



Summary of Investigation Results

Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

July 7, 2021

Non-proprietary name

Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

Branded name (Marketing authorization holder)

- a. Comirnaty intramuscular injection (Pfizer Japan Inc.)
- b. COVID-19 Vaccine Moderna Intramuscular Injection (Takeda Pharmaceutical Company Limited.)

Indications

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

Summary of revisions

1. A cautionary statement regarding myocarditis and pericarditis should be added to the IMPORTANT PRECAUTIONS section.
2. An OTHER PRECAUTIONS section should be newly added to state that although the causality is unknown, cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2).

Investigation results and background of the revision

Although no cases of myocarditis and pericarditis have been reported in Japan as suspected adverse reactions to coronavirus modified uridine RNA vaccine (SARS-CoV-2) for which a causal relationship between the vaccine and event was reasonably possible, MHLW/PMDA considering the situations described below and in consultation with expert advisors

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concluded that revision of the package inserts was necessary.

- Although the causality is unknown, cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults).
- Precautions for myocarditis and pericarditis have been issued overseas.
- Cases of myocarditis and pericarditis have also been reported in Japan although the causality is unknown.
- Prior instructions to vaccinees are considered critical for early detection and prevention of aggravation of the diseases that they should seek medical attention if they experience symptoms that could suggest myocarditis or pericarditis.
- Increase in vaccination to AYA (Adolescents and Young Adults) generation is expected in line with the extension of the scope of vaccination.

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

Cases involving myocarditis

a.

A total of 12 cases have been reported to date (A causal relationship between the vaccine and event could not be established for any of these cases.)

2 instances of patient mortalities have been reported to date (A causal relationship between the vaccine and deaths subsequent to the event could not be established for either case.)

b.

1 case has been reported to date (A causal relationship between the vaccine and event could not be established for this case.)

No patient mortalities have been reported to date.

Cases involving pericarditis

a.

A total of 3 cases have been reported to date (A causal relationship between the vaccine and event could not be established for any of these cases.)

No patient mortalities have been reported to date.



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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.

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).

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