

Provisional Translation (as of August 2025).

This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

Administrative Notice

June 23, 2009

To: Pharmaceutical Affairs Section, Prefectural Health Department (Bureau)

Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Handling of excipients approved for use only for specific products or under specific conditions

Handling of pharmaceutical excipients is instructed in the “Drug approval application” (Notification No. 0331015 by Director General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare dated March 31, 2005), of which Section 2-(10) states that “If an excipient without any precedent of use in approved drugs is used, or if an excipient with precedent of use is used via a different administration route or in the amount exceeding the precedent, data on the quality and safety of the concerned excipient should be submitted together.” The precedent of use should be interpreted in view of actual clinical use of the approved drugs.

Recent advances in formulation technology have enabled the use of various excipients. Of the excipients used in approved drugs, some are allowed to be used under limited conditions specified for individual products during regulatory reviews. For use of an excipient approved only for specific products or under specific conditions, the existing cases should not be handled as precedents of use unless the excipient is used in the relevant product or under the relevant condition. Please ensure that the relevant companies under your jurisdiction are well informed of the above matter.

Existing cases of excipients whose use has been approved only for specific products or under specific conditions are provided in the annex, but excipients that have been used in products other than those listed in the annex may be used within the range of use in these products (amount or administration route), which can be interpreted as precedents.

These cases of use of excipients will be provided on the website of the Pharmaceuticals and Medical Devices Agency

(<http://www.pmda.go.jp/operations/shonin/info/additive.html>). In the future, information on new cases will be provided on the website as needed if a case of use of an excipient is additionally approved only for specific products or under specific conditions.