

Regulation

From the Ministry of Health:

Regulation on the Amendment on the Registration Regulation for Human Medicinal Products

ARTICLE 1 — The subclause (3) of the paragraph (a) of the first clause of article 9 titled “Shortened Application” in the Registration Regulation for Human Medicinal Products published in the Official Gazette numbered 25705 and dated 19/1/2005 is changed as in the following:

"3) The medical product that is licenced according to the provisions of the legislation in force and to be similar to a medical product in principle which has fulfilled the period of data exclusivity. The data exclusivity in the application of this subclause is valid for the original products that are registered for the first time after 1/1/2001 within one of the countries in Customs Union and for which no application for generic licence is placed in Turkey by 1/1/2005 and for the original products which will be registered for the first time after 1/1/2005 in one of the Customs Union countries and its term is 6 (six) years starting from the date when it is registered for the first time within Customs Union area. The 6 (six) year data exclusivity application for the products that benefit from data protection in Turkey is limited with this patent term. "

Enforcement

ARTICLE 2 — This Regulation enters into force on the date it is published.

Execution

ARTICLE 3 — The provisions of this Regulation is executed by the Minister of Health.