



## Summary of investigation results

### Linezolid

Aug 6, 2014

#### Non-proprietary Name

Linezolid

#### Brand Name (Marketing Authorization Holder)

ZYVOX tablets 600 mg and ZYVOX injection 600 mg (Pfizer Japan Inc.)

#### Indications

- Indicated microorganisms:

Susceptible strains of Methicillin-resistant *Staphylococcus aureus*

Applicable conditions:

Sepsis, deep-seated skin infections, chronic pyoderma, secondary infections that are suffered from trauma, thermal burn, and surgical wound, and pneumonia

- Indicated microorganisms:

Susceptible strains of Vancomycin-resistant *Enterococcus faecium*

Applicable conditions:

Infections

#### Summary of revision

- Cautions about metabolic acidosis should be added in Important Precautions section.
- ‘Metabolic acidosis’ and ‘hepatic dysfunction’ should be added in Clinically significant adverse reactions section.

#### Background of the revision and investigation results

Cases of metabolic acidosis or hepatic dysfunction have been reported in patients treated with linezolid in Japan. 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.



*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

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

A total of 6 cases associated with metabolic acidosis has been reported (including 2 cases in which causality could not be ruled out). Of the 6 cases, a fatality has been reported. No causal relationship with linezolid was established in the fatal case.

A total of 5 cases associated with hepatic dysfunction has been reported (including 2 cases in which causality could not be ruled out). Of the 5 cases, a fatality has been reported. No causal relationship with linezolid was established in the fatal case.