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

Oseltamivir phosphate

March 1, 2019

Non-proprietary name

Oseltamivir phosphate

Branded name (Marketing authorization holder)

Tamiflu capsules 75, Tamiflu dry syrup 3% (Chugai Pharmaceutical Co., Ltd.), and the others

Indications

Treatment and prophylaxis of influenza A and B viral infections

Summary of revisions

1. Language concerning instructions to patients and their families regarding contacting the attending physician if haemorrhage symptom appears should be added to the Important Precautions section.
2. A Precautions for Co-administration section should be newly added including language concerning the necessity of careful monitoring of patients when this drug is co-administered with warfarin, in light of reports of prolonged prothrombin time associated with the combination administration.

Investigation results and background of the revision

In light of the overall trend of occurrence of bleeding events associated with all influenza antiviral agents currently available in Japan in their entirety and cases of the bleeding events in patients treated with oseltamivir phosphate reported in Japan, the necessity of revision of the package insert was considered. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 30 cases involving bleeding have been reported to date (including 3 cases for which a causal relationship with the product could not be ruled out.)

No patient mortalities have been reported to date.

No cases involving bleeding in patients co-administered the product with warfarin have been reported.

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