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## Opposition to reinstatement of the active recommendation of HPV vaccinations and call for relief for victims

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On November 12, 2021, an advisory board of the Ministry of Health, Labor and Welfare (MHLW) decided to resume the active recommendation of the HPV vaccines, which had been suspended since June 2013.

This decision was made despite victims of the vaccine were filing class action lawsuits seeking redress. We strongly oppose the decision. It is an unjust one that will leave a new stain on the history of Japan's pharmaceutical administration.

The advisory board states that information has been accumulated on the HPV vaccines' safety and efficacy. However, our opinion is that this is an inappropriate statement.

First, concerning the dangers of the vaccines, a number of studies were conducted by clinicians over the past eight years while active recommendation of the vaccines was suspended. These studies show that the symptoms of adverse reactions to the vaccines are multisystemic and complex, and that they are immune-mediated neurological disorders that cannot be explained by functional somatic symptoms as described by the advisory board.

The dangers are also reflected in the fact that the rate disability certifications in the compensation program of side effect of drugs is an order of magnitude higher than other vaccines.

The advisory board emphasizes the results of large-scale epidemiological surveys and states that the HPV vaccines are safe. However, these epidemiological approaches are poorly designed to detect signals of damage from the HPV vaccines, as such damage is characterized by a long-lasting, multilayered manifestation of symptoms. It is alleged that vaccine-induced adverse effects are more likely to occur in vulnerable populations who are more sensitive to immunological interventions, but these people make up a very small percentage of the general population. Therefore, epidemiological studies that simply compare the frequency of occurrence between vaccinated and unvaccinated groups or the general population are unlikely to show any statistically significant differences. The HPV vaccines cannot be considered safe based on arguments that misapply epidemiological and statistical analysis.

The advisory board pointed out that before resuming active recommendation of the HPV vaccines, there is a need to provide training for doctors at medical institutions designated by the MHLW for the treatment of adverse reactions of HPV vaccines, strengthen cooperation among related organizations including the Ministry of Education, Culture, Sports, Science and Technology and conduct medical treatment surveys at an appropriate frequency. It also pointed out the necessity to resume carefully, to evaluate adverse reaction reports more frequently, and to continue safety evaluations. There are no other routine vaccines that cannot be administered without such a system in place. This is because there are concerns that resuming active recommendation will lead to an increase in the number of victims of serious adverse reactions, and that appropriate measures will not be taken. This indicates that there are safety issues with the HPV vaccines.

On the other hand, on the efficacy side, the advisory board emphasizes recent studies from Sweden and the United Kingdom, which shows that the vaccine is effective in preventing cervical cancer. But cervical cancer has a long lead time (the period from viral infection to clinical detection) and it is not easy to evaluate the efficacy of the vaccine through rigorous randomized clinical trials. Therefore, in order to reach a conclusion more quickly, these studies were conducted using anonymized vaccination registries to capture a vast amount of data and compare the frequency of such things as cancer lesions. However, this method has serious problems such as bias due to economic and social factors that influence vaccination and non-vaccination, and bias due to differences in age structure. Therefore, the results of

these studies cannot be used to say that the HPV vaccines reduce cervical cancer incidence or death. It should also be noted that all these studies were conducted in women younger than 30, that cervical cancer is rare at this age, and that the results do not indicate a reduction in lifetime risk of developing cervical cancer.

It is a natural premise that the HPV vaccines have a certain level of preventive effect, since they are approved vaccines. Therefore, even if a study on the prevention of cervical cancer in women under 30 is reported more than 10 years after approval, it does not justify the vaccines' active recommendation. The question is whether their efficacy and safety have reached a level high enough for the government to actively recommend them as routine vaccines, imposing a duty of effort on the public. As we have already seen, HPV vaccines do not quite meet this requirement.

Instead, there should be more emphasis on screening tests that have no side effects and that have been scientifically proven to prevent cervical cancer.

In the international symposium "The Current Status of Worldwide Injuries from the HPV Vaccine" hosted by Medwatcher Japan in 2018, it was clear that victims from all participating countries shared the same characteristics of clinical symptoms. In all these countries, serious adverse reactions were also reported more frequently than other vaccines, health authorities disregarded victims' complaints, and victims were unfairly treated with social discrimination and labeled as anti-vaccine.

Victims of the HPV vaccines must receive full support in terms of financial and practical assistance. This will also help people restore their trust in vaccines.

Accordingly, we call on the MHLW to withdraw its decision to resume active recommendation and implement the following measures:

- (1) Conduct long-term follow-ups of those who received the HPV vaccines.
- (2) Establish a research team of doctors who have treated many victims of the HPV vaccine to promote research on effective treatments for adverse reactions.
- (3) Review the treatment system based on victims' opinions and take steps to support their lives, education and employment.

- (4) Review biased descriptions in current leaflets and provide sufficient information.
- (5) Review the relief system for HPV vaccine injuries and provide sufficient compensation.
- (6) Raise awareness to stop discrimination and slander against victims.
- (7) Promote cervical cancer screening.
- (8) Conduct a hearing for victims of adverse reactions to realize the above measures.