This is provisional English translation of an excerpt from the original full report.

Risk Assessment Report

An injection for veterinary use in cattle, containing dinoprost tromethamine as an active substance: Pronalgon EZ injection

(Veterinary Medicinal Products)

Food Safety Commission of Japan (FSCJ)
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ABSTRACT

FSCJ conducted a risk assessment of pronalgon EZ injection based on data in the written application for the approval of manufacture and sales of new veterinary medicinal products.

Pronalgon EZ is an injection for veterinary use in cattle, containing dinoprost tromethamine as an active substance. Main ingredient of this product, dinoprost tromethamine, is a tromethamine salt of an endogenous substance $PGF_{2\alpha}$. Dinoprost tromethamine is known to be absorbed and act as free form $PGF_{2\alpha}$ after injected into cattle. It is used as a veterinary medicinal product in Japan and abroad, and the ADI of 0.83 μg/kg bw/day has been set in EU, but MRL is not yet specified in Japan, USA and EU.

This product and pronalgon F injection were considered to be biologically equivalent based on AUC, Cmax and Tmax determined by a biological equivalence study.

A residue analysis with injection of this product and biologically equivalent pronalgon F product showed that $PGF_{2\alpha}$ concentration at 12, 24, 48 and 72 hours after the injection does not change to the extent exceeds the physiological concentration in all the tissues except the injection site. Concentration of lacteal $PGF_{2\alpha}$ was within the physiological range at 12 and 24 hours after the injection, while muscular $PGF_{2\alpha}$ concentration at the injection site exceeded the concentration two-hundred times higher than the physiological level 12 hours after the injection but gradually decreased afterword to almost physiological level after 24 hours.

Based on a safety study in cattle, FSCJ considered that this product is of no concern for safety of cattle as long as regular dose is used appropriately.
Hence, FSCJ concluded that the risk to human health of this product through consumption is negligible as long as it is appropriately used.