

REGIONAL DIFFERENCES IN POTENTIAL SAVINGS FOR THE MEDICAL TREATMENT OF ADVANCED PROSTATE CANCER IN THE GERMAN HEALTH CARE SYSTEM

C de Millas¹, A Höer¹, ¹IGES Institut GmbH, Berlin, Germany.

Objectives

Gonadotropin-releasing hormone analogues (GnRH-analogues) are well established for treating advanced prostate cancer.¹ Four GnRH-analogues were available in Germany for the whole period of 2015 and 2016: buserelin, goserelin, leuprorelin and triptorelin. Only for leuprorelin a generic version existed in the market. Four of 17 regions of physicians' associations (KV) in the statutory health insurance (SHI) had implemented quotas promoting leuprorelin in 2015 and 2016 ("Quota-KVs"). Five regions introduced quotas in 2017 ("New-KVs"). This research investigates the regional differences in market penetration and associated potential savings.

Methods

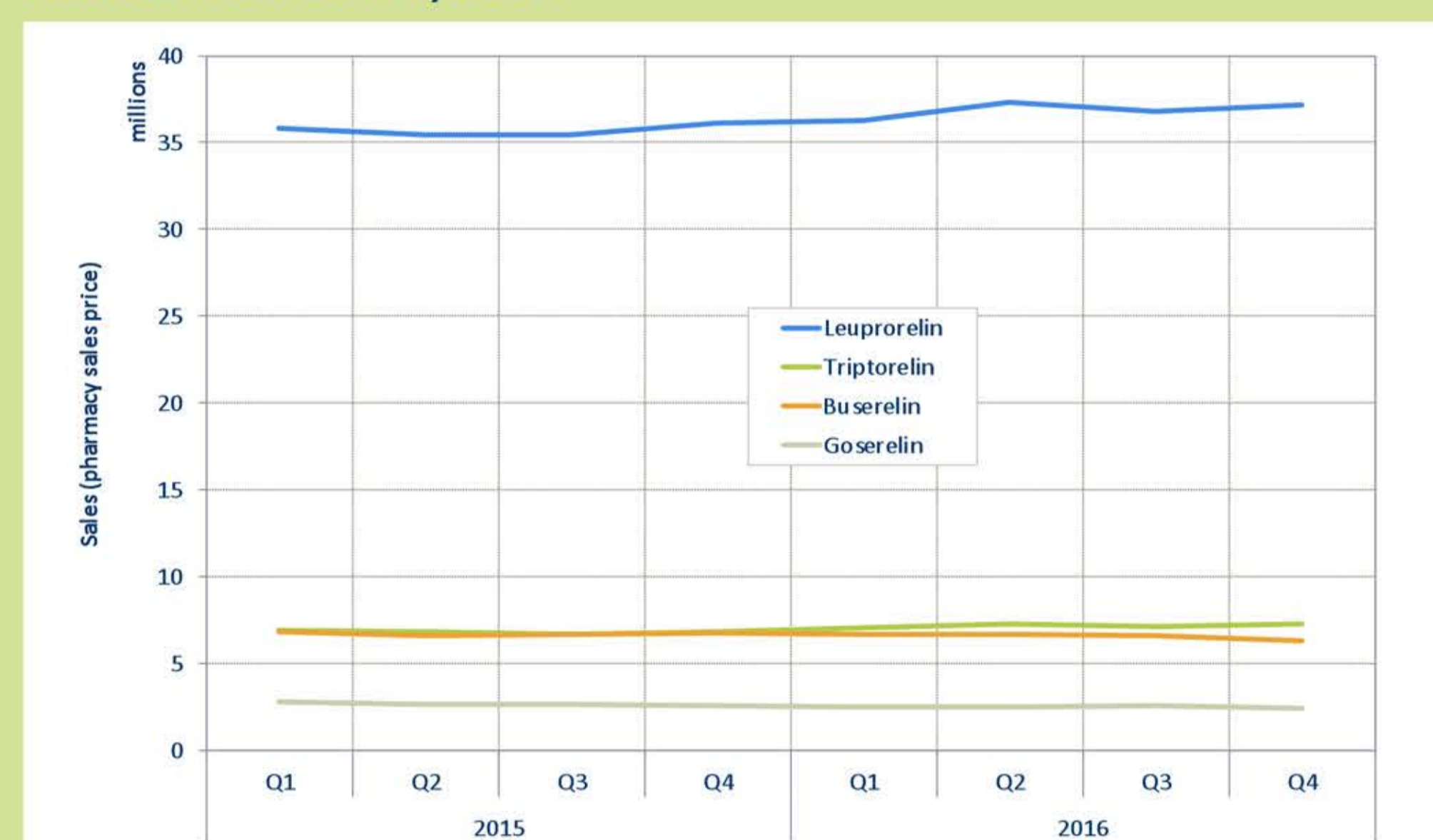
QuintilesIMS provided monthly out-patient prescription data per KV region, sickness fund and package for 2015 and 2016 for the German SHI system. Pharmacy sales prices and defined daily doses (DDD) were used for sales respectively volume calculations.

The GnRH-market was divided into three segments (generic leuprorelin, other leuprorelin products and other GnRH-analogues) to calculate potential savings. It was assumed that the market share (DDD) of leuprorelin in the GnRH-market was equal in all KV regions to the highest observed quarterly market share in one KV region. The same was assumed for the market share of generics within the leuprorelin market. Prices and market share within the three segments remained the same.

Results

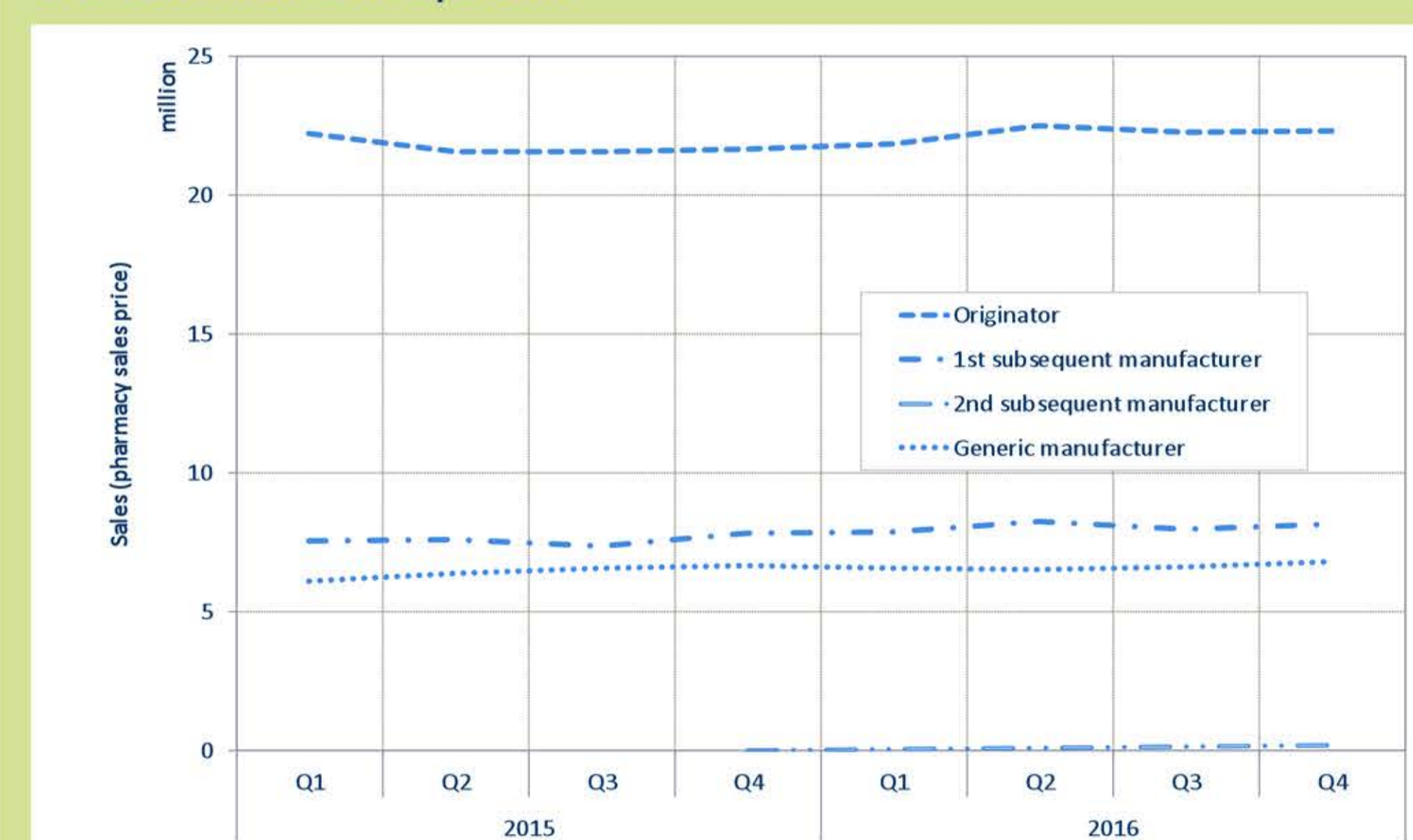
Market share between active ingredients remained quite stable in 2015 and 2016. Brand-name leuprorelin displayed the highest market share

Figure 1: Quarterly sales for GnRH-analogue compounds in the German SHI system*



* Histrelin in Germany only available until March 2015 with market share of 0.07% in Q1/2015.

Figure 2: Quarterly sales for manufacturers of leuprorelin in the German SHI system



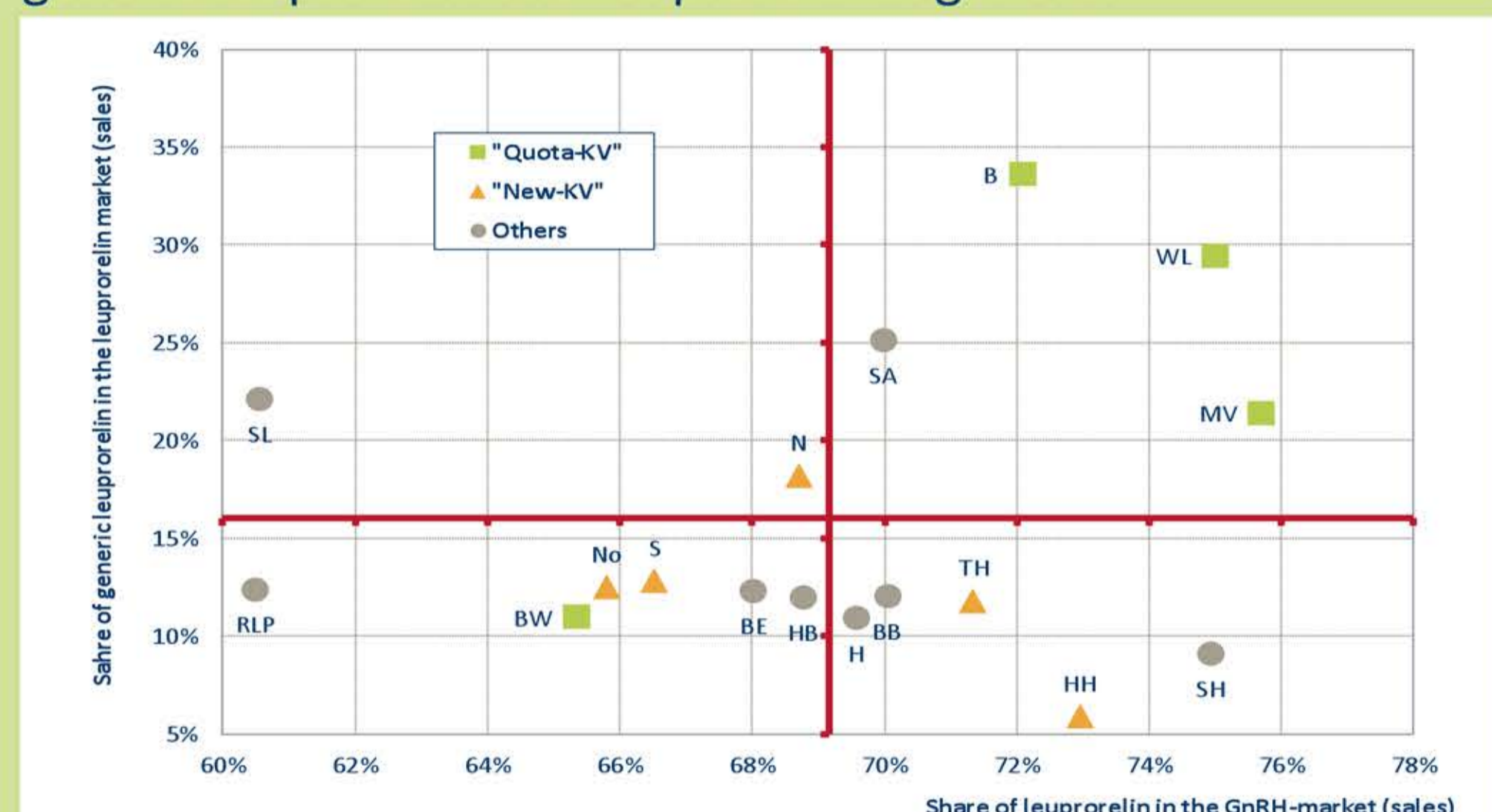
Not shown in the graphs.

Nationally, total sales for GnRH-analogues were 207.7m (212.3m) euro and volume was 37.6m (38.3m) DDD in 2015 (2016). The market situation remained quite stable in these two years. Quarterly sales for leuprorelin grew from 35.8m euro (Q1 2015) to 37.1m euro (Q4 2016). The summated total sales for triptorelin, buserelin and goserelin decreased from 16.5m euro to 16.0m euro. In consequence, the market share for leuprorelin rose from 68.4% to 69.9%.

Within the leuprorelin market, the originator exhibited the highest market share. Sales per quarter did reach approx. 22.2m euro. Market share decreased from 61.9% to 59.6%. Sales for the only generic manufacturer rose from 6.1m euro to 8.3m euro resulting in an increase in market share from 17.1% to 18.1%. The two subsequent providers had raising sales from 7.5m euro (21.0%) to 8.3m euro (22.2%).

Strong regional differences in the market penetration of generic leuprorelin

Figure 3: Average market share (sales) per KV region for generic leuprorelin and leuprorelin in general*



*intersection of the axis at the average value over all 17 KV regions

Three of the four "Quota-KV" regions (KV BW, KV B and KV WL)* had implemented quota for the market share of generic leuprorelin as "leading compound" in the GnRH-market in 2015 and 2016. In the KV MV all leuprorelin products were categorized "leading compound". All four KV region retained the regulation in 2017. Three of the "New-KV" (KV HH, KV N and KV No) introduced in 2017 generic leuprorelin as lead compounds, the others (KV S and KV TH) all leuprorelin products. The 2015 and 2016 data showed substantial regional differences in the market penetration of leuprorelin and more specifically within the leuprorelin market.

The average quarterly market share (sales) of leuprorelin differed regionally between 60.5% (KV RLP) and 75.7% (KV MV). Within the leuprorelin market, the average generics' share varied between 5.9% (KV HH) and 33.6% (KV B).

In general, "Quota-KVs" showed higher market shares. The average share of leuprorelin was 72.0% in the "Quota-KVs" compared to 69.1% in the "New-KVs" and 67.8% in the remaining eight. The respective values for the share of generics were 23.9% ("Quota-KV"), 12.2% ("New-KVs") and 14.5% (others).

*KV-regions: Baden-Württemberg (BW), Bavaria (B), Berlin (BE), Brandenburg (BB), Bremen (HB), Hamburg (HH), Hesse (H), Mecklenburg-Vorpommern (MV), Lower Saxony (N), North Rhine (No), Rhineland-Palatinate (RLP), Saarland (SL), Saxony (S), Saxony-Anhalt (SA), Schleswig-Holstein (SH), Thuringia (TH), Westphalia-Lippe (WL)

Potential savings through an increase in market share of leuprorelin

Figure 4: Relative savings per KV region through a higher share of generic leuprorelin and leuprorelin in general*



*intersection of the axis at the average value over all 17 KV regions

Generic leuprorelin displayed a more cost-effective average price level (4.51 Euro/DDD) than non-generic leuprorelin (5.38 Euro/DDD) and other GnRH-analogues (6.02 Euro/DDD). This would have allowed for potential savings through a higher market share of generics and leuprorelin products in general.

The highest share (DDD) of leuprorelin in the GnRH-market was 79.7%, observed in the KV MV (Q4 2016). The highest market share of generics was 45.8% in the KV B (Q3 2015). Both are "Quota-KVs".

When the highest quarterly market shares of generic leuprorelin would have been achieved through all quarters, the SHI system could have saved 13.9m euro or 5.2% of leuprorelin sales in 2015 and 2016. The lowest savings would have been 1.6% in the KV B and the highest ones in the KV HH with 7.5%.

If the highest observed share of leuprorelin within the GnRH-market had been applied in all quarters, the SHI system could have saved 20.6m euro or 4.9% of total GnRH-sales in this two years. Average potential savings per KV varied between 2.0% (KV N) and 6.9% (KV SL). Average potential savings would have been 3.5% in "Quota-KVs", 5.8% in "New-KVs" and 5.6% in the remaining eight.

Estimation of future development: Given constant sales based on the DDD volume in the third quarter 2016 and the price level in July 2017, potential annual savings could be around 12.4m euro (5.8% of GnRH-sales) for the SHI system.

Conclusions

Currently the GnRH-market shows a low market share for generic drugs and a strong deviation between KV-regions. Instruments of the SHI system to promote the prescription of generic drugs seem to be not effective in the market. Regulations regarding mandatory substitution ("aut-idem" rule) in pharmacies do not apply within the leuprorelin market because of different dosage forms. For the same reason, discount contracts can also not be effective. A reference price for the GnRH-market is not in place. However, "lead compound" quotas are an effective tool. The market shares show that quotas can push market penetration for generic drugs and a growing number of regions introduce them. Based on reasonable assumptions about prescription behavior, substantial savings can be expected through quotas without any loss of clinical effectiveness.

References

1. Parker C, Gillessen S, Heidenreich A, Horwich A; ESMO Guidelines Committee. Cancer of the prostate: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2015 Sep;26 Suppl 5:v69-77. doi: 10.1093/annonc/mdv222. Epub 2015 Jul 22.