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GUIDELINE ON THE APPLICATION PROCEDURE TO THE ETHICS COMMITTEE FOR COSMETIC CLINICAL TRIALS KÜD-KLVZ-46

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Purpose

ARTICLE 1- (1) This Guideline has been prepared pursuant to the requirements of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials in order to provide guidance on the form and content of the application to be made to the Ethics Committee for Cosmetic Clinical Trials regarding efficacy studies, safety studies or clinical trials of cosmetic products or raw materials to be conducted on volunteers.

Scope

ARTICLE 2- (1) This Guideline has been prepared for natural or legal persons who will conduct studies or research on cosmetic products or raw materials to be performed on volunteers.

Legal Basis

ARTICLE 3- (1) This Guideline has been prepared on the basis of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials, published in the Official Gazette No. 29481 dated 20/09/2015.

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Definitions

ARTICLE 4- (1) In this Guideline; a) Informed consent form (ICF): The document that evidences in writing the consent obtained by providing detailed and comprehensible information about the study or research, b) Study or research protocol: The document that describes in detail the purpose, methodology, statistical methods to be applied and arrangements of the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials, and the arrangements pertaining to the study or research, c) Sponsor: The person, institution or organization responsible for the initiation, conduct or financing of the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials, ç) Ethics Committee for Cosmetic Clinical Trials: The independent committees to be established or approved by the Agency in order to give scientific and ethical opinions on the study or research protocol, the suitability of the investigators, the adequacy of the sites where the study or research will be conducted, the methods and documents to be used in informing the volunteers, the consents to be obtained from the volunteers, and other matters related to the studies or research, with the aim of protecting the rights, health-related safety and well-being of the volunteers who will participate in the study or research to be conducted with cosmetic products or raw materials, and of ensuring that the study or research is conducted and followed up in accordance with the relevant legislation, ç) Agency: The Turkish Medicines and Medical Devices Agency (TİTCK), d) Responsible investigator: The person who has completed his/her education at the level required by the study or research in the field related to the subject of the study or research, and who is responsible for the conduct of the study or research, e) Contract research organization (CRO): The independent organization to which the sponsor has transferred all or part of its duties and authorities regarding the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials by means of a written contract,

shall mean the foregoing.

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Form and content of applications and notifications

ARTICLE 5- (1) The application shall be made, in compliance with the legislation, by the sponsor, the contract research organization to be assigned by the sponsor, or the responsible investigator. (2) An application shall be made to an ethics committee for cosmetic clinical trials in order to obtain scientific and ethical approval for the studies or research. (3) The application to the Ethics Committee for Cosmetic Clinical Trials shall be made using the application form and cover letter template published on the Agency's website. The said forms are updated when necessary, and the form to be used in the application must be up to date. (4) If the study or research is international, a list of the other relevant authorities to which the same application has been submitted shall be annexed to the file. If there are differences between the protocol and other matters to be implemented in other countries and the protocol and other matters to be implemented in our country, these shall be stated together with their justifications. (5) If the applicant is not the responsible investigator or the sponsor of the study or research, the original of the document indicating the matters in which the contract research organization has been authorized by the sponsor shall be annexed to the application file. (6) For initial applications and applications for substantial modifications, if requested by the ethics committee, the original and one copy of the bank receipt indicating that the fee determined so as not to exceed the application fee determined by the Agency and published on the Agency's website has been deposited into the account determined by the institution/organization where the ethics committee for cosmetic clinical trials has been established, must be annexed to the application file. (7) No application fee is required for studies or research conducted for academic purposes (thesis, project, etc.). However, the document approved by the manager of the relevant institution (the dean in faculties, the secretary general or hospital manager in hospitals), indicating that the said study or research is for academic purposes, shall be included in the application file. (8) By signing the relevant application form, the sponsor, the contract research organization to be assigned by the sponsor, or the responsible investigator undertakes that the information submitted is sufficient, that the annexed documents accurately reflect the existing information, that he/she considers it reasonable, in his/her opinion, to initiate the study or research, and that he/she accepts the initiation of the study or research.

Study or research protocol

ARTICLE 6- (1) The content of the study or research protocol shall comply with the legislation. (2) The protocol submitted as an annex to the study or research file shall cover the version number of the protocol, the explicit name of the study or research, the code numbers of all versions of the protocol determined by the sponsor, the contract research organization to be assigned by the sponsor, or the responsible investigator, the version number and date to be updated with the inclusion of modifications, or the short title or name given to this protocol, and shall be signed by the sponsor, the contract research organization to be assigned by the sponsor, or the responsible investigator.

(3) If the study or research protocol and the protocol amendment are in a different language, the original of the protocol shall be submitted together with the Turkish translation of the protocol and the protocol amendment. Notification of amendments and method of obtaining approval

ARTICLE 7- (1) Permission may be granted for making changes to the conduct of a study or research after it has been initiated. (2) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall assess whether the change is significant and shall apply to the ethics committee using the appropriate current form and cover letter template published on the Agency's website. (3) Matters to be considered as significant changes in studies or research are the following: a) A change in the sponsor or the contract research organization to be appointed by the sponsor, b) A change in the responsible investigator, c) The relocation or closure of the sites where the study or research is to be conducted, or the

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addition of new sites, ç) A change in the cosmetic products or raw materials on which the study or research is based, d) A change in the name/trade name of the cosmetic products or raw materials on which the study or research is based, e) A change in the manufacturer of the cosmetic products or raw materials on which the study or research is based, f) Changes in information related to the manufacture of the cosmetic products or raw materials on which the study or research is based, g) A change in the duration and frequency of use of the cosmetic products or raw materials on which the study or research is based, ğ) In the event that cosmetic products or raw materials used for comparison purposes exist in the study or research, the replacement thereof, h) Changes in the critical characteristics of the cosmetic products or raw materials on which the study or research is based; namely in their stability, structure, effect, formulation and the like, ı) Changes relating to the safety assessments of the cosmetic products or raw materials on which the study or research is based, i) A change concerning the safety of the cosmetic products or raw materials on which the study or research is based, occurring during their application on volunteers,

j) A change in the scientific value of the study or research, k) Changes in the manner or method by which the study or research is conducted, l) Changes relating to the study or research protocol, m) A change in the purpose of the study or research, n) A change in the design of the study or research, o) A change in the informed consent form (ICF), ö) A change in the method of recruiting volunteers for the study or research, p) The addition or removal of tests or measurements, or changes in their methods, r) A change in the number of volunteers, s) A change in the age range of the volunteers, ş) A change in the inclusion and exclusion criteria for volunteers in the study or research, t) A change in the statistical analysis method.

(4) An application regarding a change shall contain at minimum the following information: a) The cover letter template appropriate to the subject, b) The current application form published on the Agency's website; 1) The full title of the study or research and, if available, the protocol code number, 2) Information on the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator, 3) The version number and date of the updated change, 4) Indication of the changes by underlining, and, where possible, a summary of the amended documents, 5) The potential consequences for the volunteers enrolled in the study or research and an assessment of these consequences. (5) The rejection of applications does not preclude the right of the applicant to resubmit the information. Suspension of studies or research

ARTICLE 8- (1) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall inform the relevant ethics committee when suspending the study or research. Notification of the termination of studies or research

ARTICLE 9- (1) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall notify the relevant ethics committee of the termination of the study or research within ninety days of such termination.

(2) The study or research protocol shall include a section concerning the termination of the study or research. The date of the last visit of the last volunteer included in the study or research may be designated as the termination of the study or research. Any exceptional circumstances shall be set out in the protocol together with the justification thereof. (3) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall inform the relevant ethics committee in the event that the study or research is not initiated after obtaining permission from the Agency, or is not restarted after being suspended. This notification shall include a letter briefly explaining the reasons for not initiating and for terminating the study or research. (4) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall submit the study or research final report to the relevant ethics committee within ninety days of the termination of the study or research. Entry into Force

ARTICLE 10- (1) This Guide enters into force upon approval by the President of the Agency. Execution

ARTICLE 11- (1) The provisions of this Guide shall be executed by the President of the Agency.

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REVISION HISTORY Revision No Revision Date Justification and Explanations 1 15.11.2022 An update has been made in line with systemic requirements.

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