

Price Strategy Bulletin

The Growing Need to Focus on France

Changing Rules

In November 2003, Kaletra (lopinavir plus ritonavir), the combination HIV/AIDS product from Abbott Laboratories, became the first drug to submit a price under the new French price notification procedure. When the system was introduced the authorities said it would accelerate time to market for “innovative” products and allow them to be priced at “European” levels, no lower than the UK, Germany, Italy or Spain.

This bulletin explores the potential impact of the rule change, and the implications for pharmaceutical companies.

The Importance of France

From a pharmaceutical pricing perspective, France is perhaps the most important market in the world. Its high pharmaceutical consumption makes it a significant market in its own right, but France’s influence extends well beyond its own borders.

A combination of thorough product reviews, high domestic volumes and hard negotiation have resulted in French prices historically being among the lowest in Europe. The impact of those low prices filters down throughout Europe and much of the world in the form of price referencing and/or parallel trade:

- In addition to being the most referenced country in Europe, France falls into the referencing baskets of many other key international markets, such as Japan and Canada.
- The combination of low prices and high domestic volumes makes France a prime source for European parallel trade.

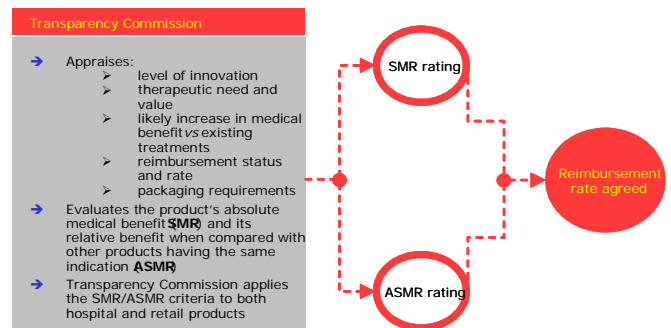
Clearly then, any opportunity to improve price levels in France will have a “multiplier” effect and warrants close scrutiny.

Current Approval Process

French price and reimbursement approval essentially involves a two step process:

1. The Transparency Commission evaluates a new drug’s absolute medical benefit (“SMR”) and improvement in medical benefit compared to existing therapies for the same condition (“ASMR”). SMR and ASMR ratings are assigned, as is the level at which the product will be reimbursed (0%, 35%, 65%, or 100%).
2. Economic Committee (CEPS) determines the product price, through negotiations with the manufacturer. The price will be heavily influenced by the ASMR rating assigned: the higher the rating, the higher the potential for a premium price.

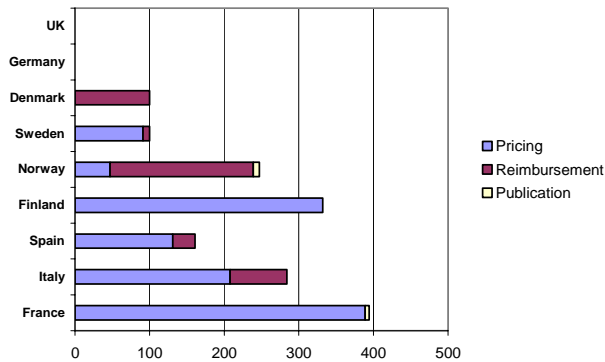
The diagram below outlines this process.



While apparently transparent and objective, the French authorities have traditionally taken a very conservative view of what constitutes an advance in therapy – and hence a high ASMR rating – and, even then, have rarely granted prices in line with those achieved in other leading European markets, such as UK and Germany.

Additionally, the French price and reimbursement process has been among the slowest in Europe. (See Fig 1).

Fig 1: Time From Application to Reimbursement (Days)



Source: G10-Commission Response, Cambridge Pharma Consultancy, Delays in Market Access, December 2002

So what has changed, and what difference can the new laws make to the way pharmaceutical companies develop their new products?

New System

The new system should allow producers of “innovative” therapies two opportunities:

1. The potential to achieve higher prices than previously.
2. The potential to receive that price approval much more quickly.

Under the new scheme, an innovative product is defined as one that receives an ASMR rating of I, II or, in some cases, III. It can then be launched at a price suggested by the company, provided it is in line with the rest of Europe. The Economic Committee (CEPS) has two weeks to object to the suggested price before it becomes official.

Implications for Strategy Development

Based on its pivotal role as a global price reference and source of trade, companies should ensure they give sufficient focus early in development to the implications of strategy decisions on the French pricing opportunity. This need is further emphasized now that the opportunity exists to obtain a reasonable price in a reasonable timeframe.

Specifically manufacturers should:

- Understand what is required to obtain a high ASMR rating in France, for example:
 - Products considered to be “me-too” drugs will not be granted high ratings, unless a substantial medical improvement can be demonstrated in certain subpopulations.
 - Products not deemed to have conducted the appropriate comparative clinical trials are also generally denied high ratings.
- Specifically consider the French requirements in the design of the development strategy. This may mean making further investments in – or modifications to -- the overall development program. Specific areas of focus would be:
 - Choice of clinical trial comparator
 - Relevant patient subpopulations
- Model the “price effect” benefits of a higher ASMR rating and weigh these against the costs and risks of the investments or modifications. ❖

PriceSpective is a pharmaceuticals pricing strategy consulting firm focused on providing expert guidance in integrated price and reimbursement strategy. PriceSpective has specific expertise in the development and global evaluation of France-focused strategy options.

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