



Global Insight Article

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Conference: A Closer Look at 2007-08
Trends and Developments

Europe: Annual Pharma Pricing Strategies Conference: A Closer Look at 2007-08 Trends and Developments

Business intelligence group Jacob Fleming held its Third Annual Pharma Pricing Strategies Conference on January 15-16, in Rome, Italy.

Global Insight Perspective	
Significance	One of the major topics, particularly in the European Union, is recognising the differences and similarities between each country, which are generally political, in order to understand the perspective of key decision makers and the basis for reimbursement.
Implications	There is an increasing focus on health economics and the value it can add to reimbursement decisions—and this discipline has yet to be fully realised and explored. Further ideas proposed included focusing reimbursement decisions issues such as epidemiology and burden of disease.
Outlook	Risk-sharing agreements are likely to become a major trend in Europe, although each case may take a slightly different form. The emphasis of reimbursement decisions on health economics will require an ongoing understanding of which policies should be used in which markets. The concept of 'EuroNICE', or a unified European drug agency, is a possibility in the future, possibly 10 years from now. However, there is still a great deal of disagreement on the subject, as many countries within the European Union have a widely different healthcare expenditure and P&R policies.

Dissecting the Payor's Perspective

There is a perpetual divide between health authorities and the pharmaceutical industry. Within the European Union (EU), each drug agency emphasises and uses different criteria for reimbursement. The German system is entrepreneurial but over-regulated, while Sweden focuses on innovation and the United Kingdom is most concerned with cost-effectiveness. Furthermore, drug agencies looking for 'innovation' in the market have different ways of defining the term. In Italy, the drugs agency defines 'innovative' as having 'added value from a therapeutic point of view', which does not take into account quality of life. If after three years a drug does not demonstrate 'added value' in Italy, the price will be lowered, essentially putting the products to the test.

Ann-Christin Tauberman, the General Director of the Pharmaceutical Benefits Board (LFN) discussed the Swedish P&R system. The Swedish system continues to be unique, as more emphasis is placed on new, innovative medicines intended to meet demand. According to Tauberman, tax payers' money is spent as efficiently as possible by investing in new medicines rather than in social benefits, for example. The Swedish reimbursement system is mainly product-oriented, and the solidarity principle takes precedence. Reimbursement and a higher price are granted if the industry provides innovation. Although drug prices tend to be high in Sweden, the effects of generic substitution have affected the average price. The LFN asserts that the government does not have the ability to price medicines, hence letting the industry decide; however, the Swedish market is still highly regulated. Following the willingness-to-pay principle, the LFN does not negotiate prices with the industry; rather the regulatory body lets the public choose. Claiming to have the right incentives for innovation, Sweden is prepared to pay more money for drugs targeting severe diseases.

The Problem of Regionalisation

A major discussion took place over how to manage P&R policy and implementation in highly regionalised countries, such as Spain and Italy. As Claudio Jommi, the Head of the Pharmaceutical Observatory in Italy (CERGAS) outlined, once the central government has decided on a policy, local governments can impose further changes. Regional actions create what is known as the "fifth hurdle"; for example, in co-payments differentiating the price of a given drug. Access to medicines also continues to be a concern due to regional variability; for example, drugs may be available in one region via hospital-only status, while they are available in other regions via community-drug status only. Furthermore, clinical governance and advice from public authorities is diffuse. Some regions are more advanced than others, and the prediction is that the situation will not change in a dramatic way. Cultural aspects tend to play a significant role as well, as Italy is a country which has a tradition of interpreting rules in a flexible way. In order for the industry to have favourable P&R policies, players would need to cultivate a strong relationship with individual regions or local governments. In January 2008, Italy introduced a major policy change in the form of a spending cap on drugs.

Harmonising Policy

According to Fridolin Marty, P&R Specialist from Santé Suisse, Switzerland has traditionally been a "pharma friendly" environment. Like the United States, Switzerland's healthcare spending is a major form of GDP; however, healthcare costs are growing much faster than the economy. One of the concerns with the system in Switzerland is that because of the national tendency to introduce drugs early there are no countries for comparison. Furthermore, drug prices usually remain the same for roughly 15 years. There is a price problem as well as a quantity problem, as demand exceeds expenditure. Since 2006, Switzerland has implemented a higher co-payment of 20% for original brands, if the price reduction is less than 30% after patent expiry. In 2007, there was a major value increase of generics. Overall, Switzerland is revising its P&R policies in a shift towards EU trends. Even though Switzerland is outside of the EU, it is

likely that the European drug market will become more integrated. As Marty asserted, Switzerland has adopted many measures aimed at standing out less and standardising policies in order to conform more to the EU.

A second major topic discussed was whether it is possible to unify data provided by the industry, rendering a more convincing case for reimbursement. There is a need for the industry to understand the expectations of drug agencies and to present information in a clear manner. For example, when utilising clinical trials, certain types of studies may support efficacy more than others. According to Sylvie Gabriel, Senior Director of Global Scientific Communication with French Sanofi-Aventis, the two main payor concerns are value for money and budget impact. But the perception of product price may differ between countries. For example, U.S. reimbursement criteria are predominantly based on the reliability of published information and evidence-based medicine. Overall, there is an increased need for the industry to communicate health economic data early on in the process. Additionally, the industry should focus on gaining support from stakeholders. Lastly, the industry must be mindful of meeting payors' requirements and must communicate clearly and simply with the media.

Outlook and Implications

Risk-sharing agreements are likely to become a major trend in Europe as exemplified by the 'risk rebate scheme' in the United Kingdom and the 'dose-creep' risk-sharing in France. Health economics is playing an increasingly larger role in European reimbursement decisions, especially in the United Kingdom. But the important question to ask is not whether health economics is important; rather, which policies should be used in which markets? Some countries, such as Switzerland, are revising policies in a bid to resemble EU countries, while the German system remains socialist and over-regulated yet entrepreneurial and competitive. Orphan drugs are a current topic of interest; specifically they present a test-case of how to ensure R&D and innovation. In the case of orphan drugs, there needs to be better assessment of total disease-related costs such as disability, family and social impact on integration, productivity, and quality of life. According to Fernando Royo, Vice President and General Manager of Genzyme (U.S.), this kind of monetary investment would save money later on because of the focus on prevention. Additionally, there is a call for more creativity from payors as well as reducing the uncertainty risk. New EU candidates such as Croatia and Turkey introduce further complications for creating a unified European drug agency, or 'EuroNICE', because of their own underdeveloped P&R systems. Croatia requires stabilisation in the drug market as well as medicines being covered by compulsory insurance in order to guarantee affordability and access. Additionally, this requires better budget control and preferably a decrease in drug prices. Problems in Turkey continue to be focused on long waiting periods, lack of a knowledge-management systems and insufficient innovation.

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