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

Summary of Investigation Results

Hydroxychloroquine sulfate

August 30, 2022

Non-proprietary name

Hydroxychloroquine sulfate

Brand name (Marketing authorization holder)

Plaquenil Tablets 200 mg (Sanofi K.K.)

Indications

Cutaneous lupus erythematosus, systemic lupus erythematosus

Summary of revisions

“Hepatic impairment” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving hepatic impairment reported in Japan and overseas were evaluated. Cases for which a causal relationship between hydroxychloroquine sulfate and hepatic impairment was reasonably possible have been reported in Japan and overseas. As a result of consultation with expert advisors, MHLW/PMDA concluded that revision of Precautions was necessary.

Number of cases and patient mortalities involving hepatic impairment reported in Japan and overseas during the previous 3 fiscal years

A total of 2 cases have been reported in Japan to date. (A causal relationship between the drug and event could not be established for any of these cases.)

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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

case.)

A total of 21 cases* have been reported overseas to date (including 4 cases for which a causal relationship between the drug and event was reasonably possible).

2 instances of patient mortality have been reported overseas to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

* Cases in which hydroxychloroquine sulfate was used to treat cutaneous lupus erythematosus and systemic lupus erythematosus, for which this drug is indicated in Japan.

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).

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp