Summary of Investigation Results

Hydroxychloroquine sulfate

November 13, 2024

Non-proprietary name

Hydroxychloroquine sulfate

Brand name (marketing authorization holder)

Plaquenil Tablets 200 mg (Sanofi K.K.) and the others

Japanese market launch

September 2015

Indications

Cutaneous lupus erythematosus, systemic lupus erythematosus

Summary of revisions

A precautionary statement regarding phospholipid accumulation should be added to the 8. IMPORTANT PRECAUTIONS section.

Investigation results and background of the revision

Cases involving events suspected to be related to phospholipid accumulation were evaluated. Cases for which a causal relationship between hydroxychloroquine sulfate and events suspected to be related to phospholipid accumulation was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases*† and patient mortalities involving events suspected to be related to phospholipid accumulation reported in Japan and overseas

A total of 5 cases have been reported in Japan to date. (A causal relationship between the

drug and the event could not be established for any of these cases.)
No patient mortalities have been reported in Japan to date.

A total of 17 cases have been reported overseas to date. (A causal relationship between the drug and the event was reasonably possible for 6 cases, including 4 cases in which the drug was administered outside the approved indications and 1 case outside the approved dosage and administration.)
One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports
†The following cases were collected:

- •Cases which fell under MedDRA v26.1 PT “Phospholipidosis” or “Renal phospholipidosis”
- •Among the cases which fell under MedDRA v26.1 PT “Cardiomyopathy,” “Myopathy,” “Myopathy toxic,” “Nephropathy toxic,” “Neurotoxicity,” “Neuromuscular toxicity,” “Neuropathy peripheral,” “Proteinuria,” or ”Renal injury,” those for which phospholipid accumulation was mentioned and an inborn error of metabolism had been ruled out
- •Cases reported in the literature that reference phospholipid accumulation

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).