**Central Administration of Pharmaceutical Policies and Market Support**
**General Administration of Export Support and Investment Promotion**
Department of Investment Support and Localization of Domestic Industry
Export Support and Follow-up Department



## Regulatory Guideline

# Rules and Procedures Governing the Mechanisms for Granting Serious Investment and Export Incentives to Companies Operating in the Pharmaceutical Industry

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## Contents of the Guideline

## 1. Introduction:

**This Guideline aims to clarify the rules and procedures governing the mechanism for granting investment and export incentives through the assessment and evaluation of plans submitted by companies operating in the pharmaceutical sector concerning serious investment initiatives and export enhancement. This is implemented pursuant to the Chairman of the Authority's Decision No. 249 of 2025 regarding the formation of a committee responsible for evaluating and reviewing applications for serious investment and export incentives, with the objective of supporting companies in their efforts to localize industries and enhance their export capabilities.**

**The Committee shall undertake the following responsibilities:**

1. **Review and approve incentive packages designed to support serious investment and export activities, thereby encouraging companies operating within the pharmaceutical sector.**
2. **Evaluate and review companies' plans for serious investment and export activities, including assessment of the scale of such plans and the extent of progress achieved in their implementation by each company.**
3. **Determine the eligibility of companies for serious investment and export incentives based on an objective assessment of investment levels and export volumes, and identify the most appropriate type of incentive for each company following a comprehensive review.**

## 2. Scope of Application

**Human Pharmaceutical Products and Biological Products.**

## 3. Key Definitions

- **Investment Incentives:**

**A set of encouraging measures, benefits, or facilitation mechanisms provided by the Egyptian Drug Authority to companies operating in the field of human medicinal products and biological products, aimed at supporting local manufacturing localization to achieve self-sufficiency, encouraging investment, and developing the sector in a way that enhances competitiveness, ensures the availability of medicines, and supports Egyptian exports.**

- **Human Pharmaceutical Product:**

**Any product or preparation containing a substance or combination of substances used for therapeutic, preventive, or diagnostic purposes in humans, or represented as possessing medicinal properties, or intended to restore, correct, or modify physiological functions by exerting a pharmacological, immunological, or metabolic effect, in accordance with the applicable guidelines and standards, including any products or substances introduced pursuant to scientific advancements and/or international standards and reviews.**

- **Biological Product:**

**Products manufactured from biological sources such as microorganisms, cells, tissues, or their derived products. These include vaccines, sera, blood products (such as plasma), and any products manufactured using biotechnology. Their definition is continuously updated in accordance with scientific advancements and international standards.**

- **Localization of an Imported Product Manufacturing:**

**The transfer of all stages of production and manufacturing of a product that was previously imported from abroad, so that it is fully produced within Egypt in a manufacturing facility licensed by the Egyptian Drug Authority.**

- **First Local Equivalent Product:**

**A product that is first manufactured domestically in Egypt as an equivalent version of an imported reference product in terms of composition and therapeutic effectiveness.**

- **First High-Technology Domestic Equivalent:**

**The first product manufactured within Egypt that is equivalent to an original imported product in terms of quality and efficacy, but produced using advanced and complex manufacturing technologies (High-Tech Manufacturing), and included in the list of rare manufacturing lines announced and updated annually by the Egyptian Drug Authority.**

- **Therapeutic Equivalents Support:**

**To encourage and facilitate the domestic manufacture of pharmaceutical products in order to provide more than one locally manufactured equivalent for imported products, through the provision of incentives and facilitation measures to operating companies, thereby supporting the availability of essential and critical medicines and meeting market needs.**

- **Rare Production Lines:**

**Pharmaceutical manufacturing lines that require advanced technology, complex infrastructure, and a high level of technical expertise, and which are available only in a limited number of manufacturing facilities within the Arab Republic of Egypt. These lines are dedicated to the production of specific types of pharmaceutical products of strategic importance or products requiring highly specialized manufacturing conditions.**

**Such lines are periodically announced on the Authority's website following their approval by the Supreme Inspection Committee and the Technical Committee for Drug Control.**

- **Non-Rare Production Line**

**A manufacturing line used for the manufacture of human pharmaceutical products, biological products, and medical devices, encompassing all manufacturing stages (production, filling/packaging, and final packaging), and not included in the list of rare manufacturing lines published on the official website of the Egyptian Drug Authority.**

- **Remote-Area Manufacturing Facilities:**

**Pharmaceutical manufacturing facilities established in remote areas located outside major industrial clusters and central urban centers, such as the governorates of Upper Egypt, border regions, and remote villages.**

- **Export Growth and Expansion:**

**Achieving a tangible growth rate in the volume of exports of human medicinal products and biological products, while attaining a minimum annual export threshold and expanding access to new markets.**

- **Categories**

**The general framework under which pharmaceutical companies are classified into multiple levels based on their actual export performance, achieved growth rates, and their ability to expand and penetrate new markets. This classification aims to distinguish companies demonstrating more advanced performance and to establish graduated incentive levels, whereby incentives are granted in proportion to each company's actual contribution to the development of export activities. The category assigned to each company shall be determined based on the number of points achieved in accordance with the Authority's approved internal evaluation mechanism and following review by the Committee for the Evaluation and Assessment of Serious Investment and Export Incentives.**

## 4. General Rules and Procedures Governing the Process:

1. **The company shall submit the supporting documents required to obtain the incentive, provided that it selects the incentive package it wishes to enroll in from among the available incentive packages through the designated electronic portal.**
2. **The submitted documents shall be reviewed by the relevant departments of the Central Administration for International Policies and Market Support (Investment Support Department / Export Support and Follow-up Department).**
3. **The competent department (Investment Support Department / Export Support and Follow-up Department) shall conduct an assessment study to evaluate the feasibility and merits of the proposed project.**
4. **Upon completion of the assessment, the study shall be discussed and presented to the members of the Committee for the Evaluation and Assessment of Serious Investment and Export Incentives for review and determination of whether the company should be granted the incentive(s), either for a period of one year only or for a specified number of products.**
5. **The company shall apply for annual renewal of the incentives through the same electronic link.**
6. **Any incentives and privileges awarded to a company shall be subject to withdrawal upon determination of non-compliance with the prescribed criteria and regulatory requirements.**

## 5. Serious Investment Incentive System

- **Admission Criteria**

| | Category |
|---|---|
| 1 | **Localization and Strengthening Pharmaceutical Security:**<br>➢ **First Locally Manufactured Equivalents**<br>➢ **First High-Technology Locally Manufactured Equivalents**<br>➢ **Localization of Imported Products**<br>➢ **Therapeutic Equivalents Support Products** |
| 2 | **Investment Injection in the Case of Licensing New Production Lines**<br>➢ **Licensing of a Rare Production Line**<br>➢ **Licensing of a Non-Rare Production Line** |
| 3 | **Remote Local Manufacturing Facilities in accordance with geographical distance and regional development** |

- Required supporting documents, including but not limited to:

➢ A comprehensive plan detailing the project objectives, anticipated deliverables, and the manner in which the project fulfills the admission requirements and criteria.
➢ A detailed report on the current status of the project, including what has been accomplished, current capabilities, infrastructure readiness, and existing challenges, if any, to enable an assessment of the project's compliance with the admission standards and criteria.
➢ A clear timeline outlining the development and implementation phases and the expected timeframes, ensuring the ability to monitor project progress in accordance with the approved standards.
➢ Export plans

Requirements and procedures for enrollment:

**To enroll in the Serious Investment Incentives Program, applications shall be submitted through the service link available on the official website of the Egyptian Drug Authority (EDA): https://forms.gle/LMjczr4dBe8NQWM7**

- **Investment incentives provided to companies and investors:**

| First: Incentives for Localization and Strengthening Pharmaceutical Security | |
|---|---|
| First Incentive | Implementation of the Fast Track system for the submission of a product registration dossier to obtain registration or re-registration notification.[1] |
| Second Incentive | An additional period of three months shall be added to the original deadline for the completion of registration/re-registration procedures. |
| Third Incentive | Implementation of the Fast Track system for witnessing the production of a pilot batch. |
| Fourth Incentive | Review of the product pricing by the Pricing Committee based on the pricing study prior to market authorization. |
| Fifth Incentive | Increasing the permitted number of applications for the issuance of two (2) Quality Information Summaries (QIS) per year.[2] |
| Sixth Incentive | Implementation of the Fast Track system for the submission and evaluation of stability studies for two (2) products.[3] |
| Seventh Incentive | Permission to submit an application for the registration of one Over-The-Counter (OTC) product, provided that the registration procedures are completed to obtain the final registration notification within 18 months from the date of obtaining approval from the Equivalents Fund.[4] |
| Eighth Incentive | Possibility of reviewing the pricing of one (1)product selected by the company, after the first two (2) production batches of the localized product have been placed on the market, while ensuring the continued import of additional shipments of active pharmaceutical ingredients to meet demand and consumption levels. |

- **The incentive scheme shall apply in the following cases:**
  - **First High-Technology Locally Manufactured Equivalent:**

**the company shall select only 3 incentives from the following packages (either the first or the second or the third) together with (the fifth or the sixth) in addition to the fourth incentive.**

  - **Localization of an Imported Product:**

**the company shall select only 3 incentives from the following packages (either the first or the second or the third), together with (either the fifth or the sixth) and (either the seventh or the eighth).**

  - **First Locally Manufactured Equivalent:**

**the company shall select only 2 incentives from the following packages (either the first or the second or the third), in addition to the fourth incentive.**

➢ **Therapeutic Equivalents Support:**

**the company shall be granted the first incentive.**

**[1] With regard to the registration of biological products, expedited registration procedures shall be applied in accordance with the mechanism of the Central Administration for Biological Products, Innovative Products, and Clinical Studies.**
**[2] With respect to biological products, no specific annual limit shall be set for the submission of QIS applications.**
**[3] Not applicable to biological products.**
**[4] Not applicable to biological products.**

| **Second: Incentives Granted for Investment Injection in the Case of Licensing New Production Lines** | |
|---|---|
| **First Incentive** | **Implementation of the Fast Track system for the submission of the registration dossier for one product owned by the License Holder, for the purpose of obtaining registration notification or re-registration, throughout the validity period of the certificate on an annual basis.[1]** |
| **Second Incentive** | **An additional period of three months shall be added to the original deadline for the completion of registration/re-registration procedures.** |
| **Third Incentive** | **Implementation of the Fast Track system for witnessing the production of a pilot batch.** |
| **Fourth Incentive** | **Increase the permitted number of applications for issuing the Quality Information Summary (QIS) on an annual basis.[2]** |
| **Fifth Incentive** | **Implementation of the Fast Track system for the submission and evaluation of stability studies for two (2) products.[3]** |
| **Sixth Incentive** | **Possibility of reviewing the pricing of two (2) products selected by the company, whereby one product is chosen after the importation and installation of the production line, and the second product after completion of the production line licensing and commencement of production.** |
| **Seventh Incentive** | **Permission to submit an application for the registration of one Over-The-Counter (OTC) product, provided that the registration procedures are completed to obtain the final registration notification within 18 months from the date of obtaining approval from the Equivalents Fund.[4]** |
| **Eighth Incentive** | **Possibility of reviewing the pricing of four products selected by the company, where two products are selected after the import and installation of the production line, and two products are selected after completion of the production line licensing and commencement of production.** |

- **The incentive system shall apply in the following cases:**

**Licensing of a Rare Manufacturing Line (as per the annually updated definition of rare manufacturing lines).**

**The company shall select only three incentives from the following packages (either the first or the second or the third), together with (either the fourth or the fifth) and (either the seventh or the eighth).**

- **Licensing of a New Non-Rare Manufacturing Line**

1- **The company shall select only two incentives from the following packages (either the first, second, or third), together with (either the fourth, fifth, or sixth).**

**Third: Incentives Granted to Local Manufacturing Facilities in Remote Areas in accordance with Geographical Distance and Regional Development:**

**The manufacturer shall receive four incentives as follows:**

- **First Incentive: Free participation shall be granted to an official representative of the manufacturer in training programs and workshops organized by the Authority, with the aim of enhancing the efficiency of technical and administrative personnel working in such facilities.**
- **Second Incentive: Implementation of the Fast Track system for the submission of the registration dossier for one product owned by the manufacturer and manufactured on its own production lines, for obtaining registration notification or re-registration.** [1]
- **Third Incentive: The manufacturer shall be granted a three (3) month extension to the original deadline for completing registration or re-registration procedures.**
- **Fourth Incentive: Possibility of reviewing the pricing of two products selected by the manufacturer from its owned products and produced on its production lines.**

## 6. Export Incentives System

- **Admission Criteria**

| | |
|---|---|
| **1.** | **Achieving a tangible increase in export volume compared to the previous year.** |
| **2.** | **Achieving a minimum annual export threshold of not less than USD 2 million.** |
| **3.** | **Access to New Markets** |

- **Requirements and Procedures for Enrollment:**

**For enrollment in the incentives system, applications shall be submitted via the designated service link on the official website of the Egyptian Drug Authority:**
**https://forms.gle/sqFTUfom9jS21JGC6**

**The application for enrollment shall be submitted via the designated link, either as a single company or as an investment group.**

1. **The application form for the company/group (Annexes 1 and 2) shall be uploaded.**
2. **Upon fulfillment of the applicable requirements, the company shall be notified by email of its inclusion in the Export Incentives System.**

**To ensure entitlement to the incentive,**
**submission of verified export data through customs declarations shall be required.**

## Export Growth and Expansion Incentives Evaluation System:

**A system that assigns points to exporting companies based on export growth and expansion criteria, producing an achieved score (SCORE) for each company, which is used to determine its classification category.**

| Export Growth and Expansion Incentives | |
|---|---|
| **First Incentive** | **Implementation of the Fast Track system for submission of the registration dossier for one product owned by the License Holder, to obtain a registration notification or re-registration.[1]** |
| **Second Incentive** | **An additional three (3) months shall be granted, to be added to the original timeframe, for the completion of registration or re-registration procedures.** |
| **Third Incentive** | **Implementation of the Fast Track system for witnessing the production of a pilot batch.** |
| **Fourth Incentive** | **Increase in the permitted annual number of applications for issuing one (1) Quality Information Summary (QIS).[2]** |
| **Fifth Incentive** | **Implementation of the Fast Track system for the submission and evaluation of stability studies for one product.[3]** |
| **Sixth Incentive** | **Permission to submit an application for the registration of one (1) Over-The-Counter (OTC) product, provided that the registration procedures are completed to obtain the final registration notification within eighteen (18) months from the date of approval of the Equivalents Fund.[4]** |
| **Seventh Incentive** | **Possibility of reviewing the pricing of two (2) products.** |

## The incentive system shall apply in the following cases:

**Achieving a tangible increase in the export volume of human medicinal products and biological products, while attaining a minimum annual export value of not less than USD 2 million, in addition to expanding into new markets.**

**In accordance with the Incentives Evaluation System, which calculates the exporting company's points based on export growth and expansion criteria and generates an achieved score (SCORE) for each company, determining its respective category.**

**Incentives and Targets for Each group Based on Its Export Performance During the Year, Relative to the Previous Year, in Addition to Access to New Markets, as Follows:**

**Group I (A)** ⟹ **3.5 ≤ score** ⟹ **Application of the Fast Track system to all registration procedures for three (3) additional products.**

**Group I (B)** ⟹ **3 ≤ score < 3.5** ⟹ **Application of the Fast Track system to all registration procedures for one (1) additional product.**

**Group II** ⟹ **2.5 ≤ score < 3** ⟹ **The company shall select only three incentives (from the first, second, or third), together with (either the fourth or fifth) and (either the sixth or seventh).**

**Group III** ⟹ **2.5 >score < 1** ⟹ **The company shall select only two incentives (from the first, second, or third) together with (either the fourth or the fifth).**

**Group IV** ⟹ **1≥ score ≤ 0.75** ⟹ **The company shall select one of the following incentives: the first, the second, or the third incentive.**

## Appendix 1: Company Application Form for Enrollment in the Export Incentives System

**To be printed on the official letterhead of the Company and duly stamped with the company's official seal.**

**To: Export Support and Follow-up Department**

**Greetings,,,,,**

**Company ..... hereby submits the following application for enrollment in the Incentives System.**

| | | |
|---|---|---|
| **1.** | **Application Date** | |
| **2.** | **Company Name** | |
| **3.** | **Company Registration Number** | |
| **4.** | **Target to Be Achieved by the End of 2025** | |

**The company hereby undertakes to ensure the accuracy and validity of all submitted data, to confirm the exportation of shipments that have received export approval, and to submit the corresponding customs declarations for the purpose of counting such shipments as part of the Group's exports.**

**Yours faithfully,,,,,**

**Responsible Manager: Job Title**

**Job Title:**

**Signature:**

**** The application shall be submitted on the company's official letterhead.**


***The document bears seal of "Export Support Initiative"**

## Appendix 2: Group Application Form for Enrollment in the Export Incentives System

**To be printed on the official letterhead of the Group and duly stamped with the Group's official seal.**

**To: Export Support and Follow-up Department**

**Greetings,,,,,**

**Group ..... hereby submits the following application for enrollment in the Incentives System.**

| | | |
|---|---|---|
| **1.** | **Application Date** | |
| **2.** | **Group Name** | |
| **3.** | **Names of the Group's Affiliated Companies and the Registration Number of Each Company in the Companies Register** | |
| **4.** | **Target to Be Achieved by the End of 2025** | |

**The group hereby undertakes to ensure the accuracy and validity of all submitted data, to confirm the exportation of shipments that have received export approval, and to submit the corresponding customs declarations for the purpose of counting such shipments as part of the Group's exports.**

**Yours faithfully,,,,,**

**Name of the Chairman of the Board / Export Representative of the Group:**

**Job Title:**

**Signature:**

**** The application shall be submitted on the group's official letterhead.**

Group seal

***The document bears seal of "Export Support Initiative".**