From the Ministry of Health

DRAFT REGULATION ON CLINICAL RESEARCH OF TRADITIONAL AND COMPLEMENTARY MEDICINE PRACTICES

GENERAL PREAMBLE

The objective of this Regulation is to regulate principles and procedures with regard to doing scientific research on human beings in the field of traditional and complementary medicine practices and protecting the rights of volunteers within the framework of international agreements that one is party to and good clinical practices.

The basis of and justification for this draft Regulation are as follows:

- Regulation on Traditional and Complementary Medicine Practices was published in the Official Gazette No. 29158 dated 27/10/2014 and entered into force. With this Regulation which is legally based on the Law No. 1219, the Presidential Decree Law No. 1 and the Law No. 3359, the conduct of traditional and complementary medicine practices on human health under the supervision of the responsible physician and/or dentist within the healthcare institutions authorized by the Ministry so as to support treatment practices has gained a legal basis.
- WHO Traditional and Complementary Medicine Strategy 2013-2017 reveals the need to extend the use of traditional and complementary medicine practices and to conduct further clinical studies to that end and encourages the countries to make legal arrangements in this field.
- CAMBrella project, which is an official project conducted by the European Union, has revealed the situation of traditional and complementary medicine practices carried out in European Union countries and has introduced a perspective on traditional and complementary medicine practices to the countries. Within this scope, it is emphasized that European countries' knowledge on and experience in traditional and complementary medicine practices should be sought and the legal status of these practices which support modern medicine should be analyzed.
- Regulation on Traditional and Complementary Medicine Practices was first introduced with the 10th Development Plan and the Ministry of Health Strategic Plan 2010 and, within this context, the General Directorate of Health Services was restructured. Furthermore, licensing works for phytotherapy and homeopathy products are proceeding within Turkish Medicines and Medical Devices Agency.
- *Regulation on Clinical Research Conducted on Drugs and Biological Products* (No. 28617 dated 13/04/2013), *Regulation On Medical Device Clinical Trials* (No. 29111 dated 6/9/2015) and *Regulation on Effectiveness and Reliability Studies and Clinical Research of Cosmetic Products or Raw Materials* (No. 29481 dated 20/9/2015) published by Turkish Medicines and Medical Devices Agency regulate clinical research legislation for the research to be conducted on drugs and biological products,

medical devices, and cosmetics. Clinical research to be conducted for Traditional and Complementary Medicine Practices other than those mentioned above are outside the scope of these Regulations, which means there is a legislation gap in this regard.

- As per Article 355 of Presidential Decree Law No. 1, the Ministry of Health is authorized to regulate traditional and complementary medical practices and the General Directorate of Health Services is the authorized and responsible unit within the Ministry of Health.
- Public and private sectors and natural and legal persons experience some challenges when they wish to conduct clinical research (on human beings) in the field of traditional and complementary medicine, and some practices and concepts of traditional and complementary medicine practices cannot be perceived as required by those who are not expert in this field, thereby causing confusion. In addition, there are uncertainties and challenges regarding from which ethical committee the approval should be obtained with regard to traditional and complementary medicine and with the permission of which institution the research should be initiated, carried on, terminated and inspected. This prevents evidence-based development and implementation of traditional and complementary medical practices.
- This Regulation aims to specify the required provisions on eliminating the uncertainties and confusion mentioned above; increasing the number of clinical research on traditional and complementary medicine practices; putting evidence-based traditional and complementary medicine practices and products into use; developing these products and practices; determining the responsibilities of researchers towards volunteers; and carrying out the actions and procedures at the legislation department, etc.
- This Regulation determines the principles and procedures to be followed in clinical research process by the scientists who wish to conduct clinical research on Traditional and Complementary Medicine.
- This regulation makes definitions on clinical research of Traditional and Complementary Medicine Practices and tries to eliminate conceptual confusion in definitions related to practices.
- Principles required to conduct research on volunteers are determined and regulations on protecting the rights of volunteers are made.
- In this Regulation; the principles and procedures and the audit requirements for clinical research of Traditional and Complementary Medicine Practices to be conducted on children; pregnant, puerperae and breastfeeding women; and the disabled are regulated.
- Clinical research periods and processes as well as the features of venues where clinical research will be conducted are defined.
- Principles and procedures of research applications are defined and the method of obtaining the approval of the ethical committee and the permission of the General Directorate is stipulated.
- The principles and procedures to determine in which case the actions and procedures of initiating, conducting, ceasing and ending the research will be carried out as well as their justifications are laid down.

- The supportive entity's and responsible researcher's responsibility principles regarding manufacture, import and labeling processes of research products are determined.
- The terms of adverse event and serious adverse event are defined and the notification principles and procedures of these events are laid down.
- Confidentiality and transfer of research records are clarified.
- The principles and procedures regarding audit of clinical research on Traditional and Complementary Medicine Practices are laid down.
- Prohibitions and sanctions are laid down.
- Conditions to establish Traditional and Complementary Medicine Practices Ethical Committees, their members, their operating principles and procedures, and their duties and powers are laid down.
- Insurance coverage for the volunteers and the conditions for insurance are clarified.
- A provision is inserted with regard to the guidelines to be published by the General Directorate.
- Provisions on situations for which there are no provisions, on entry into force and on enforcement are laid down.

JUSTIFICATIONS OF ARTICLES

ARTICLE 1- The objective of the Regulation is set.

ARTICLE 2- The scope of draft Regulation on Clinical Research of Traditional and Complementary Medicine Practices is determined. Thus the research types which are subject to provisions of this Regulation and which are outside the scope of this Regulation are clearly defined.

ARTICLE 3- It is the legal basis article of the Regulation.

ARTICLE 4- Definitions in this Regulation are presented. A detailed definition method is adopted with a view to avoiding conceptual confusion and legal gap. In this way, it is aimed to prevent any conceptual confusion related to Clinical Research of Traditional and Complementary Medicine.

ARTICLE 5- General principles of the research are laid down. International conventions which Turkey is a party to and higher legal norms are taken as a basis while laying down the principles of clinical research to be conducted on the volunteers in the field of Traditional and Complementary Medicine, and a regulation methodology which is in parallel with the general principles of the research to be conducted on human health is determined. The rights of the volunteers before, during and after the research are laid down. Main principles such as personal information security, consent, freedom of withdrawal and insurance of the volunteers are laid down.

ARTICLE 6- It is essential that clinical research to be conducted on children are subject to stricter conditions. This Article explains which principles and procedures can be taken as a basis for clinical research to be conducted on children's health.

ARTICLE 7- It is essential that clinical research to be conducted on the pregnant, the puerperant and breastfeeding women are subject to stricter conditions. This Article explains which principles and procedures can be taken as a basis for clinical research to be conducted on the pregnant, the puerperant and breastfeeding women's health.

ARTICLE 8- It is essential that clinical research to be conducted on the disabled are subject to stricter conditions. This Article explains which principles and procedures can be taken as a basis for clinical research to be conducted on the health of the disabled individuals. The procedures and principles to be taken as a basis for the consents of guardians of the disabled during clinical research to be conducted on them are laid down.

ARTICLE 9- This Article divides period of clinical research on traditional and complementary medicine into two periods as period before receiving license or permission and period after receiving license or permission.

ARTICLE 10– This Article defines the features of venues where Clinical Research on Traditional and Complementary Medicine can be conducted and the minimum requirements that these venues should meet. While doing this, regulations on other clinical research in our country and arrangements of Regulation on Traditional and Complementary Medicine Practices are taken into consideration and significant consideration is given to avoid any overlapping legislation.

ARTICLE 11– This Article lays down principles and procedures on how to prepare research application file, how to receive the approval of the ethical committee, and how to receive the permission of the General Directorate. They reveal in what order to lodge application so as to conduct the research in coordination.

ARTICLE 12– This Article regulates in which case clinical research of Traditional and Complementary Medicine Practices can be initiated and how to conduct these research activities. In this way, the Article lays down the steps to be taken by researchers before initiating the clinical research and explains how the research that are initiated should proceed.

ARTICLE 13– This Article lays down principles and procedures to be followed in case of ceasing or ending the research. Rights and responsibilities on how the research that are ceased become operational again are laid down.

ARTICLE 14- This Article lays down principles and procedures for processes of manufacturing, importing, storing, distributing, delivering, destroying, etc. of research products by the responsible researcher and the supportive entity.

ARTICLE 15- This Article lays down legal processes for manufacturing, importing and labeling of research products.

ARTICLE 16- This Article determines in which case the research products are withdrawn and lays down principles and procedures on the method of their withdrawal. This aims to ensure that products for which a license or permission has not been granted yet are not held by the individuals.

ARTICLE 17- This Article specifies by whom, by which method and to which competent authorities the adverse (unfavorable, undesirable) events that may be seen during clinical research on traditional and complementary medicine practices should be notified.

ARTICLE 18- This Article specifies by whom, by which method and to which competent authorities the serious adverse events that may be seen during clinical research on traditional and complementary medicine practices should be notified.

ARTICLE 19- This Article regulates interim reports and final reports to be submitted to the General Directorate.

ARTICLE 20- This Article specifies who will be in charge of and responsible for recordkeeping of the research, lays down confidentiality principles and procedures for research records, and determines the duties and responsibilities on confidentiality, archiving and protection of records in the event of the transfer of the research.

ARTICLE 21- This Article specifies the contents of audits to be conducted by the General Directorate, the qualifications of auditors, and the auditing principles and procedures.

ARTICLE 22- This Article lays down who will assume the legal and financial responsibility of the research.

ARTICLE 23- It is the article on prohibitions.

ARTICLE 24- It is the article on Administrative Sanctions.

ARTICLE 25- This Article defines the structure, organization, number of members and the qualifications of members of Traditional and Complementary Medicine Practices Ethical Committees.

ARTICLE 26- This Article specifies operating principles and procedures of the Ethical Committees. It lays down the approval process of the ethical committees, the nature of approval of the ethical committees, and the standard operating procedures of the ethical committees.

ARTICLE 27- This Article specifies the duties and powers of the Ethical Committee. This aims to avoid confusion in duties and powers in the upcoming processes.

ARTICLE 28- It is stipulated that upon the request of General Directorate, Clinical Research Advisory Committee organized within Turkish Medicines and Medical Devices Agency expresses opinions with regard to the applications lodged to and the objections raised against the ethical committee or the approval of the ethical committee. This aims to arrive at a permanent solution to any debatable issue regarding clinical research.

ARTICLE 29- This Article lays down the provisions on the insurance of the volunteers, the research types included in the scope of insurance, and the insurance types.

ARTICLE 30- This Article regulates the General Directorate's training activities on clinical research.

ARTICLE 31- This Article lays down the publication of guidelines by the General Directorate on the required subjects following the publication of this Regulation.

ARTICLE 32- It is the article on situations for which there are no provisions.

ARTICLE 33- It is the article on entry into force.

ARTICLE 34- It is the article on enforcement.