*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

## Lamotrigine

October 23, 2018

### Non-proprietary name

Lamotrigine

### Branded name (Marketing authorization holder)

a. Lamictal Tablets 25 mg, 100 mg (Glaxo Smith Kline K.K.), and the others

b. Lamictal Tablets for Pediatric 2 mg, 5 mg (Glaxo Smith Kline K.K.), and the others

### Indications

a.

· Monotherapy for the following types of seizures in epileptic patients:

Partial seizures (including secondary generalized seizures)

Tonic-clonic seizures

Typical absence seizures

· Concomitant therapy with antiepileptics for the following types of seizures in epileptic patients who were not sufficiently responsive to other antiepileptics:

Partial seizures (including secondary generalized seizures)

Tonic-clonic seizures

Generalized seizures associated with Lennox-Gastaut syndrome

· Suppression of recurrent/relapsed mood episodes in patients with bipolar disorder

b.

· Monotherapy for the following types of seizures in epileptic patients:

Typical absence seizures

· Concomitant therapy with antiepileptics for the following types of seizures in epileptic patients who were not sufficiently responsive to other antiepileptics:

Partial seizures (including secondary generalized seizures)

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Tonic-clonic seizures

Generalized seizures associated with Lennox-Gastaut syndrome

## Summary of revisions

"Haemophagocytic syndrome" should be added to the Clinically Significant Adverse Reactions section.

## Investigation results and background of the revision

Cases of haemophagocytic syndrome have been reported in patients treated with lamotrigine in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

## Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

1 case involving haemophagocytic syndrome has been reported to date (a causal relationship with the product could not be ruled out in this case.)

No patient mortalities have been reported to date.

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