REGULATION ON EFFICACY AND SAFETY STUDIES AND CLINICAL TRIALS OF COSMETIC PRODUCTS OR RAW MATERIALS

SECTION ONE Purpose, Scope, Legal Basis and Definitions

Purpose

ARTICLE 1 – (1) The purpose of this Regulation is to set out the procedures and principles regarding the conduct, record-keeping, reporting and validity of efficacy studies, safety studies or clinical trials of cosmetic products or raw materials to be performed on volunteers, the ensurance of scientific and ethical standards in these and other matters, and the protection of the rights of volunteers, as well as to regulate the establishment, duties, and working procedures and principles of Cosmetics Clinical Trials Ethics Committees.

Scope

ARTICLE 2 – (1) This Regulation covers the efficacy studies, safety studies or clinical trials to be conducted on volunteers with cosmetic products or raw materials, the places where such studies and trials will be conducted, and the natural or legal persons who will carry out such studies and trials.

Legal Basis

ARTICLE 3 – (1) This Regulation has been prepared on the basis of Article 10 of the Fundamental Law on Health Services No. 3359 dated 7/5/1987, and Articles 27 and 40 of the Decree Law No. 663 dated 11/10/2011 on the Organization and Duties of the Ministry of Health and Its Affiliated Organizations.

Definitions

ARTICLE 4 – (1) In this Regulation;

a) Investigator: the person who takes part in the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials under the supervision of the responsible investigator,

b) Informed consent form: the document evidencing in writing the consent obtained by providing detailed and comprehensible information about the study or trial,

c) Serious adverse effect: an adverse effect resulting in temporary or permanent functional impairment, disability, hospitalization or medical treatment, congenital anomalies, or immediate life-threatening condition or death,

ç) Study or trial protocol: the document describing in detail the objective, methodology, statistical methods to be applied of the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials, and the arrangements pertaining to the study or trial,

d) 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,

e) Volunteer: the person who will participate in the efficacy studies, safety studies or clinical trials of cosmetic products, with the written consent of himself/herself or his/her legal representative having been obtained in accordance with the provisions of this Regulation and the relevant legislation,

f) Safety assessment: the assessment carried out for a cosmetic product or raw material, taking into consideration its toxicological profile, chemical structure and exposure levels, and the specific exposure characteristics of the target population for which it is intended to be used or the area of application,

g) Adverse effect: an unexpected effect adversely affecting human health following the normal or reasonably foreseeable use of a cosmetic product,

ğ) Cosmetic raw material: the substance used in a cosmetic product, alone or in the form of a mixture, for the purpose of providing a cosmetic effect or as an auxiliary component,

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h) Cosmetics Clinical Trials Ethics Committee: the independent committees to be established or approved by the Agency for the purpose of protecting the rights, health-related safety and well-being of the volunteers who will participate in the study or trial to be conducted with cosmetic products or raw materials, and of ensuring that the study or trial is conducted and followed up in compliance with the relevant legislation, and which are to give opinions on scientific and ethical matters concerning the study or trial protocol, the suitability of the investigators, the adequacy of the places where the study or trial 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 trials,

ı) Clinical Trials Advisory Board: the advisory board established within the Agency pursuant to Article 10 of the Fundamental Law on Health Services No. 3359,

i) Cosmetic product: all substances or mixtures intended to be applied to the external parts of the human body; the epidermis, nails, hair, head hair, lips and external genital organs, or to the teeth and the mucous membranes of the oral cavity, the sole or principal purpose of which is to clean them, perfum them, change their appearance, protect them, keep them in good condition or correct body odours,

j) Efficacy or safety studies of cosmetic products or raw materials: the studies conducted on volunteers for the purpose of investigating the efficacy or safety claims of cosmetic products or raw materials,

k) Clinical trials of cosmetic products or raw materials: the studies or trials performed on humans for the purpose of identifying or confirming the clinical effects of one or more cosmetic products, identifying their adverse effects, or determining their absorption, distribution, metabolism and elimination,

l) Agency: the Turkish Medicines and Medical Devices Agency (TİTCK),

m) Centre: the place where the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials are conducted,

n) Responsible investigator: the person who has completed the education 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,

o) Contract research organization (CRO): the independent organization to which the sponsor has transferred, in whole or in part, its duties and authorities relating to the efficacy studies, safety studies or clinical trials of cosmetic products or raw materials by means of a written contract,

shall mean.

SECTION TWO General Principles of Efficacy Studies of Cosmetic Products or Raw Materials, Safety Studies or Clinical Trials, Obtaining Consent for the Study or Trial, and Principles Regarding Its Conduct

General principles of studies or trials

ARTICLE 5 – (1) In order to carry out studies or research on volunteers, the following requirements shall be met:

a) If a study or research is to be conducted on cosmetic products or raw materials, the study or research must first have been carried out in a non-human experimental environment.

b) The study or research shall be conducted on cosmetic products or raw materials that have undergone a safety assessment.

c) The expected benefits of the study or research cannot be given precedence over the health of the volunteer, the potential risks that may arise with respect to their health, or other personal rights.

ç) For studies or research to be conducted under this Regulation, an application shall first be made to the Agency. Where deemed necessary, the Agency shall decide on the scope in which the study or research is to be conducted, also obtaining the opinion of scientific committees.

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d) The study or research must not have any foreseeable harmful or permanent effect on human health and must not carry any risk of death.

e) The person wishing to volunteer to participate in the study or research, or their legal representative, shall be sufficiently informed, prior to the commencement of the study or research, by the responsible investigator, in a manner they can understand, about the purpose, method, expected benefits, foreseeable risks and discomforts of the study or research, aspects that are unsuitable with respect to the person's health and personal characteristics, and the conditions under which the study or research will be conducted and continued, as well as the fact that they have the right to withdraw from the study or research at any time.

f) The volunteer's consent, which is not dependent on any provision of benefit, shall be obtained to indicate their inclusion in the study of their own free will, and this shall be documented by means of an informed consent form (ICF) covering the matters relating to the information set forth in paragraph (e). The informed consent form (ICF) shall be prepared in two copies. One of these copies shall be given to the volunteer in exchange for their signature, and the other shall be kept by the responsible investigator.

g) During the study or research, methods that would cause pain to the volunteer to an extent incompatible with human dignity shall not be applied.

ğ) At least one person from the study or research team shall be designated to enable the volunteer to obtain information about their condition and the course of the study or research at any time and to establish contact for this purpose.

h) The volunteer may withdraw from the study or research at any time, of their own accord, with or without justification, and shall not be subjected to any sanction or detriment on this account.

ı) Apart from insurance coverage, no persuasive incentive or financial offer may be made to the volunteer to secure their participation in or continuation of the study or research. However, the expenses that will arise from the volunteers' participation in the study or research and any loss of income resulting from the loss of working days shall be indicated in the study or research budget and, if documented, covered from the budget.

i) Upon completion of the study or research, the participants have the right to receive information on the results of the study or research and on the benefits arising therefrom. Where the information obtained at the end of the study or research is published, the identity data of the volunteer shall not be disclosed without their consent.

j) The persons who will participate in efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials shall be selected according to the inclusion and exclusion criteria specified in the study or research protocol.

k) No study or research shall be conducted on substances prohibited from use as cosmetic products or ingredients. For substances whose use as cosmetic products or ingredients is restricted, no study or research shall be conducted on those intended to be used outside the established limits.

l) Samples taken from volunteers shall not be used in another study or research without the volunteer's consent. Images belonging to volunteers shall not be published without their consent.

Efficacy studies conducted on volunteers

ARTICLE 6 – (1) Efficacy studies are studies conducted to investigate the efficacy claims of cosmetic products or raw materials. Efficacy studies conducted on volunteers are consumer perception tests, perception studies conducted by trained participants, or instrumental test studies.

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Safety studies conducted on volunteers

ARTICLE 7 – (1) Safety studies conducted on volunteers are studies in which the compatibility of the cosmetic products or raw materials being tested with tissues such as skin and mucous membranes is assessed.

Cosmetic clinical trials conducted on volunteers

ARTICLE 8 – (1) Clinical trials conducted on volunteers using cosmetic products or raw materials are studies or research carried out to reveal or confirm the clinical effects of one or more cosmetic products, to identify their undesirable effects, or to determine their absorption, distribution, metabolism, and excretion.

Locations, standards, and permit application for studies or research

ARTICLE 9 – (1) Clinical trials of cosmetic products or raw materials shall be conducted in university healthcare application and research centres, approved research and development centres affiliated with universities, training and research hospitals of the Ministry of Health, and other laboratories that have personnel, equipment, and laboratory facilities suitable for ensuring the safety of the persons to be studied, for the healthy conduct, follow-up, and, where necessary, emergency intervention of the study, and appropriate to the nature of the study. Other healthcare institutions and organisations possessing the specified qualities may also be included in the studies or research conducted in these centres and hospitals, provided that this is under the coordination or administrative responsibility of these centres and hospitals where necessary.

Application and permit for studies or research

ARTICLE 10 – (1) The application for efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials shall be made to the Agency by a sponsor consisting of natural or legal persons, by a contract research organisation designated by the sponsor, or by the responsible investigator.

(2) The application shall be evaluated by the Agency. Those requiring ethics committee approval shall be referred to the ethics committee. The studies or research shall be commenced after the permit of the Agency has been obtained.

(3) If the Agency has decided against the commencement of the study or research, it shall notify the applicant thereof with justification. The applicant may, on one occasion only, reapply by making the necessary changes on the matters specified in the decision, or may object to the decision with justification. Where the requested changes are not implemented or no acceptable justification is submitted in this regard, the Agency shall reject the study.

Conduct of studies or research

ARTICLE 11 – (1) The study or research shall be conducted as follows:

a) Efficacy studies, safety studies, or clinical trials on cosmetic products or their raw materials conducted on volunteers within the scope of this Regulation shall be carried out under the chairmanship of the responsible investigator, with a team appropriate to the nature of the study or research.

b) The sponsor may delegate part of its duties to contract research organizations operating in accordance with clinical principles, provided that a written contract is concluded and the Agency is notified. The delegation of duties to a contract research organization does not eliminate the sponsor's legal liability regarding the study. The sponsor and the contract research organization to be appointed by the sponsor shall be jointly liable for the results of the works and procedures subject to the contract.

c) In studies or research conducted on volunteers, the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall take the necessary measures in the event that a new situation arises during the conduct of the study or

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research that may affect the safety of volunteers. The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall notify the Agency, and additionally the ethics committee in studies requiring ethics committee approval, of this new situation and the information regarding the measures taken.

ç) If the study or research has not been initiated on the date specified in the application file despite being authorized by the Agency, the reasons for non-initiation shall be notified to the Agency.

d) The responsible investigator, where necessary, includes investigators possessing appropriate qualifications from other centers in the study and notifies the Agency thereof.

Suspension or termination of studies or research

ARTICLE 12 – (1) If the Agency determines, during the conduct of a study or research, that one of the existing conditions under which it authorized the study or research has ceased to exist, it shall immediately suspend the study or research. The study or research shall be directly terminated in cases where these conditions are not fulfilled within the specified period, where it is understood that their fulfillment is not possible, or where the health of a volunteer is endangered within this period.

(2) If the decision to suspend or terminate the study or research has been taken by the Agency, the Agency shall notify the decision, together with its justification, to the ethics committee in cases requiring ethics committee approval, to the sponsor, to the contract research organization to be appointed by the sponsor, or to the responsible investigator.

(3) If a study or research has been suspended before completion by the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator after its initiation, the suspension decision, together with its reasons, shall be notified to the Agency and, in cases requiring ethics committee approval, to the ethics committee within fifteen days, accompanied by a written information report containing the final status of the volunteers enrolled in the study or research.

(4) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall notify the Agency, and the ethics committee in cases requiring ethics committee approval, that the study or research has been completed within ninety days from the end of the study or research.

SECTION THREE

Cosmetic Products or Raw Materials Underlying the Study or Research

Characteristics of cosmetic products or raw materials

ARTICLE 13 – (1) Cosmetic products or raw materials must comply with the cosmetic legislation, be manufactured accordingly, and, if a study or research is to be conducted on volunteers, have undergone a safety assessment.

(2) The label on the inner packaging of the cosmetic products or raw materials underlying the study or research, containing information pertaining to the study or research, and the label on the outer packaging or, if there is no outer packaging, on the outermost ready packaging, shall be prepared in Turkish.

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Liabilities regarding cosmetic products or raw materials

ARTICLE 14 – (1) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall be liable for the storage of the cosmetic products or raw materials to be studied or researched, in accordance with the characteristics of the cosmetic products or raw materials after their manufacture or import, their distribution and delivery to the center where the study is conducted, the maintenance of these conditions at that center, the collection of unused or withdrawn cosmetic products or raw materials from the center where the study or research is conducted and ensuring their return or their appropriate destruction, and the keeping or maintenance of records of this entire process.

(2) The responsible investigator at each center where the study or research is conducted, the sponsor, or the contract research organization to be appointed by the sponsor shall be liable for the receipt of the cosmetic products or raw materials used in the study or research, their preservation, their distribution in accordance with the written request or the research or study protocol, stock control, the procedures to be carried out for the remaining portion in accordance with the protocol, and the keeping of their records.

Withdrawal of cosmetic products or raw materials

ARTICLE 15 – (1) In the event of suspension of a study or research, all cosmetic products or raw materials remaining in the possession of the responsible investigator shall be immediately withdrawn from the places of distribution by the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator, and this situation shall be reported to the Agency within fifteen business days in the form of a report together with its documentation.

(2) The withdrawal of the cosmetic products or raw materials used in the study or research, the procedures to be carried out regarding the withdrawn cosmetic products or raw materials, and any measures taken shall be specified in detail in the report notified to the Agency.

Records and confidentiality of the study or research

ARTICLE 16 – (1) All records relating to the study or research shall be regularly kept by the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator, and shall be retained for at least five years after the completion of the study or research at all centers; however, this period may be longer where necessary depending on the nature of the cosmetic product or raw material studied or researched.

(2) The transfer of a study or research for any reason shall be immediately notified to the Agency. The transferee of the study or research shall be responsible for the preservation and archiving of all data and documents.

(3) The confidentiality of documents relating to the study or research is essential. These documents shall be provided only to authorized persons upon request by legally authorized persons or authorities.

SECTION FOUR

Notifications

Notification of undesirable effects

ARTICLE 17 – (1) In studies or research conducted on volunteers, the responsible investigator or an investigator to be appointed by them shall immediately notify the sponsor or the contract research organization to be appointed by the sponsor of all undesirable effects, except those specified in the protocol as not requiring immediate reporting.

(2) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall be obligated to keep records of all undesirable effects reported to it by the investigator or investigators, to notify this information to the Agency and, additionally, to the ethics committee in studies requiring ethics committee approval, and to submit any kind of

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additional information requested.

Notification of serious undesirable effects

ARTICLE 18 – (1) In studies or research conducted on volunteers, the sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall be obliged to submit records of serious adverse effects arising during the study or research to the Agency within seven days and, additionally, in studies requiring ethics committee approval, to the ethics committee; to submit monitoring reports containing additional information to the Agency within eight days and, additionally, in studies requiring ethics committee approval, to the ethics committee; and to inform all investigators at the centers where the study or research is conducted.

Other Notifications

ARTICLE 19 – (1) Appointments related to the study or research that are of a notification nature shall be reported to the Agency. For appointments deemed to be substantial modifications, an application shall be made.

(2) The sponsor, the contract research organization to be appointed by the sponsor, or the responsible investigator shall be responsible for the regular submission of notifications to the Agency.

SECTION FIVE

Structure, Working Procedures and Principles of Ethics Committees for Cosmetic Clinical Trials, Their Duties, and the Advisory Board

Establishment of Ethics Committees for Cosmetic Clinical Trials

ARTICLE 20 – (1) Ethics committees shall be established with at least seven and at most fifteen members, at least one of whom shall be a person who is not a healthcare professional and one of whom shall be a legal professional, with the majority of the members being healthcare professionals educated at the doctoral level or at the level of medical specialization, for the purpose of clinically and ethically evaluating the protocol of the study or research, the design and suitability of the study or research, the inclusion and exclusion criteria for volunteers, the suitability of the investigators, the adequacy of the places 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 these persons, 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 studies or research and of ensuring that the study or research is conducted and followed up in compliance with the legislation.

(2) A member of an ethics committee may not serve on more than one ethics committee at the same time.

(3) At least three members of the ethics committee must be from outside the institution where the secretariat of the ethics committee is located.

(4) Ethics committees shall be established as Cosmetic Clinical Trials Ethics Committees.

(5) The application shall be made to any of the ethics committees established under this Regulation.

(6) Ethics committees at universities shall be established upon the proposal of the rector, in Public Hospital Unions upon the proposal of the secretary general, and at Gülhane Military Medical Academy upon the proposal of the dean, with the approval of the Agency, and shall commence their activities as of the date of such approval.

(7) After commencing their activities, ethics committees shall conduct their correspondence, other than that concerning changes in membership, directly with the Agency or the sponsor or the contract research organization to be appointed by the sponsor, through their own secretariat.

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(8) The Agency shall issue a warning to an ethics committee that does not operate in accordance with ethical principles or regarding which deficiencies are identified, as a result of inspections to be carried out by the Agency, in terms of the premises, secretariat, archive, and other equipment necessary for the conduct of the ethics committee's activities. If the reason for the warning is not remedied within the specified period, the approval granted by the Agency shall be revoked.

(9) The following categories of members shall be found in the Cosmetic Clinical Trials Ethics Committee:

a) A pharmacist who has obtained a doctoral degree in the field of pharmaceutical technology, preferably with studies in the field of cosmetology,

b) A pharmacist or physician who has obtained a doctoral degree in the field of pharmaceutical toxicology,

c) A pharmacist who has obtained a doctoral degree in the field of pharmacognosy or pharmaceutical botany,

ç) A pharmacist who has obtained a doctoral degree in the field of pharmaceutical chemistry,

d) A pharmacist who has obtained a doctoral degree in the field of pharmacology or a physician who has completed his/her specialization,

e) A physician who has completed his/her specialization in the field of dermatology and venereal diseases,

f) A dental practitioner who has completed his/her specialization in the field of periodontology,

g) A legal professional,

ğ) A person who is not a healthcare professional,

h) If available, a person who has completed a doctoral degree or specialization in the field of medical ethics (deontology),

ı) In cases where an expert opinion is required; persons who have obtained a specialization or doctoral degree in the required field.

(10) It is mandatory for the Cosmetic Clinical Trials Ethics Committee to include members with the qualifications specified in subparagraphs (a), (b), (c), (ç), (e), (g), and (ğ) of paragraph 9.

Working Procedures and Principles of Ethics Committees for Cosmetic Clinical Trials

ARTICLE 21 – (1) The working procedures and principles of the Ethics Committees shall be as follows:

a) Ethics committees are independent in evaluating study or research applications scientifically and ethically and in granting approval.

b) Members of ethics committees are obliged to comply with the principle of confidentiality with respect to all information that comes to their attention.

c) Members of ethics committees shall commence their duties by signing the confidentiality document and undertaking to be prepared by the Agency.

ç) A member of an ethics committee who has a duty in the study or research under review may not participate in the discussions and voting of the ethics committee concerning that study or research and may not sign the committee's decision.

d) Members of ethics committees shall convene with a two-thirds majority of the total number of members and shall take decisions by an absolute majority of the total number of members.

e) The term of office of members of ethics committees is two years. The membership of members who, without a valid excuse, fail to attend three consecutive meetings or a total of five non-consecutive meetings during their term of membership shall automatically lapse. A member with the same qualifications shall be elected in place of the member whose term of office has expired or whose membership has lapsed.

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f) Where necessary, ethics committees shall obtain the written opinion of experts in the relevant field or subfield and shall invite such persons to the meeting as advisors.

g) The working methods of ethics committees shall be determined by the Agency and published on the Agency's website. Ethics committees shall conduct their activities within the framework of this arrangement.

Duties and Powers of Ethics Committees for Cosmetic Clinical Trials

ARTICLE 22 – (1) The duties and powers of the Ethics Committees are as follows:

a) Studies or research covered by this Regulation shall be evaluated by ethics committees.

b) No separate committee or structure may be established by other institutions or organizations to perform the functions of an ethics committee or ethics committee functions for the purpose of evaluating matters falling within the scope of this Regulation.

c) In forming an opinion on an application for a study or research, the ethics committees shall evaluate:

1) The analysis of the expected benefits, harms and risks of the study or research;

2) Whether the study or research is based on clinical data and a new hypothesis;

3) The suitability of the study or research;

4) In the case of studies or research to be conducted on humans for the first time, the necessity that they have first been conducted in a non-human experimental setting;

5) Whether, in light of the data obtained from experiments conducted in non-human experimental settings, the study or research has reached a level of maturity sufficient to be conducted on humans for achieving the intended objective, and whether this necessitates its conduct on humans;

6) The study or research protocol;

7) The written information provided in connection with the study or research, and the method followed for obtaining informed consent from volunteers;

8) In the event that health problems arising from the study or research occur, or in the event of the occurrence of an undesirable and/or serious undesirable effect, the liability of the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator, and the scope of the insurance certificate or policy taken out for the volunteers;

9) The suitability of the entire team taking part in the study or research;

10) The safety assessment report;

11) The arrangements concerning the enrollment of volunteers in the study or research;

12) The budget for compensation arrangements deemed appropriate for investigators and volunteers, and, where any agreement has been concluded between the sponsor and the site where the study or research will be conducted, the relevant sections of that agreement.

ç) The ethics committee may, where necessary, monitor, during and at the site of the study or research, any study or research it has approved.

d) The ethics committee shall communicate its opinion to the applicant within at most fifteen working days from the date of application.

e) Where additional information and explanations are required during the review process of the ethics committee, all necessary requests shall be conveyed to the applicant in a single submission. No second request shall be made of the applicant. The review process shall be suspended until the requested information and documents are submitted to the ethics committee.

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Duties and Powers of the Clinical Trials Advisory Board

ARTICLE 23 – (1) The Clinical Trials Advisory Board, established within the Agency and referred to in the Regulation on Clinical Trials of Medicinal Products and Biological Products published in the Official Gazette No. 28617 dated 13/4/2013, shall, upon request of the Agency, issue opinions on objections to ethics committee decisions in all cosmetic clinical trials subject to the provisions of this Regulation, complaints concerning ethics committees, and matters conveyed to the Agency by ethics committees or by the parties to the clinical trials which require expert opinion.

SECTION SIX

Training, Inspection, Liability, Prohibitions and Administrative Sanctions

Training

ARTICLE 24 – (1) The Agency shall, where necessary, organize courses or seminars for the purpose of training qualified principal investigators, investigators and other persons working in this field who have received training in efficacy studies, safety studies and/or clinical trials to be conducted with cosmetic products or their raw materials on volunteers.

Inspection

ARTICLE 25 – (1) The Agency may inspect, with or without prior notice, the centers where clinical trials of cosmetic products or their raw materials on volunteers are conducted, the sponsor and the contract research organization, the places where the cosmetic products or raw materials under research are manufactured, the laboratories where analyses related to the research are carried out, and the ethics committees, with respect to their compliance with this Regulation and other relevant legislation, or have them inspected.

Liability

ARTICLE 26 – (1) Liability for the study or research lies with the person or persons conducting the study or research, the institution, the organization, the sponsor and the contract research organization.

(2) In the event of an undesirable or serious undesirable effect, medical support services shall be provided to the volunteers by the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator. The expenses incurred in return for such medical services may not be claimed from the volunteer or the Social Security Institution.

(3) The fact that informed consent has been obtained from a volunteer participating in efficacy studies, safety studies or clinical trials of cosmetic products or their raw materials conducted on volunteers does not eliminate the volunteer's rights to compensation for damages suffered as a result of the study.

(4) The cost of the cosmetic products or raw materials under study or research, and of the devices and materials intended for the use of the cosmetic products or raw materials, shall be borne by the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator.

(5) Natural or legal persons who are to conduct the study or research are required to specify in detail in the application dossier the financing of the study or research.

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Administrative sanctions

ARTICLE 27 – (1) In the event of a breach of the provisions concerning efficacy studies, safety studies or clinical trials of cosmetic products or raw materials, where the relevant study or research is a multinational international study, the part conducted in Turkey shall be suspended or terminated by the Agency. Where the reasons for suspension are remedied, the situation shall be notified to the Agency by the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator, and where the Agency deems it appropriate, the study or research shall continue.

(2) The Agency shall issue a warning to an ethics committee that does not operate in accordance with ethical principles, that fails to fulfil the Standard Operating Procedure for Ethics Committees in Cosmetic Clinical Trials published by the Agency, or regarding which deficiencies are identified, as a result of an inspection, in terms of the premises, secretariat, archive and equipment suitable for the conduct of ethics committee activities. Where the reason for the warning is not remedied within the period determined, the approval granted by the Agency shall be revoked.

(3) Administrative sanctions shall be imposed, within the scope of the provisions of other relevant legislation and according to the nature of their acts, on those who act in violation of the provisions set out in this Regulation and who are engaged in such activities.

SECTION SEVEN

Miscellaneous and Final Provisions

Guidelines

ARTICLE 28 – (1) Guidelines shall be published by the Agency for the purpose of implementing the provisions of this Regulation.

Matters not covered

ARTICLE 29 – (1) In matters not covered by this Regulation, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and the provisions of other relevant legislation shall apply.

Entry into force

ARTICLE 30 – (1) This Regulation shall enter into force on the date of its publication.

Execution

ARTICLE 31 – (1) The provisions of this Regulation shall be executed by the President of the Turkish Medicines and Medical Devices Agency (TİTCK).

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