DO GERMANY'S NEW HEMOPHILIA REGULATIONS HAVE WIDER-REACHING IMPLICATIONS?

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PRICENTRIC BRIEF

- In July 2019, the Drug Safety and Supply Law (GSAV) was passed by Germany's Higher Chamber of Parliament, bringing about substantial changes to Germany's health policy
- Since the GSAV's implementation in August of this year, the distribution, and consequently the pricing of hemophilia treatments in Germany have been subject to more regulation under the law
- In addition, the manufacturer's ability to distribute directly to doctors and hospitals, avoiding the pharmacy distribution channel, was officially withdrawn, thereby allowing patients to receive their hemophilia products from regular pharmacies and ultimately meaning that manufacturers had to report their confidential sales prices to physicians

THE DETAILS

In July 2019, the Drug Safety and Supply Law (GSAV) was passed by Germany's Higher Chamber of Parliament, bringing about substantial changes to Germany's health policy. Besides introducing new strategies for biosimilar uptake and cell and gene therapy monitoring, GSAV provides for more stringent control of the distribution of hemophilia products.

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GSAV states, "The previous exception to pharmacy sales channels (direct sales by the manufacturer to doctors and hospitals) will be withdrawn for medicinal products for the care of patients with hemophilia. The new regulations on the distribution channel as well as the corresponding adjustment of the Drug Price Ordinance and the Pharmacy Act will come into force on August 15, 2020."

The manufacturer's ability to distribute directly to doctors and hospitals, avoiding the pharmacy distribution channel, was officially withdrawn, thereby allowing patients to receive their hemophilia products from regular pharmacies.

Despite a degree of backlash from patient associations, the law was ultimately passed, and manufacturers had to report their confidential sales prices to physicians. These sales prices were then fixed as new list prices for all products as of September 1st, 2020.

ARTICLE 14:
Change of Drug Price Regulation

The drug price regulation of November 14th 1980 (Federal Law Gazette I p. 2147), last amended by Article 12 of Law of 6 May 2019 (Federal Law Gazette I p. 646) amended is changed as follows:

1. Section 1 (3) sentence 1 is amended as follows:

a) In number 3, "to 9" is replaced by the Replaced "up to 10".

b) In number 6, the words "of blood concentrates that are used in hemophilia as well as" are deleted.

2. The following paragraph 4 is added to Section 4:

(4) If the relevant central organization of pharmacists formed to safeguard economic interests meets with the umbrella association Federation of health insurance agreements on the The amount of the fixed surcharge in accordance with paragraph 1 is the agreed surcharge deviating from paragraph 1 to be taken into account when calculating the price. The same applies if social service providers, private Health insurance companies or their associations make appropriate agreements with pharmacies or their associations. If there is no agreement according to sentence 2, the after Clause 1 agreed prices.

Price Drops for Plasma-derived Drugs

The new law and its effect on hemophilia treatment has substantial consequences for several reasons, the first and foremost being the resulting significant price drop.

Hemophilia and the surrounding treatment market are often associated with a major psychological and economic burden for patients, caregivers, and wider healthcare and reimbursement systems. A 2017 study by the Orphanet Journal of Rare Diseases found that Germany had the highest per-patient costs for hemophilia in Europe, at an average of €319,024 per patient. Further, Europe's hemophilia management market as a whole was worth over €1 billion in 2019, highlighting the budget strain of the indication.

Substantial price drops are unusual in the high-cost area of plasma-derived drugs, as it's a class of treatment that relies heavily on a limited supply of product due to the nature of needing human blood donations. The distinct issue with plasma-derived products is that, unlike other biologics or small molecules, an increase in volume doesn't directly correspond to increased economies of scale, as the root of the therapy – the plasma donor – is still in need of compensation at the same level, no matter how much manufacturing is increased.

As such, hemophilia drugs have remained at a steadily high price in order to keep the delicate balance of the system in place, simultaneously untouched by the prospects of biosimilars or competitive price demands.

According to the Plasma Protein Therapeutics Association (PPTA), approximately 1,200 donations are needed to treat one patient for a year, and the limited supply pool due to the restricted number of plasma donations means that hemophilia therapies are treated as a protected drug class.

Considering the above implications, the GSAV law was lambasted by the German Hemophilia Association (DHG), who claimed that the draft was developed too quickly without considering all consequences. DHG also noted concerns surrounding the erosion of hemophilia treatment centers, a decrease in quality of treatment, and a threat to treatment safety, traceability and documentation, leading them to spearhead a campaign against the amendments.

ARTICLE 20:
Change of Medicines Trade Ordinance

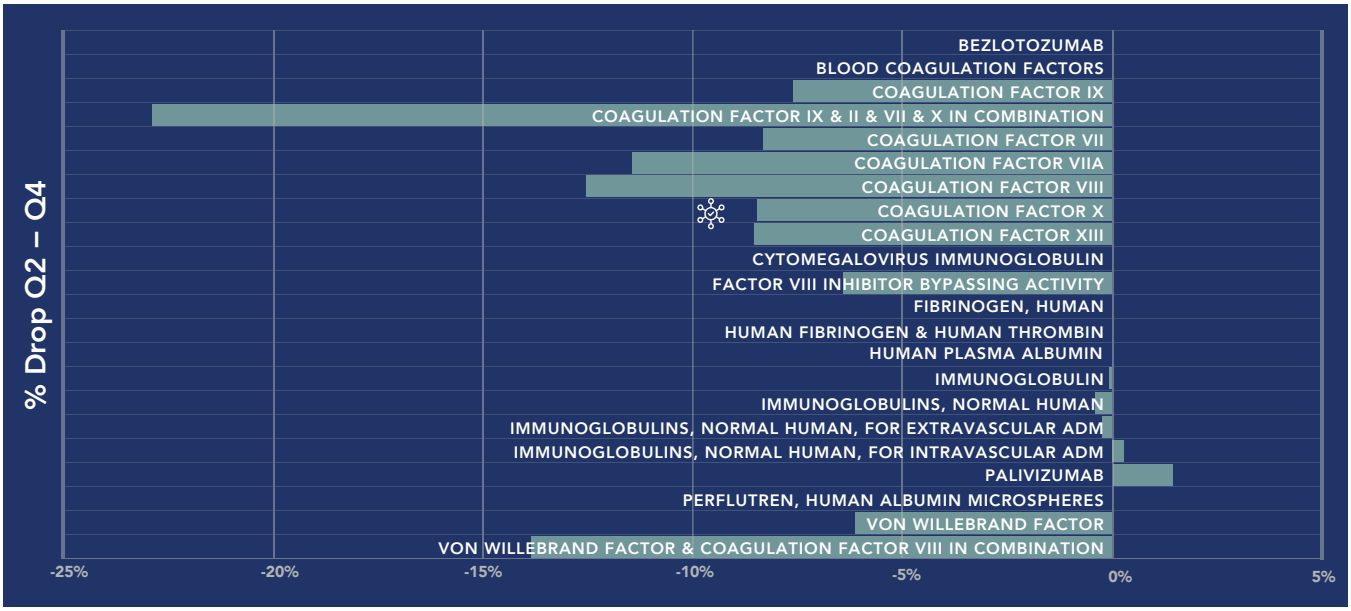
The Medicines Trade Ordinance of 10 November 1987 (Federal Law Gazette I p. 2370), which was last amended by Article 1 of the ordinance of 2 July 2018 (Federal Law Gazette I p. 1080) has been amended as follows:

1. In Section 6, Paragraph 2, Clause 4, Number 2, after the words "replace blood components" have a comma and become the words "and other medicines for the specific therapy of coagulation disorders in hemophilia "added.

2. In Section 7, Paragraph 3, Clause 2, a comma is added after the words "replace blood components" and the Words "and other medicines for specific Therapy of coagulation disorders in hemophilia" inserted.

Percentage Decreases

The GSAV law was passed in August, in the interim between the second (Q2) and fourth (Q4) financial quarter of 2020, and as such, data show that from Q2 to Q4 the average price drop for a hemophilia product in Germany was approximately 5% as a direct results of the law's implementation.



On analysis of the data, Max Klietmann, Senior Consultant and Manager of EVERSANA's PriceXpress, noted that some therapies have dropped in price as much as 23%, specifically coagulation factor IX & II & VII & X in combination.

Other significant price drops occurred for von Willebrand factor (VWF) & coagulation factor VIII in combination, which decreased in price by 14%, and coagulation factor VIII on its own, which suffered a price erosion of 13%.

Put in context, such across-the-board drops have not been seen in this area before, as demonstrated by the relative pricings of hemophilia products since Jan 2019. The data show that for the most part, each therapy retained a pretty consistent price until the passing of GSAV law.

Other Disease Areas

If the perception and treatment of hemophilia-related products is evolving in this way, there is bound to be speculation that other comparable pre-protected drug classes, such as Orphan Drugs, could be subject to similar interventions.

As it stands, Orphan Drugs tend to adhere to the rule of: The smaller the number of people a drug is treating, the higher the price is likely to be. Also, similarly to hemophilia treatments, a number of Orphan Drug products are critical for increasing overall survival, meaning they are of paramount importance for the patient. Because of this, there is a very strong incentive to provide the drug, whatever the cost.

This creates a seemingly "untouchable" category of treatment that, until now, has meant that increased price pressure could potentially equate to the elimination of certain therapeutic options for already under-served areas, ultimately having a negative effect on the Orphan Drug market.

This shift in perception ties in with the ongoing increase in Health Technology Assessment (HTA)-based pricing in Europe and Germany, where a cost-effectiveness threshold is introduced into the methodology in order to help manage fiscal challenges, pointing to a future of potentially higher price scrutiny for product categories such as Orphan Drugs and hemophilia therapies.

Downstream Implications

Germany is often seen as a pharmaceutical policy leader in the European Union, both in its early establishing of a Health Technology Assessment (HTA) system, and the resultant methods and tools applied in HTA and its place in policymaking.

HTA has been discussed in Germany since the late 1990s but was officially implemented with the formal establishment of the German Health Care Reform in 2000.

The Pharmaceuticals Market Reorganization Act (AMNOG) then developed and refined the process further when it came into play in 2011, and Germany took its place as an example for other markets to follow in regard to pharma pricing, reimbursement and benefit assessments.

AMNOG succeeded so well in lowering the government's pharmaceutical bill, the reimbursement price of new drugs then fell below the EU average and the €11 billion deficit in the state's statutory health insurance scheme significantly shrank compared to its size at the time of AMNOG's execution.

The success spearheaded the way for other, similar European markets to implement similar features, and has served as a beacon of inspiration ever since.

With the rest of Europe watching Germany's moves, the latest hemophilia price drops could send waves that filter down through other impressionable markets, resulting in an overall change in perception towards a wider section of similarly-revered drugs.

Max Klietmann, Senior Consultant with EVERSANA's Global Pricing & Market Access team shared his perspective; "The bigger-picture implication here is that previously less-scrutinized therapeutic areas are increasingly subject to HTA and other cost/benefit

evaluation that could carry far-reaching price implications. It really hammers home the point that a global perspective on pricing and disciplined price governance are critical to ensuring business success for products across the therapeutic spectrum."

Further to the policy influence, Germany is popular reference country for International Reference Pricing (IRP), in part because their pricing systems are not tied exclusively to the prevailing prices in other countries. Because of this, countries with Germany in their reference basket may ultimately adopt lower hemophilia therapy prices down the line, as the ever-complicating web of IRP schemes in high-income countries means that pricing decisions in one country will have a knock-on effect on the prices paid in many other countries.

Here to Help

EVERSANA uniquely has the people, methods, and tools to assist businesses in navigating relevant hemophilia pricing policy, even in such unsure times. This expertise is built on our combined decades of experience solving problems in and building tools for global pricing intelligence, global visibility, and product launch expertise, which puts us in a trusted position to advise clients on how to handle these changes.

Pricentric Insights delivers accurate, comprehensive insights on major policy and regulatory changes, as well as HTA decisions and drug approvals, in over 100+ markets around the world. Our team of researchers checks a database of over 700+ reliable sources, including everything from government databases to local newspapers, to provide readers with in-depth updates on the ever-changing pricing and reimbursement landscape. We also provide conference coverage and utilize our team of consultants to detail how major policy changes can impact market access a nd the global pricing landscape.