

RESTRICTED

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency

Number: E-39634851-504.99-1203313 24.08.2023 Subject: Applications to the Imports and Market Supply Unit

Reference: a) Communication to associations dated 17.12.2018 with reference number E.219564 b) Communication to associations dated 05.12.2019 with reference number E.206228

As you are aware, import procedures and processes for drug raw materials and human medicinal products which are not subject to control are conducted in line with the "Guideline on Import Applications and Market Placement Permits." According to the aforesaid Guideline, applications which are conditional on the product having a human medicinal product marketing authorization, must bear a stamp of "The results of scientific review are acceptable and the marketing authorization remains valid" as a requirement. In cases where a product's marketing authorization lacks the aforesaid stamp, the applicant must submit to our Agency the cover letter and tracking numbers for the application, or a letter of commitment that an application would be submitted, in accordance with the Guideline on Renewal of Marketing Authorization for Human Medicinal Products. Please urgently advise your members accordingly. For your information and appropriate action.

For the Agency President Dr. Mehmet Hakan Fırat Acting Vice President

Distribution: Association of Research-Based Pharmaceutical Companies Association of Developmental Pharmaceutical Companies Pharmaceutical Manufacturers' Association of Türkiye Health Products Association Turkish Pharmaceutical Manufacturers' Association

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