propharma

case study

From Approval to Reimbursement: Navigating the Nordic Pharmaceutical Landscape

The Nordic region, known for its high standards in healthcare and innovative pharmaceutical policies, offers both significant opportunities and intricate challenges for companies seeking market access.

Achieving reimbursement in these markets requires navigating diverse regulatory frameworks, pricing considerations, and reimbursement criteria unique to each country.

Challenge

A European mid-sized pharmaceutical company had successfully obtained market approval for their products but faced the challenge of securing reimbursement in the Nordic countries (Denmark, Finland, Norway, and Sweden).

While their products were already reimbursed in many other European markets, they sought ProPharma's support to enhance their sales in the Nordics by achieving full reimbursement in those countries.

One significant challenge was ensuring that the product's price did not fall below its international European prices and needed to be consistent across all Nordic markets.

Given the diverse pricing and reimbursement landscapes in these four countries, ProPharma faced an additional layer of complexity in this endeavour.

ProPharma's Strategic Approach

ProPharma began their support by conducting a comprehensive market overview and competitive landscape assessment for the client's products. This included a detailed discussion of each reimbursement agency's requirements and processes, followed by ProPharma's strategic recommendations and an assessment of the likelihood of reimbursement. This market overview required a clear understanding of the most relevant comparators, including their prices, reimbursement status, and roles within each country.

The comprehensive market overview with recommendations was presented to the client. Based on ProPharma's recommendations, the client decided that ProPharma should continue their support by preparing reimbursement dossiers to three out of four investigated markets.

In Norway, the products were automatically reimbursed, so no further action was needed beyond ensuring the price aligned with their international reference pricing system. For the other markets, Finland, Sweden, and Denmark, ProPharma prepared and submitted reimbursement application dossiers.

The biggest challenge revolved around the varying reimbursement application requirements and the differing levels of acceptance for clinical data and price differences across markets. For instance, a systematic literature review (SLR) was required in Finland and Denmark, but optional in Sweden.

Moreover, the relevant comparators to the client's products varied by country due to differences in competitor prices and reimbursement statuses. There was also a lack of clinical data available for direct comparisons between the client's products and the most relevant comparators in each country. Consequently, different arguments were needed to justify the relative efficacy between the intervention and the comparator.

Furthermore, there were discrepancies in the acceptance of cost calculation methods when comparing intervention and comparator costs. In Sweden, a weighted average of the doses most used in clinical practice was employed to calculate pharmaceutical costs, whereas this method was not accepted in Finland.

The reimbursement applications were submitted simultaneously in Finland, Denmark, and Sweden, as requested by the client. In Sweden, the highest level of post-submission support was required, including the submission of supplementary data and further argumentation. Despite this, no clock stops were initiated in any of the markets.

Successful Outcome

After six months, the products were successfully reimbursed in all three markets at the client's requested price level. Achieving reimbursement at the initially requested price made the Nordic markets competitive with other European markets. Consequently, countries that applied the international reference pricing system were not affected by the decisions made in the Nordics.

Summary of Challenges, Solutions, and Results

challenge

A European mid-sized pharmaceutical company seeks full reimbursement for their products following decentralized market approval in four Nordic countries: Norway, Finland, Sweden, and Denmark.

Main challenges:

- Requesting similar prices in all four Nordic markets despite differing reimbursement procedures.
- No single comparator fits all markets.
- Lack of clinical data fordirect comparisons between the intervention and relevant comparators.

solution

- Developed a comprehensive market overview to identify hurdles and mitigate risks, followed by strategic recommendations.
- Customized reimbursement applications for each Nordic market, incorporating targeted arguments and justifications for price and reimbursement.

results

- Reimbursement achieved in all markets within a six-month assessment period.
- Maintained pricing at the level initially requested by the client.
- Provided robust arguments for reimbursement based on price and relative efficacy.
- Ensured that Nordic prices did not impact the rest of Europe.

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Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

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