



January, 2009

Pharma News

Update to Clinical Trial Directive

Labeling of Research Products

Dear friends and clients,

“Pharma News” is brought to you by Eytan Liraz & Co., Law Offices, for the purpose of informing our friends and clients in the field of pharmaceuticals and adjacent fields about the most recent legal updates relevant to said fields.

In this issue we have elected to bring to your attention a recent update of the Medical Experimentation on Human Beings Directive with respect to labeling of research products. Herein you will be able to find a short description of said update. For further details you may of course contact us (contact information is listed below).

In the beginning of December 2008 the Pharmacist Department of the Israeli Ministry of Health (the “MOH”) promulgated an update to the “Medical Experimentation on Human Beings Directive-2006” (the “**Update**” and the “**Directive**” respectively).

The Update pertains to Section 11 of the Directive titled “Labeling of Research Products for Medical Experiments”. The purpose of the Update is to align the labeling requirements with international requirements and with the MOH’s “Labeling of Medicinal Substances Packaging Directive-2007” (directive No. 43 of the Pharmacists Department dated July, 2007).

As a result of the Update, Section 11 of the

Directive shall now be based upon the provisions for labeling of research products of the European Commission, as detailed in said commission’s directive titled “Good Manufacturing Practices – Annex 13: Manufacture of Investigational Medicinal Products”.

The Update distinguishes between the provisions for labeling research products classified as medicinal substances, and products classified as “Medical Equipment/Devices”, and sets forth specific labeling provisions for each of the aforementioned categories.

The labeling of medicinal substances - Section 11.1 of the Directive sets forth provisions, with respect to the labeling of said products and the captions to be imprinted on their packaging. Said provisions stipulate, *inter alia*, that the packages of said products shall include the following imprints: the name and contact information of the initiator of the medical experiment or his representative; the manner of provision of the product as well as the relevant quantities; directions as to use of the product or a referral to an information leaflet designated for use of the experiment participant; a warning label in three languages (Hebrew, English and Arabic), which shall bear the following imprint: “For Use in Research Treatment Only”; the storage conditions for the product; the product’s expiration date; a warning label, which shall bear the following imprint: “Keep Away from the Hands of

Children”. In the event of a medical experiment, in which use of a Placebo is made, each label shall include the identification code of the substance or the Placebo.

The labeling of medical equipment/devices – Section 11.2 of the updated Directive stipulates that said labeling shall include (in Hebrew or English), *inter alia*, the following details: identifying details of the equipment/device; a noticeable warning label, which shall bear the following imprint: “For Use in Medical Experiment Only”; use and storage directions; installation directions (if necessary), as well as various other details specified in Section 11.1

of the updated Directive.

It should be noted, that according to the provisions of the (updated) Directive, a specific monitoring and control process, with respect to the labeling of research products must be conducted.

The aforementioned provisions shall only be in force and effect with respect to new experiments/research studies, for which the recruitment of patients shall begin as of the 1st of January, 2010.

Please feel free to contact Adv. Eytan Liraz should you require any further explanations and/or clarifications with regard to the subject matter of this Newsletter.

The aforementioned is intended for provision of general information only to the friends and clients of Eytan Liraz & Co. Law Offices, and does not constitute a legal opinion or advice, which warrant individual and specific examination of the relevant circumstances, rules and regulations. Accordingly, and for the sake of clarity, it is hereby emphasized that the aforementioned information shall not be perceived as a legal opinion and therefore must not be relied upon.



Sonol Tower, 17th Floor, 52 Menachem Begin Rd., Tel Aviv 67137, Israel
Tel: (972) 3 5377 388 Fax: (972) 3 5377 399
Email: Eytan@lirazlaw.com
<https://www.lirazlaw.com>