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

Nirmatrelvir/ritonavir

June 14, 2022

Non-proprietary name

Nirmatrelvir/ritonavir

Brand name (Marketing authorization holder)

Paxlovid Pack (Pfizer Japan Inc.)

Indications

Treatment of disease caused by SARS-CoV-2 infection (COVID-19)

Summary of revisions

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

Investigation results and background of the revision

Cases involving anaphylaxis reported in Japan and overseas were evaluated. Cases for which a causal relationship between nirmatrelvir/ritonavir and anaphylaxis 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 of anaphylaxis reported in Japan and overseas during the previous 3 fiscal years

1 case has been reported in Japan to date. (A causal relationship between the drug and the event was reasonably possible for this case.)
No patient mortalities have been reported to date.
(Japanese market launch: February 2022)
A total of 3 cases have been reported overseas to date. (A causal relationship between the

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drug and events was reasonably possible for all the cases.)

No patient mortalities have been reported to date.

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).