After weathering the COVID-19 pandemic for more than a year, Taiwan has since early last month been hit by a wave of local infections. Before then, few people were concerned about vaccines, but the issue has suddenly become the focus of public attention. The urgency of obtaining vaccines has been much discussed, but many do not understand the peculiarities of the vaccine industry, or international vaccine supply and demand amid a pandemic.

Taiwan's epidemic prevention policy over the past four decades has been oriented toward public health — from the control and prevention of hepatitis B in the early 1980s and the local development of an avian influenza vaccine in the early 2000s to the development of enterovirus vaccines — with emergency situations receiving temporary policy support, but support for vaccine development ebbed as the epidemics subsided.

Over the past decade, there have only been a handful of domestic vaccine manufacturers, but they have played an important role in public health by supplying influenza vaccines. Two domestic enterovirus vaccines even entered phase 3 clinical trials.

Taiwan's excellent performance at disease prevention since the beginning of last year had given Taiwanese peace of mind as they went about their daily lives, and the recent outbreak has led to the public demanding that the government obtain an adequate supply of vaccine doses.

The market for COVID-19 vaccines is still a seller's market, with each major international player — Europe and the US on the one hand, and China and Russia on the other — following its own approach. Taiwan has struggled to find a vaccine source in the European and US supply chain.

However, those not involved in the negotiations cannot understand the hardships faced by officials. Once the outbreak has been effectively controlled and the nation's vaccine needs softened, the government should establish a vaccine industry policy based on national security.

The Taiwanese vaccine market, with a population of 24 million, is not large enough to support

an internationally competitive vaccine industry. Even in South Korea, whose population is more than double Taiwan's, vaccines at this stage are produced by contract manufacturers for international pharmaceutical companies.

Local vaccine manufacturers Medigen Vaccine Biologics and United Biomedical have conducted phase 2 clinical trials — some talk of them as phase 2/3 clinical trials — of a COVID-19 vaccine, with more than 3,000 participants. The nation would hopefully give them heartfelt support to avoid relying on foreign sources for vaccines in a future pandemic.

The vaccine industry must be positioned as one of the industries crucial to national security, and government policies must provide the industry with subsidies or tax incentives, as well as a guarantee of at least one-third to one-half of the domestic market to support normal production.

Regarding the need for vaccines, as the nation seeks sources, it should also pay attention to the nature of the vaccine industry.

The process of manufacturing vaccines at any pharmaceutical company follows a specific plan and timetable. There are basic elements that must not be ignored, such as quantity, batch number, batch production records, the original quality control inspection and qualification documents, and the cold chain records of the transportation process, among others.

Close cooperation with the Central Epidemic Command Center is still required after a vaccine shipment arrives at an airport, in the subsequent transportation, storage, distribution and administration stages. Perhaps a batch-by-batch emergency approach could be adopted, instead of being bound by administrative details such as, for example, the applicant's qualifications.

At this time of urgent need, the Food and Drug Administration ensures that the vaccine documentation confirms the quality and safety of the doses in accordance with the Regulations of the Lot Release Procedures for Biologics (□□□□□□□□□□□□□□). Because of the urgency involved, the release procedure — including testing items such as sterility and acute toxicity — should be synchronized with the distribution and transportation of the doses.

Although the release of a vaccine lot must comply with regulations, its execution should be more flexible in these extraordinary times. The batch quality control release document issued by the original manufacturer is sufficient to confirm the quality of a batch, and the inspection typically conducted only drags out the administrative process.

The release policy should be governed by a different mindset, and a batch-by-batch approach that fast-tracks the validation process should be adopted to promote a timely vaccine supply.

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