 KL on Teriflunomid; in result latest ruling of Federal Social Court of 12.08.2021 on Dimethylfumarate, B 3 KR 3/20

R.

On monetization

There is no legal basis for the question of which costs are appropriate for which benefits; in this respect, there is no model and no concept according to which the medical benefit of a health care service could be converted into costs (...). Despite the legislative goal pursued with the AMNOG to orient the prices of drugs more strongly to their medical benefit, the legislator has not established any criteria for deciding which price could be appropriate for which additional benefit. This core question is rather answered primarily to the negotiation procedure (...).

Federal Social Court, ruling of 04.07.2018, B 3 KR 20/17 R, Rd-Nr. 46



Monetizing additional benefits as a multiplier of the comparator price?

In particular, it cannot be inferred from the normative requirements for the determination of a reimbursement amount that the amount to be applied for the additional benefit must be in a certain algorithmically determined relation to the costs of the appropriate comparative therapy (...). According to the legal materials, the decision of the arbitration board is not predetermined by a concrete "decision algorithm" (...).

Federal Social Court, ruling of 04.07.2018, B 3 KR 20/17 R, marginal no. 47



However: arbitration board on the price cap (Aubagio, Esperoct, Tecfidera)

The Arbitration Board assumes that it has no room for manoeuvre in the case of Section 130b (3) SGB V, but is obliged to simply implement the statutory requirement. Even if the most cost-effective drug only has a market share of 1%, this nevertheless operationalizes the "most economical" therapy alternatives within the meaning of § 130b (3) sentence 1 and sentence 2 SGB V.

→ Unfortunately recently also: Federal Social Court, ruling of 12.08.2021, B 3 KR 3/20 R (on Dimethylfumarate):

"This allows pricing based on a drug with one of these active ingredients even if it had not yet been launched on the market at the time of the benefit assessment decision. (…) the market penetration of (…) shortly after its introduction is irrelevant"

The reimbursement amount agreement

The contract according to § 130b SGB V

- GKV-SV always uses its own contract model
- Draft contract is emailed to the PU in synoptic form after the 1st VT (3 columns: GKV-SV, pU and consensus column)
- In the 1st VT, deadlines are agreed by which the PU enters its proposed changes in the middle column and reports them back.
- GKV-SV mails back his wishes before/after the 2nd VT
- Mostly: contract is discussed at least once, negotiation of conditions in/after 4th VT in several meetings/calls

The contract synopsis

| GKV-SV (Stand:) | (Stand: []) | Konsens (Stand: [] |
|---|--------------|--------------------|
| Mit diesem Verständnis und vor diesem Hintergrund | | |
| vereinbaren die Parteien im Benehmen mit dem Verband | | |
| der privaten Krankenversicherung Folgendes: | | |
| | | |
| | | |
| § 1 | | |
| Gegenstand der Vereinbarung | | |
| | | |
| Diese Vereinbarung regelt den Erstattungsbetrag nach | | |
| § 130b Abs. 1 Satz 1 SGB V und die sonstigen Rechte | | |
| und Pflichten bezüglich aller Fertigarzneimittel mit dem | | |
| Wirkstoff die in Deutschland vor dem Ab- | | |
| schluss dieser Vereinbarung erstmalig in Verkehr ge- | | |
| bracht hat. Ferner regelt der Vertrag den Erstattungsbe- | | |
| trag und die sonstigen Rechte und Pflichten bezüglich | | |
| aller weiteren Fertigarzneimittel mit dem Wirkstoff | | |
| die dar dem Abschluss dieser Vereinba- | | |
| rung in Deutschland erstmalig in Verkehr bringt (im Fol- | | |
| genden "Neueinführungen"). Andere Fertigarzneimittel | | |
| mit dem Wirkstoff in Kombination mit anderen | | |
| Wirkstoffen sind von dieser Vereinbarung nicht erfasst. | | |
| Transforment said for dieser vereinbarding filotit errasst. | | |
| | | |
| § 2 | | |
| | | |
| Erstattungsbetrag | | |

Contractual regulations relevant to the reimbursement amount

- Start of pricing, term of contract, termination
- Replacement of manufacturer discount (yes/no),
- Reference value (for price and quantities),
- Quantities and consequences of deviation therefrom,
- Claims for susequent reimbursement
- Reporting duties
- Confidentiality rules
- Practice speciality only for drugs with an addded benefit).
- Other contractual provisions (e.g. "annual treatment costs guarantee" in case of future changes to the SmPC).

→ Importance of determining the reference value:

Life Cycle of the drug!

Extension effect of the reimbursement amount for new packages.

§ 130b para. 1 sentence 5 SGBV

The reimbursement amount agreement should also include requirements regarding the appropriateness, quality and economic efficiency of a prescription.

- 1. e.g. agreement on start and stop criteria for therapy
- 2. Notes on cost-effectiveness analogous to the G-BA's therapeutic advice
- 3. Definition of a therapy path
- 4. Information to all associations of Statutory health Insurance Physicians, health insurers and audit panels
- 5. Agreement on (mutual) communication to doctors to ensure compliance with the agreed area of operation
- 6. if necessary, agreement of failure regulations
- 7. Testability?

If the GKV-SV rejects ideas by referring to legal regulations ...

- 1. Reference to negotiating autonomy.
- 2. Reference to § 130 b Para. 4 Sentence 2 SGB V.
- 3. Situational: legal reasoning as to why the idea is permissible.
- 4. Situational: reference to arbitration board decisions and/or case law.
- 5. Objectives of the AMNOG, e.g. improvement of economic efficiency without affecting the scope of services (BT-Drs. 17/2413, p. 1).

Legal Defense



Appeal against arbitration board decisions

Social Court Action





Regional Social Court of Berlin-Brandenburg (Potsdam)

Federal Social Court of Justice (Kassel)

Federal Social Court of Justice on the level of control of arbitration board decisions

- 1. In some cases, the decision of the arbitration board is not based on facts that are accessible to evidence and are judicially qualified as correct or incorrect; rather, it is a matter of the prognosis, assessments and evaluations of a body staffed with experts.
- 2. The assessments and forecasts made on the basis of the decision of the G-BA are then reviewed by the BSG only with regard to the laws of logic and the principles of general life experience.
- 3. The expertly staffed arbitration board is a guarantor for decisions that are justifiable in terms of health economics and economically acceptable in the event of non-agreement.

vgl. BSG, U. v. 04.07.2018, B 3 KR 20/17 R



Federal Social Court on legal protection against early benefit assessment and arbitration board decision

If a challenge to an arbitration award is based on objections to the G-BA's benefit assessment decision, it is advisable to also seek a declaratory decision on the legality of the benefit assessment decision in the judicial proceedings → that separate action against the G-BA decision is inadmissible does not preclude the requirement of a separate declaratory decision.

The pharmaceutical company has an increased burden of proof in the dossier; the duty of both the G-BA and the courts to conduct official investigations is therefore limited.

BSG on Linaclotid, ruling of 28.03.2019, B 3 KR 2/18 R,

confirmed by BSG on Dimethylfumarat, ruling of 12.08.2021, B 3 KR 3/20 R

Conclusion

- 1. The law and the framework agreement set a general framework for the reimbursement amount negotiation.
- 2. Unlike the fixed amount, the reimbursement amount is strongly influenced by the element of "negotiation".
- 3. The Arbitration Board's decision-making practice is strongly oriented towards individual cases.
- 4. More and more, the reimbursement amount is arriving in the jurisdiction.



Thanks a lot!

Bibiane Schulte-Bosse

- Lawyer and specialist in medical law -

Sträter Attorneys at Law

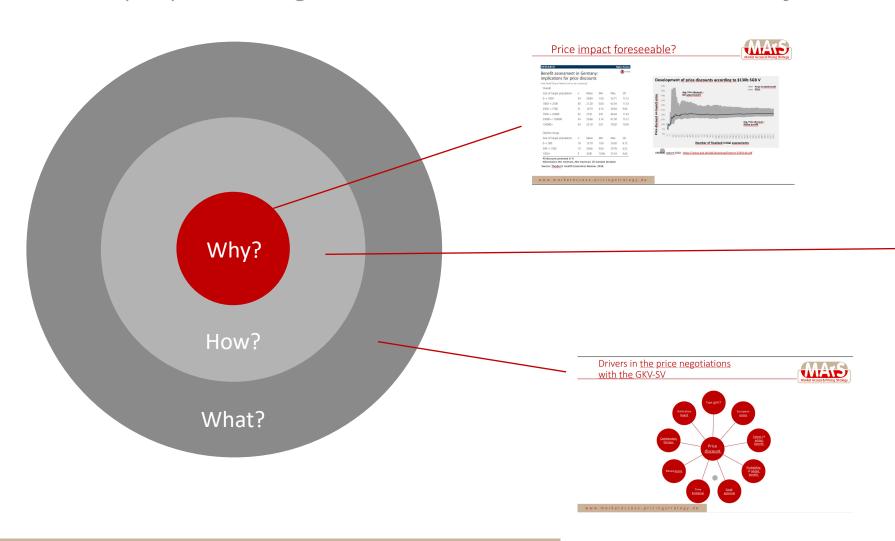
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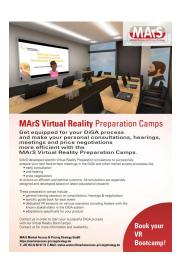
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Conclusions



Well prepared negotiations are a driver to be successfull!!





Time for questions ...



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Market Access & Pricing Strategy GmbH



Dr. Stefan Walzer Speaker



Lutz Vollmer Moderator

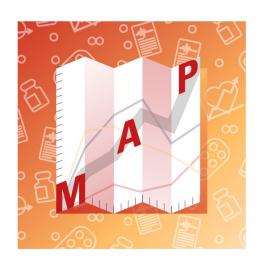


Bibiane Schulte-Bosse laywer at Straeter law firm

Recording available on our Youtube channel via www.marketaccess-pricingstrategy.de

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