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Singapore: The pharmaceutical manufacturing and sales subsidiary of Eisai, Sannova, has received approval for an additional indication and additional dosage and administration of its vitamin K2 syrup formulation, Kaytwo Syrup 0.2 percent (menatetrenone), for the prevention of vitamin K deficiency hemorrhage in neonates and infants.

In Japan, vitamin K deficiency hemorrhage is classified into two types: vitamin K deficiency hemorrhage in neonates, which occurs within seven days of birth, and vitamin K deficiency hemorrhage in infants, which presents during infancy. Although rather rare, vitamin K deficiency hemorrhage in infants, in particular, is a very serious condition involving intracranial hemorrhaging that often results in death or permanent neurological damage.

In Europe and the US, vitamin K is already approved as a preventive measure against vitamin K deficiency hemorrhage. In

Japan, however, despite the fact that majority of newborn babies are administered vitamin K2 syrup formulations for preventative purposes in accordance with recommendations in treatment guidelines published by the former Ministry of Health (currently Ministry of Health, Labour and Welfare: MHLW) Research Group and the Japan Pediatric Society, there have been no medicines approved for the prevention of vitamin K deficiency hemorrhage in neonates and infants up until now.

Against this backdrop, MHLW's study group on unapproved and off-label drugs of high medical need deemed that there was a significant need for Kaytwo Syrup 0.2 percent to be approved for the prevention of vitamin K deficiency hemorrhage in this patient population, and therefore designated it as a drug for which an application based on public knowledge may be submitted. In response to the study group's recommendation, Sannova submitted an application based on public knowledge to the MHLW on November 30, 2011, seeking approval for this additional indication and corresponding additional dosage and administration.