European Commission

e-News
14/05/2019

Health and Food Safety Directorate General

| Twitter Food | Twitter Health

Public Health

Quality of medicines: Korean active substances in line with EU standards

A Commission decision adopted today will contribute to improving the quality of medicines in the EU by ensuring the quality of active substances produced in the Republic of Korea are in line with EU standards.
To guarantee their quality, active substances manufactured in third countries like the Republic of Korea, and intended for human medicines placed on the EU market, have to be produced in an EU equivalent regulatory system including rules for good manufacturing practices (GMP).

Third countries can ask the Commission to assess whether their regulatory framework and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union. The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea requested such an assessment in 2015.

The review of the relevant documentation submitted by the MFDS was successful, and after the two audits conducted by the Commission in 2016 and 2018, today's decision confirms that the legislative framework of the Republic of Korea applicable to active substances is capable of ensuring a level of protection of public health equivalent to that of the Union.

The Republic of Korea will join the list of third countries recognised so far: Australia, Brazil, Israel, Japan, Switzerland and the United States of America.

For more information:

- Commission Implementing Decision and Annex
- EU action on good manufacturing practices (GMP)