

To: Commissioners of Prefectural Health Departments (BUREAUS)

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

Self-inspection etc. of Package Inserts of Blood Glucose Meters, etc.

Medical devices or in-vitro diagnostics that measure and display glucose concentration in blood or tissue (hereinafter referred to as "blood glucose meters, etc.") include glucose monitoring systems, self-monitoring blood glucose meters, glucose analyzers, self-testing glucose kits, blood-testing glucose kits, and others.

Recently, a warning has been issued regarding the package insert for drugs containing hydroxycarbamide as the active ingredient. It states that when taking those drugs, blood glucose measurement results may show values higher than actual values (false high values). Therefore, as similar warnings are required for the package inserts for blood glucose meters, etc. as well, you are kindly requested to thoroughly inform the MAHs under your jurisdiction to conduct self-inspection of the package inserts of blood glucose meters, etc. they manufacture and market as follows, and to revise the package inserts and provide information to medical facilities etc., as necessary.

1. To confirm whether hydroxycarbamide may affect the blood glucose measurement results when using the blood glucose meters, etc., manufactured and marketed by the company on patients who have taken hydroxycarbamide or their samples.

2. To confirm that the following are included in the package inserts, regarding the items whose measurement results may be affected as a result of 1 above. However, depending on the actual usage of the items, it does not necessarily have to be identical to the following content.

- (1) For medical devices, the following description shall be included in the section of “Precautions for Concomitant Use (concomitant use should be with caution)” under the <Interactions (concomitant use with other drugs, medical devices, etc.) > in the [Precautions].

Name, etc. of drug/medical device	Clinical symptoms/measures	Mechanism/risk factors
Hydroxycarbamide	Hypoglycemia may occur if the measured value is higher than the actual glucose concentration and the measurement result is used to determine the insulin dosage.	When taking hydroxycarbamide, it may cause false high values.

- (2) For in-vitro diagnostics, “samples from patients taking hydroxycarbamide may show false high values, which could lead to hypoglycemia if the measurement results are used to determine the insulin dosage” shall be included in the section of [Precautions (interfering substances/drugs)].

3. As a result of 2 above, if package inserts do not include 2 (1) or (2) above, revisions shall be promptly made to the package inserts as shown in 2 (1) or (2) above, and the necessary information shall be provided to medical facilities etc. However, regardless of where they are mentioned, if equivalent content is already included in the package inserts, revision of those package inserts shall not be required. Additionally, depending on the actual usage of the items, it is possible to omit descriptions of cases where measurement results are used to determine insulin dosage. In addition, there is no need to consult Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA") regarding responses to this notification, such as revisions to package inserts. However, consultations shall be requested as necessary for responses to matters other than this notification.

4. For all blood glucose meters, etc. using the enzyme electrode method, MAHs are required to reports on the results of confirmation of 1 to 3 above and revisions to package inserts shall be made to Medical Device Safety Division, Office of Vigilance and Standards for Medical Devices, PMDA by February 6, 2026. The report shall be made by e-mail (md-chousakekka@pmda.go.jp) using the attached form. If the revision of package inserts has not been completed as of February 6,2026, a report shall be made on the status of consideration at that time.