



## Summary of investigation results

### Pentamidine isetionate

April 23, 2014

#### Non-proprietary Name

Pentamidine isetionate

#### Brand Name (Marketing Authorization Holder)

Benambax 300mg for Injection (Sanofi K.K.)

#### Indications

- Applicable microorganisms  
Pneumocystis carinii
- Applicable conditions  
Carinii pneumonia

#### Summary of revision

‘Severe bradycardia’ should be added in hypotension, prolonged QT interval, and ventricular arrhythmia subsection in Clinically significant adverse reactions section.

#### Background of the revision and investigation results

A safety information document corresponding to a company core data sheet (CCDS)\* has been updated to include information on severe bradycardia. Cases of severe bradycardia have been reported in patients treated with pentamidine isetionate in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of PRECUTIONS was necessary.

#### The number of reported adverse reaction and fatal cases in the last 3 fiscal years

No severe bradycardia-associated cases have been reported.

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#### NOTE

\* CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.