

BACKGROUND

- Within the framework of AMNOG, the final price - also referred to as reimbursement price - of a new medicinal product is negotiated between manufacturers and the National Association of Statutory Health Insurance Funds (SHI/"GKV-Spitzenverband") or will be set by the arbitration board in case of non-agreement of both parties.
- In this regard, a relevant quantity for the SHI and manufacturers is the pricing structure of the reimbursed price after negotiations:
 - The SHI has its own requirements concerning budgetary burdens for pharmaceutical expenditures, so a **linear pricing structure** (price increases with dose) - which enables planned dosage-related daily treatment costs per patient - is generally favored.
 - For manufacturers, the choice of pricing structure between **flat pricing** (identical price for different doses), **linear pricing** or a combination of the two ("**mixed pricing**") depends on different parameters such as indication, expected physicians' prescription behavior or conditions of parallel trade issues due to the European reference pricing.

OBJECTIVES

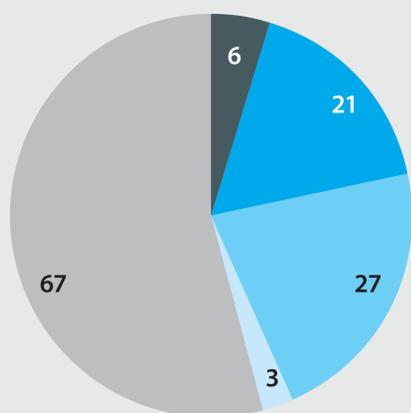
The objective of this analysis is to assess if manufacturers could maintain their favored pricing structure for new medicinal products at market launch in Germany after price negotiations.

METHODS

- Our analysis is based on all price negotiations completed until September 1st 2016, in which manufacturers entered with a linear, a flat or a mixed pricing structure.
- Negotiations were excluded in this analysis if the respective drug was available only in one dose or if the drug has been withdrawn from the market before negotiation started.
- Afterwards, the selected negotiations were analyzed by comparing initial ex-factory prices of all packages for each drug at market launch and final prices after negotiations.
- Furthermore, it was investigated by means of arbitral awards whether the final pricing structure of each drug's reimbursement price was set by the arbitration board in cases of non-agreement.

RESULTS

Total number of identified price negotiations (as of Sep 1st, 2016)



- 118 price negotiations for new medicinal products have been completed as of Sep 1st, 2016 while 6 new medicinal products were withdrawn from the German pharmaceutical market before price negotiations with the SHI started.
- 51 relevant completed price negotiations were identified, in which pharmaceutical manufacturers entered either with a linear pricing (n=21), a flat pricing (n=27) or a mixed-pricing structure (n=3) for the respective drug.
- The remaining 67 completed negotiations were excluded from this analysis since the respective drug was only available in one dose.

Overview pricing structure before and after price negotiations

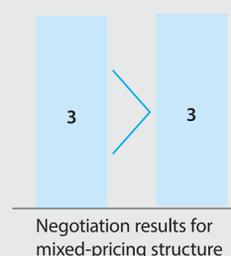
- Manufacturers could maintain their initial linear pricing structure in 19 negotiations. A switch to a flat-pricing model and a mixed-pricing model was performed in 1 negotiation each.



- In 27 cases, manufacturers entered into price negotiations with an initial flat-pricing model. After conclusion of negotiations, 20 medicinal products continued to show a flat-pricing structure. In 6 negotiations, the initial flat pricing was changed into a linear-pricing model while in 1 negotiation a switch to a mixed-pricing structure was performed.



- An initial mixed-pricing model for new medicinal products was chosen by manufacturers in 3 cases. A consensus with the SHI was reached to maintain this pricing structure after conclusion of all 3 negotiations.



Pricing structure set by the arbitration board (as of Sep 1st, 2016)

Substance (Brand name)	Pricing model before negotiation	Pricing model after arbitration proceeding
Albiglutide (Eperzan®)	Flat pricing for all doses	Maintained
Daclatasvir (Daklinza®)	Flat pricing for all doses	Maintained
Dulaglutide (Trulicity®)	Flat pricing for all doses	Maintained
Idelalisib (Zydelig®)	Flat pricing for all doses	Maintained
Mirabegron (Betmiga®)	Flat pricing for all doses	Maintained
Perampanel (Fycompa®)	Flat pricing for all doses	Maintained
Pomalidomide (Imnovid®)	Approximately flat pricing for all doses	Switch to mixed pricing: <ul style="list-style-type: none"> • Linear pricing between 1 mg, 2 mg and 3 mg • Flat pricing between 3 mg and 4 mg

Market withdrawal of 1 mg and 2 mg in 2015 after price negotiation

- In 7 price negotiations, the arbitration board set the final pricing structure of the respective drug's reimbursement price. It is notable that these arbitration processes concerned only products with an initial flat pricing structure.
- In 6 arbitration processes, manufacturers could finally enforce their flat pricing structure.
- In the price negotiation of pomalidomide (Imnovid®), Celgene could only partially maintain the flat pricing structure against the SHI and the arbitration board, eventually responding with a market withdrawal of the low linear priced doses in Germany in 2015.

Color code for price negotiations: ■ Linear pricing structure ■ Flat-pricing structure ■ Mixed-pricing structure ■ Market withdrawal before negotiations ■ Excluded from analysis (only one dose available)

CONCLUSIONS

- Based on the results of our analysis, it can be shown that pharmaceutical manufacturers can mainly maintain their favored pricing model for a new medicinal product in Germany.
- Even a flat pricing structure, although resulting in additional expenditures for the SHI in certain cases, has a high probability of being accepted in negotiations and arbitration proceedings.

REFERENCES

- Jönsson, B. „Flat or Monotonic Pricing of Pharmaceuticals: Practice and Consequences“, European Journal of Health Economics, 2001; 2:104-112
- National Association of Statutory Health Insurance Funds (SHI/"GKV-Spitzenverband") [Internet]: Overview of all price negotiations on the online presence of the "GKV-Spitzenverband" [only available in German, last modified on Sep 1st, 2016, last accessed: Sep 1st, 2016]. URL: www.gkv-spitzenverband.de/krankenversicherung/arzneimittel/rabatt_verhandlungen_nach_amnog/erstattungsbeitragsverhandlungen_nach___130_b_sgb_v/erstattungsbeitragsverhandlungen_nach_130b_sgb_v_vl.jsp
- Initial prices and reimbursement prices were taken from: ABDA Pharma-Daten-Service der Werbe- & Vertriebsgesellschaft Deutscher Apotheker (WuV), ABDA-Artikelstamm, www.pharmazie.com/dacon32/global/infoseiten_eng/abdaartikelstamm.htm

