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

Piperacillin Sodium

January 12, 2016

Non-proprietary name

Piperacillin Sodium

Brand name (Marketing authorization holder)

Pentcillin Injections 1 g, 2 g, Pentcillin Injections Bag 1 g, 2 g (Toyama Chemical Co., Ltd.), and the others

Indications

(Applicable microorganisms)

Piperacillin-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, genus *Pneumococcus*, genus *Enterococcus*, *Escherichia coli*, genus *Citrobacter*, *Klebsiella pneumoniae*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, *Morganella morganii*, genus *Providencia*, *Haemophilus influenzae*, *Pseudomonas aeruginosa*, genus *Bacteroides*, and genus *Prevotella* (excluding *Prevotella bivia*).

(Applicable conditions)

Sepsis, acute bronchitis, pneumonia, lung abscess, pyothorax, secondary infection of chronic respiratory lesions, cystitis, pyelonephritis, cholecystitis, cholangitis, bartholinitis, intrauterine infection, adnexitis, parametritis, and pyogenic meningitis.

Summary of revision

“Acute generalised exanthematous pustulosis” should be added to the “toxic epidermal necrolysis, oculomucocutaneous syndrome” subsection in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with piperacillin sodium and tazobactam/piperacillin hydrate in Japan. Following an

investigation result based on the opinions of expert advisors and the 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 case of acute generalised exanthematous pustulosis has been reported.

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