

## Japan Pharmaceuticals Market – Distinguishing Features and Industry Practices Episode Guide

### ■ Overview of pharma industry in Japan

### Overview of pharma industry Japan

The Japanese market accounts for approximately 7% of the global pharmaceuticals market and is the third largest market in the world following the US and China. A snapshot of Japanese Pharma industry is as follows:

#### 1. NHI System

- Japan has a universal health insurance scheme (National Health Insurance, "NHI"), under which all Japanese citizens and residents must be enrolled in national health insurance and pay a medical insurance. NHI contributes to the delivery of high-quality medical services and products to patients in Japan.
- Under the NHI system, the price which is reimbursed by the NHI is determined for each and every pharmaceutical product approved for sale in Japan ("yakka" or "NHI Price" in English), which is the basis for the pricing of the pharma products to be sold by pharma companies to wholesalers.

#### 2. Generic drugs

- In the past, prescription of generic drugs was not so prevalent in Japan. The market share of generic drugs was lower than 50% in terms of volume in 2014; however, as a result of the government's initiative for promoting the use of generic drugs, the market share in January 2020 was 78%.
- The patent linkage system exists in Japan. If a valid patent exists for an innovative drug, the Ministry of Health, Labour and Welfare of Japan ("MHLW") will not approve the generic equivalent.

#### 3. Drug approval system

- Similar to the system in other jurisdictions, pharmaceutical companies wanting to market product in Japan have to conduct the necessary clinical trials pursuant to Japanese GCP and then, based on the resulting efficacy and safety data, apply for approval from the MHLW.
- An entity which manufactures or imports a pharmaceutical product and sells the product in Japan needs to obtain the requisite approval. A "Marketing Authorization Holder" is primarily responsible for distribution of the approved product in Japan.

#### 4. Supply chain

- All drugs are supplied to hospitals and pharmacies by wholesalers. There is no direct sale by pharmaceutical companies to hospitals.
- Hospitals want to buy product at the lowest price possible and this drives fierce price competition among wholesalers. So wholesaler profit margins are generally razor thin and in some instance they make no margin and even suffer a loss. To survive, they basically negotiate either discounts or rebates with the pharmaceutical companies.

#### 5. Sales Promotion

- Pharmaceutical companies engage in sales promotion targeting hospitals. Sales promotion is handled by "Medical Representatives" or "MRs".

#### 6. Digital transformation

- Pharmaceutical companies are making significant investments in digitalization of various aspects of the business. The new trend gives rises to a number of new issues including data privacy and regulatory issues.

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