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Life Science News

Health Basket and Patients' Rights: Recent Court Rulings

Dear friends and clients,

“Life Science News” is brought to you by the Israel Export & International Cooperation Institute in collaboration with Eytan Liraz & Co., Law Offices, for the purpose of informing you about the most recent legal updates relevant to the field of Life Science.

The implications of the scope of patients' rights to receive proper treatment and the scope of services to be supplied in the frame of the health basket to such patients on companies in the pharmaceutical domain are obvious and require no lengthy explanations. Accordingly, many companies in said field devote a great deal of effort to introduce new technologies to the health basket. In case such efforts fail, we witness, from time to time, petitions of patients and/or patients associations submitted to the courts of law as a last line of action. These petitions target the validity of the decisions of the Health Basket Committee and more importantly – its future decisions.

In the last couple of months we have witnessed several court deliberations relating to such patients' rights. In this publication we will detail, in a nutshell, the major court decisions recently published in this matter.

1. The Israel Medical Association Petition – decision of the High Court of Justice of March 2009

On March 30th 2009 the High Court of Justice

issued an order instructing the Minister of Health, the Minister of Finance, the Sick Funds and the Health Basket Committee to supply the court with their reasoning for not formally regulating (in legislation) the composition and working procedures of the Health Basket Committee; for not determining specific criteria for its decision making; and for not compelling the Health Basket Committee to reason its decisions.

Regarding the portion of the petition requesting that the Health Basket Committee will take decisions according to specific criteria it should be noted that today such criteria indeed exist; however, said criteria are not organized according to an order of importance. The current criteria include: the efficiency of the new technology; the existence of an alternative and the efficiency of such alternative; the nature of the technology (life saving, disease preventing, prolonging life expectancy); existing experience (with the technology); financial implication; number of patients who will be treated with the technology etc.

The above order was issued after the Israel Medical Association submitted to the High Court of Justice a petition in the frame of which the association claimed that the Health Basket Committee operates without a policy, standards and criteria which are transparent to the public.

It was also claimed that the fact that the Health Basket Committee does not publish protocols

on a regular basis and does not reason its decisions prevents the public (and the courts) from tracking its discretion and hence due criticism of said decisions is de facto also prevented.

The High Court of Justice allowed the respondents to submit their claims within 4 months court deliberations will resume thereafter.

A favorable decision in the petition will directly affect future patients and current court rulings and similar to the one granted in the Davidiv case (detailed herein).

1. The Michael Davidov and Myeloma Foundation Petition – decision of the High Court of Justice of May 2009

On May 3rd 2009 the High Court of Justice dismissed the petition submitted by Michael Davidov and the Myeloma Foundation against the decision of the Health Basket Committee, the Minister of Health and the Minister of Finance not to include the pharmaceutical product Revlimid in the health basket.

In their detailed judgment, President Beinisch, Judge Procaccia and Judge Danziger (written by Judge Danziger), the following arguments have been dismissed:

- (a) The decision of the Health Basket Committee prejudices the constitutional rights of the petitioner (which are set forth in the Basic Law of Human Dignity and Freedom);
- (b) The decision of the Health Basket Committee prejudices the legal rights of the petitioner to health (which is set forth in the Patients' Rights Law and the Good Samaritan Law);
- (c) The decision of the Health Basket

Committee constitutes (unlawful) discrimination (in this case between Myeloma patients and cancer patients who will be treated with new technologies approved by the Health Basket Committee);

- (d) The decision of the Health Basket Committee is unreasonable (said argument is based on general principles of Administrative Law).

In view of the above, the court dismissed the petition.

While a favorable decision in the Israel Medical Association Petition (described above) is not anticipated to affect the court's decisions regarding the claims detailed in sub-sections (a) – (c) above, it will supply the courts with additional (procedural and substantial) "legal tools" to criticize the committees' decisions and thus will indeed affect the decision regarding the claim detailed in sub-section (d) above.

In other words, in future cases the courts will scrutinize the operations of the Health Basket Committee, both from a procedural point of view and from a substantial point of view and in the frame thereof may scrutinize the way the committee implemented the criteria so (to be) defined.

It should be noted however that even if the Health Basket Committee's operations will be regulated, and thus its decisions will be more thoroughly reviewed by the courts, it is still anticipated that the courts will only intervene and dismiss the committee's decisions in rare and extreme cases.

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.

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