# Summary of Investigation Results

## Salbutamol sulfate

February 25, 2021

**Non-proprietary name**

Salbutamol sulfate

**Branded name (Marketing authorization holder)**

a. Venetlin for Inhalation 0.5% (Glaxo Smith Kline K.K.)
b. Venetlin Tablets 2 mg (Glaxo Smith Kline K.K.), and the others
c. Venetlin Syrup 0.04% (Glaxo Smith Kline K.K.)
d. Sultanol Inhaler 100 μg (Glaxo Smith Kline K.K.)

**Indications**

a, d.

Relief of symptoms associated with airflow obstruction in the following diseases:

Bronchial asthma, childhood asthma, emphysema, bronchitis acute/chronic, pulmonary tuberculosis

b.

Relief of symptoms associated with airflow obstruction in the following diseases:

Bronchial asthma, childhood asthma, emphysema, bronchitis acute/chronic, pulmonary tuberculosis, silicotuberculosis

c.

Relief of bronchospasm in the following diseases:

Bronchial asthma, bronchitis, asthmatoid bronchitis

**Summary of revisions**

“Shock, anaphylaxis” should be added to the Clinically Significant Adverse Reactions section.

**Investigation results and background of the revision**

Cases of shock or anaphylaxis have been reported in patients treated with salbutamol sulfate in Japan. 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 3 cases involving shock or anaphylaxis have been reported to date (including 1 case for which a causal relationship between the drug and event was reasonably possible). 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).

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