Changes to Guideline for Working Principles and Procedures of Turkish Medicines and Medical Devices Agency Human Medicinal Products Priority Assessment Commission

A few articles of Guideline for Working Principles and Procedures of Turkish Medicines and Medical Devices Agency Human Medicinal Products Priority Assessment Commission which was drawn up to define working principles and procedures of Priority Assessment Commission established through Ministerial Consent dated 13/04/2016 no. 2165621 and approved through Consent of Competent Authority dated 12/05/2016 no. 38188 have been changed and updated forms are below.

ARTICLE 1- Related guideline's Annex 1: Declaration and commitment document for locally manufactured products for exportation requested during prioritization of marketing authorization applications of products for locally manufactured products for exportation purposes has been changed as follows:

"We declare, agree and commit that the marketing authorization taken from the exporting country and its Notary certified Turkish translation or CPP document issued by the Agency and the document providing that the exportation has been realized about the product with _____ active substance and named _____ which takes part within the scope of marketing authorization applications of locally manufactured products for exportation will be submitted to the Commission secretariat, at least 99% of first three full scale production series will be exported, the exportation data relating to the product will be reported to the Unit once every six months, if otherwise specified, the sanction within the scope of the prioritization will be imposed."

ARTICLE 2- Guideline's tenth paragraph of Article 7 "Working Principles and Procedures" has been changed as follows:
"The Commission convenes at least once a month."

ARTICLE 3- Guideline's clause (b) of first paragraph of Article 4 has been changed as follows:
"Unit: Human Medicinal Products Prioritization Assessment Unit within the Department of Economic Assessments and Medicine Supply Management"

ARTICLE 4- Guideline's third paragraph of Article 5 has been changed as follows:
"In the event that any one of the Commission members excluding The President, Vice Presidents, academic members and Head of Pharmaceuticals and Pharmacy Department of Social Security Institution and its reserve, does not attend the meeting, the reserve member determined by the President beforehand attends the meeting in his stead. People apart from members may attend the meetings only when they are invited."

ARTICLE 5- This Guideline enters into force on the date of publication**.**

ANNEX-1:

Declaration and Commitment for locally manufactured products for exportation

DECLARATION AND COMMITMENT

"We declare, agree and commit that the marketing authorization taken from the exporting country and its notary certified Turkish translation or CPP document issued by the Agency and the document providing that the exportation has been realized about the product with _____ active substance and named _____ which takes part within the scope of marketing authorization applications of locally manufactured products for exportation will be submitted to the Commission secretariat, at least 99% of first three full scale production series will be exported, the exportation data relating to the product will be reported to the Unit once every six months, if otherwise specified, the sanction within the scope of the prioritization will be imposed."

Company Seal

Name/Surname of the Authority

Date

Signature