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

Ivermectin

October 12, 2021

Non-proprietary name

Ivermectin

Branded name (Marketing authorization holder)

Stromectol Tablets 3 mg (MSD K.K.)

Indications

1. Intestinal strongyloidiasis
2. Scabies

Summary of revisions

1. A statement should be added to the IMPORTANT PRECAUTIONS section that patients should be informed of the caution required when engaging in hazardous machine operation such as driving a car.
2. “Disturbed consciousness” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of disturbed consciousness have been reported in patients treated with ivermectin in Japan and overseas. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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

A total of 4 cases have been reported to date. (A causal relationship between the drug and event could not be established in any of these cases.)

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1 instance of patient mortality has been reported to date. (A causal relationship between the drug and the death subsequent to event could not be established for this case.)

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).