Precautions in Handling of Drug Products Attached with Reconstitution Solution

Key points for safe use

(Case 1) A resident was instructed to administer an intravenous steroid injection to a patient. However, the resident administered only the reconstitution solution to the patient for consecutive days.

Handling precautions (part 1)

- Before injection, be aware that some injection drugs come with reconstitution solutions to be mixed. Make sure to check the label.

Cases of administering the reconstitution solution alone have been reported in these products. Many other injection drugs come with reconstitution solution. The drug formulary should be checked to take preventive actions against dosing errors.

Note) Photos showing Japanese products.
Cause of dosing errors: package types

There are a variety of types of product packages. Be careful not to take out only the reconstitution solution from the box!

In some cases, only the reconstitution solution was taken out of the emergency cart by mistake and administered.

Storing the drug and the reconstitution solution together as shown in the right could be helpful to avoid dosing errors!

**Example 1**
Keep the vials together with a rubber band.

**Example 2**
Circle individual pairs with a marker pen.
(Case 2) A pharmacist dispensed to the ward only the reconstitution solution, which should be mixed with BESTRON FOR OPHTHALMIC. A ward nurse administered only the reconstitution solution to the patient for consecutive days without being aware of it.

2 Handling precautions (part 2)

- Before use, be aware that some topical drugs come with reconstitution solutions to be mixed. Make sure to check the label.

The following ways could be helpful to indicate whether or not the drug has been dissolved in the solution!

- Write the date on the label after dissolving the drug.
- Put a sticker on the cap after dissolving the drug.
- Put a sticker on the container to indicate the drug has been dissolved in the solution.

Note) Photos showing Japanese products.
Handling precautions (part 3)

- When the drug and the reconstitution solution are stored separately due to different storage temperatures, caution should be exercised to avoid using only the reconstitution solution.

### Enbrel for S.C. injection

**Drug vials**
- To be stored in a cool place

**Subcutaneous injection set**
- To be stored at room temperature

*Note: Photos showing Japanese products.*

**Putting a note on the package of reconstitution solution could be helpful to indicate that the drug is stored in a different place (e.g., in the refrigerator).**

**Example**
- Drug in the refrig.
- Put a note on the package.

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**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.