Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Commentary

Legal and regulatory processes for Japan's COVID-19 immunization program

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Immunizations have played a significant role in public health, with immense societal health benefits [1]. The vaccines for the coronavirus disease 2019 (COVID-19) have been developed with an unprecedented speed and several types of vaccine have been used worldwide [2,3]. In Japan, the vaccination program for COVID-19 started under the Immunization Act on 17 February 2021. Ahead of implementation of the vaccination program, the Government of Japan reformed the Immunization Act and related regulations, and granted special approval for emergency use to Tozinameran COVID-19 mRNA Vaccine, manufactured by the Pfizer-BioNTech. This article describes the reformed Immunization Act and the procedure of the special approval for emergency use in Japan.

The act was revised in December 2020, since the vaccinations implemented by the national government need to be stipulated in the Immunization Act of 1948. COVID-19 vaccines were added to the category of "Temporary Vaccinations" in this revised Act, which is intended for "immunizations with an urgent need for prevention". Through this reform, the national government can take urgent steps of securing, allocating, and distributing vaccines, and cooperates with the prefectural and municipal governments in implementation of the program. All the residents in Japan are eligible to receive the vaccines free of charge. Since the COVID-19 has been posing enormous burden nationwide especially in terms of public health and economy, the expenditure for vaccination is covered by the national government.

Immunizations may cause serious side effects in extremely rare occasion, thus the no-fault relief system for vaccine injuries is written in the Act. However, for fear of legal risks of product liability, manufacturers may require indemnification in a procurement agreement. The COVID-19 vaccines have been developed at an unprecedented speed and are being manufactured on a massive scale. The vaccines are urgently needed to protect people's life and health, and there is a heavy demand globally. The revised Act enables the government to contract with the manufactures to compensate them in case they sustain certain losses, given the nature of the COVID-19 vaccines procured by the government, as this type of compensation is only available via our legal provisions. The scope of such indemnification shall be limited to the extent that Japanese citizens would consider it reasonable, such as the liabilities caused by unavoidable side effects, and it does not mean the government is willing to compensate for any possible liabilities incurred by the manufacturer.

The medications for COVID-19 have been reviewed with top priority and the Tozinameran COVID-19 mRNA Vaccine was approved under special approval scheme as the first COVID-19 vaccine in Japan on 14 February 2021. The special approval scheme can be applied to the pharmaceuticals for any urgent needs in the prevention of the spread of disease that may pose serious effects on lives and health of the general public, and when no alternative option is available. Furthermore, these pharmaceuticals need to be authorized in another country which has equivalent level of approval system to that of Japan. Four pharmaceuticals were approved as of 9 May 2021 since this scheme was established in 1996 (Table 1). In the review process, available data on nonclinical trials, clinical trials, quality and so forth was carefully evaluated. Prior to reviewing, the clinical trial for the Tozinameran COVID-19 mRNA Vaccine have been independently implemented in Japan, and its data was also evaluated in the process.

In addition to such legal and regulatory processes, a mountain of tasks such as technical issues for distribution, preparation for monitoring adverse events, and risk communication efforts were carried out simultaneously. The vaccination program is still in its early stages and the national government continues to work rigorously on this.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Table 1
List of pharmaceuticals approved under special approval scheme as of 9 May 2021.

No.	Manufacturer	General name	Date of application	Date of approval	Days from application to approval*
1	GlaxoSmithKline K.K.	Emulsified, Influenza A/H1N1 HA vaccine	16/10/2009	20/01/2010	97
2	Novartis Pharma K.K.	Emulsified, cell culture-derived, Influenza A/H1N1 HA vaccine	06/11/2009	20/01/2010	76
3	Gilead Sciences Inc.	Remdesivir	04/05/2020	07/05/2020	4
4	Pfizer Japan Inc.	Tozinameran COVID-19 mRNA Vaccine (nucleoside modified)	18/12/2020	14/02/2021	59

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