

BACKGROUND

Formerly, pharmaceutical manufacturers in Germany were allowed to freely set the selling price of a medicinal product. The Act on the Reform of the Market for Medicinal Products (so-called AMNOG) in 2011 still allows initial free pricing for new patented drugs but introduces after an initial year a final reimbursement price.

This reimbursed price is negotiated between pharmaceutical manufacturers and the National Association of Statutory Health Insurance Funds (SHI) based on the outcome of the early benefit assessment with both parties being led by different motivations and goals:

- Manufacturers often prefer a flat pricing model (identical price for different doses) in order to take into account e. g. the expected physicians' prescription behavior as well as conditions of parallel trade issues due to the European reference pricing.
- The SHI has its own requirements concerning budgetary burdens for pharmaceutical expenditure, so a linear pricing (price increases with dose) is generally favored. This pricing structure yields fixed prices per defined daily dose (DDD) for an active ingredient, enabling for the SHI planned dosage-related daily treatment costs per patient.

RESEARCH QUESTION

Is a flat pricing model for new patented drugs in Germany enforceable in price negotiations with the SHI?

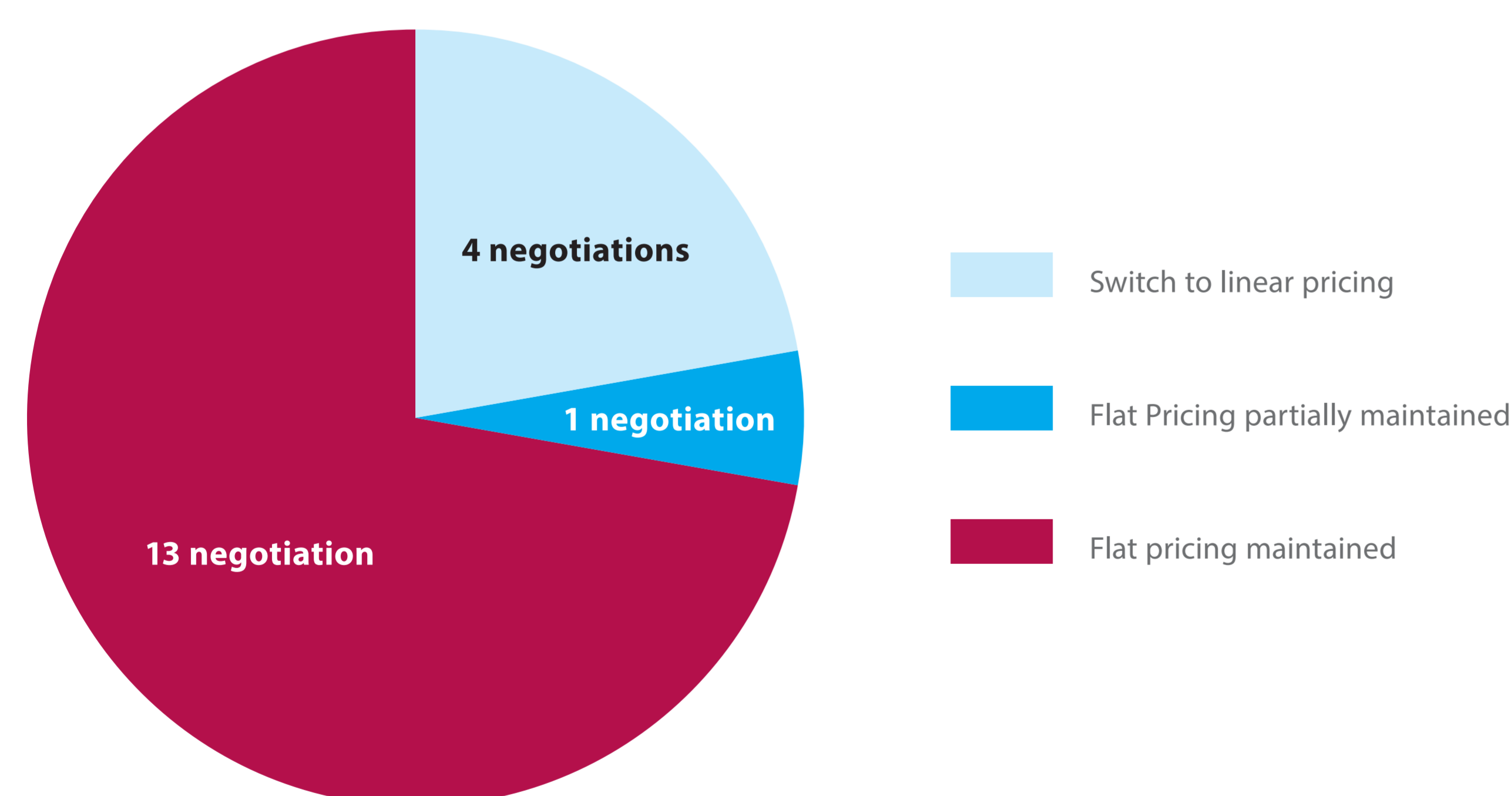
METHODS

From all price negotiations concluded until January 1st, 2016, only those were selected where companies entered into the market with an initial flat pricing. Negotiations were excluded in this analysis if the respective drug was available only in one dose or if the drug had been withdrawn from the market before the negotiation started.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.

RESULTS – OVERVIEW

18 negotiations were identified with a flat pricing structure for the respective drug at market launch. Manufacturers were able to enforce their favored pricing model in 13 negotiations, while the reimbursed price showed a linear pricing structure in 4 negotiations. In the price negotiation of pomalidomide (Imnovid®), Celgene could only partially maintain the flat pricing structure against the SHI and the arbitration board, eventually responded with a market withdrawal of the low linear priced doses in Germany.

Negotiation results for new patented drugs with flat pricing structure at market launch



CONCLUSIONS

When launching a new patented drug in the German pharmaceutical market, a flat pricing model has a high probability of being accepted in the price negotiations by the SHI.

RESULTS OF SELECTED NEGOTIATIONS

SUBSTANCE (BRAND NAME)	PRICING MODEL BEFORE NEGOTIATION	PRICING MODEL AFTER NEGOTIATION
Afatinib (Giotrif®)	Flat pricing for all doses	Maintained
Apixaban (Eliquis®)	Flat pricing for all doses	Maintained
Cabozantinib (Cometriq®)	Flat pricing for all doses	Maintained
Daclatasvir (Daklinza®)	Flat pricing for all doses	Maintained
Dapagliflozin (Forxiga®)	Flat pricing for all doses	Maintained
Mirabegron (Betmiga®)	Flat pricing for all doses	Maintained
Perampanel (Fycompa®)	Flat pricing for all doses	Maintained
Ponatinib (Iclusig®)	Flat pricing for all doses	Maintained
Riociguat (Adempas®)	Flat pricing for all doses	Maintained
Saxagliptin (Onglyza®)	Flat pricing for all doses	Maintained
Pasireotide (Signifor®) Treatment of Cushing's disease	Mixed pricing: • Linear pricing between 0.3 mg and 0.6 mg • Flat pricing between 0.6 mg and 0.9 mg	Maintained
Pasireotide (Signifor®) Treatment of acromegaly	Mixed pricing: • Linear pricing between 20 mg and 40 mg • Flat pricing between 40 mg and 60 mg	Maintained
Ruxolitinib (Jakavi®)	Mixed pricing: • Linear pricing between 5 mg and 10 mg • Flat pricing between 10 mg, 15 mg and 20 mg	Maintained
Crizotinib (Xalkori®)	Flat pricing for all doses	Switch to linear pricing
Dimethylfumarate (Tecfidera®)	Flat pricing for all doses	Switch to linear pricing
Lurasidon (Latuda®)	Flat pricing for all doses	Switch to linear pricing ¹⁾
Sitagliptin (Januvia® / Xeluvia®)	Flat pricing for all doses	Switch to linear pricing
Pomalidomide (Imnovid®)	Approximately flat pricing for all doses	Switch to mixed pricing: • 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 after price negotiation

¹⁾ Since Takeda withdrew the original product in Germany, the reimbursement price for Latuda® was negotiated between the SHI and parallel importers

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 April 1st, 2016, last accessed: April 11th, 2016]. URL: www.gkv-spitzenverband.de/krankensversicherung/arzneimittel/rabatt_verhandlungen_nach_amnog/erstattungsbeitraegeverhandlungen_nach_130b_sgb_v_erstattungsbeitraegeverhandlungen_nach_130b_sgb_v_vl.jsp

