1. OBJECTIVE

This Guidance sets out the principles and procedures regarding insurance coverage which a sponsor(s) of a clinical trial(s) must provide to protect patients and healthy volunteers recruited for a clinical trial against any injury associated with taking part in a clinical trial according to the Good Clinical Practice Guidance, and the Regulation on Clinical Trials.

2. GENERAL PRINCIPLES

2.1 Insurance coverage shall be provided against injury or death of volunteers taking part in a clinical trial due to the investigational medicinal product or any procedures applied at the time of the trial. It must be documented in accordance with the relevant legislation, therefore, by the sponsor of the trial that all patients and healthy volunteers taking part in a clinical trial have been provided insurance coverage by the sponsor of the clinical trial

2.2 Insurance policy, in the case an insurance policy cannot be submitted, a certified authentic copy of the insurance policy or certificates of insurance clearly indicating the terms and conditions of insurance in reference to the insurance policy concerned should be presented to the ethics committee and Turkey Pharmaceuticals and Medical Devices Agency. In this respect, the insurance policy to be presented to the ethics committee and Turkey Pharmaceuticals and Medical Devices Agency must specifically include;

2.2.1 the name and surname or commercial title and address of the insurer,

2.2.2 the names, surnames or commercial title and address of the policy owner (sponsor or legal representative)

2.2.3 the name and surname or commercial title and domicile of the insured (sponsor or legal representative or investigational site)

2.2.4 the subject of insurance (full name, protocol number and scope of the proposed clinical trial)

2.2.5 Type of insurance (such as clinical trials liability policy, third party financial liability insurance policy),

2.2.6 the risks undertaken by the insurer (insurance coverage including for illness, incapacitation and death as well as treatment costs) with the dates on which insurance coverage begins and ends,

2.2.7 the insurance amount (the insurance indemnification limit set per person as well as the total insurance limit),

2.2.8 the insurance premiums as well as the date and place of payment,

2.2.9 the number of volunteers to be recruited for the clinical trial (minimum number of volunteers planned to be included in the trial),

2.2.10 all circumstances and events by which the insurer shall determine the actual nature of the risks it shall have undertaken,

2.2.11 insurance period (insurance period should at least cover the starting and the ending dates of the trial),

2.2.12 the date of issue and wet-signature,

2.2.13 the special conditions of insurance subject to which the insurance coverage is provided,

2.2.14 Exceptions in the insurance policy if available

2.2.15 , any additional perils for which coverage is provided with the investigational product,
2.2.16 the countries where insurance coverage applies,
2.2.17 arrangements relating to any foreign elements in the agreement,
2.2.18 any details regarding exemption or coinsurance if available
2.2.19 General conditions of insurance printed legibly and certified by the appropriate Ministry.

2.3. Furthermore, the insurance policies and certificates must incorporate a wording that, in case the insurer are covered by any professional liability insurance, life insurance, or any other similar insurances, the coverage of such policies shall be sufficient, and in case such coverage is short of covering the damages which may arise from the clinical trial, the clinical trial insurance coverage shall apply accordingly.

2.4. Clinical trial insurances should be issued regardless of other insurance coverage and as binding over protection from any damages which may arise from the clinical trial,

2.5 Where an insurance policy or certificate of insurance satisfying all above stipulations is issued by an insurance company which is established and authorized to operate in Turkey pursuant to applicable regulations, the documents should be issued in Turkish, while Turkish translations (by a sworn translator and notarized) of all documents issued in a language other than Turkish should be submitted with the original or certified authentic copy of the documents where the insured and insurer are foreign nationals.

2.6 Admissibility of insurance documents issued by insurance companies established in Turkey is subject to registration of these companies by the Undersecretariat of Treasury.

3. REGULATIONS REPEALED

The Regulation "Guideline for Insurance Policy on Clinical Trials" *which has been put* into force upon the Authority Consent dated 23.08.2011 and numbered 7481 has been repealed.

4. ENFORCEMENT

This guideline shall be effective as of its date of approval.