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** updated *Guidelines for the submission of a request to include a pharmaceutical product in the national list of health services – January 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

Guidelines for the submission of a request to include a pharmaceutical product in the national list of health services

The National Health Insurance Law, 1994

*The original text in Hebrew is the legally binding text. In case of conflict the Hebrew version prevails.

1. General instructions for submission of a request to include a pharmaceutical product in the health services "basket":

1.1 The inclusion of a pharmaceutical product in the national list of health services is made in accordance with specific budget allocated for it, according to decision of a public committee for updating of health basket of services, appointed by the Ministers of Health and Treasure. The Pharmacoepidemiology and Pharmacoeconomics of Drugs Department will evaluate the proposals and submit its recommendations to the relevant forums. Therefore, receiving a full detailed and complete application does not constitute any commitment by the Ministry of Health to recommend the inclusion of the pharmaceutical drug in the Health Basket of services.
Nevetheless, the decision making process is based on data included in the application and hence the critical importance of data contained.(1.6)

1.2 The data submitted will be processed by the Pharmacoepidemiology and Pharmacoeconomics of Drugs Department and presented to the public committee in a uniform format (1.8).

1.3 The application for inclusion of a pharmaceutical product in the health services basket shall include a comprehensive data file (strictly filling every paragraph as indicated in this guideline) which is submitted to by the Pharmaepidemiologics and Drug Economics department of the Medical Technologies & Infrastructure Division at the Ministry of Health. (1.1)

1.4 For every requested indication – a separate data file needs to be submitted.

1.5 Regarding previously submitted applications, when the license holder wishes to re-submit (repeat submission). In case the file is complete, it may be re-submitted and the new data should be highlighted.

1.6 The data file will be submitted by the appointed pharmacist of the license holder of the pharmaceutical product. (1.3)

1.7 All data will be submitted in Hebrew. Supporting sources and references should be submitted in their original language, If different than English please attach a Hebrew translation of the original source.

1.8 The application should be submitted in paralel also electronically. File names will be set in accordance with relevant paragraph or referenced source name (1.5)

2. Structure of the data file:

2.1 A request to include a pharmaceutical product in the national health services basket will be composed of four parts to be submitted according to section 3 of these guidelines (2.1):

Part I: Request forms and documents pertaining to details of the pharmaceutical product.

Part II: Clinical data.

Part III: epidemiological data .

Part IV: economic evaluation.

2.2 The request will be submitted in a single binder separated by dividers.
Every paragraph in the file will be numbered according to relevant paragraph in this guideline.

2.3 On the back of the binder the name of the pharmaceutical product and the license holder's name, will be stated.

2.4 All pages in application must be numbered, including appendixes and attachments