Innovations in Drug Pricing and Reimbursement: Payer Perspectives (2016)

A FirstWord Dossier Advisory report
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Research Objective and Methodology

This report looks at current drug pricing trends and their relationship to healthcare costs, value, health outcomes, R&D investment and innovation. It assesses the most pressing challenges for payers in the present environment, both in terms of existing high-priced products and the growing number of pipeline drugs reaching the market at high prices.

It explores the various strategies and systems payers are using to manage high drug prices and costs, including schemes such as co-payments, tiered formulary access, risk-sharing or cost caps, conditional reimbursement and straight discounting.

The research methodology included a wide-ranging review of available literature on, and media coverage of, pricing and reimbursement developments worldwide, followed by in-depth interviews with payers responsible for drug budgets in the US and five European countries. Information was obtained from publicly available sources of information and from previously published FirstWord reports and analysis.

Experts interviewed for this report include:

1. Pharmacy director at US-based pharmacy-benefit management organisation
2. Pharmacy director at US-based pharmacy-benefit management organisation
3. Chief pharmacist at NHS Foundation Trust in England
4. Drug-reimbursement manager for German health insurers
5. Head of pharmacy at French university hospital
6. Advisor to Spanish hospitals on pharmacoeconomics and formulary inclusion of new medicines
7. Director, department of clinical pharmacy in Italy
Key questions answered in the report

Key questions that were asked during the course of the research included:

- How and to what extent are government policies and interventions by associated bodies, such as HTA agencies, shaping the drug pricing environment in the EU and US markets?
- Which pricing trends and strategies are likely to prove the most challenging for payers in different markets and what impact will they have over the next five years?
- What strategies are payers in US and European markets using to cope with the rising cost of premium-priced new medicines?
- What kind of impact are these strategies having and are they sustainable?
- How are manufacturers responding to increasing payer pressure for sustainable drug prices?
- Are these strategies being determined independently, in collaboration with other payers, or by negotiating mutually acceptable cost- and risk-sharing schemes with manufacturers?
- How much (if at all) does independent assessment and monitoring of real-world evidence by payers contribute to coverage designs for high-priced drugs?
- Are more radical pricing strategies needed if healthcare payers are to absorb the long-term impact of high-priced therapies, escalating patient demand, population ageing, and the associated burden of chronic disease?
- Do you see an eventual move towards value/indication-based and performance-based reimbursement of expensive new medicines?
New strategic alliances to manage costs

Cost pressures have prompted some unprecedented strategic alliances in Europe. These include a declaration of intent signed in April 2015 by the health ministers of the Netherlands and Belgium, whereby the two countries will jointly negotiate with pharmaceutical companies on the pricing and reimbursement of medicines with significant budget impact. In September 2015, Luxembourg said it was joining the initiative, which will start in 2016 as a pilot project focused exclusively on orphan drugs – although the scheme could eventually expand to other product categories.

The three-way partnership also involves data exchange, registry-sharing and co-ordination of methodologies for assessing the value of orphan drugs. In addition, the three countries will consult on horizon-scanning for new medicines and determine how best they can prepare for market entry. Bulgaria and Romania have also signalled their intention to team up and leverage economies of scale in negotiating supply terms for high-priced medicines.

These moves followed the European Commission’s introduction in April 2014 of a new provision whereby participating EU member states could activate a Joint Procurement Agreement for vaccines and other medical ‘countermeasures’ to “ensure that pandemic vaccines and medicines are available in sufficient quantities and at a correct price should a cross border health threat emerge.”

It was also suggested that participating member states could extend the scope of the agreement to situations involving other infectious diseases, such as botulism, anthrax, hepatitis B or polio.

France, which had previously enlisted several other EU member states in a joint initiative involving dialogue and information exchange to support national price negotiations on Sovaldi and other new hepatitis C treatments (while also taking its own measures to limit costs nationally), became the twenty-second out of 28 member states to sign up for the Joint Procurement Agreement in September 2015.


A German payer lists as the most significant budget-management strategies used nationally:

- quarterly spending budgets for primary-care doctors, negotiated with the sickfunds;
- prescribing-volume targets and efficiency quotas (e.g., for generic-drug use), imposed by the sickfunds and backed up by monitoring, audits and the threat of financial penalties; and
- G-BA’s benefit assessments.

**Spain’s therapeutic-positioning reports**

In Spain, the national therapeutic-positioning reports (IPT) issued since 2013 for all newly licensed drugs by the Spanish Medicines Agency (AEMPS), with input from regional authorities, are seen as an important new tool in pharmaceutical budget management.

The IPTs look at a product’s clinical benefits, degree of innovation and place in the therapeutic pathway, serving as a consensus document for pricing and reimbursement discussions at national and regional levels. They draw on data from clinical trials, direct and indirect comparisons with existing therapies, and information on disease prevalence and target populations.

Eventually, pharmacoeconomic assessments are expected to enter the equation as well. “I don’t know what are the variables used to fix a price, to authorise a price, or what the reason is to reimburse or not some drugs,” comments a Spanish payer.

“In this therapeutic positioning of new drugs, there isn’t any budget-impact study for estimation. It’s very surprising, given the price of some of the new drugs: for example, Yervoy (ipilimumab; Bristol-Myers Squibb): it’s not a new drug and the price is very expensive. If you compare the clinical benefit, the price is just very expensive.”

Payers in Spain may themselves ask companies for cost-benefit or outcomes data to justify premium drug prices, as was the case with the new wave of oral hepatitis C treatments, the FirstWord interviewee notes.

National budget ceilings have also been set for expensive new drugs such as Sovaldi. In this particular case, the limited funding allocation was backed up by a highly restrictive clinical protocol rationing product use to the most critical patients. This sparked a public outcry against the government’s hepatitis C policy and the pharmaceutical industry’s pricing practices.34

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