

Japan's Ministry of Health, Labor and Welfare Sets Out to Define Wholesalers' Role

(Source: A staff article in Pharma Japan)

Japan's Ministry of Health, Labor and Welfare (MHLW) plans to spell out the essential roles being played by drug wholesalers in its new pharma industry outlook due out this summer. This new vision aims to foster appropriate price-setting in their transactions with drug makers and healthcare customers.

Toshihiro Hayashi, Director of the Economic Affairs Division of the Health Policy Bureau, revealed the plan in a recent interview with Jiho. "Under universal health coverage, Japanese people can receive insured medical care and drugs at any medical institution or pharmacy across the country with their insurance cards alone. For that to happen, the role of wholesalers taking on stable drug supplies is crucial," Mr Hayashi stressed. "By clarifying this point in the vision, we want medical institutions, pharmacies, and manufacturers to boost recognition on that," he added.

Mr. Hayashi also said that wholesalers are not only taking on the function of drug distribution but also price formation in the market. "In addition to these two functions, their financial functions, among other add-on functions, will also be included in the vision," he noted.

The MHLW believes that the move would help drug makers and purchasers understand what is necessary in the distribution environment for wholesalers to stay in business, and by extension, would promote appropriate price negotiations in both upstream and downstream transactions.

To create an environment that helps wholesalers more proactively lead price talks, Mr. Hayashi also said that the MHLW will clarify a policy to promote single-product, single-price "negotiations" in the planned revision of the Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs this fall.

The current guidelines call for raising the "ratio of single-product, single-price contracts" versus overall drug transactions. While the MHLW has seen a rise in this ratio, Mr. Hayashi said that single-product bundling (product-by-product discounting) practices are present in actual negotiations - where haggling takes place over the total price of a transaction, rather than the unit price of each product, which will be set later by wholesalers to match the total sum. Such pricing is not necessarily based on the value of each medicine, running counter to the principal of value-based price-setting.

At a meeting of the "Ryukaikon" council for the improvement of the drug distribution environment early this month, the Federation of Japan Pharmaceutical Wholesalers Association (JPWA) stressed the need for a survey on such trade practices. "We'll be conducting a survey to capture the actual state of negotiations based on the request at Ryukaikon," Mr. Hayashi said

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In Brief...

- ♦ **Moderna** confirmed that it plans to expand the size of its clinical trial testing for its Covid-19 vaccine in kids ages 5 to 11. The U.S. drugmaker is expanding the trial, which began in late March, to increase the likelihood of detecting potential rare side effects. Moderna is actively discussing a proposal with the U.S. FDA, according to company officials, and expects to have a package that supports authorization in late 2021/early 2022, should the FDA choose to use the authorization avenue.
- ♦ Korea's leading pharmaceutical companies are quickly entering the Covid-19 diagnostic kit distribution business. Their move came as the fourth wave of the virus outbreak recently hit the nation despite the increasing rollouts of vaccines. The need for screening asymptomatic Covid-19 cases has also risen. Local drugmakers said they would utilize their existing distribution channels to provide diagnostic kits for pharmacies.
- ♦ Global healthcare company **AmerisourceBergen** has been named a 2021 honoree of "The Civic 50 Greater Philadelphia" by the **Philadelphia Foundation** in partnership with Points of Light and local partners. Modeled after Points of Light's national program, The Civic 50 Greater Philadelphia provides a standard for corporate citizenship and showcases how employers use

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As Cases of the Delta Variant Rise Globally, Policy Changes Loom on the Horizon

(Sources: Articles from CNBC, FiercePharma, Health and Science, and Reuters)

The rise in cases of the delta variant of COVID-19 has governments around the world re-evaluating their current recommendations and policies. Experts say COVID prevention strategies remain critical to protect people from the virus, especially in areas of moderate-to-high community transmission levels.

Only this week, the U.S. Centers for Disease Control announced recommendations for fully vaccinated people to begin wearing masks indoors again in places with high COVID-19 transmission rates. The updated guidance comes ahead of the fall season, when the delta variant is expected to cause another surge in new coronavirus cases and many large employers plan to bring workers back to the office.

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Japan's Ministry (cont.)...

in the interview. No decision has been made as to the timeline according to Hayashi.

In the revision of the guidelines, the MHLW plans to stress the importance of wholesalers presenting and explaining the prices that include distribution costs. Commenting on the rationale behind it, Hayashi said, "One of the cruxes of the problem is that parties see discounting as a foregone conclusion in price negotiations. In these negotiations, they might lack the perspective of (buyers) shouldering necessary costs including distribution costs, he said. "How we can realize reasonable delivery price formation, including the negotiation process for delivery prices, will hold the key?"

Mr. Hayashi also touched on growing calls for discussions on the 2% price adjustment rate. "We are not quite sure how discussions will evolve going forward. It depends also on future arguments by members representing each party at the Central Social Insurance Medical Council (Chuikyo)," he said.

In market price based NHI price revisions, new NHI prices are usually set based on products' market prices plus the customary addition of the 2% adjustment rate. This rate, previously called the "reasonable zone (R-zone)" is generally considered as a cushion for the price reduction rate to ensure stable drug distribution. With the rate unchanged at 2% for as long as two decades, calls are growing for its fundamental review, particularly from the Ministry of Finance (MOF) and payer reps on Chuikyo.

"It's highly likely that there will be discussions on the adjustment rate. How we can convince parties on the validity of the 2% rate is a very difficult question, and we are discussing within the MHLW the types of documentation that should be presented moving forward," Mr. Hayashi said.

Delta Variant (cont.)...

U.S. officials are pleading for Americans to get vaccinated against the delta variant, which is highly infectious.

People infected with the delta strain can carry up to 1,000 times more virus in their nasal passages than those infected with the original strain, according to new data.

Health experts fear that the delta variant, already dominating the surge in COVID cases, is hitting states with unvaccinated populations the hardest. The reinstatement of mask mandates, capacity limits and other public health measures is likely in the coming weeks and months.

In India, which has suffered enormously with cases of the delta variant, there is a rush by officials to vaccinate as much of the population as quickly as possible. The Indian government expects to have around 150 million COVID-19 vaccine doses in August, and India will meet its target of supplying more than half a billion COVID-19 vaccine doses by the end of this month, according to officials.

The delta variant was first detected COVID-19 cases in the country. Since then, the highly infectious strain has spread globally.

The variant has usurped the previously dominant alpha variant, first detected in the U.K. last fall, and has prompted further waves of infections in Europe and an ominous incline in cases in the U.S.

England's experience during the pandemic has been viewed as a harbinger for the U.S. and other countries, offering insight

into how new strains of the virus may spread. "I think the more observable trend is what's going on in the United Kingdom, where cases are clearly coming down at this point. There's a very clear trend down. It seems like they've peaked," former U.S. FDA director, Scott Gottlieb said in a recent interview.

The U.K.'s seven-day average of new infections reached roughly 47,700 on July 18, after a steady increase beginning in late May, according to government data. Cases have started to fall in recent days, with 29,173 being reported Sunday.

The World Health Organization has already warned that, based on the estimated transmission advantage of the delta variant, "it is expected that it will rapidly outcompete other variants and become the dominant circulating lineage over the coming months."

In its latest weekly report issued July 26th, the WHO noted that as of July 20, the prevalence of delta among the specimens sequenced over the past four weeks exceeded 75% in many countries worldwide including Australia, Bangladesh, Botswana, China, Denmark, India, Indonesia, Israel, Portugal, Russia, Singapore, South Africa, and the U.K.

In Brief (cont.)...

their time, skills, and resources to drive social impact in their communities and company.

- ◆ For the sixth consecutive year, **McKesson** was honored as one of the "Best Places to Work for Disability Inclusion" by Disability Equality Index (DEI). McKesson also earned a top score of 100% for displaying best-in-class commitments to culture and leadership, accessibility, strong employment practices, community engagement and supplier diversity.

- ◆ The first COVID-19 vaccine doses donated by Japan to the **Gavi COVAX Advance Market Commitment** have been shipped, with the first shipments arriving in Cambodia, Bangladesh and Iran. These deliveries are part of a donation of over 11 million doses of the **AstraZeneca** vaccine to countries across Asia, the Pacific Islands and other regions.

- ◆ U.S. President Biden issued an "Executive Order on Promoting Competition in the American Economy." The Order focuses on antitrust issues and contains provisions directly affecting pharmaceutical companies and pharmaceutical pricing. The Order states that Americans are paying too much for prescription drugs and healthcare services. It further states that patent laws have been misused to inhibit and delay competition from generic drugs and biosimilars, thus denying Americans access to lower-cost drugs. The Order indicates that the Administration will support aggressive legislative reforms that would lower prescription drug prices, including allowing Medicare to negotiate drug prices.

- ◆ The U.S. is helping to address the shortfall in available COVID-19 vaccines in Africa with a US\$200 million investment in an **Aspen Pharmacare** manufacturing facility in South Africa. The investment will allow the plant to expand its capacity beyond its current rate of 300 million doses per year. Aspen, the largest pharmaceutical company in Africa, produces the **Johnson & Johnson** vaccine in the port city of Gqeberha, formerly Port Elizabeth, in South Africa's Eastern Cape. J&J and Aspen announced their vaccine partnership in November of last year.

(Sources: FiercePharma, Korean BioPharma Review, Press Releases, Reuters and World Pharma News)