

Japan's Pharmaceutical Industry Vision for 2025

(Source: edited excerpts from an article published by Pharma Japan)

The Japan Pharmaceutical Manufacturers Association (JPMA) announced its vision for the pharmaceutical industry, the first of its kind drawn up by the trade group, which outlines business models for drug makers to survive in an increasingly challenging economic environment by foreseeing industry landscapes 10 years ahead.

The "industry vision 2025" paper comes at a time when governments in Japan and other countries are struggling to reduce cost escalations on social security spending while drug makers struggle with spiking R&D costs due to more complexity in drug discoveries. In Japan, rapid generic inroads will make it even harder for companies to pull in revenues from off-patent, brand name drugs, which used to be a source of R&D investments for new drugs.

JPMA's vision focuses on five segments, the first being state-of-the-art drug discoveries. The vision predicts that the industry will usher in an era where genomic and epidemiologic data enable the preclinical diagnosis of diseases and preventive and preemptive medicines thus become increasingly important, while seeing a further advancement in existing technologies. In this context, the group said, Japan should bring together resources and wisdom from around the world and boost collaborations between the industry, academia, and government - and collaborations across different business sectors - to become a global leader in the drug discovery arena.

The second focal point sets out the group's eagerness to deliver drugs to "8 billion people," the estimated global population in 2025. It said that its member companies are keen on bringing innovative new drugs to patients in the world who are in need of such therapies, although there are country-by-country differences in economies, healthcare systems, and social cultures.

The third segment of the paper is titled, "Leading the Japanese economy." As an organization representing a high value-added industry, the JPMA will play a leading role in the Japanese economy to bring in talent, technologies, and funding to resource challenged Japan. The group also points to the need to secure R&D resources by streamlining R&D activities and business operations as well as the need to accelerate overseas expansions. Touching on the scale of drug companies and industry realignments, the JPMA notes: "Several options have emerged such as the expansion of business scales, field-by-field business collaborations, specialization in specific areas, and entries into different fields. Drug makers will make their own decisions to pursue the best solutions in view of opinions by stakeholders."

In the paper's fourth section, the JPMA calls for a drastic overhaul of Japan's drug pricing system. "Optimizing the scope of health coverage and other reforms are inevitable. Drug costs are no exception. In order to bolster the sustainability of the social security system, health coverage needs to be revised from the standpoint of prioritization and efficiency," it says. "Setting our sights on 2025, we will discuss and propose drug pricing that keeps a good balance between social security sustainability and the development of innovative medicines as well as patient access, and call on parties involved to make our proposals come true." The final focal point of the paper stresses the need for the industry to improve transparency, ethics, and compliance. The JPMA intends to refine its detailing and promotion rules, while strengthening environmental measures and external communications initiatives.

The Movement towards Payment for Performance

(Source: an article prepared by Cathy Kelly and published by Scrip)

The financial challenges posed by the launch of expensive but highly effective specialty drugs over the past two years may have finally tipped the scales toward a more serious pursuit of innovative performance based risk sharing contracts between manufacturers and payers. Under such contracts, drug pricing is tied to prespecified outcomes demonstrating the value of treatment. Agreements may also include guarantees that drug utilization will be limited to certain types of patients to control payer costs. In return, payers provide preferred coverage and may also offer assistance with other access challenges, such as medication adherence. Although these models have been talked about for years, performance based risk sharing arrangements have not moved very far beyond the pilot stage in the US. One challenge to widespread adoption has been the lack of detailed information on their effectiveness. Other obstacles have included defining outcomes, determining who would measure outcomes and agreeing on how they would be measured. Nevertheless, as manufacturers face serious resistance from payers concerned with the prospect of covering highly priced drugs that could be prescribed

very broadly, the incentives are there to persevere through some of the difficulties and execute these kinds of arrangements.

The article uses the example of Gilead's hepatitis C drugs among others. The introduction of Gilead Sciences Inc.'s hepatitis C drug, *Sovaldi*, in early 2014 at a list price of US\$84,000 per treatment regimen galvanized payer demands for value-based contracts. *Sovaldi*'s launch was followed in October 2014 by the introduction of Gilead's follow-on hepatitis C drug, *Harvoni*, at a comparable cost. It wasn't until competition to *Harvoni* and *Sovaldi* came out in December of 2014 that payers were equipped with better leverage to negotiate innovative deals with the manufacturers. Although the most highly publicized aspect of those contracts have been big discounts in pricing – Gilead estimates average discounts to *Harvoni* approached 50% in 2015; they also involve assurances that patients achieve a sustained virologic response (SVR), the accepted surrogate for a cure. For example, national insurer Cigna Corp. announced a performance based contract in early 2015 that

(continued on page 2)

Payment for Performance (cont.) . . .

provides exclusive formulary coverage to Harvoni for hepatitis C patients with genotype 1 premised on patients achieving SVR. Cigna has been one of the more proactive payers pursuing outcomes based agreements.

Although innovative payment arrangements are accelerating among commercial payers, performance based contracts have not taken hold in one of the largest markets for hepatitis C drugs, Medicaid (a U.S. program for the impoverished), due to manufacturer concerns they don't fit the traditional drug rebating model in that program. The current approach to Medicaid rebating is based on per unit pricing, which is a model that performance based contracts attempt to move away from. Manufacturers are required to pay a rebate to Medicaid programs that are the greater of either 23.1% of the average manufacturer price for brand drugs, or the difference between AMP (Average Manufacturer's Price - *The Average manufacturer price (AMP) is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts*) and the best price offered to any purchaser of the drug. In the hopes of encouraging outcomes based contracts in Medicaid, the Centers for Medicare and Medicaid Services (CMS) recently took the unusual step of contacting manufacturers of hepatitis C drugs to better understand their concerns. The goal is for CMS to develop guidance on how such contracts could comply with the rules regarding Medicaid rebates.

If the challenges of covering the costly hepatitis C drugs constituted a wakeup call for payers and providers, the advent of the super cholesterol reducing PCSK9 inhibitors have further heightened concerns. As a result, performance based contracts for the PCSK9s are already coming to light. Harvard Pilgrim Health Care announced in November that it had reached a "first in the nation" type of contract with Amgen for its *Repatha*. Under the arrangement, Amgen will provide pricing discounts to the insurer if patients taking the cholesterol lowering drug fail to reach certain outcome measures or its utilization exceeds predetermined levels. The payer described the deal as containing "a pay for performance guarantee through which Amgen is taking financial risk by providing the health plan with an enhanced discount if the reduction in LDL levels for Harvard Pilgrim members are less than what was observed during clinical trials." Patients will also need to reach the acceptable level of cholesterol reduction within six months of use.

Amgen's approach is noteworthy because it signaled a new level of support in the industry for such contracts. In another example, Novartis AG invited innovative coverage arrangements for its heart failure treatment, *Entresto*, around the time the drug was approved in July. Like the PCSK9s, *Entresto* would be a chronic use drug, possibly taken for life, and payers worry it could be prescribed more widely than its current labeled indications. However, its annual list price of US\$4,560 is considerably lower than the US\$14,100 and US\$14,600 prices for *Repatha* and *Praluent*, which has kept it out of the news as another example of egregious pricing by the biopharma industry. Novartis has said it is interested in pursuing outcomes based reimbursement models for *Entresto* that are similar to a pilot coverage program underway for its multiple sclerosis therapy *Gilenya*. Such an approach might involve a lower wholesale acquisition cost, company executives said, but Novartis would receive additional payment if a certain cost reduction threshold is met. No performance based contracts for *Entresto* have been

announced to date. However, a technology assessment of the drug by the independent Institute for Clinical and Economic Review modeled the potential savings that might result from a performance based contract. In the risk sharing arrangement envisioned for *Entresto*, payers would not have to pay for the drug for six months if a congestive heart failure hospitalization occurs following initiation of treatment. If a patient on the drug dies of cardiovascular disease, any payments made in the previous six months would be refunded.

The US Pharmaceutical Research and Manufacturers of America (PhRMA) is advocating regulatory changes that might facilitate innovative contracting, such as relaxing FDA restrictions around communications between biopharma manufacturers and payers about the value of treatment. It is promoting the idea that manufacturers should be able to provide more information to payers and other health care professionals before a drug is approved, to allow them to better prepare for the expense of a new treatment. After a drug is approved, manufacturers should be able to proactively go to payers and discuss outcomes that are not necessarily part of the approved label, such as a reduction in hospital stays, according to the organization. Nevertheless defining patient endpoints is a key part of any risk sharing arrangement and that many outcomes based contracts in the past have failed because of disagreements between manufacturers and payers over measuring endpoints. The reality is that every single one of these experiments has collapsed under its own weight because the administrative overhead consumed the potential savings.

In Brief...

- ◆ **Cardinal Health** reported a 23% increase in revenue, to US\$31.4 billion, and a 3% increase in operating earnings (to US\$563 million) for its fiscal 2nd quarter. Pharmaceutical segment revenue increased 25% to US\$28.3 billion with the segment's profit increasing 16% (to US\$627 million) in the period while Medical segment revenue increased 9% to US\$3.2 billion with profits of US\$106 million (-8%), including a Cordis-related inventory adjustment.

- ◆ **McKesson's** revenues rose 3% to US\$47.9 billion for its 3rd quarter ended December 31. Distribution Solutions revenues were US\$47.2 billion for the quarter, up 3% on a reported basis and up 6% on a constant currency basis. Separately, the company's **Celesio AG** business announced that it would sell its Brazilian businesses, including Panpharma and Oncoprod, to **SC Participações Empresariais** (Brazil) for an undisclosed sum.

- ◆ **Celesio** reported group revenue of €16.2 billion / US\$ 16.7 billion, up 6.8%, for the first 9 months of fiscal 2016. Adjusted earnings before interest and taxes (EBIT) increased 7.8% to €343.5 million / US\$375.1 million for the period.

- ◆ **YLOG Industry Solutions**, the specialist in customized logistics solutions within the KNAPP Group which was formed in 2013 and is headquartered in Dobl, Austria, has been renamed **KNAPP Industry Solutions**, effective immediately. The KNAPP Group is also expanding its sector focus with its core sectors of pharma, fashion, retail and food retail now joined by a new core sector - industry.

(Sources: Cardinal Health, Celesio, Drug Store News and Knapp)