

## Pharma cos must assess real-world evidence to keep up with global market access landscape shifts

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As the overall costs of drugs continue to increase and pricing pressures shift the dynamics of the healthcare market, pharmaceutical companies must analyze real-world trends in different treatment spaces, and assess existing and expected levels of competition, in order to gain optimal market access, says business intelligence provider GBI Research.

According to the company's latest CBR Pharma report, this kind of analysis, known as Health Economics and Outcome Research (HEOR) is an important element of market access which encompasses aspects such as real-world data, quality of life, budget impact, and cost-effectiveness, along with clinical efficiency.

Mr Rodrigo Gutierrez Gamboa, Managing Analyst for GBI Research, states that: "Traditionally, once a drug was registered in a country, it was automatically reimbursed and available for an eligible population of patients. Today, however, regulatory approval does not guarantee market access, as the cost-effectiveness of any given drug must be thoroughly demonstrated before it receives coverage in a health system.

"HEOR offers some solutions to this aspect of drug development and marketing, as it helps to collect the evidence that demonstrates the impact of new therapies on healthcare budgets, which in turn will help to price products optimally.

"Cost-effectiveness takes into consideration the concerns of regulators and payers, which helps speed up a product's entry into the market. Hence, such studies should be carried out alongside clinical trials by including end points of interest in the design."

Currently, a significant number of European payers, continuing to play a key role in pricing decisions, expect companies to conduct comparator trials for easy evaluation of drug effectiveness in order to list the drugs on formularies.

Mr Gutierrez Gamboa notes: "Ultimately, this might change the information basis for investment decision and commercial expectations. Therefore, it is important not only to gather the relevant information from the market, but to ensure that this

information has the right weight and presence."