

Looming tipping point for Japan pharma



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Changes to Japan's drug reimbursement system are inevitable. The only questions are the extent of changes and when they will be implemented. We should have answers to these questions at year end so they can be implemented in April 2018, says P Reed Maurer, long-time Japan pharma watcher and president of International Alliances Limited in his regular column for The Pharma Letter.

Forces driving change

For a very long time the growth of medical expenses paralleled the growth of Gross National Product (GNP), money saved by cutting drug reimbursement prices was used to increase medical fees, and the population was relatively young. Recently these factors completely changed. GNP growth slowed and medical expenses increased. Doctors' political power weakened so the growth of medical fees was curtailed. The population aged, thus becoming more intensive users of the health care system.

These factors caused the powerful Finance Ministry to get involved in policies previously solely managed by the Ministry of Health Labor and Welfare (MHLW). At first, their advice was offered

via polite suggestions for reform. When these were equally politely ignored, the Finance Ministry turned to aggressive recommendations that must be implemented.

MHLW officials responded to the pressure by launching incentives to increase the use of generics versus higher priced brand name drugs. Generic usage increased, but the expense of incentives minimized the overall savings. The Finance Ministry is well aware that money saved by promoting generics is peanuts compared to aggressive price cutting of the so called long-listed drugs, that is drugs whose patents expired.

Questions vs answers

Decisions regarding actions to be implemented are now being debated within and between various stakeholders. Typically the issues are not widely reported by the media, therefore we can only speculate as to outcomes. Given this caveat let's review some of the key questions.

Will Japan abandon its policy to reward innovation?

Japan historically rewarded innovative drugs with high reimbursement prices, strong patent protection, unrestricted access to doctors, exemption from price revisions during the patent life, and timely regulatory review.

Even a cursory review of actions in this society will conclude the Japanese prefer new to old or used. The used car market is relatively small. Public laundromats are few and far between because people do not like doing laundry in a machine used by others. Japan, since its doors were opened, consistently sought the best technology outside Japan and innovated to make it better.

Will there be changes in the pricing policy?

One aspect of the pricing policy is to reward drugs used to treat orphan diseases where there are few patients with very high prices. To some extent pharma companies gamed this system to seek

regulatory approval for an orphan indication, receive a high price, then expand the indications to more common diseases without an adjustment in the price. Expect this loophole to be closed.

Another hotly debated issue is the frequency of price reviews which are currently conducted every two years. Some insist Japan should turn the clock back to when price and medical fees were revised every year.

When reimbursement prices are revised, it kicks off a long negotiation process between manufacturers/wholesalers and dispensers of drugs to agree on new selling prices. At the next revision of reimbursement prices the government requires accurate data on net selling prices. This is simply not available if the objective is to revise prices annually.

This leads to arbitrary revisions not backed up by actual pricing data. The result is non-transparency and abuse of the system to favor special interests. Pricing decisions made every other year are totally transparent because the data on actual net selling prices is available. Hopefully Japan will not revert to revising prices behind a dark curtain. Sunlight is the best disinfectant.

Will long-listed drugs (LLD) be exposed to severe price reductions? That is, to the price level of their generic competitors?

No doubt LLD's are vulnerable to Finance Ministry logic on pricing. Thus, we can expect to see LLD prices slashed beyond the normal calculations used for revisions. This action, depending on the magnitude of the reductions, will definitely hurt companies dependent on old drugs because they have failed to develop new drugs. Cutting LLD prices to their generic price equivalent level will cause significant turmoil in the market. Thus, expect some change from previous years but not to the extent of decimating the industry.

Will generics continue to receive support?

Generic penetration of the market continues its upward trend. Whether or not they will reach the goal of 80% penetration is debatable, particularly if the spread between generic prices and original brand

drugs narrows. Nevertheless, as stated earlier, reducing the LLD prices will yield much greater savings in the health care system than subsidizing increased generic usage.

Expect a full court press on this issue by the Finance Ministry. The MHLW gave up trying to protect companies that do not innovate, and continue to live off their LLD's.

What will happen to the fees given to health care providers?

Doctor fees always moved upward in direct proportion to the decrease in drug prices. This linkage was broken two years ago so do not expect it to be resumed. Doctors no longer have the political power they wielded in the past. However, doctors are highly respected and will not be treated harshly. Expect moderation but sensible increases in doctor fees.

In short

The aging of Japan's society is putting severe pressure on the increase in health care expenses. Annual increases above economic growth are not acceptable. That is the bad news. The good news is this country can afford to spend more on health care relative to its GNP. The really bad news will hit those pharma companies and medical institutions that fail to innovate. Those who innovate will continue to prosper.