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

Oral live attenuated human rotavirus vaccine

January 17, 2023

Non-proprietary name

Oral live attenuated human rotavirus vaccine

Brand name (marketing authorization holder)

Rotarix oral liquid formulation (GlaxoSmithKline K.K.)

Japanese market launch

November 2011

Indications

Prevention of gastroenteritis caused by rotavirus

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 were evaluated. Cases for which a causal relationship between oral live attenuated human rotavirus vaccine and anaphylaxis was reasonably possible have been reported in Japan. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of the Precautions, MHLW/PMDA concluded that revision was necessary.

Reference: Number of cases* and patient mortalities involving anaphylaxis reported in Japan

A total of 28 cases have been reported to date (including 2 cases for which a causal

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relationship between the drug and event was reasonably possible).
No patient mortalities have been reported to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

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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