Guidelines

MindPharma
Strategic Regulatory Affairs Services

Mind Pharma provides a full scale of regulatory, strategic, business, and market analysis services.

Enclosed are sample pages from the **Israeli Ministry of Health** ***Medical Device Law*** – *May 2012*.

For a complete translation of the guideline please call us @ +972.54.4500453
Or email us: info@ mind-farma.com

Who we are

MindPharma is a strategic consulting agency led by Shavit Fragman.

Mind Pharma believes that new drugs and latest technologies for improved health should be made available as soon as possible to patients.

We help companies bring safer and more advanced therapies to improve health care and quality of life for patients, and strive to deliver a smooth fast-track bridge from innovation to market.

What we do

We deliver creative legitimate solutions and pathways to obtain, in an efficient and optimal manner, a marketing authorization for the products that we handle.
We serve companies who wish to be first to deliver high quality reimbursed medical solutions and better health to our market.

How we do it

Mind Pharma leverages latent periods when a company is busy in other markets, accelerating product registration and market access.

With our expertise, experience, and dedication we serve companies who wish to be first to deliver high quality reimbursed medical solutions and better health to our market.
Our unique strategy frees our client's time and enabling them to focus on their core business goals and objectives.

The time we save for our customers allows extracting higher value to patients' health, society, company and shareholders, with highest ethics and integrity standards.

By selecting Mind Pharma as your strategic partner your company can benefit from our unique strategic solutions and outstanding relationships with the local regulator to accelerate the completion of registration and market access.

Mind Pharma Europe Ltd. ▪ www.mind-farma.com
P.O.Box 22224, Tel Aviv 61221, Israel ▪ Tel: 054-4500453 ▪ Fax: 03-9014118 ▪ Email: info@mind-farma.com

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Chapter A: Definitions

Definitions

1. In this law -

"Batch" – Quantity or manufacturing series of medical equipment manufactured in one manufacturing campaign;

"Registration owner" – To whom given a certificate indicating the registration of a medical equipment in the register according to para 6(e);

"Medical treatment", Care giver" and "Patient" – As they are defined in the patient rights law 1996[1]

"Manufacture" – Including , fusion, stirring, construction, distillation, processing, form change, programming and applying of any chemical, physical, or other biological process for the preparation of a medical equipment and packaging of medical equipment, including repackaging, excluding activities that are part of the usage of such medical equipment for providing the treatment and routine maintenance;

"Recognized country " – Each of the countries specified in the first appendix;

"Health Institute – Any of the following:

(1) Sick fund, as defined in national health insurance law, 1994[2];

(2) Hospital as defined in public health act, 1940[3];

"Recycling of medical equipment" – Whole actions required for making re-use of medical equipment for single use;

"The manager" – The general manager of the Ministry of Health or whom he has given authority for the matters of this law in part or whole;

"The register" – Register of medical device, managed as per the instructions of para 3;

"Publication" - Oral publication, in writing or in any other way, of medical equipment, aimed at the public, all or in part, excluding publication in scientific literature;

"Medical equipment" – Any of the hereunder detailed, excluding preparation as defined in pharmacists act [new version], 1981[4]:

(1) Equipment used for medical treatment, and equipment or computer software required to operate such equipment; For this matter, "equipment" – including accessory, chemical material, biological product or biotechnology product;

(2) Contact lenses;

(3) Electrical device emitting ionic or nonionic radiation used for cosmetics treatment;

"Registered medical equipment" – Medical equipment requiring registration in the registrar according to instructions of para 2 that has been registered in the registrar;

"Physician" - A physician as defined in the physicians act [new version], 1976[5], or a dentist as defined in dentists act [new version],1979[6];

"Marketing" – Selling, supplying, import, export, or change of ownership or holding in other way;

"Medical equipment corporation" – Corporate established according to a government decision for supply of medical equipment' acting for marketing of medical equipment to government hospitals

"The Minister" – The Minister of Health

* Received by the Knesset on May 8th, 2012 [in a meeting that started on May 7th, 2012; Law proposal and explanation published in the Government law proposals – 337 dated 24 October 2007, page 190.

1 L.B. 1996, page 327

2 L.B. 1994, page 156.

3 R.A. 1940, sup 1, page (p) 191, (a) 239

4 State of Israel laws, new version 35, page 694