

Vet drug price system to keep it healthy

The Japanese public is now paying a lot of attention to the country's prescription drug price system after learning that Opdivo, a novel cancer treatment medicine, is extraordinarily expensive. Opdivo was developed by Ono Pharmaceutical Co. to treat about 500 patients suffering from an intractable disease. When the health ministry gave man-



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WORLD

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ufacturing and marketing approval in July 2014, the drug's price was officially set at about ¥730,000 per 100 milligrams.

This high price was thought to be inevitable, given that the pharmaceutical company was believed to have invested an extraordinary amount of funds for research and development to come up with an innovative drug exclusively to treat a very small group of patients with unresectable melanoma, a type of skin cancer.

But it became known later that the drug was effective in treating a type of lung cancer as well. In December 2015, Opdivo received "approval for indication" to cover small-cell lung cancer. This meant that the drug can now be prescribed to as many as 15,000 patients, a 30-fold jump from the original estimate. In addition, supplemental applications may be possible in the future with the number of patients benefiting from it estimated to rise 100 times to about 50,000.

If the Opdivo medical bills had been kept unchanged, annual doses of the drug for each lung cancer patient would have amounted to about ¥35 million. If the drug was used for all 50,000 patients, it would cost a total of ¥1.75 trillion a year. In the end, spending for this brand-name drug alone would have accounted for a significant portion of the country's overall medical expenditures.

What has surprised the Japanese is that a 100-milligram dose of Opdivo costs about ¥300,000 in the United States and ¥150,000 in Britain, compared to ¥730,000 in Japan. It is quite natural for many people to think something must be wrong with Japan's drug pricing system because a medicine developed in this country is prescribed in Britain at one-fifth of the price in Japan.

Tip of the iceberg

The Abe administration recently decided to halve the prescription cost of Opdivo in this country from February. Yet, the reduced price will remain more than twice that in

Britain. Assuming that R&D spending for a new drug is mostly a fixed one-off cost, a simple calculation shows that the new price should be one-thirtieth of the current level when taking into account that there has been a 30-fold increase in the number of patients covered by the drug.

In reality, such a simple calculation may not be acceptable from the standpoint of the pharmaceutical firm because it is required to pay patent royalties, among other running costs. Nevertheless, the general public has not received sufficient information as to what extent the drug-maker can afford to lower the price of Opdivo.

What we have learned about Opdivo is just the tip of the iceberg concerning a variety of issues with the country's prescription drug pricing system under the National Health Insurance (NHI) Law. When national medical expenditures rise, the state coffers have to bear a greater fiscal burden to keep the NHI program healthy, while the people see their premium payments increase. Therefore, the country's NHI drug pricing system ought to be thoroughly scrutinized.

Data recently submitted to the Council on Economic and Fiscal Policy — which is chaired by the prime minister — show that the country's medical expenditures in fiscal 2015 posted a year-on-year increase of 3.8 percent. Of this, pharmaceutical expenditures went up by 1.4 percentage points, outpacing a 1.2-percentage-point contribution attributed to the aging of the population.

It may be necessary for our society to accept a situation in which the pharmaceutical industry develops one breakthrough drug after another to help improve the quality of medicine. But if the development of innovative drugs ends up ballooning NHI medical expenditures, the government's budgetary fundamentals will be jeopardized. To avert such a serious drawback, I repeat that our society must examine the drug pricing system with a discerning eye.

Under the current NHI drug pricing system, the government is responsible for setting prescription drug prices. Once the price of a drug is determined, it will remain unchanged for two years — in other words, NHI drug prices are revised every two years.

Those NHI drug prices are applied to the insured, while the prices of drugs hospitals and pharmacies purchase from the market — drug wholesale distributors — are determined competitively. In many cases, the market prices of drugs purchased by hospitals and pharmacies are lower than the prices of drugs prescribed to patients. For hospitals and pharmacies, this positive spread is an important source of revenue.

In the recent past, market-based drug prices for hospitals and pharmacies have continued to fall by an average of

more than 2 percent every year. With the NHI drug price standards set to be revised every two years, the positive spread in favor of hospitals and pharmacies tends to increase during the two-year period.

Significant savings possible

If the NHI price revision is conducted every year — with an annual reduction of more than 2 percent, for example — instead of a cumulative decrease of more than 4 percent every two years in a delayed reaction, the country can save an estimated ¥190 billion in health care expenditures over a two-year period. This translates into a drop of about ¥48 billion in the NHI-related fiscal burden over the same period. Those numbers are not small as the aggregate savings over a 10-year period can amount to more than ¥1 trillion.

The country's pharmaceutical expenditures total nearly ¥9 trillion a year. Since the prices of prescription drugs can be defined as the most important public-service cost for the people, it is unacceptable for the drug pricing system to remain subject to a biennial revision.

The pharmaceutical industry says it would be burdensome to examine the market prices of drugs every year. Therefore, the industry should continue what it has been doing — submit the findings of a biennial market survey that are necessary to update the NHI drug price standards. For its part, the government should adopt an annual revision of drug prices by considering recent market-based price trends. If the industry's two-year market survey shows that the government has lowered drug prices excessively, it should introduce a system to return the prices of relevant drugs back or close to the pre-revision levels.

We already have utility billing systems that change charges to automatically reflect consumer price index changes under a price cap or ceiling price system. Regardless of whether the pharmaceutical industry conducts a market survey annually or not, the government should consider revising NHI drug prices on an annual basis.

Information disclosure

To reform the drug pricing system, all relevant information has to be disclosed. The general public has no idea at all why the NHI price of Opdivo was set at about ¥730,000 per 100 milligrams. The government may say, "The price was determined by a group of specialists. So, please respect it." But I would like it to disclose the information used in the pricing process and the reasoning behind the price.

For the public, the mechanism of setting NHI drug prices, not only for Opdivo but also for other types of

drugs, has been largely inscrutable. The government defines as "general statistics" the findings of relevant market surveys utilized for updating NHI drug price standards. However, its website says such survey findings are "not for publication," whether they will eventually be made public or not is "not for disclosure" and there is "no" archive of past information.

NHI drug prices are determined on the basis of market surveys and an enormous amount of money totaling about ¥9 trillion a year is spent on prescription drugs. The government has to keep the people duly informed of what is going on in the drug pricing process.

Likewise, the price-setting process for generic drugs also is opaque. The use of generic drugs — which are copies of brand-name drugs with expired patents — can help curb the country's health care expenditures. While other countries have accelerated their people's access to generic drugs, Japan has been slow in following suit.

Japan is now making every effort to encourage greater use of generic drugs. That is good. However, strange though it may seem, there are different price levels for certain types of generic drugs even though they are basically identical or "bioequivalent" to each brand name drug in effectiveness. The highest price tier tends to be adopted in those cases. When generic drugs are used in this way, they can hardly be expected to keep health care expenditures from rising.

There is more to be done to improve the treatment of drugs, including poultices, mouthwashes and eyedrops, for instance.

Those medicines are sold to consumers at pharmacies. When people buy over-the-counter (OTC) medications on their own or without prescriptions from physicians, they are required to pay the full price, but when they get prescriptions, they pay far less as the remainder is covered by the NHI program.

In the case of poultices, an OTC purchase costs as much as ¥980, whereas the NHI prescription price is set at ¥120 for the same drug. When a consumer opts to receive a prescription, they need to pay only ¥36 or one-third of the NHI price. As a result, an increasing number of people visit medical institutions to get prescriptions for poultices.

However, those who believe they benefit from NHI coverage in reducing the financial burden when getting OTC items should be aware that NHI coverage is financed by tax money and insurance premiums. In this regard, many people question the advisability of using national health insurance to enable the insured to pay less to buy poultices and other OTC medications that are readily available at any pharmacy.

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