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GUIDELINE ON TRAINING FOR EFFICACY STUDIES, SAFETY STUDIES AND/OR CLINICAL TRIALS TO BE CONDUCTED WITH COSMETIC PRODUCTS OR THEIR RAW MATERIALS ON VOLUNTEERS KÜD-KLVZ-50

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Purpose

ARTICLE 1- (1) This Guideline has been prepared in accordance with the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials, with the aim of providing guidance on training programmes to be organised for the purpose of training responsible investigators, investigators and other persons working in this field, on the subjects of efficacy studies, safety studies and/or clinical trials to be conducted with cosmetic products or raw materials on volunteers.

Scope

ARTICLE 2- (1) This Guideline has been prepared for natural or legal persons wishing to provide training on the subjects of efficacy studies, safety studies and/or clinical trials to be conducted with cosmetic products or raw materials on volunteers.

Legal Basis

ARTICLE 3- (1) This Guideline has been prepared on the basis of Articles 24 and 28 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, and subparagraph (ç) of Article 9 of the Directive on the Duties of the Department Directorates Affiliated to the Service Units of the Turkish Medicines and Medical Devices Agency.

Definitions

ARTICLE 4- (1) As used in this Guideline: (a) Training: courses, seminars, training meetings and similar events organised for the purpose of training qualified responsible investigators, investigators and other persons working in this field who have received training on the subjects of efficacy studies, safety studies and/or clinical trials to be conducted with cosmetic products or raw materials on volunteers, (b) Cosmetic product: all substances or mixtures intended to be applied to the external parts of the human body; the epidermis, nails, hair, hairs, lips and external genital organs, or the teeth and the mucous membranes of the oral cavity, the sole or main purpose of which is to clean them, to perfume them, to change their appearance, to protect them, to keep them in good condition or to correct body odours, (c) Cosmetic raw material: a substance used alone or in mixture form within a cosmetic product for the purpose of providing a cosmetic effect or as an auxiliary component, (ç) Efficacy studies: efficacy studies are studies conducted with the aim of investigating the efficacy claims of cosmetic products or raw materials; efficacy studies conducted on volunteers include consumer perception tests, perception studies conducted by trained participants, or instrumental test studies,

(d) Safety studies: safety studies conducted on volunteers, studies in which the compatibility of the cosmetic products or raw materials being tested with tissues such as skin and mucous

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membranes is evaluated, (e) Cosmetic clinical trial: studies or research conducted on volunteers for the purpose of revealing or confirming the clinical effects of one or more cosmetic products, identifying their undesirable effects, or determining their absorption, distribution, metabolism and excretion, (f) Agency: the Turkish Medicines and Medical Devices Agency.

Fundamental Principles

ARTICLE 5- (1) All trainers who will take part in the training programmes to be conducted concerning efficacy studies, safety studies and/or clinical trials to be carried out with cosmetic products or raw materials must prove, by means of documents, that they possess a sufficient level of scientific and/or technical education relevant to the subject on which they will provide training. (2) The qualifications of the persons who will attend the training programme must be adequate for receiving the training to be provided. (3) The scope of the training programme and the qualifications of the participants must be compatible. (4) The certificate to be issued at the end of the training programme must be named in accordance with the scope of the training. (5) The total number of persons who may attend the training programme is limited to a minimum of 20 persons and a maximum of 80 persons, in groups of no more than 20 persons. (6) Depending on the scope of the training programme, practical parts are included in the training. (7) It is considered appropriate that the following be stipulated: "The environment in which the training is provided possesses the conditions required by the training, and includes the necessary technological equipment such as projection, computers, DVD or VCD players, sound systems, electronic hardware for participants, and other necessary apparatus and devices that will enhance the effectiveness of the training." (8) At least one examination is administered by which the scope of the training can be measured at an adequate level. (9) The training programme is conducted under the responsibility of "academic coordinator/coordinators who are experts in the field."

Implementation

ARTICLE 6- (1) At the beginning of the training, the expectations of the participants are surveyed and compared with the anticipated objectives. (2) A compulsory attendance requirement of 70% per lesson is stipulated for the training, and it is monitored by means of an attendance sheet.

(3) For trainings lasting more than one day, a summary of the training given on the previous day is provided at the start of the second day. (4) Before commencing advanced-level trainings organised after basic training, reminders are given regarding the information provided in the basic training. (5) The presentations in the training do not exceed 40 minutes, and in the practical study part, the sections do not exceed 90 minutes. (7) Each participant is given a name badge, a programme, training notes, and additionally a notepad and a pen.

Evaluation

ARTICLE 7- (1) At the beginning of the training, a pre-test is administered to measure the participants' level of knowledge. (2) The participants' success is evaluated by means of an examination to be held at the end of the training; a "certificate of achievement" is issued to those who are successful, and a "certificate of attendance" certifying their participation in the training is issued to those who are unsuccessful. (3) For the purpose of evaluating the effectiveness of the training programme, feedback is obtained from the participants through questionnaires and similar tools. (4) The "certificate of achievement" or "certificate of attendance" bears the signature of the coordinator of the training programme.

Trainers

ARTICLE 8- (1) Trainers must be selected from among persons who are experts in their field. These persons possess documentation proving their competence in the necessary scientific and/or technical knowledge.

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Training Programme Contents

Article 9- (1) The course content is determined according to the title of the training to be provided. (2) Topics covering the following titles may be included in the scope of the training in the Basic Course on Ethical Approach in Studies/Research to be Conducted with Cosmetic Products or Raw Materials on Volunteers.

a) Introduction/Basic Training to Clinical Trials

1) Ethical principles to be complied with in studies to be conducted on volunteers 2) Stakeholders and their responsibilities in clinical trials: cosmetics clinical research ethics committee / principal investigator / investigator / sponsor / contract research organization 3) Relevant legal regulations and the practices carried out by the Agency in accordance with the legislation 4) The requirement to apply to the cosmetics clinical research ethics committee for research 5) Databases that investigators may benefit from

6) Rights of volunteers 7) Volunteer recruitment and retention of volunteers in the study 8) The importance of the Informed Consent Form (ICF) 9) The reason for and content of using standard study methodology, and preparation of documentation 10) Preparation of the research budget 11) Statistical evaluation in research and the reliability of research results 12) Data management: data collection, data entry, data validation, etc. 13) Reporting: reporting of undesirable effects, reporting of statistical results, reporting of the study or research, etc.

b) Safety studies conducted on volunteers 1) Skin irritation tests 1.1 Cumulative irritation tests 1.2 In-home use tests 2) Ophthalmological test 3) Comedogenicity test 4) Phototoxicity and photosensitization tests

c) Efficacy studies conducted on volunteers 1) Sensory tests: 1.1. Personal evaluation studies i. Consumer evaluation tests ii. Sensory evaluation studies conducted by participants trained in cosmetic products 1.2. Evaluation conducted by professionals i. Studies under medical supervision ii. Studies conducted under the supervision of other professionals 2) Instrumental tests

2.1. Measurement of skin hydration 2.2. Measurement of transepidermal water loss (Trans Epidermal Water Loss - TEWL) 2.3. Sebum measurement 2.4. Measurement of skin pH 2.5. Measurement of skin color

2.6. Measurement of skin blood flow: Laser Doppler Flowmeter (LDF) 2.7. Measurement of skin elasticity 2.8. Examination of the skin surface structure

(3) Examples of these tests are provided in the Guideline on Efficacy Studies and Safety Studies of Cosmetic Products or Raw Materials to be Conducted on Volunteers, dated 27/10/2015.

Entry into Force

Article 10- (1) This Guideline enters into force upon the approval of the President of the Agency.

Execution

Article 11- (1) The President of the Agency executes the provisions of this Guideline.

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

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