**Social Security Institution inspects approved clinical research**

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On 4 October 2017, the Clinical Research Association announced that the Social Security Institution (SSI) had initiated general inspections on clinical research approved by the Ministry of Health in 2015 and 2016 on the grounds of ensuring compliance with SSI legislation. Clinical research is regulated by the Regulation on Clinical Research of Drugs and Biological Products, published on 13 April 2013.
Pursuant to the regulation, the sponsor of a clinical research study shall cover the costs of: (i) equipment and materials that are associated with the usage of any kind of research products specified to be used in the research protocol; and (iii) any examination, observation, analysis and treatment of those products. These costs are not to be paid by the volunteer or the SSI. An exception to this that is provided for in the regulation is where there is public benefit and the SSI finds it appropriate to pay the expenses. The inspections that are being conducted by the SSI are based on this provision.
Source: *Notification on SSI Investigations in the website of Clinical Research Association, 4 October 2017* (Turkish language).

**New Regulation on the Manufacturing Plants of Human Medicinal Products**

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The Regulation on the Manufacturing Plants of Human Medicinal Products was published in Official Gazette no. 30217 of 21 October 2017, effectively replacing the old regulation of the same name.

The new regulation provides a revised list of definitions and introduces comprehensive provisions on the obligations of manufacturers and new specifications that were previously unclear. For Example, details on the mandates of manufacturers in cases of medical gases and imported products have been added, and an obligation on direct compliance with the marketing authorisation and/or licence of the product has been made explicit.
The regulation appears to have deleted in its entirety the provision on harmonisation with EU rules: the statement that the regulations were prepared in line with EU Directive 91/356/EEC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use are no longer present in the new Regulation.
Source: Turkish Pharmacists: Announcement, 21 October 2017 (Turkish Language).