



FOCUS



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Japan to Create Expert Panel for Drug Distribution and Pricing

(Source: An article by Izuru Ando for Pharma Japan)

Japan's health ministry plans to set up a new panel of experts to discuss the ideal setup of drug distribution and pricing, with a goal of system reform. Health Minister Shigeuki Goto revealed the plan in a "kanmin taiwa" public/private confab earlier this month.

The panel will be named the "expert panel on distribution and drug pricing system for prompt and stable supply of pharmaceuticals." Further details of the panel, including the discussion timeline and members will be decided under the supervision of a "councilor for pharmaceutical industry promotion and medical information," – a new post that will be created later this summer by the Health Policy Bureau.

The panel is expected draw up a report that will conceptualize the future structure and business model of the pharma industry, which will eventually be reflected in system reform discussions at the Central Social Insurance Medical Council, a reimbursement policy panel better known as Chuikyo, and other forums.

Points for discussion by the panel include: 1) the current status and challenges of the pharma industry and the drug wholesale industry; 2) the ideal distribution system and drug pricing system that ensures the quality and stable supply of pharmaceuticals as well as the sustainability of universal healthcare; and, 3) the ideal future of the pharma industry (industry structure and business model) that would drive sustainable growth.

At the public-private meeting, which included top ministry officials, industry leaders and academic representatives, Mr. Goto said, "We've recently seen issues affecting drug supplies to Japanese citizens, such as problems around quality assurance and supply disruptions as well as concerns about drug lags for new medicines." He continued, "To ensure the prompt and stable supply of needed medicines to Japanese people, we will set up a panel to deliberate on the ideal drug distributing and pricing system. We will promote broad discussions and pursue system reforms."

Industry organizations that joined the confab welcomed the launch of the new panel but made a variety of requests for topics to be covered during deliberations. Sunao Manabe, chairman of the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) said, "With the progress of digital transformations, we've seen significant changes in values that can be provided by healthcare stakeholders. We share the view that it's important to ensure the sustainability of universal healthcare, but if the government is to consider the scope of universal coverage, discussions should be held on issues other than drug prices as well."

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In Brief...

♦ Walgreens announced the launch of its clinical trial business, which the company said will "redefine the patient experience and increase access and retention in sponsor-led drug development research." The company also said that its flexible clinical trial model combines the company's vast foundation of patient insights, partner-enabled health and technology capabilities and in-person and virtual care options to break through barriers to encourage engagement of broader and more diverse communities. The introduction of Walgreens clinical trial offerings coincides with the **U.S. Food and Drug Administration's** recent steps to increase racial and ethnic diversity in clinical trials.

♦ **Pfizer Inc.** announced that it will further strengthen its commitment to U.S. manufacturing with a US\$120 million investment in its Kalamazoo, Michigan facility. This will further support its COVID-19 oral treatment *Paxlovid* tablet production. The investment will expand the production of active pharmaceutical ingredients and registered start materials used in manufacturing of *nirmatrelvir*, a novel main protease inhibitor originating in Pfizer's laboratories. Separately, Pfizer will invest US\$95.24 million to purchase 8.1% of French vaccines company **Valneva**. Valneva will use the proceeds from Pfizer's equity investment to support its Phase 3 development contribution to its Lyme disease program.

♦ A modified coronavirus vaccine that targets the Omicron variant can be administered as a booster dose to broaden immunity, a technical advisory group set up by the **World Health Organization** announced. Such a variant-adapted

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South Korea's SK Group Sees Significant Potential for Biotech Investment

(Source: An article by Jung Won Shin for Scrip Intelligence)

There is a trend for multinational pharma companies to go on a shopping spree for companies and technologies, while simultaneously trimming their own R&D operations. The need for partnerships and acquisitions to enrich their pipelines is rising as more approvals are coming from up-and-coming activities originally conducted by smaller companies.

In the past few years, big pharma may have been cautious about potential M&A targets due to the overpricing of bioventures. But major firms have become more active recently and are increasingly bringing in assets rather than pursuing in-house development, sometimes even buying a whole asset and using a consolidation strategy.

Korean conglomerate SK Group has been one such organization looking to make strategic investments in small- and

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Japan (cont.)...

Yasushi Okada, president of the Japan Pharmaceutical Manufacturers' Association (JPMA) praised the launch, saying "We clearly see 'system fatigue' with distribution and drug prices. It's time for a fundamental review." He also stressed the importance of setting KPIs when contemplating the future of the pharma industry, adding "How the category of innovative drugs, long-listed products, and generics should be structured effectively will be directly linked to how the industry structure should be. We are prepared to have thorough dialogues."

Responding to comments, Mr. Goto said, "We want to hold broad discussions on the healthcare system including the drug pricing system, rather than discussions on how to secure financial savings. It's important to look for the overall picture by having a vision on how to create a drug discovery ecosystem that takes advantage of the characteristics of universal healthcare."

SK Group (cont.)...

medium-sized biotechs, making it a priority over the next three years.

As an example, SK Biopharmaceuticals Co., Ltd. just two years ago began to independently sell the novel anti-epileptic *cenobamate* in the U.S.

"This [going it alone] was a huge challenge. It is tough but we are handling this to directly deal with the novel drugs by ourselves. We are on the right track but there are more obstacles to overcome and become a global top 50 pharma," remarked Donghoon Lee, executive vice president of SK Holdings Co. Ltd. (the holding firm for SK Group) at the recent Pharma/Biotech Development Strategy Forum led by the Korea Business Development Professional's Group.

SK set four major target investment areas three years ago – protein degraders, antibody technology, cell and gene therapy, and artificial intelligence/digital technology related to drug development. It has already made some investments in these categories, including in Hummingbird Bioscience and Roivant Sciences, and has now moved to the second stage of its broader strategy, which is focused on co-operation. As of last year, it is only investing money in assets that it intends to jointly operate.

The next stage for SK will be to acquire major stakes in companies with platform technologies. It is investigating potential domestic and foreign targets now and aims to expand its global base, set up relevant platforms and recruit top talent. Pursuit of innovation will also be needed to create the next innovative operation.

SK's goal is also to build business with partners. Its investment in Singapore-based antibody therapeutics firm Hummingbird Bioscience is an example of how SK desires to help these companies grow globally. In general, biotechs move fast, but big pharma has the deep resources needed to fund new innovation.

By SK seeking out good technologies at lower prices, it will create a design, build the process and support an "entrepreneur-in-residence" scheme similar to that adopted by other leading healthcare investment firms such as OrbiMed. This incubation concept will allow SK to help these companies build business both home and abroad.

In Brief (cont.)...

vaccine may benefit those who have already received the primary series of shots, the panel said, citing available data. The vaccines could be considered for use globally by the agency once they receive emergency use authorization or an approval by a stringent national regulatory authority.

♦ **GSK** has opened its US\$110.45 million new aseptic smart manufacturing plant in Barnard Castle, England. The facility, named *Q Block*, will center around both new and existing biologics in GSK's portfolio and pipeline. The plant will be fully automated and leverages digitalization to streamline the manufacturing process. This will allow GSK to speed up the launch of new medicines while cutting down on waste, according to a statement by *Regis Simard*, president of GSK's global supply chain.

♦ A new study from **Tel Aviv University** offers a new and unique treatment for AIDS which may be developed into a vaccine or a one-time treatment for patients with HIV. The study involves the engineering of type B white blood cells in the patient's body so as to secrete anti-HIV antibodies in response to the virus. The study (published in the journal *Nature*) was led by *Dr. Adi Barzel* and Ph.D. student *Alessio Nehmad*, both from the School of Neurobiology, Biochemistry and Biophysics and the George S. Wise faculty of Life Sciences and the Dotan Center for Advanced Therapies in collaboration with the Sourasky Medical Center, and conducted with additional researchers from Israel and the U.S.

♦ **Boehringer Ingelheim** announced the signing of an option to acquire **Trutino Biosciences**, a San Diego-based pre-clinical stage biotech company dedicated to the discovery and development of next-generation cytokine therapies to treat immune-oncology and autoimmune diseases. The partnership between Boehringer Ingelheim and Trutino is part of an effort to mobilize a patient's immune system to fight cancer through cell-directed and immune cell-targeting compounds. Under the agreement, Boehringer reserves the right to purchase all shares of Trutino once specified program milestones are achieved.

♦ The Japanese government plans to set up a new agency within the Cabinet Secretariat as part of its drive to reinforce "command tower" functions for pandemic responses, informed sources said. Announcement of the plan is expected shortly. The government also intends to reorganize the Ministry of Health, Labor and Welfare by establishing a new team to handle pandemic responses and crisis control, among other changes. The new team will be created by combining existing divisions relevant to these tasks.

♦ **Hanmi Pharmaceuticals** and South Korean telecom company KT announced a joint investment in digital therapeutics developer **Digital Pharm**, a subsidiary of the Catholic University of Korea's holdings company. Hanmi will focus on business development, marketing, sales and licensing capabilities it has accumulated in the traditional pharmaceutical market while KT plans to establish Digital Pharm's business-to-consumer and business-to-business strategies, and focus on digital therapeutics platform development, as well as various technology-intensive pipelines to promote sustainable growth by securing technology.

(Sources: *Drug Store News*, *FiercePharma*, *Korean Business Review*, *Press Releases*, *Reuters* and *World Pharma News*)