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STATE OF ISRAEL



**Ministry of Industry, Trade and Labor
Office of the Chief Scientist**

**Ministry of Finance
Budgets Department**

REQUEST FOR INFORMATION (RFI)

RELATED TO: ESTABLISHMENT OF A PROGRAM TO ENCOURAGE MULTINATIONAL CORPORATIONS FROM THE LIFE SCIENCES FIELD TO CONDUCT AND SUPPORT RESEARCH AND DEVELOPMENT ACTIVITIES IN ISRAEL

The Office of the Chief Scientist in the Ministry of Industry, Trade and Labor and The Ministry of Finance (hereinafter: "the Ministries") requesting to receive information from entities with appropriate experience and knowledge in the field of Life Sciences, including foreign multinational corporations from this field, with a view to examining the possibility of establishing a program, to be operated by the Office of the Chief Scientist in the Ministry of Industry, Trade and Labor (hereinafter: "the OCS"), for encouraging multinational corporations from the field of Life Sciences to conduct and support research and development activities in Israel (hereinafter: "the Program").

The purpose of this RFI is to receive information from the addressees, based on their experience in the field, in order to facilitate the formulation of rules and principles which, in the event it is decided to establish the Program, will render the process more efficient and enable the achievement of optimal results.

It should be emphasized that the Ministries have not yet decided whether to launch the Program and this RFI is not an invitation to submit proposals and is not part of tender procedures or any other procedure for receiving proposals, but a Request for Information only further to which the Ministries will consider their next steps. Without derogating from that stated in this document, the Ministries reserve the right to contact the recipients, all or some, with clarification questions or request for additional information or data. However such a request shall not create any commitment towards the entities approached by the Ministries. It is hereby clarified and emphasized that this RFI does not constitute an offer, or invitation to submit an application or create an engagement under the Mandatory Tenders Law, 5753-1993, or under any other law or procedure.

A. Background

Israel's high-tech industry is one of the main growth engines of its economy. In terms of GDP and number of employed persons, the country's high-tech industry today is based mainly on ICT (Information and Communication Technologies) and is marked by strong activity in all stages of the industry, from startups through to large Israeli companies and numerous R&D centers of multinational companies in Israel. The activity of the development centers of multinational companies in Israel is a significant factor contributing to the advancement of the industry as a whole in the relevant technological fields.

In contrast to ICT, in the field of Life Sciences, despite Israel's strong scientific and innovative capabilities in the areas of Life Sciences, Medicine and the Exact Sciences, the country still lacks a well-developed and broad-based industry. Moreover, unlike the ICT field, in which giant international companies operate numerous and large development centers in Israel, there is no such activity on a similar scale in the field of Life Sciences.

As part of the efforts to meet the unique challenges that characterize the Life Sciences industry, the Government of Israel initiated in 2009 a venture capital investment fund dedicated to the field of Life Sciences (hereinafter: "**the Fund**"), which began operating this year. As a supplementary step to the establishment of the Fund, the Ministries are considering formulating a program to encourage multinational corporations from the field of Life Sciences to conduct and support research and development activities in Israel, for the achievement of the following goals (hereinafter: "**the Program's goals**"):

1. Enabling Israeli developers, to accumulate knowledge and gain experience in the development of an ethical medical product, including widening the knowledge and experience of service companies in performing validated & controlled experiments, processes development and manufacturing (CROs, CMOs).
2. Enlarging and improving the cadre of managerial and professional personnel in the Life Sciences industry in Israel.
3. Expanding the sources of funding for research and development activity in the field of Life Sciences.
4. Increasing the number of employees in the Life Sciences industry in Israel.

B. Principles of the Program under Examination

1. In this Section B, the terms below will have the meaning set out alongside them, unless stated explicitly otherwise in the section:

- "Foreign Multinational " or "the Company"** - A corporation which on the day of submission of the application for recognition as a Foreign Multinational company complied with all the following conditions, cumulatively:
- a. Its center of business is outside Israel and it does not carry out directly research and development activity in Israel.
 - b. It had minimum revenues of USD 10 Billion in the year prior to the date of submission of the application.
 - c. Its main operations are in the field of Life Sciences.
- "field of Life Sciences"** - The development of innovative therapeutic products which will need to undergo an advanced regulatory process in order to receive a regulatory approval from the FDA, the EMA, the Israeli Ministry of Health or a corresponding entity outside Israel.
- "Life Sciences R&D Center" or "the Center"** - A center established in Israel, in which Projects will be carried out in Israel.

"Project"

- R&D activity of the Foreign Multinational in the field of Life Sciences that will be carried out in Israel and that is intended by the Company to be further developed for its own internal or commercial needs, whether in or outside Israel.

"Project Center"

- A company incorporated in Israel and operating in accordance with Israel's laws, that is fully owned by the Foreign Multinational and acts as its representative in Israel. The company works mainly to set up Projects with Israeli companies, providing technological support, and facilitate direct contacts with the Foreign Multinational's relevant units.

2. The Office of the Chief Scientist in the Ministry of Industry, Trade and Labor is considering to operate two optional tracks within the Program, both aimed at increasing R&D activity of Foreign Multinationals in the field of Life Sciences in Israel. The Foreign Multinational will be permitted to apply for support either in one of the two tracks described below, or in both of them simultaneously.

Notwithstanding the stated above in this section, it is emphasized that the purpose of this RFI is to receive information from relevant entities in relation to the Program, and respondents may suggest also other ways of operating the Program not necessarily in accordance with tracks A and B set out below:

Track A – R&D Center in Israel

- a) Under this track, the Foreign Multinational will be able to receive approval for a multiannual operation framework for the Life Sciences R&D Center.
- b) The Foreign Multinational will undertake to establish and operate a Life Sciences R&D center in Israel during a period of no less than five years. The OCS will participate in the funding of the Center's R&D activity. Such Center's R&D activity may include, among others, research and discovery of new molecules and their mechanisms of action; production process development; prototype development; analytical assay development; efficacy trials; toxicology trials; pharmacological development.

The application submitted by the Foreign Multinational will include details on the planned scope of R&D activities at the Center during a period of up to five years, the number of persons expected to be employed during that period (with the Company attaching to the application an undertaking regarding the period of their employment), the Center's planned multiannual budget, the Company's individuals who will manage the Center's activities, expected Projects that will be carried out at the Center and the anticipated scope of investment in them. If the Projects will be executed by a subcontractor, details of any such contractor should be provided.

The committee operating the Program (hereinafter: "**the Committee**") will consider the application after it has received the recommendation of a professional examiner appointed by the OCS. The Committee will evaluate the quality of the application and the level of its technological innovation, and it will be authorized to approve or reject the application and the Projects proposed, at its sole discretion.

- c) By the end of the first year of the approved operating period, at least 15 R&D workers will be employed by the Company at the R&D Center in Israel, increasing to at least 35 R&D workers by the end of the second year and at least 60 R&D workers from the end of the third year and onwards, up to the end of the period of the proposed activity.
- d) The Center's personnel will be employees of the Foreign Multinational or a wholly owned Israeli subsidiary of the Foreign Multinational which operates the Center, and at least 90% of them will be Israeli citizens.

- e) Under the Program, the Government will subsidize 30% of the overall budget approved for Projects performed in the first, second and third years, 25% in the fourth year, and 20% in the fifth year. Projects carried out in the country's periphery will receive a 40% subsidy in the first, second and third years, 35% in the fourth year, and 30% in the fifth year. Total government support will not exceed NIS 19 Million for the period of activity approved for the Center, and NIS 32 Million in the periphery.
- f) Under this track, recognition will be granted to activities of the Center that are conducted through specialty service companies in Israel (CROs, CMOs), on condition that they are in contact with the global company and act in a manner so as to achieve the Program's goals and objectives.
- g) Recognition of R&D expenses will be in accordance with OCS procedures.
- h) The knowledge developed at the Center, as well as its products, including intellectual property rights in the knowledge and its products may be owned by the Foreign Multinational, which will be permitted to use them in any way it sees fit, in or outside Israel.

Track B – Collaboration between the Foreign Multinational and Israeli Life Sciences companies and the establishment of a Project Center in Israel

- a) Under this track, the Foreign Multinational will invest in Projects of Israeli companies from the field of Life Sciences no less than USD 20 Million during a five year period. The OCS will grant the Israeli company funding of up to 50% of the Project's approved budget, but not more than the Foreign Multinational's investment in the R&D carried out in the framework of the Project, and subject to a maximum total grant of USD 20 Million during a five year period.
- b) Apart from the monetary investment, the Foreign Multinational will be required to contribute to the Israeli companies' R&D activities in other additional constructive ways, such as professional oversight of the process, guidance in the management of the Project and exposure to the knowledge and work methods of the Foreign Multinational.
- c) The scope of government funding will be conditional based, among others, on the amount of the investment as well as on the added value of the collaboration for the Israeli company.
- d) The committee operating the Program (hereinafter: "**the Committee**") will consider the application after it has received the recommendation of a professional examiner appointed by the OCS. The Committee will evaluate the quality of the Projects and the level of their technological innovation, and it will be authorized to approve or reject any application including the Projects proposed in its framework, at its sole discretion.
- e) The Committee will be authorized to approve Projects for a period of up to three years.
- f) Should the Foreign Multinational establish in Israel a Project Center under this track, the State will participate in up to 30% of the Project Center's R&D or R&D related costs, subject to a maximum of NIS 2 Million per year.
- g) Recognition of R&D expenses will be in accordance with OCS procedures.
- h) The knowledge developed in the framework of the Project will be the property of the Israeli company, and the provisions of the Encouragement of Research and Development in Industry Law, 5744-1984, will apply to such knowledge, *mutatis mutandis*. Where the Project incorporated knowledge of the Foreign Multinational, joint ownership of the new knowledge will be allowed.

C. General Information

1. Information pursuant to this RFI may be submitted, in a sealed envelope bearing the words "Request for Information – Establishment of a Program to Encourage Multinational Corporations from the Life Sciences Field to conduct and support research and development activities in Israel" up to March 1, 2012, to Mr. Dovi Ollech in the Office of the Chief Scientist in the Ministry of Industry, Trade and Labor, 5 Bank of Israel St., 3rd floor, and/or emailed to: bioprogram@moital.gov.il
2. Without derogating from that stated in this RFI, the Ministries reserve the right to submit any request for clarifications or information or other data to all or any of the respondents (to this RFI), starting from the date of publication of this document.
3. The Ministries may use the contents of the documents that will be submitted to them for the purpose of formulating the Program, and they reserve the right to reply or not to reply to the responses, if any, received to this RFI.
4. The Ministries may possibly use the information provided to them by the respondents to this RFI at some stage. Accordingly, the respondents will be precluded from making any assertion and/or demand and/or claim against the Government or anyone acting on its behalf concerning rights related to and/or arising from their response to this RFI and/or from any attached material. It is clarified that the Ministries will be permitted to use the information provided to them by any of the respondents, and the respondents agree that they will not have any claims or demands against the Ministries in such case.
5. This RFI does not create any obligation towards any of the respondents hereto. The terms of the program which the Ministries are considering establishing, as published in this RFI, shall not bind the Government or anyone acting on its behalf, both as to the terms of the Program and even as to its actual implementation. The Ministries may modify all or any of the terms of the Program, as they see fit in their sole discretion. The Ministries or anyone on their behalf may meet at any stage with any entity they choose, in accordance with the provisions of any law, without being restricted in any way whatsoever.
6. The publication of this Request for Information and any related act may not be regarded as a commitment on the part of the Government of Israel or anyone acting on its behalf to any person or entity.
7. All the costs of preparation and submission of the information in response to this RFI are solely the responsibility of the addressees or the respondents hereto and will be borne by them.
8. The submission of a response to this RFI is not a condition for participating in any future process, should one be held.
9. This RFI does not create any obligation towards any of the respondents hereto, and the Ministries may consider their course of action at their discretion.