This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Preparations containing acetaminophen (oral dosage form, suppositories) (OTC drugs)

January 17, 2023

Non-proprietary name

a. Acetaminophen (oral dosage form)

b. Acetaminophen (suppositories)

Brand name (marketing authorization holder)

a. Tylenol A (TOA Pharmaceuticals Co., Ltd.), and the other OTC drugs

b. Kio Fever (Hiya Pharmaceutical Co., Ltd.), and the other OTC drugs

Japanese market launch

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Indications

a. ·Analgesia for headache, painful menses (period pains), toothache, pain after tooth extraction, sore throat, ear pain, arthralgia, neuralgia, low back pain, myalgia, pain associated with shoulder muscle stiffness, bruising pain, fracture pain, sprain pain, and traumatic pain
·Antipyresis of chills or pyrexia

b. Temporal antipyresis of pyrexia in children

Summary of revisions

“Drug-induced hypersensitivity syndrome” should be added to the Consultation section.

Investigation results and background of the revision

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Drug-induced hypersensitivity syndrome will be newly added in the Precautions for the prescription drug preparations containing acetaminophen. Accordingly, cases involving drug-induced hypersensitivity syndrome reported in Japan concerning OTC drugs were evaluated. A case for which a causal relationship between the OTC drug and drug-induced hypersensitivity syndrome was reasonably possible has been reported in Japan. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of Precautions, MHLW/PMDA concluded that a similar revision of Precautions was necessary for the OTC drugs.

Reference: Number of cases* and patient mortalities involving drug-induced hypersensitivity syndrome reported in Japan

A total of 3 cases have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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