

September 4, 2020

EFPIA Japan

Statement on the Vaccination System under COVID-19 pandemic

Due to the COVID-19 pandemic, many people around the world continue to lose their health and lives.

In addition, we will enter the 2020-2021 infectious disease season with no established COVID-19 vaccines or treatment. If respiratory infections, such as influenza, becomes an epidemic at the same time as COVID-19, the impact on the medical system will be significant due to increased burden on the medical site that undertakes diagnosis and treatment. In order to protect the health of the people and the medical site, we must urgently promote the development of an environment in which all people from children to the elderly understand the significance of vaccination and receive vaccination (Life course immunization).

- **Propose to develop a system that promotes fundamental understanding of the effectiveness, safety, and necessity of vaccination.**
- **Promote the establishment of a system to promptly and comprehensively evaluate the efficacy and safety of vaccines**

Under such emergency state never experienced before, COVID-19 vaccine development by EFPIA member companies is proceeding at a rapid pace with unprecedented collaboration between industry, government and academia. (Introduction of member companies' efforts for COVID-19: <http://efpia.jp/covid-19/index.html>)

EFPIA aims to distribute vaccines promptly and equitably around the world, once COVID-19 vaccine obtains manufacturing approval. However, there are several issues that impede the introduction of imported vaccines to Japan, which we believe needs to be considered in advance in order to promptly deliver COVID-19 vaccines to the Japanese people.

- **Promote international harmonization of domestic regulations related to quality (test items and standard setting by the Japanese Pharmacopoeia and MRBP) .**
- **Propose a system that allows vaccination to start immediately after COVID-19 vaccine manufacturing approval by establishing operational standards that clarify the roles of vaccination personnel**

EFPIA Japan will strengthen cooperation with all stakeholders involved in infectious disease control based on four urgent proposals.

Propose to develop a system that promotes fundamental understanding of the effectiveness, safety, and necessity of vaccination, rather than a temporary epidemic prevention boom due to the COVID-19 pandemic. Improving the understanding of vaccination for adults and the elderly is particularly urgent.

- **Enhancing awareness of vaccination for the public**
Preventing infectious diseases means not only protecting one's own health, but also

family and society. As vaccination is not “non-essential and non-urgent”, stakeholders need to work together to disseminate the importance of not missing vaccination opportunities. However, it is generally not easy to access the right information about vaccines and diseases, so there is an urgent need to take measures to connect physicians who are partners in preventive medicine with every citizen.

– ***Formulation of two-way communication guidelines for physicians***

Vaccination is the most effective measure to prevent infectious diseases, but at the same time, all vaccines that have shown effectiveness also have side reactions. We will initiate industry-government-academia discussions to develop guidelines for a two-way communication between physicians and vaccine recipients for the recipient's understanding. To start, we will summarize the minimum required communication guidance under emergency.

– ***Enhancing infection prevention measures at clinics for vaccination***

Many pediatrics have already taken infection prevention measures in clinics by distinguishing the time and place of medical consultation and vaccination. Due to ongoing concerns over COVID-19, clinics need further control over infections. Clinics such as internal medicine that vaccinate adults and elderly need to take new infection control measures. However, as internal medicine conduct a much smaller number of vaccinations than pediatrics, it is desirable to secure a budget to support strengthen the vaccination efforts at medical institutions.

– ***Enhancing awareness of vaccination information for physicians***

In order to promote vaccination of adults and the elderly, it is necessary for doctors, nurses, pharmacists, and other physicians who prepare and inoculate to understand the basic knowledge of vaccines and points to note when performing vaccinations. In order to support this, we have to develop an educational mechanism for physicians to reconfirm their knowledge.

Promote the establishment of a system to promptly and comprehensively evaluate the efficacy and safety of vaccines.

– ***Enhancing of epidemiological survey system***

In order to evaluate the efficacy and safety of vaccinations, there is an urgent need to enhance epidemiological surveys. In addition, it is required to construct a database that maintains vaccination records, medical receipt information and side reaction reports. This allows for large scale post-market monitoring at all times. Database enhancement will effectively support the vaccine development needed in Japan even at normal times.

– ***Establishment of an organization directly controlled by the Government make comprehensive vaccination decisions***

In the event of a life-threatening situation, economic crisis or a great amount of social loss or burden due to the rapid spread of infectious diseases, it is necessary to establish an organization directly controlled by the Cabinet that is organized across industry, government, academia and ministries. Based on comprehensive verification of social situations, it is desirable to make swift political decisions regarding the establishment of vaccine R&D/manufacturing system and the setting of vaccination recommendations.

– ***Establishment of vaccination centers in all prefectures***

Enhancing communication between companies and physicians and between

physicians and vaccination recipients is important for safe vaccination. In addition, it is necessary to clarify the contact point for various consultations (including side reactions) regarding vaccination. The establishment of vaccination centers in each prefecture that plays a role in leading regional vaccinations not only during normal times but also during emergencies should be promoted.

Promote international harmonization of domestic regulations related to quality (test items and standard setting by the Japanese Pharmacopoeia and MRBP) in order to shorten the lead time that occurs after importing the COVID-19 vaccine.

– ***Harmonize Japanese original test items and standards (i.e. abnormal toxicity test) with international standards***

Due to the increasing demand for COVID-19 vaccines worldwide, it is necessary to promote harmonization of regulations, which is a major obstacle in considering the supply of vaccines to Japan. In particular, by making the standard test items consistent with overseas standards, additional tests to obtain test results for new applications and after importation becomes unnecessary. Most self-tests were significantly reduced when MRA became applicable for vaccines. However as it is still necessary to conduct an additional self-test in Japan for items set by the requirements of Japan only, its consideration should be done immediately.

Due to the existence of Japan's unique standards, it will take substantial time to comply when there are any changes in international or overseas standards.

– ***Allow batch release testing of imported vaccines by inspecting only SLP documents***

For products that have received a certificate after being tested by EU member state authorities, we recommend exempting the region test and performing only SLP-based document inspection. Currently, many of the COVID-19 vaccines are in the development stage and it is estimated that the effective period of the vaccine will be limited when it is introduced into Japan. By adopting the aforementioned method, lead-time in units of several months can be shortened while still maintaining quality standards. As such, it becomes possible to stably supply products with a longer shelf life to the Japanese population.

Propose a system that allows vaccination to start immediately after COVID-19 vaccine manufacturing approval by establishing operational standards that clarify the roles of vaccination personnel.

– ***Preparation of vaccination system in emergency situations***

Emergency vaccination is different from usual, as it is necessary to establish a system for many people to be vaccinated across the country in a short period of time. For example, it is necessary to urgently prepare a vaccination system manual, such as establishing a vaccination system for group vaccination and establishing a vaccine supply/distribution method.

– ***Clarification of vaccination policy in emergency situations***

Even if the total volume of COVID-19 vaccines can be secured for all Japanese population, there are restrictions due to amount of vaccine that can be supplied at a time and the vaccination environment. As such, it is necessary to determine the

priority of vaccination in consideration of these factors and to obtain a sufficient understanding of the people in advance with clear reasons.

– **Securing budget for emergency vaccination**

When performing emergency vaccination, it is necessary to establish a system that is different from the usual. The government should secure the budget necessary for system development in order to maintain fairness among local governments.

– **Support for health hazards caused by emergency approved vaccines**

The government should create or leverage existing no-fault compensation systems to provide speedy, accessible and effective compensation to parties suffering serious physical injury or death validly attributable to a COVID-19 vaccine, and provide protection from civil liability (not indemnification) to all parties involved in the development, manufacturing, distribution, funding, procurement and deployment for vaccines administered during the pandemic period.

About EFPIA Japan (<http://efpia.jp/>)

Established in April 2002, EFPIA Japan represents 21 R&D-based European pharmaceutical companies operating in Japan. In 2019, combined sales from the member companies accounted for roughly 23% of the pharmaceutical market in Japan. The mission of EFPIA Japan is to “Contribute to healthcare and patients in Japan through the early introduction of innovative medicines and vaccines”. EFPIA Japan aims to strengthen dialogue with decision-makers in order to improve Japanese healthcare for all.

About EFPIA (European Federation of Pharmaceutical Industries and Associations)

(<http://www.efpia.eu>)

EFPIA, EFPIA Japan’s partner organisation, is headquartered in Brussels and represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 39 leading pharmaceutical companies, EFPIA provides the voice of companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world.