

<5th recommendation>

**Recommendation on the Reporting System of Adverse Reactions to Vaccines and
the Development of
Infrastructure related to Vaccine Risk Management in Japan**

<<Executive Summary>>

Introduction

Immunization is a key factor in preventing infectious diseases. “Vaccine gap” has mostly been filled, and inclusion of vaccines in the national immunization program has been promoted through the revision to Preventive Vaccinations Act in 2013. At the same time, many problems are yet to be solved regarding building a mechanism for efficient collection, evaluation, and provision of immunization-related information. We would like to make the following recommendations to people in general including healthcare providers, vaccine specialists, administrative authorities, and healthcare educators.

1. Legal matters

(1) Use of correct terms: At the Ministry of Health, Labour and Welfare’s Adverse Reactions to Vaccines Reviewing Committee, “adverse reactions,” “suspected adverse reactions,” and “adverse events” have not been appropriately used in a separate manner, which causes unnecessary worries and misunderstandings among people. This should be corrected.

(2) Clarification of the objective of the reporting systems: The criteria for unsolicited reporting are different in Preventive Vaccinations Act and Pharmaceuticals and Medical Devices Act. The objective of these systems should be clearly explained to ensure that each evaluation is conducted in accordance with the objective.

(3) Construction of the system for managing vaccination history: Information relating to vaccination rates and vaccination history is important for public health. The national government should digitalize, centrally organize and manage vaccination records using “MY NUMBER*” (national identity number) and other methods, and maximize its value as an infrastructure for scientific risk managements.

(4) Enrichment and effective use of health survey following vaccination: The significance of the survey has changed after it became a requirement by the revised Preventive Vaccinations Act in 2013 to report suspected adverse reactions. The survey should be revised so that healthcare providers and people can utilize its result effectively.

(5) Enrichment of relief service system for adverse health effects: Enrichment of and offering relief service system is important for the peace of mind of the people. While reviews of relief applications should be accelerated, it is also important to offer information about the current relief service systems for regular and optional vaccinations in a way to gain full understanding of vaccinees.

2. Enrichment of information provided by the central government

(1) More flexible operation of the Adverse Reactions to Vaccines Reviewing Committee: Efficient management of the **Adverse Reactions to Vaccines Reviewing Committee** should be considered by taking measures such as making explanation materials available in advance and inviting companies to the meetings.

(2) Provision of appropriate information: In Japan, people are required to make an effort to receive vaccination, but ultimately, the decision is up to vaccinees and their parents. The national government (National Institute of Infectious Diseases, etc.) should, from a neutral standpoint, offer reliable information about vaccination benefits and risks in a plain and prompt manner. It is also desired that appropriate information including background should be actively offered to news media. In view of globalization, a summary of materials from the **Adverse Reactions to Vaccines Reviewing Committee** should also be made available in English.

3. Improvement of education

(1) Ensuring that healthcare providers are fully aware of Preventive Vaccinations Act and Pharmaceuticals and Medical Devices Act: Reporting of suspected adverse reactions is essential for improving healthcare and is an important responsibility of healthcare providers. Healthcare providers should be fully informed of the details and significance of the reporting system through educational programs for those who are about to start working in a clinical setting and at the time of legal revisions.

(2) Cultivation of experts on evaluation of adverse reactions to vaccines and their use: Evaluating individual cases and accumulated data requires different skills. Medical, chronological and geographic validities should be considered. Vaccines' main effects and adverse reactions are both related with immune response. Molecular biological and physiological knowledge is required to evaluate medical validity. The national government should positively foster epidemiologists, who have knowledge about immunology, molecular biology, and physiology and are familiar with vaccine science, as "specialists of adverse reactions to vaccines" from a long-term standpoint.

(3) Enriching vaccine education at school: The Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare are expected to work jointly to enrich vaccine education in compulsory education for all the people and specialized education for healthcare providers.

* MY NUMBER: MY NUMBER (national identity number) is assigned to each person holding a resident card and is used to efficiently manage information in the areas of social security administration, taxation, and disaster response and tie personal information owned by different organizations. Under the law, each person will be notified of My Number in and after October 2015.