

GUIDELINE ON THE CLASSIFICATION OF VARIATION APPLICATIONS AND RELATED VARIATION APPLICATIONS

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Çankaya/ANKARA Telephone No: (0 312) 218 30 00 Fax No: (0 312) 218 34 60 E-mail: halkla.iliskiler@titck.gov.tr Web Address: <https://www.titck.gov.tr> Kep Address: titck@hs01.kep.tr

GUIDELINE ON THE TIMELINING PROCESSES OF MARKETING AUTHORISATION APPLICATIONS FOR HUMAN MEDICINAL PRODUCTS İRD-KLVZ-22

FIRST SECTION Introductory Provisions Objective

ARTICLE 1 – (1) This Guideline has been prepared for the purpose of establishing the procedures and principles regarding the timelining processes for applications for marketing authorisation of human medicinal products submitted to the Turkish Medicines and Medical Devices Agency, whose validation assessment has been found suitable by the Agency as a result of the evaluation carried out by the Agency. Scope

ARTICLE 2 – (1) This Guideline covers the procedures and principles regarding the conduct of the timelining processes of marketing authorisation applications for human medicinal products whose validation assessment has been found suitable. Legal Basis

ARTICLE 3 – (1) This Guideline has been prepared on the basis of Article 39 of the Regulation on Marketing Authorisation of Human Medicinal Products published in the Official Gazette dated 11/12/2021 and numbered 31686. Definitions

antitoxin, anti-smallpox globulin and antilymphocytic globulin; or 2) "Allergen products" in the meaning of any medicinal product intended to induce or identify a specific acquired change in the immunological response to an allergising agent; or 3) Any human medicinal product covering products of immunoglobulin structure derived from the blood of animals (rabbit, horse and the like) and exerting an effect on the human immune system, f) Reliance: the taking into account, or giving significant weight to, evaluations and other reliable information performed by another regulatory authority or trusted institution, by the Agency within a given jurisdiction, when making its own decision, g) Blood product: human medicinal products whose active substance(s) are blood components, obtained from human blood or plasma by industrial methods and containing, in particular, products such as albumin, immunoglobulin and coagulation factors, ğ) Agency: the Turkish Medicines and Medical Devices Agency, h) Timelining: the time schedule determined by the Agency, in accordance with the provisions of this Guideline, for the initiation of the authorisation process of marketing authorisation applications for human medicinal products whose validation assessment has been found suitable, ı) Medicines on the List of Essential Medicines: human medicinal products having the same active substance, same strength, same pharmaceutical form and same route of administration as the human medicinal products included in the list of medicines prepared and published by the World Health Organization to meet the basic priority health needs of the population, i) Other essential medicines: medicines which, among the medicines on the List of Essential Medicines, contain the same active substance but differ in terms of strength, pharmaceutical form or route of administration, j) Innovative product: human medicinal products determined to be innovative as a result of the evaluation as to whether they relate to mechanism of action, rapid onset of action, stepwise treatment, added benefit, patient compliance, specific effect on certain diseases, safety advantage, synergistic-additive effect, interaction with other medicines, duration of effect or unmet therapeutic need. k) Human medicinal products on the Foreign Medicine Price List: human medicinal products included in Annex 4-C of the Health Implementation Communiqué published by the Social Security Institution.

SECOND SECTION General Provisions

ARTICLE 5 – (1) The list of active substances awaiting scheduling in relation to marketing authorisation applications for medicinal products for human use whose preliminary assessment has been found satisfactory, and the list of active substances of medicinal products for human use whose authorisation process has commenced, are published on the official website of the Agency during the first week of each month.

(2) In cases where there is more than one first pharmaceutical equivalent product application among the marketing authorisation applications for medicinal products for human use whose preliminary assessment has been found satisfactory, in accordance with Article 7 of this Guideline, the authorisation process is initiated only for the first five applications, based on the date of application.

(3) In cases where there is more than one first biosimilar product application among the marketing authorisation applications for medicinal products for human use whose preliminary assessment has been found satisfactory, in accordance with Article 7 of this Guideline, the authorisation process is initiated only for the first three applications, based on the date of application.

(4) Applications for assessment as to whether a product applied for as an innovative product is indeed an innovative product shall be submitted to the Priority Assessment Unit in accordance with the Guideline on the Working Procedures and Principles of the Priority Assessment Board for Medicinal Products for Human Use. A marketing authorisation application shall be filed following the outcome of the assessment."

(5) The list of essential medicines and other essential medicines is tracked on the basis of the current WHO Model List of Essential Medicines, the WHO Model List of Essential Medicines for Children, and the "List of Active Products" included in the current SKRS e-Prescription Medicines and Other Pharmaceutical Products List aligned with these lists.

(6) The total number of products among the medicinal products for human use included in the scheduling list for which the authorisation process is to be initiated is determined taking into account the authorisation capacity of the Agency.

(7) For medicinal products for human use where it is determined that the information and documents in question, or the necessary explanation that these information and documents could not be submitted together with the date on which they are to be submitted, have not been provided within thirty days pursuant to Article 13, paragraph one, clause (c) of the Regulation on Licensing of Medicinal Products for Human Use, and whose applications have accordingly been rejected on procedural grounds; where a new marketing authorisation application is filed by the applicant, the authorisation processes of the applications whose preliminary assessment has been found satisfactory shall be initiated without waiting on the scheduling list.

(8) The authorisation processes of applications made in accordance with the Guideline on Reliance Practices Regarding the Authorisation Process of Medicinal Products for Human Use, under the Collaborative Registration Procedure with the WHO, commence after the WHO obtains access to the relevant data of the Agency.

(9) In marketing authorisation applications to be filed for medicinal products for human use for which the Priority Assessment Board has decided to prioritise in audit processes, the application shall be evaluated without requiring a GMP certificate issued by the Agency for the manufacturing steps covered by the audit conducted by the Agency. Where the preliminary assessment of the application is found satisfactory, the application shall be included in the scheduling list. However, for marketing authorisation applications to be filed for medicinal products for human use which are found suitable for evaluation within the scope of a conditional marketing authorisation (CMA) or exceptional marketing authorisation application pursuant to the decision of the Priority Assessment Board, where the preliminary assessment of the application is found satisfactory, the authorisation processes shall be initiated on a high-priority basis without being included in the scheduling list.

THIRD SECTION

Evaluation of Applications

Preliminary Assessment of the Application

ARTICLE 6 – (1) Whether the application dossier submitted to the Agency for the purpose of obtaining a marketing authorisation for a medicinal product for human use constitutes a complete application in terms of the documents required to be submitted according to the nature of the application and the electronic marketing authorisation application requirements is examined by the Preliminary Assessment (CTD) Unit through a preliminary assessment. This assessment is carried out in the order of the date of application. Medicinal products for human use whose preliminary assessment has been found satisfactory are included in the scheduling list.

Scheduling of the Application

ARTICLE 7 – (1) The marketing authorisation applications of medicinal products for human use whose preliminary assessment has been found satisfactory are ranked in the scheduling list on the basis of the group category priority set out below and the date of application of the authorisation application submitted in a complete and full manner within each group.

i. First biosimilar group ii. First pharmaceutical equivalent group iii. Medicinal products for human use containing the active substances contained in the medicines included in the Foreign Medicine Price List iv. Innovative product group v. Blood products group vi. Other biological medicinal products group, including immunological medicinal products for human use (excluding allergen products and blood products) vii. Allergen products group viii. Medicinal products for human use included in the list of essential medicines group ix. Medicinal products for human use designated as other essential medicines group x. Other medicinal products for human use group

(2) The medicinal products for human use included in the scheduling list are taken into the process taking into account the numbers indicated in accordance with the group category priority and the order of dates set out in the table. Where a decision is taken to initiate the process for a greater number of products than the numbers specified in the table, the processes are again initiated taking into account the group category priority and the date of application.

Group name | Number First biosimilar group | 3 applications First pharmaceutical equivalent group | 5 applications Medicinal products for human use group containing the active substances contained in the medicines included in the Foreign Medicine Price List | All Innovative product group | All Blood products group | All

Other biological medicinal products group, including immunological medicinal products for human use (excluding allergen products and blood products) | All Allergen products group | 3 applications Medicinal products for human use included in the list of essential medicines group | 3 applications Medicinal products for human use designated as other essential medicines group | 3 applications Medicinal products for human use group falling outside the product groups specified above | 5 applications

Table: Group names and numbers of marketing authorisation applications found satisfactory in the preliminary assessment to be taken into the process

(2) The authorisation process of the medicinal products for human use included in the scheduling list may be initiated, in accordance with paragraph one, only in the months of February, May, August and November of the year.

(3) In accordance with paragraph one, the group category of the products ranked on the basis of the date of application is updated immediately prior to their being taken into the authorisation process, according to the current list of authorised products, the list of essential medicines, and the foreign medicine price list, and their processes are initiated in accordance with paragraph 2 of this Article.

(4) The processes of marketing authorisation applications for medicinal products for human use whose prioritisation in authorisation processes has been found appropriate by the Agency

within the scope of the Guideline on the Procedures and Principles of the Priority Assessment Board shall be initiated without being included in the scheduling list.

PROVISIONAL ARTICLE 1 – (1) Products for which a marketing authorisation application was filed before this Guideline enters into force shall be listed solely on the basis of their dates of application. Their authorisation processes shall be initiated in such a way as to precede the products included in the scheduling list to be created under this Guideline, in the month/months in which the authorisation process is to be initiated.

Entry into Force

ARTICLE 8 – (1) This Guideline enters into force on 1.1.2024.

(2) The provisions of this Guideline shall not apply to medicinal products for human use whose marketing authorisation application date precedes the entry into force date of this Guideline. Medicinal products for human use for which a marketing authorisation application has been filed as of the entry into force date of the Guideline shall be processed in accordance with Article 7 of this Guideline, in the order of the date of application.

Enforcement

ARTICLE 9 – (1) The provisions of this Guideline shall be executed by the President of the Agency.

Revision history

Revision No Revision Date Justification and Explanations 1 29.12.2023 1- The first paragraph of Article 7 and the second paragraph of Article 8 were updated and made more comprehensible.

2- Provisional Article 1 was added. 2 27.02.2024 1- A ninth paragraph has been added to Article 5 regarding the processes for products that are of priority in inspection procedures and for marketing authorization applications considered under conditional and exceptional special priority status.