

MArS Webinar: The end in drug pricing negotiations? The "mystic" arbitration board?!

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Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill

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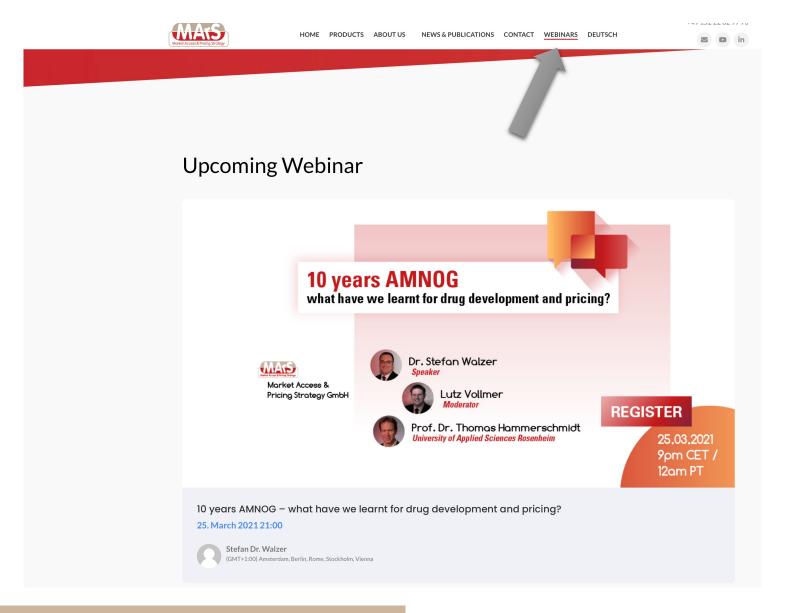
Broekens J., et al. (2012) Virtual Reality Negotiation Training Increases Negotiation Knowledge and Skill. In: Nakano Y., et al. (eds) Intelligent Virtual Agents. IVA 2012. Lecture Notes in Computer Science, vol 7502. Springer, Berlin, Heidelberg

Questions welcome!



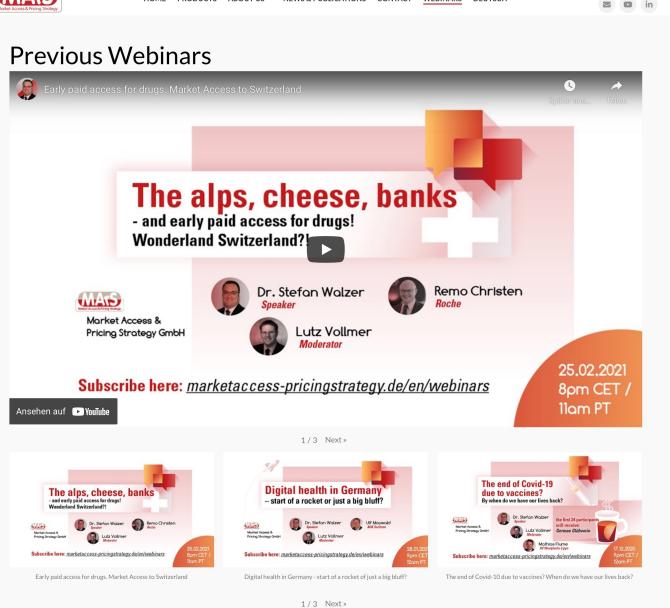
- Feel free to ask questions. After the presentation, we will have time for your questions.
- Use either the Zoom chat function or the Q&A function to raise your questions or comments.
- As always, slides will be provided afterwards, and the video will be published on our website.



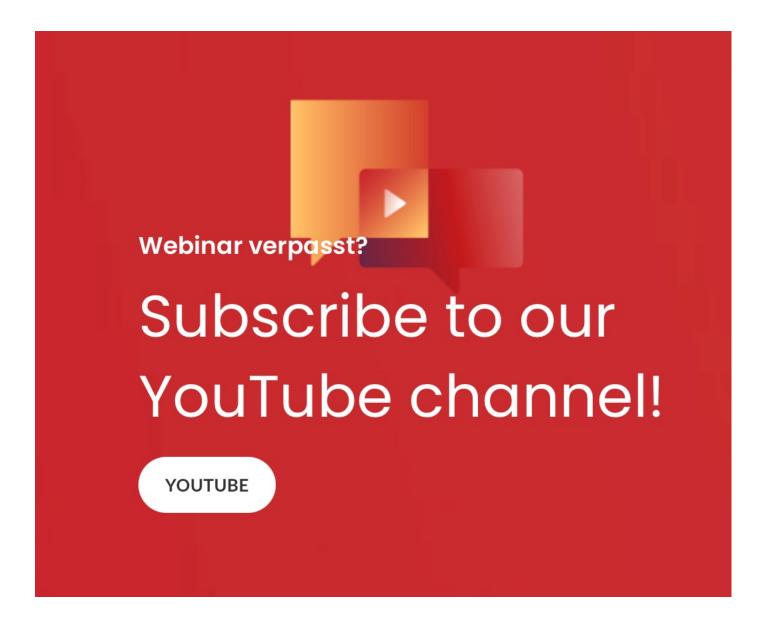














Our presenters and discussants today





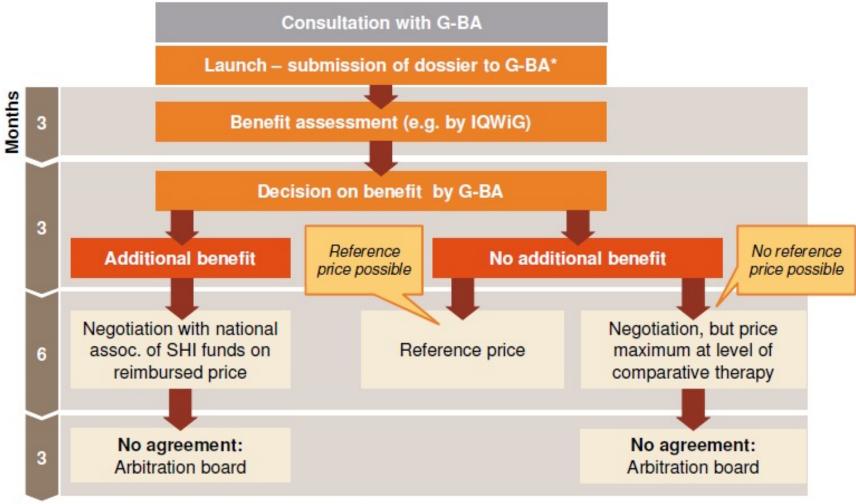




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How does the AMNOG process look like?





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

The price negotiation





- GKV-SV Berlin
- Negotiation room
- Preparation room

Since Covid-19 pandemic

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

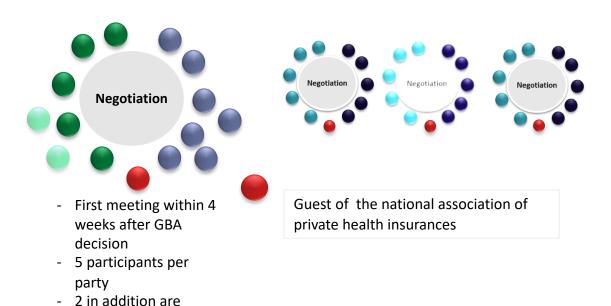
Pre- and post-Covid-19

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





Publication in official price list: Lauer Taxe

Private health insurance has to be informed within 5 working days after last negotiation date about rebate / reimbursement price.

allowed upon agreement.

No agreement? What happens then?





What is the arbitration board?





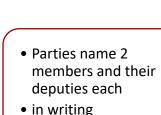
Head of arbitration board since 2019: Prof. Huster

- Consists of:
 - 1 impartial chairman (term of office 4 years)
 - 2 further impartial members (term of office 4 years)
 - 2 representatives of each party (term of office ends when the arbitration award becomes effective)

 Patient representation (BAG-Selbsthilfe) and BMG can participate in the meetings

The start of the arbitration process





within 14 days

Start of the procedure

- With the receipt of the application
- At the latest after 6 month period after JCC decision

- In writing to the chairman
- Facts
- Negotiation results
- Non-consensual contract contents

Request

Communication

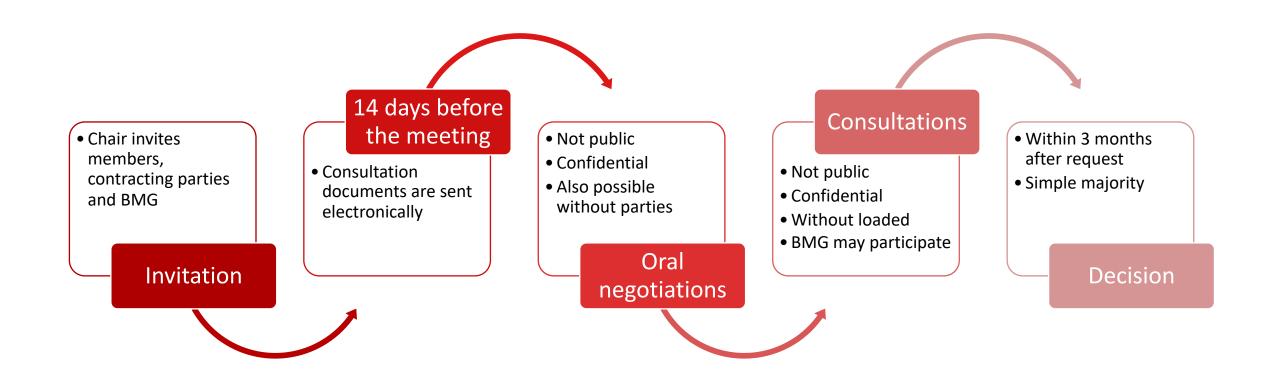
• Chairperson informs the other Party

- Parties may submit requests for more specific information
- Proposals are communicated to both parties

within 14 days

The process of the arbitration





Topics of arbitration board decisions



It is not all about the price!

- Reimbursement amount
- Start of validity of the new reimbursement amount
- Prescription quantities, regulation in case of exceeding
- Contract term, notice periods and requirements
- Replacement of manufacturer discounts
- Subsequent refund of the deductions and notification to IFA
- Practice exemption

Examples of decisions: Prescription quantities, regulation in case of exceeding



Number	Date	Active ingredient	Therapeutic area
19 P 28-20	12.03.2021	Betibeglogene autotemcel	Transfusion dependent ß-thalassemia without ß0/ß0-genotype (ATMP)
2 P 3-20	18.07.2020	Apalutamid	Metastatic prostate cancer
4 P 12-18	14.02.2019	Dimethyl fumarate	Multiple sclerosis (diseases of the nervous system)
8 P 16-18	19.09.2018	Rolapitant	Nausea and vomiting during chemotherapy (other)
3 P 10-18	25.06.2018	Teriflunomide	Multiple sclerosis (diseases of the nervous system)
130b-SSt. 13-17	27.09.2017	Vortioxetine	Major depression (mental illness)
130b-SSt. 2-17	25.04.2017	Mepolizumab	sthma bronchiale (diseases of the respiratory system)
1130b-SSt. 1-17	03.04.2017	Afamelanotide	erythropoietic protoporphyria (metabolic diseases)
130b-SSt. 17-16	17.03.2017	Sacubitril/Valsartan	Heart failure (cardiovascular disease)
130b-SSt. 12-16	05.12.2016	Idebenon	Leber's hereditary optic neuropathy (eye disease)
130b-SSt. 11-16	19.10.2016	Netupitant/palonosetron	Nausea and vomiting during chemotherapy (other)
130b-SSt. 4-16	29.06.2016	Vortioxetine	Major depression (mental illness)
130-SSt. 17-15	11.03.2016	Insulin degludec	Diabetes mellitus type 2 (metabolic diseases)
130b-SSt. 9-15	19.09.2015	Siltuximab	Multicenter Castleman disease (MCD) (oncologic diseases)
130b-SSt. 3-14	25.08.2014	Vildagliptin/metformin	Diabetes mellitus type 2 (metabolic diseases)
130b-SSt. 4-14	20.08.2014	Vildagliptin	Diabetes mellitus type 2 (metabolic diseases)
130b-SSt. 1-12	30.08.2012	Bromfenac	in case of postoperative inflammation of the eye after cataract surgery (eye diseases)

Example: Practice exemption



Number	Date	Active ingredient	Therapeutic area	Orphan Drug
130b-SSt. 14-17	23.10.2017	Tasimelteon	Sleep disorders (sleep-wake rhythm) (diseases of the nervous system)	yes
130b-SSt. 6-17	28.06.2017	Daratumumab	Multiple myeloma (oncological diseases)	yes
130b-SSt. 17-16	17.03.2017	Sacubitril/Valsartan	Heart failure (cardiovascular disease)	no
130b-SSt. 12-16	05.12.2016	Idebenon	Leber's hereditary optic neuropathy (eye disease).	yes
130b-SSt. 9-16	07.11.2016	Nivolumab	Melanoma (oncologic diseases); non-small cell lung carcinoma (oncologic diseases).	no
130b-SSt. 1-16	15.04.2016	Dulaglutide	Diabetes mellitus type 2 (metabolic diseases)	no
130b-SSt. 16-15	25.02.2016	Ataluren	Duchenne muscular dystrophy (diseases of the musculoskeletal system)	yes
130b-SSt. 9-15	19.09.2015	Siltuximab	Multicenter Castleman disease (MCD) (oncologic diseases).	yes

- Agreement of a practice speciality is a "shall" regulation.
- Decision against, only with important reasons: e.g. dulaglutide -> added benefit only in 1 out of 5 subgroups

Most important?! Reimbursement amount



Drugs without an added benefit

Drugs without added benefit

- JTK ≤ JTK zVT
- JTK of the most economical zVT, if no individual case exists.
- JTK of zVT for different patient groups are weighted according to patient distribution
- If JTK of zVT shown as range in G-BA decision - upper limit or mean value.
- Surcharge or discount in justified individual cases

Exemplarily chosen list of decisions with reimbursement amount as key topic

Number	Date	Active ingredient	Therapeutic area	Wish GKV, Euro	Increase in the decision, %.	Wish manufactur er, Euro	Increase in the decision, %.	Decision, Euro	Deviation from the center
11 P 12- 19	06.06.2019	Hydrocortisone	Adrenocortical insufficiency (metabolic diseases)	0,55569	83,56%	1,32	-22,73%	1,02	8,76%
130b- SSt. 11- 16	19.10.2016	Netupitant/palonosetron	Nausea and vomiting during chemotherapy (other)	30,1	104,12%	104,45	-41,18%	61,44	-8,67%
130b- SSt. 5- 16	04.07.2016	Insulin degludec/liraglutide	Diabetes mellitus type 2 (metabolic diseases)	0,022864	0,00%	0,08315	-72,50%	0,022864	-56,87%
130b- SSt. 4- 16	29.06.2016	Vortioxetine	Major depression (mental illness)	0,07581	23,11%	0,95	-90,18%	0,09333	-81,80%
130-SSt. 17-15	11.03.2016	Insulin degludec	Diabetes mellitus type 2 (metabolic diseases)	0,0244	0,00%	0,037575	-35,06%	0,0244	-21,26%
130b- SSt. 7- 15	03.11.2015	Mirabegron	Overactive bladder (diseases of the genitourinary system)	0,3827	43,98%	0,7256	-24,06%	0,551	-0,57%
130b- SSt. 4- 15	02.09.2015	Insulin degludec	Diabetes mellitus type 1 and type 2 (metabolic diseases)	0,0192	27,08%	0,051	-52,16%	0,0244	-30,48%
130b- SSt. 6- 14	08.09.2014	Elvitegravir/cobicistat/emtri citabine/tenofovirdisoproxil	HIV infection (infectious diseases)	19,50342	57,23%	37,58	-18,40%	30,665	7,44%
130b- SSt. 3- 14	25.08.2014	Vildagliptin/metformin	Diabetes mellitus type 2 (metabolic diseases)	0,2395	146,35%	0,98	-39,80%	0,59	-3,24%
130b- SSt. 4- 14	20.08.2014	Vildagliptin	Diabetes mellitus type 2 (metabolic diseases)	0,1704	246,24%	0,98	-39,80%	0,59	2,57%
130b- SSt. 5- 14	10.07.2014	Linaclotide	Irritable bowel syndrome with constipation (diseases of the digestive system)	0,6289	-0,05%	1,89	-66,74%	0,6286	-50,09%
130b- SSt. 1- 14	18.06.2014	Lixisenatide	Diabetes mellitus type 2 (metabolic diseases)	0,10137	440,54%	1,8	-69,56%	0,54795	-42,36%
130b- SSt. 2- 13	28.11.2013	Perampanel	partial epilepsy (diseases of the nervous system)	0,6799	0,49%	1,1349	-39,80%	0,6832	-24,71%
130b- SSt. 3- 12	26.02.2013	Retigabine	Epilepsy (diseases of the nervous system)	0,65	-0,68%	1,45	-55,48%	0,6456	-38,51%
130b- SSt. 1- 12	30.08.2012	Bromfenac	in case of postoperative inflammation of the eye after cataract surgery (eye diseases)	7,17	-17,85%	8,33	-29,29%	5,89	-24,00%

Most important?! Reimbursement amount



Drugs with added benefit

Drugs with added benefit

- Weighting:
 - Extent of additional benefit: 50 100%
 - Selling prices in the other European countries: 15-49%
 - JTK comparable drug(s): 30-35%
- Consideration of only ZN and IRP_{EU} for orphan drugs
- No consideration of IRP_{EU} if drug is only available in a few countries
- Orientation to IRP_{EU}, if ZN are not quantifiable
- Consideration of the previous decisions

Exemplarily chosen list of decisions with reimbursement amount as key topic

Number	Date	Active ingredient	Therapeutic area	Added value		Wish GKV, Euro	Increase in the decision, %.	Wish manufactur er, Euro	Increase in the decision, %.	Decision, Euro	Deviation from the center
130b-SSt. 14-17	23.10.2017		Sleep disorders (sleep-wake rhythm) (diseases of the nervous system)	Not quantifiab le		5.000	92,31%	93.899	-44,46%	65.000	31,45%
130b-SSt. 9- 17	30.08.2017	Ataluren	Duchenne muscular dystrophy (diseases of the musculoskeletal system)	with low ZN	yes	4,00	71,43%	30,50	-117,86%	14,00	-18,84%
1130b-SSt. 1-17	03.04.2017	Afamelanot ide	erythropoietic protoporphyria (metabolic diseases)	Not quantifiab le	yes	3.120,32	77,87%	16.482	-16,89%	14.100,95	43,87%
130b-SSt. 15-16	06.03.2017	Blinatumo mab	acute lymphatic leukemia (oncological diseases)	Not quantifiab le	yes	903,11	60,06%	2.553	-12,91%	2.261,11	30,85%
130b-SSt. 16-15	25.02.2016	Ataluren	Duchenne muscular dystrophy (diseases of the musculoskeletal system)	with low ZN	yes	7,86	43,86%	30,80192	-120,01%	14	-27,58%
130b-SSt. 9- 15	19.09.2015	Siltuximab	Multicenter Castleman disease (MCD) (oncologic diseases).	Not quantifiab le	yes	4,08496	18,77%	5,63	-11,96%	5,0286	3,52%
130b-SSt. 1- 13	29.05.2013	Vermurafen ib	Melanoma (oncological diseases)	with considera ble ZN	No	1009,82	18,96%	2.115,88	-69,80%	1.246,13	-20,27%
130b-SSt. 4- 12	14.03.2013	Cannabis Sativa Extract	Spasticity in multiple sclerosis (diseases of the nervous system)		no	3,81984	14,05%	10,95	-146,38%	4,4444	-39,82%

Most important?! Reimbursement amount



Drugs with and without added benefit

Drugs with and without added benefit

- Mixed price
- Patient group-specific partial reimbursement amounts
- Corresponding price determination for patient groups with and without ZN

Individual case:

- Consideration of only patient group with ZN (actual patient distribution deviates from G-BA decision)
- Total price with adequacy check for drug with unquantifiable and unproven ZN.

Exemplarily chosen list of decisions with reimbursement amount as key topic

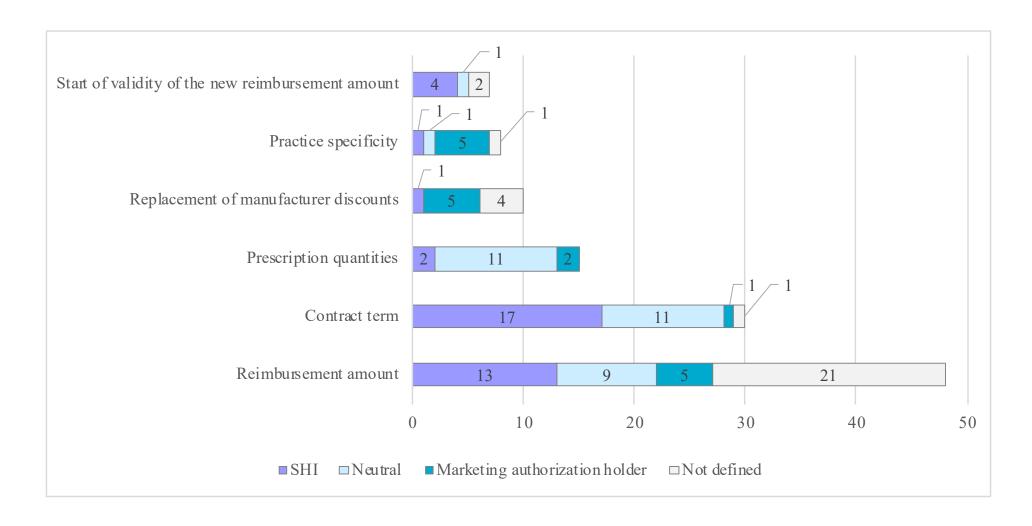
Number	Date	Active ingredi ent	Therapeutic area	Adde d value	Wish GKV, Euro	Increase in the decision, %.	Wish manufac turer, Euro	Increase in the decision, %.	Decision, Euro	Deviatio n from the center
130b- SSt. 9-16	07.11.20 16	Nivolu mab	Melanoma (oncologic diseases); non- small cell lung carcinoma (oncologic diseases).	with consi derab le ZN; not occup ied.	7,96	30,48%	14,398	-25,75%	11,45	2,42%
130b- SSt. 15- 15	14.04.20 16	Albiglut ide	Diabetes mellitus type 2 (metabolic diseases)	not occup ied; with low ZN	6,707 9	66,48%	21,41	-7,00%	20,01	42,33%
130b- SSt. 13- 15	11.11.20 15	Daclata svir	chronic hepatitis C (infectious diseases)	with low ZN; with consi derab le ZN; not used	76,27 13	70,61%	321,43	-23,86%	259,52	30,51%

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ZN: Added benefit

Can conclusions been drawn?





Learnings from arbitration decisions



- Decides "under free appraisal of all circumstances of the individual case".
- Takes into account "the specifics of each therapeutic area".
- BUT the decisions can indirectly influence all future decisions
- BUT the arbitration board is bound by the framework agreement
- No hint of an algorithm:
 - Prescription quantities, regulation in case of exceeding
 - Start of validity of the new reimbursement amount
 - Reimbursed price

Some informal considerations by the former chairperson of the arbitration board

- Internal situation of the 3 unpartial members: unanimity or majority vote?
- Consistency of decisions via vs. selective responsibility?
- Risking the drug leaving the German market?
- New challenges: ATMPs, especially gene therapies





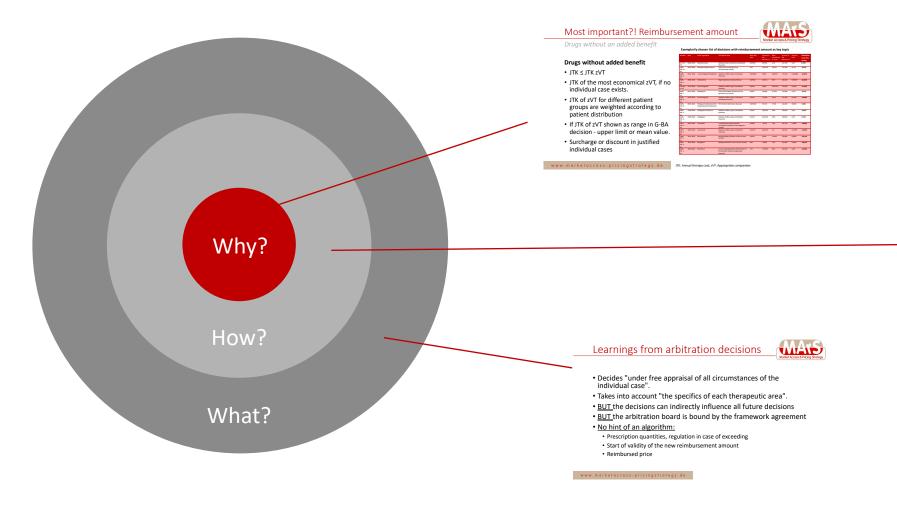




Conclusions



Prepare carefully for the full negotiations including arbitration





Time for questions ...



The end in drug price negotiations in Germany? The "mystic" arbitration board?!



Market Access & Pricing Strategy GmbH



Dr. Stefan Walzer Speaker



Lutz Vollmer Moderator



Prof. Dr. Jürgen Wosem Former Head of arbitration board

Recording available on our Youtube channel via

www.marketaccesspricingstrategy.de

Register already now for our next webinar!





Webinar Calendar



Ariane Schenk

Bitkom Health

24.06.2021

1 year DiGAs in Germany Garden of Eden?



Prof. Dr. Uwe Wagschal University Freiburg i. Brsg.

29.07,2021

German elections ahead – potential outcomes and its implications on healthcare market access

at 9pm CET / 12am PT





Bibiane Schulte-Bosse Laywer at Straeter law firm

26.08.2021

Price negotiations in Germany

– live and let die or die hard?