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Germany's Confidential Pricing Move Could Protect Companies From Potential Trumpian US Reference Pricing

by Francesca Bruce

Confidential pricing would give companies more flexibility to negotiate discounts and prevent withdrawals.

Germany's draft Medicines Research Law if passed would allow companies to keep discounted reimbursement drug prices confidential.

The move would give companies more pricing protection in launch markets that reference prices in Germany to set their own prices, potentially including the US if Donald Trump wins this year's US general election says Alexander Natz, secretary general of EUCOPE, which represents small and mid-sized pharmaceutical and biotech companies in Europe

The draft law follows the government's Pharma Strategy plan published in December, which set out priorities for making Germany a more attractive market by reevaluating the Amnog drug pricing system, reducing bureaucracy and improving the environment for clinical research. (Also see "[German Pharma Strategy Promises Drug Pricing Review & Stronger R&D Environment](#)" - Pink Sheet, 24 Jan, 2024.)

The draft law is expected to pass through the legislative process this year and become operational in January 2025.

How Amnog Works

Under the Amnog pricing system prices are freely set for the first six months in Germany following launch, during which time an assessment on the product's additional benefits compared to other treatments is carried out.

A new price is then negotiated with the GKV-SV, the association that represents German

Under the current system, prices including the ex-manufacturer price, mandatory discounts and the price that companies negotiate with health insurers following the Amnog benefit assessment are available through databases such as the Laura Taxe. They can also be made visible to patients who pay for their medicines privately. (See box for more details on the Amnog process).

health insurers. The results of the benefit assessment are factored into negotiations. A negative benefit assessment score can result in a lower price, which has on occasion prompted companies to withdraw from the market, for example, bluebird bio.

Under the new proposals a company could opt to keep the price it negotiates with health insurers confidential while the list price that excludes any rebates or negotiated discounts would remain public. The government hopes that this would encourage companies to offer bigger discounts.

Welcome Move

The move would be very welcome, says Natz. Indeed, industry has been lobbying for confidential pricing for some time. The main benefit, according to Natz, is that companies would not be so vulnerable to the effects of external reference pricing. Reference pricing means that a low price in Germany will have a knock on effect in markets that benchmark German prices to set their own.

According to Natz, the move would also be a crucial step in preparing for what could happen if Donald Trump wins the 2024 general election and introduces reference pricing to cut US drug prices.

Towards the end of his first term as president, Trump issued an executive order to this effect, although it was later withdrawn. (Also see "[CMS Scraps 'Most Favored Nation' Rule To Lower Medicare Part B Drug Costs](#)" - Pink Sheet, 8 Aug, 2021.)

Drug pricing has not been as prominent in Trumps election campaigning this time around, but in June 2023 he announced that he would revive the plan. "On Day One of my new term, I will sign an Executive Order to end this global freeloading on American consumers for once and for all," he said.

Such a move would have enormous ramifications for companies operating in countries that are referenced, which could well include Germany, said Natz. The pressure to resist conceding any discount on price would increase dramatically. "Even a 0.5% discount would be tough to give if prices in the US were to fall by 0.5%. The US is simply way too important a market because it's where companies make 40% of their revenue," he said.

In addition, companies are more likely to concede bigger discounts if they are confident the price will not have ramifications in other markets. It may even help prevent companies from withdrawing their products rather than settling for an untenable price, as has happened on occasion, for example, bluebird bio withdrew Zynteglo in the EU and Novartis withdrew Piqray in Germany. (Also see "[Bluebird Bio Withdraws Zynteglo From Germany Over Pricing](#)" - Pink Sheet, 22 Apr, 2021.) (Also see "[Piqray: German Withdrawal, European Reimbursement Deals & Broader Indication Plans](#)" - Pink Sheet, 6 May, 2021.)

There has been some debate about whether keeping prices confidential is possible, particularly as the Germany's draft law includes measures that would allow patients who have bought these drugs to access the confidential price.

However, Natz is more optimistic and believes there are ways to make it work, particularly as prices are kept confidential in the generic drugs space.

"It's a political discussion, and people who don't like the idea want to water it down," he said, pointing to strong opposition to the move from health insurers, among others.

The bill also proposes to remove external reference pricing from German Amnog negotiations between companies and health insurers. While the price of comparators has the biggest influence on a new product's price, the price in other European countries is also considered.

This move serves no clear purpose, says Natz. "I don't see why we should take that out of that negotiations. It's a view of the medicine in the real world and what the prices are in other countries ... we would be very much in favor of keeping it in," he said.