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GUIDELINE ON INSURANCE COVERAGE TO BE PROVIDED FOR EFFICACY AND SAFETY STUDIES CONDUCTED ON COSMETIC PRODUCTS OR RAW MATERIALS AND CLINICAL TRIALS THEREOF KÜD-KLVZ-49

First Version Date of Entry into Force: 27.10.2015 1st Revision Date of Entry into Force: 15.11.2022

Objective

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 provision of insurance coverage by the sponsor of the study or trial, the contract research organization appointed by the sponsor, or the responsible investigator, for the purpose of protecting the volunteers participating in the studies and trials against any harm that may arise from the procedures applied.

Scope

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

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.

Definitions

ARTICLE 4- (1) In this Guideline; a) Study or trial protocol: the document that describes in detail the objective, methodology, statistical methods to be applied, and the arrangements of the efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials, b) 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, c) Agency: the Turkish Medicines and Medical Devices Agency (TİTCK), ç) Insurance: the financial instrument used to compensate for damages that may arise as a result of the occurrence of risks, d) Insurance policy: the written, legal evidence of the insurance contract between the insurer and the insured, e) Insurance certificate: a document issued by the insurance company and given to the insured, which may be used as evidence of the existence of the insurance contract, f) Insurance company: insurance companies established in Turkey and the organizations in Turkey of insurance companies established abroad, g) Responsible investigator: the person who has completed education at the level required by the study or trial in the field related to the subject of the study or trial, and who is responsible for the conduct of the study or trial, ğ) Contract research organization (CRO): the independent organization to which the sponsor has transferred all or part of its duties and authorities related to the efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials through a written contract,

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shall mean.

General Principles

ARTICLE 5- (1) In studies or research that do not require ethics committee approval; it is the responsibility of the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator, according to the nature of the study or research, to assess the necessity of insuring the volunteers and to carry it out.

(2) For studies or research requiring insurance;

a) In the event that volunteers participating in the study or research suffer harm that may arise from the cosmetic products or raw materials used during the study or research and from the procedures to be applied, insurance coverage shall be provided. In this context, it is required to document that the volunteers participating in the studies or research are covered by insurance, in accordance with the legislation, by the sponsor of the study or research, the contract research organization to be appointed by the sponsor, or the responsible investigator.

b) The insurance policy, or, in cases where the insurance policy cannot be submitted with justification, the certified copy of the insurance policy or insurance certificates clearly indicating the conditions in the policy and referring to the policy, shall also be submitted to the ethics committee and the Agency. In this context, the insurance policy or insurance certificates to be submitted to the ethics committee and the Agency shall:

1) Include the insurer's full name, trade title, and contact details including address,

2) Include the name and contact details, including address, of the policyholder (the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator),

3) Include the name and contact details, including address, of the insured (the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator),

4) Include the subject of the insurance (the full title of the study or research and the protocol number),

5) Include the type of insurance (such as clinical trials liability policy, third-party financial liability insurance policy),

6) Include the risks assumed by the insurer (the scope of the insurance, including illness, disability, and death, and treatment expenses) and the moments at which they commence and terminate,

7) Include the insurance amount (the insurance compensation limit determined per event/per person and the total insurance compensation limit),

8) Include the amount of the premium and the time and place of payment,

9) Include the number of volunteers to be enrolled in the study or research (the minimum number of volunteers planned to be enrolled in our country),

10) Include all circumstances that serve to determine the true nature of the risks assumed by the insurer,

11) Include the duration of the insurance (the period of insurance must, at a minimum, cover the period from the commencement to the completion of the study or research),

12) Include the date of issuance and the wet-ink signature,

13) Include the special conditions under which the insurance is to be provided,

14) Include the exclusions set forth in the insurance policy, if any,

15) Include the additional coverages to be provided together with the cosmetic products or raw materials on which the study or research is based,

16) Include the countries in which the insurance is valid,

17) Include the arrangements related thereto if the contract contains a foreign element,

18) Include information on exemptions or coinsurance, if any, regarding the insurance taken out,

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19) Be printed in a clear and easily legible manner, approved by the relevant Ministry, and expressly contain in writing the general conditions of insurance.

c) The insurance policy and certificates shall not contain a clause stating that, in the event the policyholder is covered under another similar insurance coverage, the coverage of such insurances not specific to the study or research shall come into effect.

ç) Study or research insurances shall be arranged independently of other insurance coverage and in a manner that provides coverage for protection against any harm that may arise from the study or research.

d) If the insurance policy or insurance certificates containing all of the above matters are issued by insurance companies established in Türkiye and licensed to operate in Türkiye in accordance with the relevant legislation, the documents shall be drawn up in Turkish; if the insured and the insurance company are foreign, the original or certified copy of the documents drawn up in a language other than Turkish shall be submitted together with a Turkish translation (certified by a notary or a sworn translator).

e) The acceptance of insurance documents drawn up by insurance companies established in Türkiye is subject to the condition that these companies are licensed by the Undersecretariat of Treasury.

Entry into Force

ARTICLE 6- (1) This Guide enters into force upon the approval of the President of the Agency.

Execution

ARTICLE 7- (1) The provisions of this Guide shall be executed by the President of the Agency.

REVISION HISTORY Revision No Revision Date Reasons and Explanations 1 15.11.2022 An update has been made regarding systemic requirements.

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