Maurer's Healthcare Insight (94)

Double in Five Years?

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Don't know about you, but I am tired of reading, "Government aims to have generics account of 30% of market volume by 2012." There is debate as to the current generic share of volume, but let's assume it was 15% at the end of 2007. Estimates range from 13 to 17%. Thus, we are talking about a doubling in five years. Is this a realistic goal or a pipedream used by the MHLW to calculate "savings" in medical expenditures to impress the Ministry of Finance?

Growth to Achieve Goal

The chart below shows the ethical market growth per annum in Japan:

	1991-1995	1996-2000	2001-2004
Wholesalers price basis	+5%	+1.3%	+2.9%
Price	-1.8%	-4.0%	-2.2%
Volume	+6.9%	+5.5%	+5.2%

Over the above time frame, volume growth gradually slowed, i.e. from 6.9% per annum to 5.5%, to 5.2%. I assume total volume growth during 2008 to 2012 will be 5% per annum.

The next chart shows the generic share of volume:

	2001	2004	2007
Generic share	10%	12%	15%

Recall, as an example, total volume growth from 2001 to 2004 was 5.2% per annum. Because generics increased their share of volume during this time frame, they obviously had a higher growth rate than patent protected products. Running the calculations, annual generic volume growth was 11.8%, and all other yearly growth was 4.4% from 2001 to 2004.

Using this same logic, assume generics will increase their share of volume from 15% at the end of 2007 to 30% at the end of 2012. Total volume grows at 5% per annum. This means generics must increase at a rate of 20.6% per annum, versus all other products' growth at 1.0%.

Another approach is to look at the share increases for generics. It grew two percentage points from 2001 to 2004, and three percentage points from 2004 to 2007. An increase of five percentage points in six years. To reach the stated goal, generics must increase their share by 15 percentage points in five years.

These numbers imply the generic growth rate must double in the 2008 - 2012 time period versus the growth rate during the 2001 - 2007. I can understand high growth rates when volume is low. In this case the growth rate accelerates as volume increases.

Also note the volume growth rate of non-generic products from 2008 - 2012 is estimated at 1% per annum. Given price reductions in 2008, 2010, and 2012 of say 4% to 6% each time, the sales value of all other products will decline. As far as I recall, this would be unprecedented.

Every businessman understands the necessity to set high goals. But goals must be backed up by specific actions. So let's turn our attention to actions that support the growth projections.

Change of the Prescription Form

The new prescription form introduced in April will allow generic substitution unless specifically denied by checking off a designated box. Certain MHLW officials believe the new prescription form will "dramatically" increase the use of generics. Their math goes like this, 80% of doctors will allow substitution and 80% of patients will choose a generic. Therefore, the generic substitution rate will be 64% (80% ~80%). The current rate is 1.4%.

A large survey covering 755,545 prescriptions received by pharmacies indicated 131,337, or 17.4% permitted generic substitution. However, of these, only 10,709 or 8.2%, were filled with generics. Of all pharmacies receiving prescriptions permitting generic substitution, 34.8% made no generic substitution.

Three key questions emerge:

1. Will 80% of doctors allow generic substitution?
2. Will all pharmacists substitute generics when permitted to do so?
3. Will 80% of patients accept generics?

As to doctors, the ¥20 fee they received for permitting a generic will be abolished. Thus, there is no financial incentive for a doctor to permit generic substitution. Second, you can bet every MR promoting a product with generic substitutes will ask the doctor to check off the box to prohibit substitution. Few MRs ask him to leave the box blank.

As to pharmacists, they will be empowered to make decisions they never made before. In April, dispensing fees will be increased by 0.17%. The mix of fees is complicated but changes will promote both stocking and

dispensing of generics. But a 0.17% overall increase is not much of an incentive. The real question is, "Do pharmacists want the power to select a drug?" If they dispense what the doctor ordered, they have no problem with the doctor or patient. If they select a substitute, they may have problems with both.

As to patients, will TV advertisements and pharmacist explanations convince them cheaper is just as good. Much will depend on the price spread and out of pocket cost. In my opinion, patient demand will ultimately make or break the 30% goal. Up to now, patients did not decide which drug they should buy. Do they want this responsibility?

Follow the Money

Doctors will not receive a financial incentive for allowing generic substitution. Pharmacists will receive higher fees if they stock up to 500 or 700 generic drugs, but the more they stock the higher are their inventory costs. Wholesalers have no incentive to promote generics as they lower revenue and profit margins, but they must satisfy demand. Patients have an economic incentive to ask for the lowest price substitute. Welfare patients have no out of pocket costs so they are indifferent. However, *Korosho* will start "suggesting" to 1.53 million persons on welfare they should chose generics when they receive prescriptions that permit generic substitution.

What about the *Korosho* budget for FY2008? A total of ¥25.6 billion is earmarked to promote the development of innovative new drugs and medical devices.

METI has approval for ¥10.2 billion to be spent on measures to accelerate commercialization of innovative new drugs and medical devices.

So a total of ¥35.8 billion is allocated for innovation. What about promoting generics? The budget is ¥240 million, or 0.7% of the total budget for innovation.

More Frequent Listings for Generics

"New" generics are now listed two times per year, up from once per year in the past. One action to increase generic sales is to increase the listing frequency to four times per year like original drugs. The bill payers made this proposal late last year but it was not approved by *Chuikyo*. The government side said they could not cope with the increased work load.

DPC Hospitals

In a DPC (diagnosis procedure combination) hospital the pharmacy is a cost center versus a profit center as it is a hospital that gets reimbursed on a fee for service basis. Thus, it should be a perfect target for lower priced generics. An action plan would increase the number of DPC hospitals. The *Korosho* target for 2012 is 1,000 hospitals. Currently there are 360, and 370 are in the planning stage. That leaves a gap of 270 to reach the target.

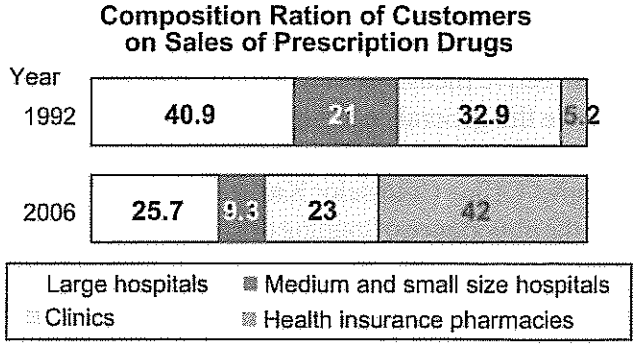
There are just over 9,000 hospitals in Japan so the 1,000 target is modest. Furthermore, some hospitals that adopted DPC reverted to a fee for service because they were losing money under the DPC system.

The Goal Is Clear,
How to Achieve It Is a Mystery

In the spring of 2007, the Ministry of Finance (MOF) announced it wanted increases in social security related spending to be reduced by ¥1.1 trillion over the five years from FY2007, i.e. to 2012. In response, *Korosho* said generic volume could be increased to 30%, or double the current rate. However, they did not project the savings of a 30% share for generics on medical expenditures.

We could argue the government has limited options to force doctors to permit generic substitution, to force pharmacists to substitute generics, and to force patients to request generics. Thus, it is not a surprise that *Korosho* considers guidance, education, and evaluation of progress as effective measures to achieve the 30% goal.

Finally, I well remember in the early 1990's many people did not believe *Bungyo* (separation of dispensing from prescribing) could be achieved in Japan because Japan was "different" from the US and Europe. Look at the chart below to see what happened:



Research by CRECON R&C

Dispensing through independent pharmacies went from 5.2% of sales in 1992 to 42% of sales in 2006. *Bungyo* took time, but it did occur.

P. Reed Maurer knows Japan changes, but does not know how fast.