Global pricing strategies for pharmaceutical goods

In the context of national price controls in many pharmaceutical markets and strong interdependencies between these markets as a result of parallel trade and international price referencing, a global pricing strategy is essential. A global approach is necessary to maximise the long-term revenue and profit for new pharmaceutical drugs.

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The current situation

The pricing of new pharmaceutical drugs has become an extremely difficult task of the highest priority. Only when there is absolute clarity about the pricing and reimbursement opportunities and challenges can we understand the true value of a new drug and decide whether or not any investment in such a drug is justifiable.

The pricing challenge is so difficult because it has to account not only for market forces such as competitive pricing and customers’ pricing sensitivity, but also for national pricing and reimbursement systems, parallel traders who exploit price differences between countries and national pricing authorities who reference prices in other countries. This pricing challenge also has to cope with the legal inconsistencies within the European Union (EU), where free movement of goods is one of the basic concepts but the pricing of pharmaceuticals is regulated nationally. National price regulation creates artificial price differences between countries and the free movement of goods principle allows parallel traders to exploit the differentials, to the cost of research-based pharmaceutical companies.

The development of a global pricing strategy is a three-step process that starts bottom-up at the national level, takes a global view during the second step and comes back top-down to the national level when the national prices are to be implemented. The three steps are therefore:

• pricing in individual countries
• international global pricing
• price implementation.

Pricing in individual countries

When setting prices in individual countries, the new pharmaceutical drug first has to be evaluated in terms of its medical performance. The quantified medical value of a drug is then translated into a price by measuring the price elasticity of the relevant customers. Pricing therefore starts with a value assessment because value will directly influence the price, a concept that is illustrated in Figure 1.

Figure 1: The ‘magic triangle’

The pharmaceutical world has become highly globalised in terms of pricing, with prices in one country influencing those in many other countries. The solution is to develop a global pricing strategy before the product is launched in the first country.

Over the years, international price referencing has become more sophisticated and now not only takes place within the EU, but has become a global phenomenon, with countries such as Japan referencing to prices in the USA and the EU. Thus the pharmaceutical world has become highly globalised in terms of pricing, with prices in one country influencing the prices in many other countries. The only solution to this situation is the development of a global pricing strategy before the product is launched in the first country.

Here ‘value’ is defined as the therapeutic benefit provided by the drug compared to that provided by other existing drugs. This is a systematic measurement of relative performance in efficacy and safety and other criteria that provides an aggregate measure of the therapeutic benefit, the so-called value. As illustrated in Figure 1, an increase in value has a positive effect on both the price that can be charged and the volume that can be sold.
Value drives price and volume and therefore has a multiplicative effect on revenue and profit. A higher price may also signal higher value, as indicated by the broken line, but this effect is of lesser importance. The relationship between price and volume is negative, i.e., a higher price results in lower volume sales, and vice versa. Once we have a clear understanding of a product’s value and also of the customer’s price elasticity, we can use this information to derive the profit-optimal price (see Figure 2).

**Figure 2: Profit-optimal price**

The sales function decreases with increasing price. The slope of this function reflects the price elasticity. The steeper the slope, the more the unit sales are influenced by price. Once we have quantified this so-called price response curve, we can easily derive the profit function. This is a bell-shaped curve. At very low prices we may sell many units of the product, but when there is no unit contribution margin the total profit becomes very small. Profit increases with increasing price, reaches a maximum and then decreases again because at very high prices the unit contribution margin is extremely high but we are no longer selling any units. The profit-optimal price is to be found where the profit reaches its maximum.

While this approach is mainly valid for free-pricing markets like the UK, Germany or the USA, for the price-controlled countries the likelihood of reimbursement at various price levels must also be taken into consideration. We are talking about a range of prices rather than a single price. At very low prices, the likelihood of reimbursement may be as high as 100%, but as the prices increase the likelihood decreases. In other words, the use of the product will be increasingly restricted until a price is reached at which the likelihood of reimbursement becomes very small. These reimbursement thresholds may cover a broad price range and the profit-optimal price may be within this range or, as shown in Figure 2, may also be outside this range. In the latter case, the profit-optimal price may not be achieved in a certain market or may only be achieved with severe usage restrictions.

Using such a systematic approach to pricing, where the value of a new drug is quantified and the price and reimbursement elasticity is measured, results in substantially higher profits compared to a less sophisticated approach. The following example may demonstrate the impact of the more systematic approach. A company was ready to launch a new product for a chronic disease requiring daily drug usage. The management was unsure about the value of the product and therefore wanted to set a low price of €0.60 per day. However, after systematically quantifying the value of the drug and measuring price elasticity, the derived profit-optimal price was three times higher, at €1.80 per day. The management was now more confident and launched the product at €1.95, just below the potential psychological price threshold at €2.00. The product sold even better than anticipated, there were only a few complaints about the price, and the profit was more than triple what it would have been at a daily price of €0.60.

Pricing in individual countries therefore means two things:
1. We have to deliver value to the market, which requires quantifying the overall therapeutic benefit provided by the drug in relation to other existing drugs.
2. We must extract value from the market by measuring price and reimbursement sensitivity and setting a price.

**International global pricing**

After carrying out a systematic pricing approach in all major individual countries where the product is to be launched, we can then use the information gathered to develop a global pricing strategy. The need for such a global approach is obvious. If we were to launch the product at all the different prices we have found to be optimal in the various countries, parallel traders and pricing authorities would use these price differentials between countries to their own advantage and would rather quickly drive down the prices to the lowest price level that was set. The impact of parallel trade only becomes evident after the launch. However, pricing authorities may decrease the prices even sooner.

In Europe, only the UK and Germany do not reference other countries’ prices. What we see is that all other countries reference prices with different systems in place. Some, like the Netherlands, have formal systems in place. They look at the prices in France, Germany, the UK and Belgium and simply calculate the average price. Many other countries have more informal systems, either referencing at launch or after launch, more or less regularly. Some countries may reference the prices in a large number of EU countries, but many focus on countries that have a higher influence.

This only illustrates the European situation, but price referencing also occurs in other parts of the world and between continents. Japan references prices in the USA, Germany, the UK, France and Switzerland. Canada looks at prices in selected EU countries and the USA. The Latin American countries also look at prices in Europe.
If a new pharmaceutical drug was to be launched at greatly different prices in various countries, this global referencing system would kill the product’s profit potential before it had even been launched in all markets. The only solution to this is the development of a global price corridor.

Following this logic of a global price corridor, we must also mention its implications for the pricing of new drugs. It should be clear that neither individual country pricing nor a uniform pricing approach is optimal. We may not want to eliminate parallel trade completely, but rather accept certain levels of parallel trade. It is important that such a corridor is established before the product is launched in the first country. This also implies that the pricing cannot be determined by the country affiliates; it has to be a central decision. Therefore we need stronger centralisation of the pricing know-how and analyses as well as centralisation of authority. This central pricing authority may also decide not to launch the product in certain countries where the minimum prices cannot be reached, or decide to launch it even if it will not be reimbursed.

**Price implementation**

With a global price strategy in place, we must then ensure that the target prices are also successfully implemented in the various countries. This is not an issue in the free-pricing markets, but in the price-controlled countries further action is necessary, i.e., we need to obtain reimbursement.

For effective reimbursement negotiations, one has to set the cornerstones of these negotiations very early on in the clinical development process. Much later, when the actual negotiations are taking place, the launch sequence is of utmost importance.

**Setting the cornerstones**

The reimbursement process differs from country to country and is characterised by continuous change. There are, however, some factors that are considered in almost all countries, and these are:

- the budget impact of the new drug
- the medical benefit provided by the new drug vs. existing drugs
- the prices of comparable drugs and prices in other countries.

All of these factors can be influenced by the pharmaceutical manufacturers if they do the groundwork early enough, i.e., during phase II of the clinical trials. First of all, the target indication and patient population must be defined. If we target all patients in a given indication, the potential budget impact may be very high. Targeting a subset of all potential patients reduces the budget impact and may allow us to achieve a higher reimbursement price. In addition, a more carefully selected patient population may allow us to demonstrate a higher medical benefit, again increasing the chances of higher prices.

The medical benefit of a new drug is heavily influenced not only by the selected patient population but also by the selection of both the clinical comparators and the clinical endpoints for phase III of the clinical trials.
Selecting a clinical comparator based solely on medical criteria may endanger the reimbursement negotiations. Selecting one comparator that allows us to easily demonstrate superior efficacy or safety is only one side of the coin. If this comparator then has a low price it will be used against us during the reimbursement negotiations and we may never be able to achieve a price far above the low-priced comparator. Therefore clinical comparators for phase III must not only be selected based on medical factors, but the reimbursement negotiations must also be taken into consideration.

The same is true when it comes to the selection of clinical endpoints. Some endpoints may allow us to demonstrate superiority, but payers may be interested in different endpoints. So it is worthwhile investigating which endpoints would help us during reimbursement negotiations. In addition, in some countries payers are interested in pharmacoeconomic data. We should know in advance what they are looking for and collect these data during phase III clinical trials. Data that only become available one year after the launch do not help us during the negotiation process. Therefore the design of phase III trials and the type of data collected during these trials should be heavily influenced by data needed for the reimbursement negotiations.

An example may help illustrate the importance of collecting the right data early on. A global price corridor was set for a new drug, with a minimum price of $50 and a maximum price of $60 per pack (see Figure 4).

After the first negotiations for the country of origin were completed, the reimbursement authority only granted a price of $40. This was not acceptable for the company and a pharmacoeconomic model was presented that demonstrated good cost-effectiveness even at a price of $66. Based on this model and the underlying assumptions made in it, the authority granted a price of $55, which was within the price corridor and therefore acceptable. The prices achieved in the other countries were all within the corridor, with the exception of the USA, in which a higher price was set. To achieve relatively high prices in Italy and Spain, an appropriate launch sequence was used.

Launch sequencing
Launch sequencing is the solution to the global referencing practice of the pricing and reimbursement authorities. Through specific launch sequences, higher prices can be achieved in the price-controlled countries and overall revenues and profits can be increased on a global basis. The logic of launch sequences seems to be simple: launch first in the high-price countries in order to have a higher reference price for the potential low-price countries. A classic example is illustrated in Figure 5.

However, the launch sequence may be very different for another product or in another indication. Launch sequences very much depend on the individual product and situation. The sequence may be different for an indication enlargement than for the initial indication. The same product may have a different launch sequence if its form of administration is intravenous rather than a tablet. So, in practice, the classic sequence often does not apply and finding the optimal sequence is much more complex than it may initially appear to be. Many factors influence the launch sequence, such as:
- the prices that one can expect to achieve in the various countries
- the price referencing process in all countries involved

![Figure 4: Price negotiation example – recommended price corridor](image)

![Figure 5: Launch sequence – classic example](image)
• the costs incurred by delaying a launch in one
or several countries
• and many more factors, including very specific
rules that are applied in different countries
and different situations.

Conclusion

Global pricing is characterised by a three-step
process that starts at the individual country level
by quantifying the perceived value of a new
product and measuring price and reimbursement
elasticity. During the second step, centralised
pricing analyses and a central pricing authority
must ensure that a global pricing strategy
maximises the long-term profitability of a new
product. To do so, it must develop a global price
corridor and define target prices for all countries,
taking international price referencing and parallel
trade into account. The central authority must
also identify those countries in which it may not
make economic sense to launch the product. In
the third step, the implementation phase, the
objective is achieving reimbursement. Here the
setting of the cornerstones prior to phase III
clinical trials and the optimisation of the launch
sequence is of utmost importance.

Note

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