THE IMPACT OF LABEL EXTENSIONS ON THE REIMBURSED PRICE OF PHARMACEUTICAL PRODUCTS ASSESSED ACCORDING TO §35a SGB V IN GERMANY - ONCOLOGICAL AND METABOLIC DISEASES

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Background

In Germany, with each label extension of a pharmaceutical with a new ingredient the additional benefit is assessed according to §35a SGB V and the reimbursed drug price is renegotiated with the National Association of Statutory Health Insurance Funds (GKV-SV).

With this study, we aimed to investigate the price development of pharmaceuticals with at least one label extension and potential factors for price decreases in the therapeutic areas oncology and metabolic diseases.

Methods

First, the data from all AMNOG dossiers in oncology and metabolic diseases evaluated by the Federal Joint Committee (G-BA) from January 2011 until December 2017 were extracted. Information on the active substance, product name, therapeutic area, orphan status, decision date, for all dossiers including the initial submission and label extension dossiers, were included in the analysis.

In a second step, the product prices of the SmPC recommended packages were taken from the official German database for drug prices (LAUER-Taxe). The initially negotiated prices and negotiated prices after the first label extension were then linked to each dossier. In a first general analysis we included all dossiers (n=78), to give an overview of the price development after label extension. For the more specific correlation analysis, we only included the initial dossier and the first label extension (n=44).

The price change (in %) was calculated as a change between the negotiated price after the first price negotiation to the negotiated price after the first label extension.

The change of the cost (in %) of the annual appropriate comparator therapy (ACT) was calculated as a change between the comparator costs from the initial dossier to the costs of ACT for the first label extension.

The change in population size (in %) was calculated as the change between the population size of the initial dossier versus the sum of both populations from the initial dossier and the label extension.

Finally, a correlation (Pearson correlation) between price development and change of the size of patient populations as well as the change of the amount of the annual therapy costs of the ACT was analyzed. Also, the relation between reimbursed price extent and change in additional benefit was descriptively analyzed.

Results

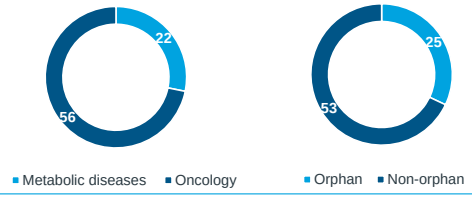
Altogether, n=44 (oncology: n=38 and metabolic diseases: n=6) dossiers were included into the correlation analysis. Of those, n=30 were non-orphan dossiers and n=14 were orphan dossiers. Mean decrease of product prices after first label extension was -9% among all products, -9% among oncological and -9% among the metabolic disease products. The most common price reduction after first label extension was in the category between 0% and -10.0% (n=11).

There is statistically significant negative correlation between the change in reimbursed price and the change in population size ($p < 0.01$). However, the extent of the correlation was low ($r=-0.12$). This might be due to the low number of analyzed dossier (n=44) which were included into the analysis. Between change in reimbursed price and change in ACT costs, there was a positive correlation of $r=0,20$, however not statistically significant ($p>0,05$).

Conclusion

In general, the reimbursed price after a label extension likely decreased. However, for pharmaceuticals in which the extent of additional benefit increased, some could achieve an increase of reimbursed price after the first label extension.

1 Share of oncology vs. metabolic diseases dossiers and orphan vs. non-orphan dossiers (Total: n=78)



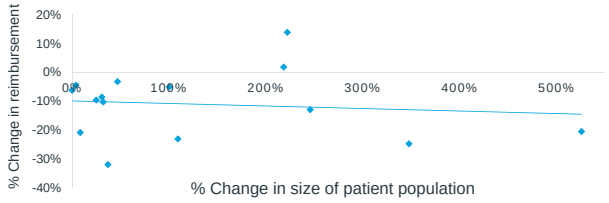
2 Extent of price change after the first label extension per disease are and for both disease areas

Price change	Oncology	Metabolic diseases	Total
≥ 0%	4	0	4
up to - 10%	9	2	11
up to - 20%	2	0	2
> - 20%	4	1	5
Total	19	3	22

3 Mean price changes (in %) of non-orphan dossiers in relation to change of additional benefit after label extension

Change in extent of additional benefit	Mean price change	Min.	Max.
Decrease	-11%	-3%	-21%
No change	-11%	2%	-25%
Increase	-5%	-23%	14%
Total	-9%	-25%	14%

4 Correlation between decrease in reimbursed price and increase in patient population



Key findings

In general, the analysis shows that the negotiated prices decrease with the first label extension.

Hereby, the decrease in reimbursed price per label extension showed a correlation with the extent of increase in the patient population.

The mean price change of non-orphan dossiers was -10% after the first label extension and ranged from -25% to 14%.

Sources:

1. Lauer Taxe (2018). Information system: Prices. Accessed under: https://www.lauer-fischer.de/LF/Seiten/Verwaltung/Kundencenter/1.aspx. Last access date: 06.11.2018.

Disclosures

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