

Arab Republic of Egypt President's Decree

No. 94 of 1972

Concerning Establishing the General Egyptian Authority for Biological Products and Vaccines⁽¹⁾

President of the Republic

Having perused the constitution;

Law No. (127) of 1955 on Practicing the Profession of Pharmacy;

Law No. (308) of 1955 on Administrative Seizure;

Law No. (113) of 1962 on Reorganizing Importation, Manufacturing, and Trading of Drugs, Medical and Chemical Devices;

Law No. (61) of 1963 on Promulgating Law of General Authorities;

President of the Republic's Decree No. (613) of 1962 on the Responsibilities and Organization of the Ministry of Health and Population;

President of the Republic's Decree No. (994) of 1962 on Organizing and Defining the areas of competence of the General Egyptian Organization for Drugs, Chemicals and Medical Devices;

President of the Republic's Decree No. (1025) of 1962 on Determining the Capitals of the General Organizations';

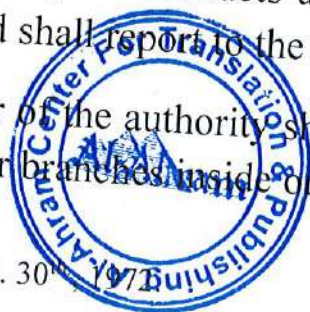
President of the Republic's Decree No. (2420) of 1971 on Organizing the Governmental Apparatus; and

Having considered the legal opinion of the Council of State;

has decided:

Article 1 - A general authority shall be established and called the "General Egyptian Authority for Biological Products and Vaccines". This authority shall have a legal personality and shall report to the Minister of Health and Population.

Article 2 - The headquarter of the authority shall be situated in Cairo and it may establish affiliated offices or branches inside or outside the Republic.



¹- Official Gazette, issue 3, on Jan. 30, 1972

Article 3 - The authority shall undertake, directly or indirectly, producing sera, vaccines and biological products, meeting the country needs of these substances, marketing them, exporting the surplus thereof, fulfilling the requirements of scientific research in this field and following up the new developments thereof, for which purpose the authority may undertake the following:

(a) Establishing laboratories for production, establishing farms for raising animals necessary for production or experiments, or expanding the existing laboratories and farms.

(b) Developing the appropriate programs to enhance this industry and achieve self- sufficiency in these products.

(c) Pursuing research necessary for production, developing it whether by itself or by the use of specialized authorities, institutes and professional scientists and preparing and publishing its scientific research papers.

Article 4 - The authority shall be managed by a board of directors that shall be formed as follows:

Chairman of the Board of Directors
.....
General Director of the authority
.....

} The appointment and salaries of these two employees shall be determined by a decree passed by the President of the Republic.

Chairman of the Board of Directors of the General Egyptian Organization for Drugs, Chemicals and Medical Devices.

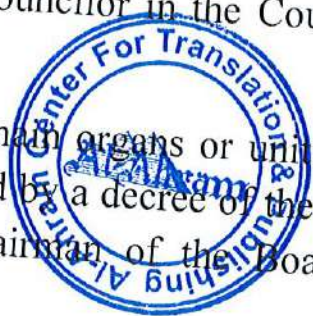
A number of no more three under-secretaries of the Minister of Health to be chosen by the Minister of Health.

Under-Secretary of the Ministry of Economy and Foreign Trade.

Under-Secretary of Ministry of the Treasury.

Legal Advice Department Councilor in the Council of State or whomsoever he may delegate.

One of the directors of the main organs or units affiliated to the authority. The said person shall be appointed by a decree of the Minister of Health, to be issued upon nomination by the Chairman of the Board of Directors for renewable terms of two years.



Two of specialists experienced at laboratory affairs.

A professor at Department of Bacteriology in a Faculty of Medicine in one of the Egyptian universities.

A professor at Department of Pathology in a Faculty of Medicine in one of the Egyptian universities.

} These persons shall be appointed by a decree of the Minister of Health for renewable terms of two years.

Article 5 – The Authority Board of Directors is the supreme body that shall dominate its activities, administer its affairs, propose the general policy that it adopts to achieve the proposes for which it has been established within the country general health policy. In particular, the board has right to accomplish the following tasks:

- (a) To issue decisions, rules of procedure and resolutions related to fiscal, administrative and technical affairs of the Authority, without being required to conform to governmental rules and regulations.
- (b) To set up the organizational structure of the authority.
- (c) To approve the authority **annual draft budget and its final financial reports.**
- (d) To set up plans that shall guarantee production development and the tight control of its quality.
- (e) To approve the appropriate programs for strengthening the authority, achieving self-sufficiency in the products, increasing exports and linking them to production and consumption plan.
- (f) To determine products' prices in the light of production costs, taking into consideration the relationship of each type with the level of public health and its importance for the patients.
- (g) To reconsider the submitted periodic reports on work progress in the authority, its branches and its financial position.
- (h) To accept gifts, bequests and donations.
- (i) To underwrite loans in accordance to legally established rules.
- (j) To prepare a report on the authority activities throughout the fiscal year.



(k) To reconsider any matter which is within the purview of the authority and which Minister of Health may deem it necessary to be presented to the authority.

The Board of Directors may entrust a committee of its members or the chairman of the Board with some of its mandates. The Board may, as well, authorize one of its members to undertake a specific task.

Article 6 - The Board of Directors shall convene at least once a month. Its meetings shall be valid when attended by the majority of members. Its resolutions shall be adopted when they are voted for by the majority of the present members. When votes are equal, the opinion favored by the chairman shall be adopted as a resolution.

Article 7 - Meeting minutes shall be registered in a special record to be signed by the Chairman of the Board and the secretary whom the Chairman of the Board shall choose from among the authority employees.

A member of the board has the right to request that his opinion be recorded in the meeting minutes, and the secretary has to record this request.

Article 8 - Chairman of the Authority Board of Directors shall undertake its management and administer its affairs in accordance with the provisions of this DECREE. He shall be responsible for the implementation of the general policy adopted to achieve the objectives of the authority. Chairman of the Authority Board has the right to authorize one or more of the directors to exercise some of the powers of the Chairman of the Authority Board.

Article 9 - Chairman of the Authority Board of Directors shall represent the authority in its links with other authorities, organizations, persons and before courts.

Article 10 - Board of directors' resolutions shall be reported to Minister of Health for approval. These resolutions shall come into effect if they are not approved nor rejected within thirty days of reporting date. The minister shall submit to the President of the Republic the matters that require a decree therefrom.

Article 11 - The authority shall replace the production laboratories, animal raising farms and other Ministry of Health affiliated units whose activities are



pertinent to the authority work and are specified by a decree from Minister of Health.

The authority shall be entitled to undertake all activities which were exercised by the above-mentioned bodies. The authority shall succeed to all the rights these bodies enjoyed and to all obligations they incurred.

Article 12- The authority's capital shall be made up of net assets of production laboratories, animal raising farms and other units that shall be integrated in the authority as prescribed in the previous article.

Minister of the Treasury shall issue a decree to form a committee for assessing the authority's capital in accordance with the provisions of the President of the Republic's Decree No. (1025) of 1962, which is mentioned above.

Article 13 - Authority Recourses shall be provided by the following:

(a) Its gains resulting from its activity or from its works and services for others.

(b) Loans that it underwrites.

(c) Gifts, bequests and donations accepted by Board of Directors.

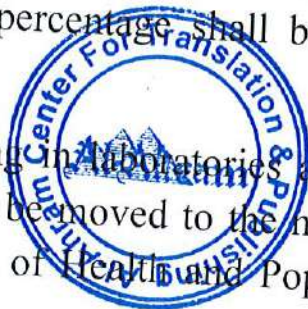
(d) Allocated annual funds in the State general budget.

Article 14 - The authority shall have a special budget prepared in the style of the State general budget. The Authority's fiscal year shall begin with the beginning of the State's fiscal year and ends with its end.

The authority may set a special budget of its own and this budget shall be prepared in the style of commercial budgets.

Article 15 - 10% of authority revenue surplus shall be allocated for spending on research and scientific development of its activity. At the end of the fiscal year, any residual amount of this percentage shall be carried forward to the State general revenues.

Article 16 - Personnel working in laboratories and units whose affiliation has changed to the Authority shall be moved to the new Authority along with other personnel working in Ministry of Health and Population's organs who shall be



specified in a decree issued by Minister of Health and Population in agreement with the Minister of the Treasury.

Article 17- To retain its rights, the authority shall have the right to implement direct execution procedures and Administrative Seizure in accordance with the abovementioned provisions of Law No. (308) of 1955.

Article 18 - Any provision that may contradict this DECREE shall be nullified.

Article 19 - This DECREE shall be published in the 'Official Gazette' and shall come into effect from the date of its publication therein. Both Minister of Health and Population and Minister of the Treasury shall issue regulations necessary for implementing this DECREE.

Issued at the Presidency of the Republic on Dhul Qi'dah 30th., 1391 (Jan. 16th, 1972).

