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PSB/PSD Notification

No.0210-2

February 10, 2026

To: Director of Prefectural Health Department (Bureau)

Director of the Pharmaceutical Safety Division, Pharmaceutical Safety Bureau,  
Ministry of Health, Labour and Welfare  
(Official seal omitted)

Revisions of PRECAUTIONS in the Electronic Package Insert of Sulfite-containing  
Prescription Drugs, Medical Devices, and Regenerative Medical Products

In the current electronic package inserts (hereinafter “EPIs”) of prescription drugs containing sulfites as active ingredients or inactive ingredients (excipients), the description status of precautions for patients with a history of hypersensitivity to any of the ingredients of sulfite-containing drugs differs according to the drug product. From the viewpoint of ensuring precautions concerning prescription drugs that contain sulfites as active ingredients or excipients, the “Precautions” sections of the EPIs of sulfite-containing prescription drugs are to be handled as described below. This handling also applies to the EPIs of sulfite-containing medical devices and regenerative medical products.

Therefore, marketing authorization holders (MAHs) of such drugs or products and all related organizations under each prefectural control should be notified of the following matters:

**Pharmaceuticals and Medical Devices Agency**



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1. In the EPIs of prescription drugs that contain sulfites as active ingredients or excipients, the “15.1 Information Based on Clinical Use” section must provide the description that “this drug contains sulfites as active ingredients or excipients, and hypersensitivity to sulfites has been reported more frequently in asthmatic patients than in non-asthmatic patients.”  
Sulfites used as active ingredients or excipients of prescription drugs include lysine sulfite, sodium sulfite, sodium bisulfite, dried sodium sulfite, potassium pyrosulfite, and sodium pyrosulfite.
2. If the “Precautions” sections of the current EPIs of prescription drugs that contain sulfites as active ingredients or excipients provide no precaution for patients with a history of hypersensitivity to the ingredients of such drugs, “patients with a history of hypersensitivity to any of the ingredients of this drug” must be additionally mentioned in the “9.1 Patients with Complication or History of Diseases, etc.” section.
3. For actions to be taken for medical devices that contain sulfites in the raw materials of their parts that come into contact with the blood, body fluids, mucous membranes, or the like (irrespective of direct or indirect contact), some phrases and sections in items 1 and 2 above should be rewritten as follows: “prescription drugs” to be replaced with “medical devices,” “15.1 Information Based on Clinical Use” to be replaced with “Other Precautions” under “PRECAUTIONS,” “this drug” to be replaced with “this product,” and “9.1 Patients with Complication or History of Diseases, etc.” to be replaced with “Precautions concerning Use (This product should be cautiously applied to the following patients.)” under “PRECAUTIONS.”
4. For actions to be taken for regenerative medical products that contain sulfites as excipients, two phrases in items 1 and 2 above should be rewritten as follows: “prescription drugs” to be replaced with “regenerative medical products” and “this drug” to be replaced with “this product.”
5. The EPIs of prescription drugs, medical devices, and regenerative medical products that meet any of items 1 to 4 above must be revised as soon as possible, and necessary measures, such as provision of information to healthcare professionals and other related personnel, should be taken.

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6. When the EPIs of prescription drugs, medical devices, and regenerative medical products are revised according to items 1 to 5 above, no prior consultation with the Pharmaceuticals and Medical Devices Agency (“PMDA”) is required; however, these revisions should be handled as follows:

(1) Prescription drugs

Prior notices of revisions to the EPIs of sulfite-containing drugs should be submitted to the PMDA to update the source data for the collation of notified items that are automatically accepted.

(2) Medical devices

A report on each sulfite-containing product, the EPI of which is to be revised, should be prepared using the attached form and sent by e-mail to the Safety Division, Office of Vigilance and Standards for Medical Devices, PMDA (md-chousakekka@pmda.go.jp). If any revision to the EPI of the medical device is subject to notification to the PMDA, “25\_K\_000246” is to be entered in the notification as the consultation reference number at the time of submission of the notification.

(3) Regenerative medical products

When revisions to the EPIs of sulfite-containing regenerative medical products are notified to the PMDA, they must be described in the remarks section of the notification that the “Precautions” concerning sulfite-containing regenerative medical products have been revised.

7. The U.S. Food and Drug Administration (FDA) has alerted healthcare professionals to the risk of hypersensitivity associated with sulfite-containing prescription drugs. The aforementioned revisions specified in this notification should be made with reference to the following FDA website:

(Reference) Website where the FDA provides alerts on potential safety risks associated with sulfite-containing drugs.

The FDA alerts health care professionals, compounders, and patients to potential safety risks associated with sulfite-containing compounded drugs (<https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-professionals-compounders-and-patients-potential-safety-risks-associated>).