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THE INFLATION REDUCTION ACT: What Makes a Price a Maximum Fair Price?

Objective

The Inflation Reduction Act (IRA) allows Medicare to negotiate prices, leading to a Maximum Fair Price (MFP). Interestingly, the IRA leaves criteria for the MFP to the negotiation parties.

This mirrors Germany post 2011. Price negotiation follows an HTA assessment by G-BA which determines the existence and the degree of additional benefit of the new product over the "appropriate comparator", as determined by G-BA. And the law is also short on details.

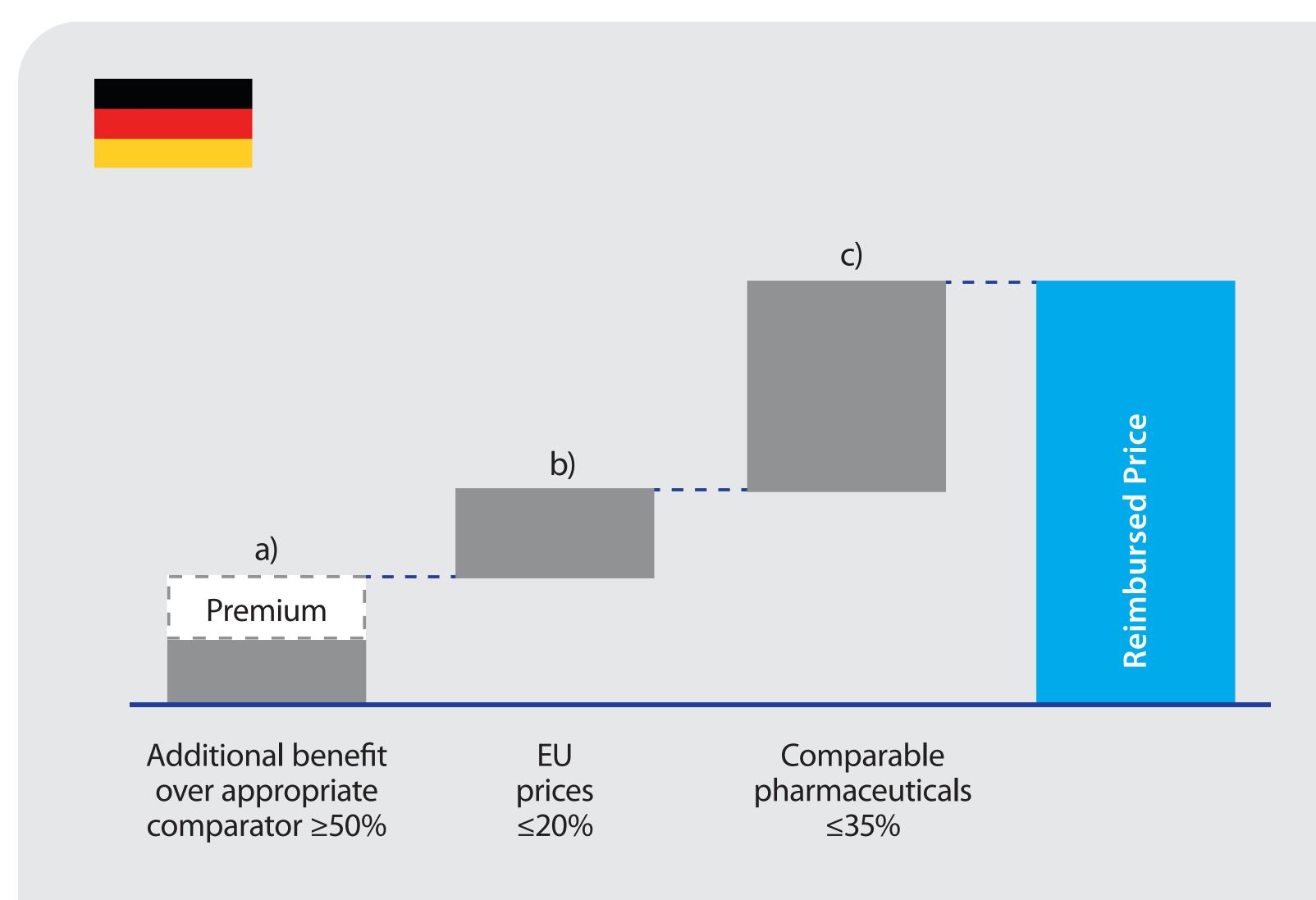
Most prices are negotiated in a strict sense. Only once negotiations fail and the arbitration board has to decide, rationale for decision making becomes transparent. Hence, this analysis explores how a potential MFP can be derived, based on German experience, using arbitration board decisions.

Methods

The analysis reviews all arbitration board decisions 2011 – 2022. For products with no additional benefit the negotiated price is around the same level as the comparator. Only products with an additional benefit rating receive a price that is based on several factors which have to be quantified and synthesized. Hence, only arbitration board decisions for products with additional benefit are taken into account; in total 32 decisions.

Key criteria for decision making by arbitration board are extracted and condensed. This approach is then transferred to the IRA, as per CMS memorandum, published March 15th, 2023.

Results



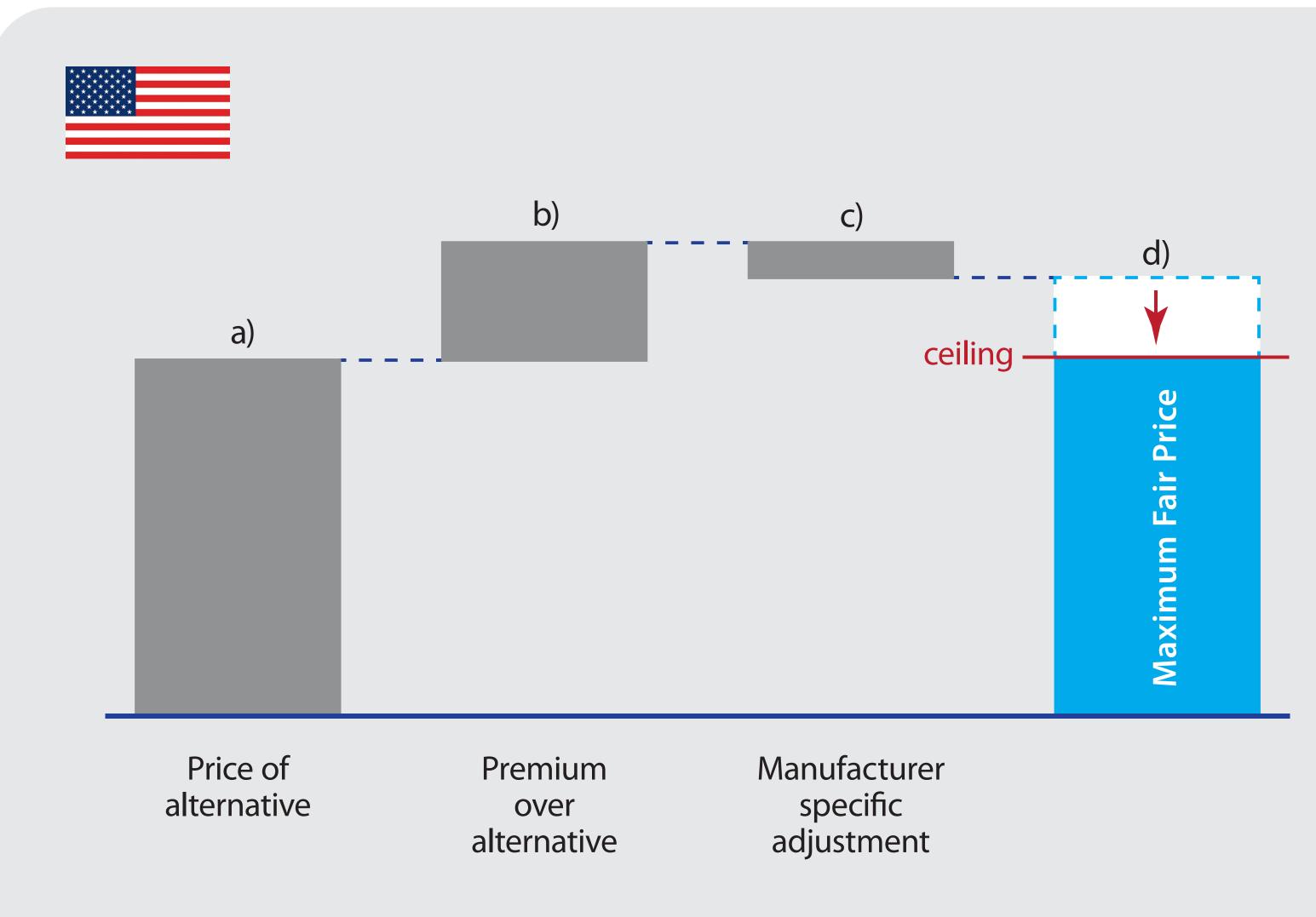
AMNOG (GERMANY)

Reimbursed prices are based on 3 criteria. All prices are standardized on a per year base.

- a) Price impact of additional benefit over the appropriate comparator is determined arbitrarily as a fixed amount, taking into account indication and extent of additional benefit. The price of the comparator and a potential multiplier were explicitly rejected as a concept by arbitration board, due to potentially inconsistent results. Relative weighting of this component is at least 50% up to 90%.
- b) EU prices of the negotiated product are relevant from countries where it is officially reimbursed. Values are taken as net, i.e. including hidden rebates. Relative weighting of this component is up to 20%.
- c) Prices of comparable pharmaceuticals are taken into account for products which have a similar clinical relevance according to accepted guidelines. Their relative weight can be up to 35%.

If one or more components are not available, the weight of the remaining components increases to a total of 100%. In case of subpopulations, respective prices per subpopulation are calculated and synthesized by relative epidemiological weight.

In some cases the calculated price was doublechecked in a subsequent step with a test of plausibility to make sure that the decision is consistent with other arbitration board decisions.



IRA (US)

- a) Maximum fair price (MFP) is based on the price of alternative treatments, using comparable treatment durations as denominator according sec. 1194 (e)(2)(B).
- b) Based on comparable evidence according sec. 1194 (e)(2)(C) the extent of therapeutic advance is determined according sec. 1194 (e)(2)(A). In case of unmet medical need according sec. 1194 (e)(2)(D) relevant other (non-comparative) evidence is used. The monetary impact of this evidence is derived based on a value judgement. This premium can be positive or negative in value, depending on the direction of the comparable evidence.
- c) Manufacturer specific data according sec. 1194 (e)(1), i.e. outstanding research and development costs, prior financial support, unit costs of production and distribution, remaining market exclusivity, and average commercial net price, can justify a modification of the price offering.
- d) However, after this calculation a ceiling is applied. This ceiling is derived from the lower of (1) the sum of Plan D specific enrollment weighted amounts across all dosage forms and strength of the selected drug and (2) the average non-federal average manufacturer price.

Conclusion

- Although IRA is short on what constitutes an MFP and how a premium over comparators can be determined, German experience shows how such a price can be identified based on the information required and making (explicit) value judgements.
- The concept of "price of alternatives" is similar to "comparable pharmaceuticals" in Germany, which have to be approved in the relevant indication and recommended in appropriate clinical guidelines. Also the idea of a premium is similar to the premium in Germany, which is determined according to the extent of additional benefit. Especially the plausibility test by arbitration board in Germany has shown to be an important tool in order to maintain a balanced price structure in the overall market.
- However, the lack of a formal HTA process might create an obstacle in reaching a consensus as to if there is higher comparative effectiveness, therapeutic advance and unmet medical need.
- From a German perspective it will be very interesting to observe which MFPs will be negotiated. Whereas currently only EU prices play a role, in the future it might be possible that the MFP will also be taken into account.

References

- All arbitration board decisions are available upon request at: Schiedsstelle nach §130b (https://www.schiedsstelle.de/schiedsstellen/ 130b_abs_5_sgb_v/130b.jsp)
- US Congress: Inflation Reduction Act (https://www.congress. gov/117/plaws/publ169/PLAW-117publ169.pdf)
- Center for Medicare: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (https://www.cms.gov/files/document/ medicare-drug-price-negotiation-program-initial-guidance.pdf)









