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

Preparations containing dolutegravir sodium

September 18, 2018

Non-proprietary name

a. Dolutegravir sodium

b. Dolutegravir sodium/abacavir sulfate/lamivudine

Branded name (Marketing authorization holder)

a. Tivicay Tablets 50 mg (ViiV Healthcare (ViiV) K.K)

b. Triumeq Combination Tablets (ViiV Healthcare (ViiV) K.K)

Indications

HIV infection

Summary of revisions

A cautionary statement concerning hepatic impairment and jaundice should be added to the Important Precautions section.

”Hepatic impairment, jaundice” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hepatic impairment and jaundice have been reported in patients treated with preparations containing dolutegravir sodium in Japan. 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.

Pharmaceuticals and Medical Devices Agency
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Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

a. Dolutegravir sodium

A total of 3 cases involving hepatic impairment have been reported to date (a causal relationship with the product could not be ruled out for these cases.) No patient mortalities have been reported to date.

b. Dolutegravir sodium/abacavir sulfate/lamivudine

1 case involving hepatic impairment has been reported to date (a causal relationship with the product could not be established for this case.) No patient mortalities have been reported to date.

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