

Reimbursement Strategies for New Specialty Drugs in Selected Countries: Implications for Korea

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Introduction: high-priced new drugs on the increase

As medical technology keeps progressing, new medicines keep flooding into the market, among them an increasing number of drugs with significant therapeutic benefit in treating rare diseases and serious conditions like cancer. High-priced specialty medicines, including orphan drugs and anticancer agents, are expected to take up an increasing share of the global pharmaceutical market, from 30 percent in 2016 to 35 percent in 2021¹. These specialty drugs will account for a smaller, but still substantial, share of about 20 percent in the pharmaceutical market in Korea in 2021. Many of the new drugs that have been developed of late, high-priced as they represent technological advances over old ones, are likely to place a growing burden on the national pharmaceutical budget. In the US, as a 2015 *Lancet* article² notes, the price of new cancer drugs is five-to-ten times higher than it was 15 years ago, with all cancer drugs approved in 2014 being priced at a hefty USD120,000 or above for one-year treatment.

In Korea, most of such premium-priced new drugs have been approved with high reimbursement rates. The prices and reimbursement levels of drugs are determined based in general on listing agreements and price negotiation. However, reimbursement decisions concerning the rising number of high-priced new drugs often involve non-standard arrangements such as risk-sharing and exemption from economic evaluation, making regulatory decision-making increasingly difficult.

Value-based pricing on the rise

Many of the new drugs entering the market year after year are found to be not innovative enough. In a study conducted of a total of 992 new drugs or new indications introduced to the French pharmaceutical market in the years 2007 to 2016, as few as 65 (6.6 percent) represented an advance over their precedents.

[Table 1] Ratings of new products and indications introduced in the French pharmaceutical market over the years 2007~2016

Ratings	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Bravo	1	0	0	0	0	0	0	1	0	0
A real advance	2	0	0	1	0	1	0	2	3	1
Offers and advantage	14	6	3	3	3	3	6	5	5	5
Possibly helpful	27	25	14	22	13	14	12	15	15	9
Nothing new	79	57	62	49	53	42	48	35	43	56
Not acceptable	15	23	19	19	16	15	15	19	15	16
Judgment reserved	3	9	6	3	7	7	9	10	6	5
Total	141	120	104	97	92	82	90	87	87	92

Source: New products and new indications in 2016: a system that favours imitation over the pursuit of real progress (2017). *Prescrire Int*, 26 (182), pp 136-139.

¹ Quintiles IMS. (2016). Outlook for Global Medicines through 2021

² Paying a high price for cancer drugs. (2015). *The Lancet*, 386, P. 404

An assessment conducted in Germany found that only 34 (29 percent) of a total of 116 new drugs introduced in 2011 were an advance over existing products, with 71 (61 percent) having no improvement and one representing even a turn for the worse³. In Australia, only seven of the 217 drugs approved in the years 2005 to 2007 were assessed to have added therapeutic value⁴.

There is a growing tendency in many countries to introduce or strengthen value-based approaches—relative-effectiveness and cost-effectiveness analyses—to pricing and reimbursement decisions. For example, Australia, the UK, Sweden, and Canada have all adopted a value-based approach where pricing and reimbursement decisions are made based on economic evaluation. In France since October 2013, cost-effectiveness has been taken into account in drug evaluation; as for products of high clinical value (ASMR tiers 1~3), pharmaceutical firms are mandated to demonstrate the cost-effectiveness of the drugs for which they are applying for reimbursement. Such evidence, although not considered in reimbursement decisions, may affect the pricing⁵.

The German AMNOG (Act on the Reform of the Market for Medical Products), implemented in January 2011, is yet another example that requires new drugs to be evaluated of their additional therapeutic benefit and the result taken into account in pricing.

Alternative pricing for high-priced new drugs: for sustainable national pharmaceutical financing

With the number of high-priced new drugs entering the market on the rise, the sustainability of value-based pricing has increasingly been questioned. Pharmaceutical companies with monopoly power often attribute the high prices they charge to the vast amount they claim to spend on research and development. Also, those new drugs, in part because they have no alternatives, get reimbursed at an overly generous level. Given the increasing development of new drugs, price comparisons and cost-effectiveness analyses as they stand may end up placing a stupendous burden on the national health budget. A recent case in point can be found in the highly effective hepatitis C drug which was introduced in 2014 to the global pharmaceutical market and which, as a non-orphan product targeting a sizable patient population, with a per-person price tag of USD84,000~89,000 for treatment, has come as a challenge to drug reimbursement regulators in many countries.

Suggestions have emerged that the pricing of specialty drugs should take into account the actual development cost, and, with the number of new drugs rising, social pressure has been growing for pharmaceutical firms to disclose their cost information⁶. Some researchers have pointed out that cost-effectiveness analyses and price comparisons, while widely applied in drug pricing in most national health insurance systems around the world, are not adequate for high-priced orphan drugs⁷. They suggested a cost-based pricing for orphan drugs, which are marked by high R&D costs and low marginal production costs. Others like Simoens⁸ have

³ Collier, G. (2014, February 14). Chance of positive benefit assessment in Germany? Less than 30%. SCRIIP.

⁴ Vitry, A. I., Shin, N. H., Vitre, P. (2003). Assessment of the therapeutic value of new medicines marketed in Australia. *J Pharm Policy Pract*, 6(2)

⁵ WHO Europe. (2015). Access to New Medicines in Europe. Copenhagen: WHO Europe

⁶ Pollack, A. (July 23, 2015). Drug prices soar, prompting calls for justification, *New York Times*

⁷ Fellows, G. K., Hollis, A. (2013). Funding innovation for treatment for rare diseases: adopting a cost-based yardstick approach. *Orphanet Journal of Rare Diseases*, 8(180).

⁸ Simoens, S. (2011). Pricing and reimbursement of orphan drugs: the need for more transparency. *Orphanet Journal of Rare Diseases*, 6(42).

claimed that pricing decisions as to orphan drugs should be made on an individual basis based on detailed information about R&D costs. Further discussion is needed as to what institutional measures and strategies to use to ensure that orphan drug pricing is based on accurate estimation of R&D costs, which vary widely across one product from another and depending on the method of calculation used.

In an attempt to improve both health security and financial predictability, the Australian government has closed a billion-dollar volume-based bargain with pharmaceutical companies to treat 62,000 people over a five-year period, which boils down to an average treatment price of USD11,715, one-eighth of the list price.

Separate funding

In response to the increasing number of cancer drugs that did not meet NICE's cost-effectiveness requirement and, therefore, were not recommended for use on the National Health Service, the England government in 2010 established the Cancer Drug Fund (CDF) to secure access to these drugs. However, as the number of approved cancer drugs increased steadily over time, the CDF came to spend more than its budget allowed, slipping into a financial predicament. The GBP1.3 billion that the CDF spent during the years of its operation (2010~July 2016), although having increased access to cancer drugs, was heavily condemned as a "great budgetary waste," as only a fraction of CDF-approved cancer drugs demonstrated a clinical benefit to patients. Of the 47 cancer drugs that had been reimbursed by the CDF until 2015, only 18 showed a meaningful overall survival benefit, with a median of 3 months (range 1.4~15.7 months)⁹. In July 2016, a new CDF came into operation, whereby all new cancer drugs are appraised by NICE and funded by the NHS. Any cancer drug that gains a positive recommendation is paid for by the CDF on a time-limited basis before it gets a final appraisal from NICE within 90 days of approval. The result of the appraisal decides whether the drug "will be funded by the NHS," "shall not be used on the NHS," or "will be reimbursed through the CDF on a time-limited basis." The cancer drugs that remain with the CDF get reviewed again by NICE after 2 years as to whether they should be recommended for use on the NHS. The implication is that separate funding mechanisms such as the CDF, aimed as they are not so much at value-based evaluation as at prompt reimbursement, are likely to be financially unsustainable.

Concluding remarks

The ongoing globalization of the pharmaceutical market has brought with it a rapid increase in high-priced specialty drugs, which in turn have posed to policymakers the question of how to reimburse them in an effective yet sustainable way. Considering the pace of increases in these drugs, over-prioritizing prompt reimbursement will likely run the risk of expenditure overruns. This calls for a stronger value-based pricing in pharmaceutical reimbursement. Also, further research efforts should be devoted to discussing how alternative pricing and reimbursement approaches can help ensure access to new high-therapeutic-value drugs of significant financial impact.

⁹ Aggarwal, A., Fojo, T., Chamberlain, C., Davis, C. & Sullivan, R. (2017). Do patient access schemes for high cost cancer drugs deliver value to society?—Lessons from the NHS Cancer Drugs Fund, *Annals of Oncology*. doi: 10. 1093/annonc/mdx110