Summary of investigation results

Amphotericin B (non-liposome preparation)

July 8, 2014

Non-proprietary Name
Amphotericin B

Brand Name (Marketing Authorization Holder)
FUNGIZONE for infusion 50 mg (Bristol-Myers K.K.)

Indications
Indicated microorganisms:
- Aspergillus, Candida, Mucor, Cryptococcus, Blastomyces, Histoplasma, Coccidioides,
- Hormodendrum, Phialophora, and Hormiscium

Applicable conditions:
- Deep-mycosis by above-mentioned fungi

Summary of revision
‘Central nervous system disorder’ should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results
Cases of central nervous system disorder have been reported in patients treated with amphotericin B in Japan and foreign countries and a company core data sheet (CCDS)* has been updated. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan
No central nervous system disorder-associated cases have been reported in Japan.

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