

Evolution of manufacturer-set list prices and GKV rebates for Orphan Drugs (OD) in Germany 2013-2024: How much US WAC is in German OD-prices?

Andras Ruppert

Charles River Associates, München, Germany – aruppert@crai.com

CRA Charles River Associates

HPR80

Introduction and Objective

A recent analysis (ISPOR 2025, Poster HPR92)² introduced the CRA-developed RADAR database. RADAR includes all orphan drugs (ODs) that received European Medicines Agency marketing authorization between July 1, 2013, and September 30, 2024. The research, a cross-sectional, static analysis, tried to identify and quantify if and how factors such as G-BA benefit rating, clinical comparator, prevalence, manufacturer (MNF)-set list prices, and different groups of indications (oncology vs non-oncology) impact the outcome of rebate negotiations between manufacturers and the GKV. With 12 years of available German data, it is possible to perform a longitudinal (dynamic) analysis to assess how the German Medicines Market Reorganization Act (AMNOG) process has impacted over time manufacturers' list-price setting and negotiation of GKV rebates for ODs. Additionally, we tried to understand how manufacturers develop their list-price strategy for ODs in Germany. Earlier research³ suggested that US WAC prices might serve as a starting point for OD price strategies in Germany. Our research tries to validate the hypothesis and to quantify its effect.

Methodology

For the evolution of OD list-prices and GKV rebates over time, we used the same 115 ODs as in the static analysis.² We divided all 115 OD launches into two equal, six-year time periods: 2013–2018 and 2019–2024. Within each period we examined the progression of mean annual cost, based on MNF-set list prices and SmPC dosing schemes, and negotiated rebates for the ODs' first-listed indication. We also analyzed if and how G-BA ratings, indication, and prevalence impact negotiated GKV rebates.

For the analyses if and how US WAC impacts German MNF-list price setting and GKV rebates, we screened the 115 ODs for products that:

- were approved by the US Food and Drug Administration (FDA) after July 1, 2013, for the same launch indication as approved by EMA later
- were provided for the same population and had the same formulation and strength as the US product and a comparable pack size
- had a publicly available WAC for their first indication before the appearance of an MNF-set list price for the same OD in Lauer Taxe

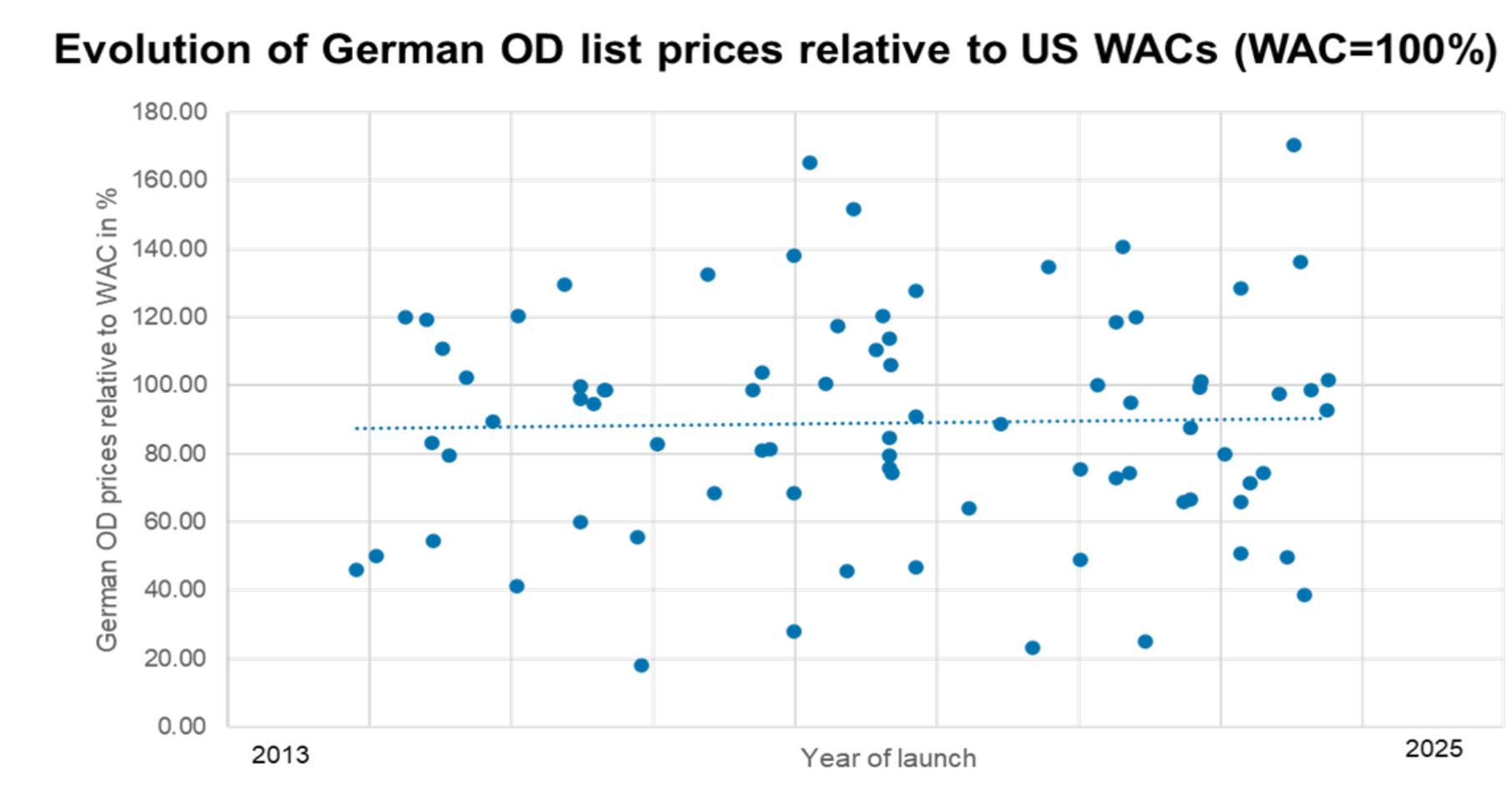
In total, 79 of the 115 ODs fulfilled all criteria. Of these, 34 were ODs with oncology indications and 45 were ODs with non-oncology indications.

For the US–Germany list price comparison, we calculated annual treatment cost, using SmPC / FDA dosing regimen and pack-by-pack price comparisons. Lauer Taxe manufacturer list prices were converted into US dollars (USD) using the exchange rate at the date of the product's EMA approval. For the analysis of German list price as percentage of US WAC, the US WAC was set at 100%, and the German list price level was calculated as a percentage of the US WAC denominated in €, using the exchange rate as of each OD's date of EMA marketing authorization.⁴

Results

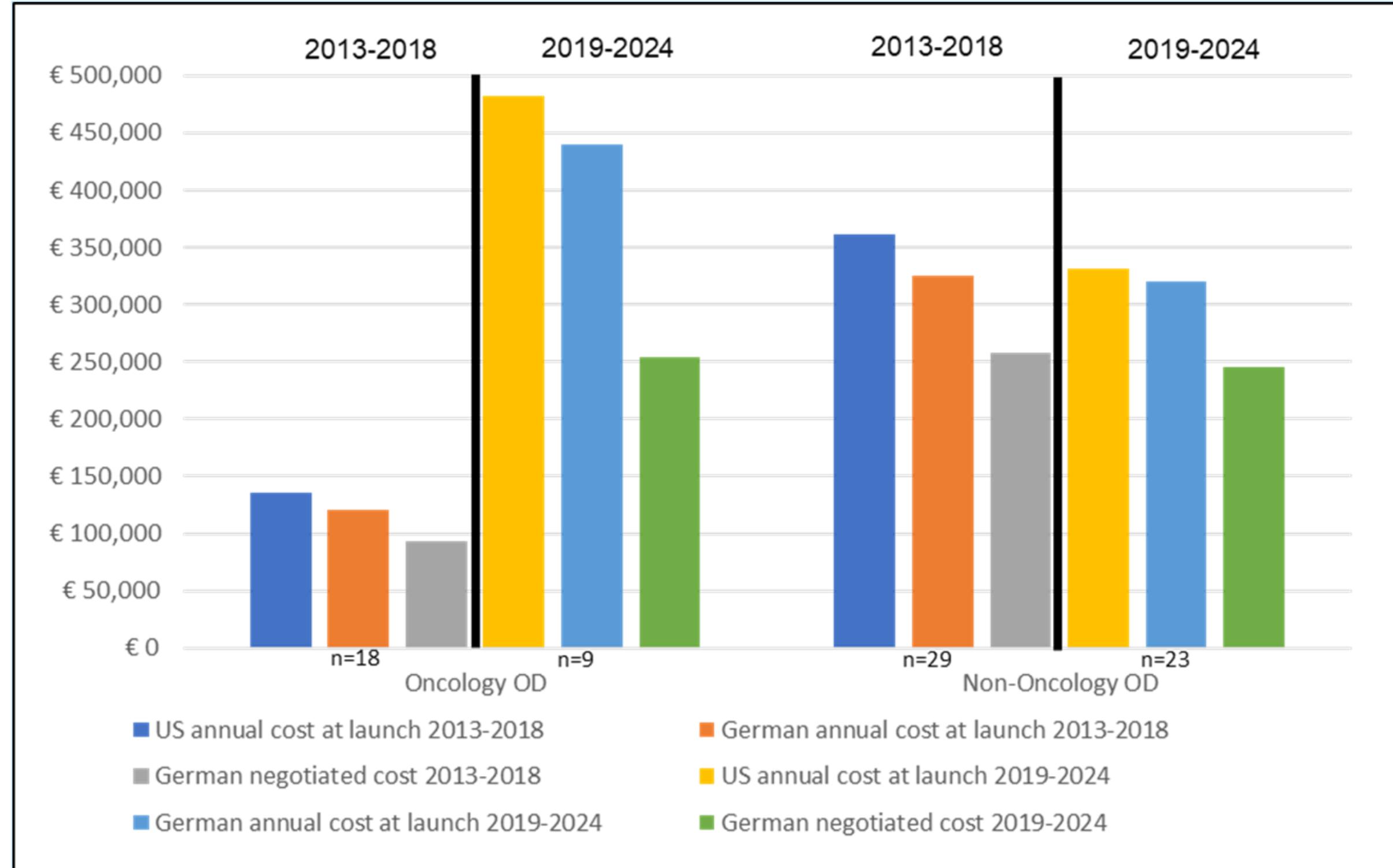
Data suggests a relationship between manufacturer-set list prices of ODs in their launch indication in Germany and the previously established US WAC for the same OD

The trend analysis shows the correlation between the €-denominated US WAC and MNF-set German list prices to remain relatively steady over time between 88–90%. This suggests that whatever the list price dynamics are in the US, where all included products launched ahead of Germany, these will spill over to Germany through MNF-set list prices at launch.



Time-period and indication comparison identified behavioral patterns of manufacturers that strengthen the argument of list-price transfer from the US to Germany for ODs*

In period 1, mean WAC for oncology ODs in the US and mean MNF-set list prices in Germany are very close (German mean list price ~94% of US WAC). Period 2 saw an increase of mean US WAC for new oncology ODs of >250% ($p<0.005$) compared to period 1. Data shows the same increase in MNF-set list prices of >250% ($p<0.016$) in Germany. The pattern suggests that manufacturers used the US WAC of their oncology ODs to set the list prices in Germany. Mean GKV rebates of new oncology ODs in period 2 were 30%, vs 23% in period 1.



*The analysis was performed with annual treatment cost using MNF-set list prices and FDA/SmPC dosing for the calculation.

For non-oncology ODs, the mean US WAC decreased slightly between period 1 and 2. The same decrease was also observed in MNF-set list prices in Germany. The pattern suggests, as for oncology ODs, the use of US WAC as MNF-set list price in Germany. As mean rebates increased for non-oncology ODs from 19% to 24%, it seems GKV achieved a net price reduction for later compared to earlier launched non-oncology ODs.

Using US WAC as pre negotiation list price in Germany seems to result in higher net prices post negotiation compared to using a lower starting point

Of all 79 ODs within the US/German analysis, 25% show a German list price within a +/- 10% range of US WAC, half of them are within a +/- 20% range of US WAC. For 29 of the 79 OD, the German list price was <80% of US WAC, while 11 ODs show a German list price >20% above US WAC. For all 79 ODs, the mean German list price was 89% of US WAC, and the mean GKV rebate was 22.7%.

For those 19 products in the figure that were prices by the manufacturer in Germany at a premium of >10% over €-denominated US WAC (with a mean list price at 131% of US WAC), the mean GKV rebate was 24%. The resulting mean reimbursed net price for these 19 products in Germany is 107% of the US WAC.



Conclusions

Main driver for a significant increase in MNF-set list and net-prices of ODs in Germany over time are a) significantly higher list prices set by manufacturers for oncology ODs, and b) a higher GKV willingness to pay for innovative (gene) therapies within oncology, targeting indications with substantially lower prevalence. While G-BA ratings have not changed over time, MNF-set list prices have, often by using earlier established US WAC prices as initial list price in Germany. The data cannot provide any conclusions to what extent this list price import is justified by non-quantifiable product characteristics that might lead to a higher GKV willingness to pay. What the analysis does show is that it seems an appropriate price optimizing strategy for Germany: Those manufacturers who used US WAC as list price in Lauer Taxe or even set the German list price above US WAC, seem to have achieved higher net price levels than those who do not, as increasing GKV rebates do not seem to offset list prices / premiums imported from the US. It also looks like if list-prices in US and Germany are closer than one might have thought - at least for ODs.

References

1. Busting a myth: Is achieving US drug prices in Europe impossible? – CRA Insights: Life Sciences; 2021, A. Ruppert, S. Baily, L. Ziegler; Charles River Associates; www.crai.com
2. Factors impacting GKV rebates for Orphan Drugs in Germany – Part 1 of a deep dive decision analysis using the CRA RADAR database; 2025, A. Ruppert; Charles River Associates; www.crai.com
3. Evolution of manufacturer-set list prices and GKV rebates for orphan drugs - Part 2: Decision analysis using the CRA RADAR database; 2025, A. Ruppert; Charles River Associates; www.crai.com
4. Impact of US pricing strategies for orphan drugs on price levels in Germany - Part 3: Analysis using German and US data from the RADAR database; 2025, A. Ruppert, Charles River Associate, www.crai.com

CRA Charles River Associates