

Japan's attempts to import swine flu vaccine may be too late

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The Japanese government might not be able to import vaccine to combat the new type of influenza -- the H1N1 virus, or swine flu -- before autumn, when an epidemic of the disease is feared will intensify, as experts want pre-import confirmation that the vaccine is safe for Japanese patients, sources familiar with the matter said.

According to the sources, the three Western pharmaceutical companies that manufacture the vaccine have submitted terms of contract, among which the government is asked to exempt them from liability in case the vaccine causes side effects. Additionally, the firms indicated they would prioritize shipments to other countries unless the contract is signed by the end of this month.

The companies likely offered such tough terms because of expectations of a new-flu vaccine shortage around October or November, when the Northern Hemisphere enters its winter flu season.

Last month, Health, Labor and Welfare Minister Yoichi Masuzoe said the nation would need vaccine for 53 million people. The health ministry was negotiating with the foreign pharmaceutical firms to import 15 million to 20 million doses to cover an expected shortage that domestic makers cannot cover.

The ministry intends to accept the contract terms so it can import the vaccine as soon as possible, the sources said. Therefore, it asked a government advisory panel to examine the advisability of importing the



vaccine, which has undergone only overseas safety verification procedures, by applying the Pharmaceutical Affairs Law's "special approval" provision to this case, according to the sources.

However, many experts on the advisory panel opposed such a move, with one reportedly saying such approval cannot guarantee the safety of the vaccine because overseas vaccine-injection methods might be different from those of domestically produced vaccine, and foreign-made <u>vaccine</u> might contain immunopotentiating agents (that upon injection enhance <u>immune response</u>).

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