# Pharmaceuticals and Medical Devices Safety Information

## No. 299 February 2013

## Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 299, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

## 1. Utilization of the PMDA Medical Safety Information

The aims of the PMDA Medical Safety Information are to extensively provide precautions to be taken for ensuring safe use of drugs and medical devices to healthcare professionals. For this purpose, it provides information in an easy-to-understand manner with illustrations and pictures. This section of the full text introduces the PMDA Medical Safety Information. Healthcare professionals are encouraged to utilize them for safe use of drugs and medical devices.

## 2. Important Safety Information

Regarding the revision of the Precautions section of package inserts of drugs in accordance with the Notification dated January 8, 2013, the contents of important revisions and case summaries that served as the basis for these revisions will be provided in section 2 of the full text.

1. Zanamivir Hydrate
2. Josamycin, Josamycin Propionate
3. Sunitinib Malate
4. Ryutanshakanto (for ethical use)

## 3. Revision of Precautions (No. 243)

Revisions of Precautions etc. for the following pharmaceuticals:
Glimepiride, Pioglitazone Hydrochloride/Glimepiride, Cefozopran Hydrochloride, Cefotiam

Hydrochloride, Atazanavir Sulfate, Abacavir Sulfate, Indinavir Sulfate Ethanolate, Etravirine, Efavirenz, Emtricitabine, Emtricitabine/Tenofovir Disoproxil Fumarate, Saquinavir Mesilate, Sanilvudine, Didanosine, Zidovudine, Zidovudine/Lamivudine, Darunavir Ethanolate, Tenofovir Disoproxil Fumarate, Nevirapine, Nelfinavir Mesilate, Fosamprenavir Calcium Hydrate, Maraviroc, Lamivudine (150.mg, 300 mg), Lamivudine/Abacavir Sulfate, Raltegravir Potassium, Ritonavir, Rilpivirine Hydrochloride, Lopinavir/Ritonavir, Ryutanshakanto (over-the-counter drugs)

## 4. List of Products Subject to Early Post-marketing Phase Vigilance (as of February 2013)

A list of products subject to Early Post-marketing Phase Vigilance as of February 1, 2013 will be provided in section 4 of the full text.

## <Reference>
## Adverse Drug Reaction “Anaphylaxis”

An adverse drug reaction term “anaphylactoid symptoms,” which has been used in package inserts, will be changed to “anaphylaxis” based on recent evidence. An outline of the background and future handling of the term is presented in the full text.