

<div><div>대한민국 대전환 한국판뉴딜</div></div> <div><div>Ministry of Food and Drug Safety</div></div>	<div>Press Release</div>	Distributed on	April 29, 2021 (Thu)
		Division in Charge	Expedited Review Division of Medicine and Medical Devices National Institute of Food and Drug Safety Evaluation
		Director	김희성 (☎043-719-5061)
		Researcher	고용석 (☎043-719-5062)

MFDS Begins Rolling Review of Sputnik V COVID-19 Vaccine

- ☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) has announced that Huons Co., Ltd. filed for rolling review of Russia's Sputnik V COVID-19 vaccine on April 29 prior to submitting an application for marketing authorization.
- Since Sputnik V is not included in the Korean government's COVID-19 vaccination program, Huons has filed for rolling review of the non-clinical data (toxicity and efficacy tests) in accordance with Pharmaceutical Affairs Act.
- The MFDS will rigorously review the safety and efficacy of the vaccine, based on the submitted non-clinical data.
- Sputnik V is a viral vector vaccine which has been authorized in 61 countries including Russia, but not in the U.S. and the E.U.
- The vaccine is currently under the European Medicines Agency (EMA)'s rolling review and the WHO Emergency Use Listing (EUL) evaluation.
 - * The EMA's rolling review: since March 4, 2021
 - The WHO EUL evaluation: since October 2020
- ☐ The MFDS will spare no effort for a timely provision of safe and effective vaccines.