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.

Summary of investigation results

Teriparatide

July 8, 2014

Non-proprietary Name

Teriparatide (genetical recombination)

Brand Name (Marketing Authorization Holder)

Forteo subcutaneous injection kit 600 μg (Eli Lilly Japan K.K.)

Indications

Osteoporosis at high risk for fracture

Summary of revision

'Shock and anaphylaxis' should be added in new Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of shock or anaphylaxis have been reported in patients treated with teriparatide 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

Two cases associated with shock or anaphylaxis have been reported (including a case in which causality could not be ruled out). Of the 2 cases, no fatalities have been reported.

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

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp