

Medical Safety Information

Pharmaceuticals and Medical Devices Agency



No. 40 October 2013

Precautions in the Handling of Vaccines

POINT Key points for safe use

(Case 1) A measles-rubella (MR) vaccine was mistakenly administrated to the recipient, instead of the Japanese encephalitis (JE) vaccine due to a medical staff assumption.

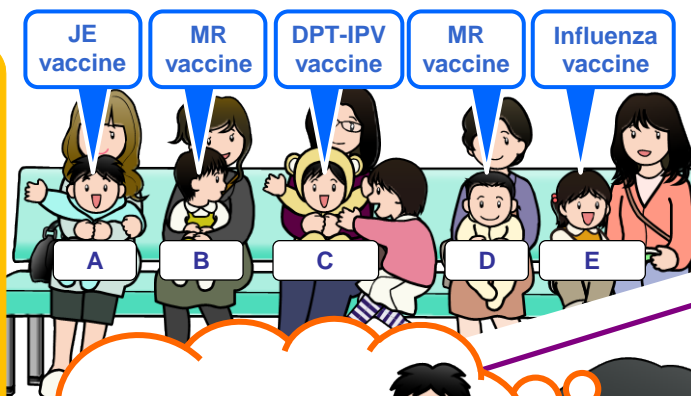
1 Vaccine recipient mix-up

- In advance, ensure the 5Rs, and ask the vaccine recipient or his/her guardian which vaccine he/she will receive.

Pre-vaccination 5Rs

- 1 Right Drug
- 2 Right Dose
- 3 Right Route [Subcutaneous or Intramuscular]
- 4 Right Time
- 5 Right Recipient

- 6 Ask the vaccine recipient or his/her guardian directly about which vaccine he/she will receive!



MR vaccine for A

JE vaccine for B

A number of people may visit to receive a specific vaccine at once depending on the time of year. In haste or based on assumptions, vaccine recipients have been mixed up.

(Case 2) A number of people were at the clinic to receive vaccines. The DPT-IPV (4 combined) vaccine was administered by mistake instead of the DPT (3 combined) vaccine due to a similar package color.

2 Vaccine product mix-up

Examples of vaccine products with similar appearance or color

DPT-IPV (4 Combined) Vaccine

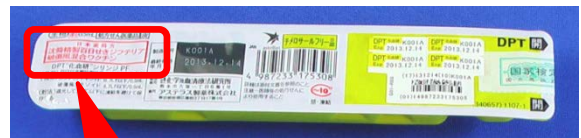


Adsorbed Diphtheria-Purified Pertussis
-Tetanus-Inactivated Polio
(Sabin Strain) Combined Vaccine

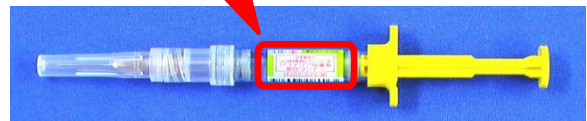


Quattrovac

DPT (3 Combined) Vaccine



The Japanese Pharmacopoeia
Adsorbed Diphtheria-Purified
Pertussis-Tetanus Combined Vaccine



DPT "KAKETSUKEN"
Syringe PF

Japanese Encephalitis Vaccine



Freeze-Dried, Cell Culture-
Derived Japanese Encephalitis
Vaccine (Inactivated)

ENCEVAC

Influenza HA (Seasonal) Vaccine



Influenza HA
Vaccine

INFLUENZA HA
VACCINE "BIKEN"

Mumps Vaccine



Freeze-Dried Live
Attenuated Mumps
Vaccine

Freeze-Dried Live Attenuated
Mumps Virus Vaccine
"Kitasatodaiichisankyo"

There are different vaccine products
with **very similar appearance or label color**.
Please pay attention and check before use.

















Colors of vaccine product labels and containers



An identical color is used for the label and container of vaccine products of the same type. **Make sure to check the label** to avoid mix-up!

Colors of vaccine product containers (for routine vaccination)

Excerpt from FY2013 version:
Written and edited by The Review Committee for Vaccination Guidelines
Published by Public Foundation of the Vaccination Research Center

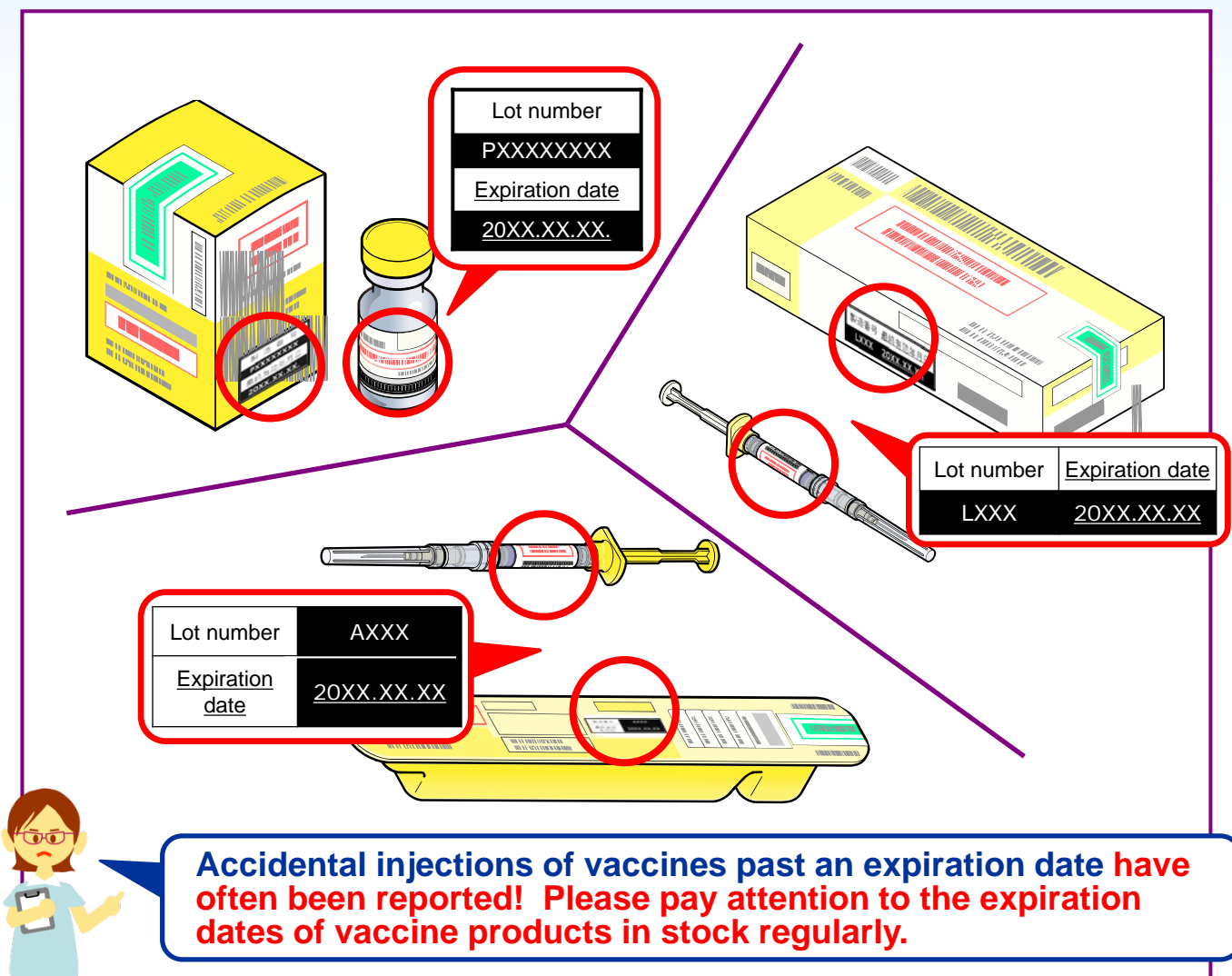
Tuberculosis (BCG)  Blue	Measles  Orange	Rubella  Pink	MR (Combined Measles-Rubella)  Creamy brown
Hib (Haemophilus influenza type b)  Bamboo green	Japanese Encephalitis  Light purple	Pneumococcus  Blue	DT (Combined Diphtheria-Tetanus)  Grass green
Inactivated Poliomyelitis  White	Bivalent HPV (Human Papillomavirus)  Orange	DPT (Combined Diphtheria-Pertussis-Tetanus)  Yellow	
Influenza HA (seasonal)  Aqua	Quadrivalent HPV (Human Papillomavirus)  Cool green	DPT-IPV (Combined Diphtheria-Pertussis-Tetanus-Polio)  Beige	

Note) Colors of active products may slightly differ from the pictures shown.

(Case 3) Vaccines past an expiration date were accidentally injected.

3 Accidental use of vaccines past an expiration date

- **Make sure to check the expiration date before vaccination.**



About this information

- * PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.
- * We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- * This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.