RGS1 5Q[S1]3Tm()TA announced today that its pharmaceutical manufacturing and sales subsidiary Sawai Pharmaceutical Co., Ltd. (Headquarters: Gunma, President: Toshio Kaneko) has received approval for an additional indication and additional dosage and administration of its vitamin K

$_2$ syrup formulation, Kaytwo®

[Notes to editors]

1. Kaytwo® Syrup 0.2% Approval Outline

(Underlined parts indicate newly approved indication/dosage and administration)

1) Indications

Treatment of neonatal hemorrhage and hypoprothrombinemia

Prevention of vitamin K deficiency hemorrhage in neonates and infants

2) Dosage and Administration

Treatment of neonatal hemorrhage and hypoprothrombinemia

The usual neonate dosage for oral use is 1 mL (2 mg of menatetrenone), once a day.

The dose may be increased up to 3 mL (6 mg of menatetrenone) depending on the patient's symptoms.

Prevention of vitamin K deficiency hemorrhage in neonates and infants

The usual initial dosage for oral use, once the neonate is satisfactorily able to ingest milk, is 1 mL (2 mg of menatetrenone). This should be followed by a second 1mL dose one week after birth or upon discharge from the maternity ward, whichever is earlier, and a third 1 mL dose one month after birth.

2. Application Based on Public Knowledge

An application based on public knowledge is a marketing authorization application that seeks additional indication approval for a currently approved drug. This type of application is submitted on the pretense that overseas usage of the drug and medical literature published both in Japan and other countries are sufficient to prove that the drug's safety and efficacy is public knowledge within the medical and pharmacological community, and does not require that additional clinical studies be conducted, either in whole or in part.