Summary of investigation results

Loxoprofen sodium hydrate (dermatologic preparation)

July 4, 2017

Non-proprietary name
Loxoprofen sodium hydrate (dermatologic preparation)

Brand name (Marketing authorization holder)
Loxonin Pap 100 mg, Loxonin Tape 50 mg, 100 mg (Lead Chemical Co., Ltd.), Loxonin Gel 1% (Daiichi Sankyo Co., Ltd.), Loxoprofen Na Spray 1% YD (Yoshindo Inc.), and others

Indications
Anti-inflammation/Pain relief in the following diseases and symptoms
Osteoarthritis, myalgia, post-traumatic pain/swelling

Summary of revision
The Clinically Significant Adverse Reactions subsection should be newly added in the Adverse Reactions section in the package insert, and “shock, anaphylaxis” should be added.

Background of the revision and investigation results
Cases of shock or anaphylaxis have been reported in patients treated with loxoprofen sodium hydrate in Japan. Following investigation results 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 reactions and fatal cases in the last 3 fiscal years in Japan
A total of 6 cases associated with shock or anaphylaxis have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.