CURRENT TRENDS IN US & EUROPEAN PRICING OF UNIQUE BIOPHARMA PRODUCTS

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Objectives

In recent years, the pharmaceutical industry has received approval in the US and Europe for several products that are unique, meet previously unmet needs, and yield important reductions in mortality and morbidity. Frequently, these products are orphan, rare, and ultra-orphan drugs targeted at very small patient populations. It is not uncommon for these products to be priced from $100,000 to $500,000 per annum.

This research reviewed the pricing trends of these unique products, identified the primary characteristics driving these prices and explored alternative payer strategies that have been implemented (e.g. outcome contracts) and/or are being proposed (e.g. reimbursement methods).

Methods

A review of publicly available data on unique biopharma products and their pricing was conducted via literature review of PubMed and targeted (non-systematic) internet searches.

Inferences were also drawn from the authors’ experience and qualitative interviews conducted with key opinion leaders (payers and Biopharma pricing experts).

Results

Post-2005 US Price Trends

Oncology products launch prices ranged from $50,000 to $120,000 per annum (e.g., Avastin®, Stiefne®, Tarceva®, Provenge®, Vemurafenib®, Revivicor®, Sprycel®, Ponatinib®, Gleevec®, Perjeta®, Herceptin®). Some combination treatments cost over $200,000 per annum (e.g., Perjeta® & Herceptin®). Oncology drugs are 50% to 100% more costly in the US than in other countries.1

Orphan drugs and ultra-orphan drugs had launch prices between $50,000- $500,000 per annum with $200,000 not being uncommon (e.g., Zavesca® Fabryzme®, Elaprase®, Kalydeco®, Naglzyme®, Cerzyme®, Sofirl®). 2

Earlier Hepatitis C products (i.e., Incivek® & Victrelis®) were launched at prices between $45-$50,000 per treatment while newer more effective products (i.e., Sofrol® & Harvoni®) were priced from $80,000-$95,000 per treatment. 3

Among established products, some drugs (e.g., Betaseron, Aremos, Copaxone) had price increases of 20%-30% per year, as compared to single digit inflation for most pharmaceuticals. Some established drugs had 10%-50% price increases in a year (e.g., Nitropress®, Lisupril®, Dilzem®, Vimovo®). 4,5

US Payers/Government Response

Insurers, whether managing private or public lives, have limited to no negotiation leverage for pricing associated with unique products. Government (especially Medicare) is legally not permitted to negotiate or mandate price.

Interventions:
• Appropriate utilization interventions (e.g., medical policies, specialty pharmacy management/ closed networks, treatment protocols/step therapy, off-label usage, prior authorization, split-fills, periodic re-evaluations).
• Higher patient cost-sharing (deductibles & copays/coinsurances) - often 20%-30% cost-sharing.
• Increase use of multiple tiers/formularies for specialty drugs.
• Increased implementation of innovative payment schemes (e.g., bundling, risk-sharing, Medicare’s oncology care program).

Post-2005 European Price Trends

Prices vary across European countries and have been reported to vary by up to 25% across European Union member states.6

IMS Health reported (in a 2014 article) that prices of oncology drugs (which includes cancer orphan drugs) were 20-40% lower in European countries than in America.7

Fourteen ultra-orphan drugs were reported in a 2013 article to have average mean cost across several European countries from €3,523 to €137,501.8

Product Characteristics Driving Price

• Uniqueness/innovation/need (even with multiple products for disease).
• Reduction of mortality and morbidity in high unmet needs area.
• Treatment of small populations (orphan diseases).

European Payer/Government Response

European governments/payers negotiate price with Pharma/Biotech with varying, but limited, level of success for these products which results in varied pricing by countries. The payers ability to negotiate differ by the country’s size, size, affluence, health care structure (in particular the structure of health technology assessment (HTA) bodies) and other factors.

Interventions:
• Several countries use health technology assessments.
• Others use external reference pricing.
• Some negotiate additional proprietary rebates (e.g., risk-sharing agreements, US patient access schemes, France’s direct purchasing from manufacturers).
• Sometimes unique or strategic pricing opportunities exist for Pharma in some countries (e.g., French temporary authorization for use (ATU)).

Conclusions

There are distinctive differences in the approaches to pricing negotiations between payers in the US and Europe. These lead to determinable patterns in the methods that Biopharma companies leverage to price their products and in the methods that payers use, by either working with the biopharma companies or creating reimbursement mechanisms to guide the appropriate utilization of these products.

European payers have more central negotiation leverage, often more formalized health technology assessments, and reference pricing which enable them to negotiate and even mandate prices and/or develop outcome-based contracts.

Unlike European payer, most US payers do not have the support of similar government-backed organizations for negotiating price. This forces US payers to seek more creative ways of managing the appropriate utilization of products through medical policies, increased patient cost sharing, limited usage of formularies, and creative reimbursement methods.

References