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

Methylphenidate Hydrochloride

February 16, 2016

Non-proprietary name

Methylphenidate Hydrochloride

Brand name (Marketing authorization holder)

a. Concerta Tablets 18 mg, 27 mg, 36 mg (Janssen Pharmaceutical K.K.)

b. Ritalin Tablets 10 mg, Ritalin Powder 1 % (Novartis Pharma K.K.)

Indications

a. Attention deficit/hyperactivity disorder (AD/HD)

b. Narcolepsy

Summary of revision

“Hepatic failure and hepatic function disorder” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of hepatic failure and hepatic function disorder have been reported in patients treated with Concerta Tablets overseas*, and the company core datasheet (CCDS)† has been updated. In addition, cases have been reported in patients treated with Ritalin Tablets overseas. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No case associated with hepatic failure or hepatic function disorder has been reported.

NOTE:

* Hoi Y. Tong et al., Case Rep. Pediatr., 2015; 2015: 1-5, etc.

† CCDS is prepared by the marketing authorization holder and covers materials retaining to safety, indications, dosing, pharmacology, and other information concerning the product.

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