

# 医薬品添付文書に記載されている 製造・販売中止薬物に関する調査研究

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## A Study of References to Discontinued Drugs in Ethical Drug Package Inserts

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### Abstract

**Objective:** To clarify current references to discontinued drugs in an insert included in packages of ethical drugs sent by pharmaceutical companies to pharmacists and physicians (ethical drug package insert).

**Methods:** Discontinued drugs were determined based on the list of pharmaceutical preparations deleted between 1997 and 2004 from national health insurance drug price list. The online database of the Pharmaceuticals and Medical Devices Agency was searched to determine whether these drugs had been mentioned in ethical drug package inserts.

**Results:** We found that 32 discontinued drugs were still mentioned under “drug interactions” in 1098 package inserts as of April 2005. The drug that was most commonly mentioned as being unsuitable for coadministration was terfenadine (referred to in 50 inserts of 13 drugs). Terfenadine was also mentioned under “contraindicated patients” in the inserts of 53 drugs. The speed at which references to such drugs are erased from inserts was not uniform across different sections of the inserts or across different drugs. This is considered to be because declaration of deletion is performed voluntarily by manufacturers.

**Conclusion:** Guidelines are necessary for inclusion or deletion of these drugs to avoid inconsistencies between drugs.

**Keywords :** Discontinued Drug, Ethical Drug Package Insert, Drug Interactions.