The Official Gazette – Issue 13 (bis), March 29, 2020

Prime Minister's Decree
No. 777 for Year 2020

Promulgating the Executive Regulation of the law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and Egyptian Drug Authority (EDA)
Promulgated by Law No. 151 for Year 2019

The Prime Minister
After perusal of the constitution;
The criminal proceedings Law promulgated by Law No. 150 for Year 1950;
Law No. 127 for Year 1955 regarding the pharmacy profession practice;
Law No. 53 for Year 1973 regarding the State budget law;
Law No. 118 for Year 1975 regarding import and export;
Law No. 127 for Year 1981 regarding State accountancy law;
The law on protection of competition and prohibition of monopolistic practices as promulgated by Law No. 3 for Year 2005;
Law No. 5 for Year 2015 regarding Egyptian products preference in governmental contracts;
The law regarding the Industrial Establishments licenses granting procedures facilitation as promulgated by Law No. 15 for Year 2017;
Investment law as promulgated by Law No. 72 for year 2017;
Law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and Egyptian Drug Authority (EDA) as promulgated by Law No. 151 for Year 2019;
The President of the Republic decree No. 382 for Year 1976 establishing the National Organization for Drug Control and Research (NODCAR);
The President of the Republic decree No. 404 for Year 1983 establishing a fund to improve services and support joint research within (NODCAR); and;
The President of the Republic decree No. 398 for Year 1995 establishing the National Organization for Research and Control of Biologicals (NORCB);

Decreed:
(Article One)

Provisions of attached executive regulations of the law of establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management **(AUPP)** and Egyptian Drug Authority (EDA), mentioned beforehand, shall come to force.

(Article Two)

This decree shall be published in the official journal and shall come into force on the day following its publication.
Issued at the office of prime Minister on 5 Shaaban 5, 1441
(March 29, 2020, A.D).

Prime Minister
Dr. / Mostafa Kamal Madbouly

(Chapter One)
Definitions

Article (1)

In the application of the provisions of this regulation; the definitions stated in the hereabove mentioned law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology **Management (AUPP)** and Egyptian Drug Authority **(EDA)**, will have the meaning intended for these definitions, and in application of the provisions of this regulation, the following words and phrases shall have the meaning assigned thereto:

1. **The Law:** The hereabove mentioned law establishing AUPP and EDA.

2. **The Egyptian Authority for Unified Procurement (AUPP):** The Egyptian Authority for Unified Procurement, Medical Supply and Medical Technology Management ("AUPP")**.**

3. **Stakeholders**: Government entities, procuring entities as stipulated under the law, public sector companies, private and foreign companies involved in the procurement, supply, distribution and storing processes.

4. **Instance of necessity:** Are instances in which the completion of works or securing procurements in a short time is a matter of essence and necessity to ensure the efficiency and constancy of work in government entities.

5. **Pharmaceutical Establishments:** They are the pharmaceutical institutions referred to in Article (10) of Law No. 127 for Year 1955 hereabove mentioned, as well as laboratories and centers conducting studies required to ensure the quality, efficacy and safety of medical products and devices subject to the provisions of the law, and raw

materials involved in manufacture, and conformity assessment bodies to verify compliance with relevant technical requirements.

(Second Chapter)
The Egyptian Authority for Unified Procurement (AUPP)

Article 2

The purchase fee stipulated in
Article 3 of the law shall be collected as follows:

Firstly: Fee Calculating RULES

fee shall be 7% of the net value of what The Egyptian Authority for Unified Procurement Purchase without adding custom duties, or tax charges on VAT or other costs. According to the following rules:

(A) In case of contracting with a supplier outside the republic to deliver the items in the (ports/ airports) inside the Republic, the fee shall be calculated for the price of the item at the port of arrival.

(B) In case of contacting with company, agent, distributer or local factory to deliver the items in the stores of ("AUPP") or one of the requesting entities, the fee shall be calculated from the price of the item mentioned in the contract concluded between ("AUPP") and the company, agent, distributer or local factory.

In all cases, customs duties and taxes will be incurred by requesting entities on VAT and other costs, as the case may be

Secondly: Exemption from paying of fees partially:

(A) Fee shall be (3.5%) in the case of purchasing any of following items:

1. compulsory immunization.
2. Dialysis appliances.
3. Prosthetics and wheelchairs.
4. Cochlear implants.
5. stethoscopes.

(B) Fee shall be estimated at 5%

in case of purchasing the Egyptian industrial product stipulated in Law No. 5 for Year 2015 referred to.

Thirdly: Exemption from paying of fees totally:

exemption from paying the fees shall be in cases of disasters and epidemics as decreed by the prime minister.

Article (3)

The financial resources of (''AUPP") consist of the following:

1- Financial allocations that the State grants for purchasing and maintaining the pharmaceuticals and medical devices in its general budget.

2. Purchase Fee collected by Authority.

3- Fees for services rendered to others in accordance to the percentages and rules approved by board of directors.

4- Return on investments of the authority funds.

5- Gifts, grants and donations that the board of directors of the authority decides to accept by a majority of its members in a way that does not contradict the goals of the authority in accordance with the governing laws and rules.

The financial amounts mentioned in Clause 1 of The Article shall be transferred to the authority after the coordination with the Ministries of Finance and Planning and Economic Development, the distribution percentage of the authority budget surplus shall be determined annually in agreement with the Minister of Finance.

The authority replaces Government authorities funded by the State's general budget in implementing contracts of purchasing and maintaining pharmaceuticals and medical devices that were concluded by those authorities before the provisions Law came into force and its implementation continues until after it is in force.

Article (4)

In order to implement its competence regarding the medical technology assessment, The Egyptian Authority for Unified Procurement may review and evaluate the annual needs of the requesting entities and do the following:

1- Developing systems of calculating, grouping and assessing the needs of the requesting entities for pharmaceuticals and medical devices that are subject to provisions of Law annually.

2- Setting specifications and pilot criteria for the requesting entities in preparing their needs for pharmaceuticals and medical devices that are subject to provisions of Law.
3- Addressing requesting entities with pilot criteria to make the best use of available resources.
4- Studying and examining the needs of requesting entities in terms of the economic health feasibility of such needs according to international standards.
5- Cooperating and coordinating with relevant international and national organizations and bodies for adopting the Medical Technology Assessment System.

6- Examining periodically the government stock to study the actual consumption rate and forecasting the future consumption rate.
7- Obligating the requesting entities to submit reports on the assessment of products based on modern technologies in coordination with "EDA".
8- Developing an integrated database for the medical technology in centers, hospitals, warehouses and all public health facilities to monitor the needs, use, maintenance and training.

9- Coordinating periodically with non-governmental organizations and institutions in order to identify the amount of medical services they provide in order to maximize the potential utilization of their efforts and to ensure that they are consistent with the State's efforts in this area.

Article (5)

In order to implement its competence regarding purchasing the pharmaceuticals and medical devices, the Egyptian Authority for Unified Procurement may do the following:

1- Strengthening its financial resources through various sources of funding, including charities, donors and benefactors, to cover the deficit between actual needs and appropriations for the purchase and maintenance of pharmaceuticals and medical devices in general budget, all that shall be in coordination with the requesting entities.

2- Contracting with companies holding a global certificate of reference that are handled in a country of origin and that are not registered in the Republic for the benefit of certain entities of a private nature in the cases in which a decision has been issued by the Prime Minister based on a proposal submitted by the authority chairman, provided that such decision should include a permission of handling.

3· Contracting in cases of necessity and emergency with the companies referred to in the preceding clause, after A Prime Minister approval and the coordination with "EDA" Provided that such approval should include permission of handling.

Article (6)

In order to implement its competence regarding medical supply, The Egyptian Authority for Unified Procurement may do the following:

1- Ensuring that the requirements and procedures for the proper storage of pharmaceuticals and medical devices are consistent.

2- Establishing connectivity between the stocks of pharmaceuticals and medical devices throughout the Republic and their own system through coordination with "EDA", taking all necessary measures to maintain data confidentiality.

3- Facilitating redistribution of products among different authorities in case of need after coordination with them.

Article (7)

The Egyptian Authority for Unified Procurement may notify Egyptian Competition Authority (ECA) and prohibition of monopolistic practices if it finds agreement, contract, exchange of information, directly or indirectly, or coordination through third party- whether between any of the specialists in Contract Management and bidders or among bidders themselves, that would lead to:

1- Raising, reducing or stabilizing the prices of goods handled.

2- Partitioning and allocating the markets based on geographical regions, distribution centers, customer quality, product quality, market shares or time periods.

3- Coordinating with regard to applying for tenders, bidding and tender offers or refraining therefrom and other bidding processes.

Article (8)

In order to implement its competence to upgrade after-sales services and to ensure the continuity of efficient and effective delivery of medical service, The Egyptian Authority for Unified Procurement may manage a unified maintenance system and periodic calibration for medical equipment.

Article (9)

In compliance with the provisions of Law, The Egyptian Authority for Unified Procurement may do the following:

1-Developing policies and issuing directives, instructions and guidelines: in accordance with the internal regulations governing its work relating to financial and administrative affairs, purchasing and storages.

2- Providing an advisory service in accordance with the rules that a decision of its board of directors is issued hereby.

Article (10)

The Egyptian Authority for Unified Procurement may use the retained surplus obtained by virtue of an agreement with Minister of Finance that shall be disbursed therefrom in accordance with Board of Directors Approval.

(Chapter Three)
Egyptian Drug Authority (EDA)

Article (11)

EDA shall use and manage all headquarters and assets previously owned by entities replaced by EDA in accordance with the provisions of Paragraph One of Article Two of the abovementioned Law No. 151 for Year 2019 and shall manage the affairs of these entities, EDA also shall use and manage all headquarters and assets previously owned by the Central Administration of Pharmaceutical Affairs affiliated to the Ministry of Health and Population.

Purposes of EDA
Article (12)

EDA's objective is to regulate, implement and supervise the quality, efficacy and safety of medical products and devices stipulated under this law, and the raw materials involved in their manufacture, EDA in particularly may:

First: Set policies, rules and procedures pertaining to all that is related to regulating, implementing and supervision of production circulation of medical products and devices and raw materials and verifying their quality, efficacy, and safety within and outside the republic, all of which by coordinating with the concerned ministries and authorities and in accordance with applicable international standards and norms.

Second: Develop and guarantee the quality, efficacy, and safety of medical products and devices and raw materials in line with science innovations used in diagnosis or treatment or disease prevention per science developments.

Third: Create accurate and continuously updated databases on all issues related to medical products and devices and raw materials described under the law and this regulation.

Fourth: Promote pharmaceutical awareness and education in all segments of society and use all applicable means to communicate correct messages and documented information regarding medical products and devices to healthcare professionals and the public.

Fifth: Regulate and supervise the production and circulation of medical products and devices and raw materials stipulated under this law, and verify its quality, efficacy, and safety within and outside the republic in the context of regulating Egyptian products and its representation aboard.

Sixth: Propose and express opinion regarding all draft laws, regulations and resolutions pertaining to medical products and devices and raw materials, as well as relevant regulatory issues.

Seventh: Cooperate, coordinate, and exchange information with national and international entities and organizations concerned with medical products and public health and those concerned with the issuance of relevant standards and participate in domestic and international conferences and organize the same where necessary, within the scope of achieving EDA's objectives, and in accordance with relevant rules and procedures applicable therein.

EDA's Jurisdictions
Article (13)

EDA shall replace the Ministry of Health and Population, and The Chairman of the board of EDA shall replace the minister of health and population in all jurisdictions stipulated under the abovementioned Law No. 127 for Year 1955 related to the regulation of the registration, circulation and control of the products and devices subject to the

provisions of this law and raw materials involved in their manufacture, wherever it appears in the law or relevant laws, regulations, and decrees. EDA shall exercise, excluding others, all regulatory, executive, and **supervisory** jurisdictions necessary to achieve its **assigned** purposes and **desired** objectives, in accordance with the **regulatory authorities**' international standards.

The authority shall also replace the National Organization for Drug Control and Research (NODCAR), established pursuant to the aforementioned presidential decree No. 382 for Year 1976, and the National Organization for Research and Control of Biologicals (NORCB), established pursuant to the aforementioned presidential decree No. 398 for Year 1995, and other administrative authorities and bodies having supervisory jurisdiction over medical products and devices subject to the provisions of the law, namely in every jurisdictions provided for under the laws or decrees stipulating their establishment.

Article (14)

It is prohibited to circulate medical products and devices, subject to the provisions of the law, without EDA prior approval.

The Regulatory Jurisdictions
Article (15)

EDA shall exercise the following regulatory jurisdictions:

1. Develop policies and plans that aim at ensuring the availability of medical products and devices and ensure its quality and safety through coordination with the ministries and entities concerned.

2. Review all supervisory frameworks and bylaws pertaining to EDA's scope of work and amend the same for development to keep at pace with international quality and safety health standards. EDA may propose

necessary amendments or new rules within frameworks and bylaws falling outside the scope of its jurisdiction, provided that such proposals shall be escalated and referred to competent entities for perusal and promulgation in accordance with applicable processes and procedures.

3. Establish and document the sound principles and technical and health requirements to be met by pharmaceutical establishments and its personnel.

4. Coordinate with the Industrial Development Authority (IDA) to set the requirements for the allocation of lands for medical products and devices factories, in the manner indicated by the executive regulation of this law and coordinate with the Industrial Development Authority (IDA) to set the licensing granting requirements for factories that produce medical products and devices subject to this law in accordance with applicable standards, all of which to ensure the prompt issuance of final licenses. EDA shall also implement common mechanisms that ensure achieving full cooperation in the abovementioned aspects, to guarantee smooth and orderly workflow and all of which in favor of the public interest.

5. - Set the rules and requirements for the licensing of laboratories and conformity assessment bodies in charge of verifying the technical requirements and compliance procedures and ensuring quality, efficacy and safety of medical products and devices subject to the law, as well as lab results accreditation requirements and procedures.

6. Set the rules and procedures that regulate the process of examination of medical products and devices subject to this law and raw materials involved in their manufacture.

7. Set the rules and procedures that regulate the processes of import, export, registration, circulation, supervision and inspection of medical products and devices subject to the provisions of the law, as well as, raw materials used in their manufacture, and production tools, through

coordination with relevant entities and in accordance with international standards, as well as, implementing controls and procedures that regulate the pricing of any medical, biological products or devises subject to the provisions of the law.

8. Set binding regulations that guarantee the quality, efficacy and safety of medical products and devices subject to this law and raw materials involved in the their manufacture, and tracking and monitoring throughout all stages of circulation, and implementing such regulations on all entities taking part in this process, including producers, importers and distributers of such products, as well as, all issues related to the circulation of these products, and to take necessary actions to withdraw products from circulation. Such regulations and other pertaining to Drug track and trace system shall be issued by a decision rendered by the Chairman of the board of directors of EDA after the approval of the board of directors.

9. Prepare and develop training programs needed to boost the efficiency of EDA personnel and others working in the same field.

The Executive Jurisdictions
Article (16)

EDA shall implement laws, regulations, regulatory decisions, norms, and procedures governing the registration, pricing, circulation and supervision of medical products and devices subject to the provisions of the law, as well as, raw materials involved in their production, and shall monitor the application of relevant procedures to ensure consumer protection and take legal actions against violators. EDA may particularly resort to the following:

1. Issue licenses to all types of pharmaceutical establishments without prejudice to Pharmacy Profession Practice Law No. 127 for Year 1955, and the law regarding facilities for licensing of industrial establishments

hereabove mentioned, EDA shall have jurisdiction to issue operation licenses only and verify the application of good manufacturing practice but not the rest of licensing procedures for factories that produce medical products and devices and raw materials, to ensure prompt coordination for the purpose of issuing the final licenses.

2. Evaluate medical products and devices subject to the provisions of the law and pricing medical and biological products in accordance with rules, standards and norms approved by EDA board of directors.

3. Inspect and analyze medical, biological products, veterinary products, herbal medicine, botanical extracts and its pharmaceutical extracts, and cosmetic products and the like in accordance with international standards and references to verify their quality, validity, efficacy, and safety and to verify that drugs conform with the pharmaceutical pharmacopeias and with the mandatory standard specifications approved by EDA.

4. Inspect medical devices, spectacles, contact lenses and electronic devices that may have an impact on public health and verify their quality, efficacy, safety, and compliance with the mandatory standard specifications approved by EDA.

5. Inspect and analyze *in vitro* diagnostic medical device to verify their quality, efficacy, safety, and compliance with the mandatory standard specifications approved by EDA.

6. Inspect and analyze pesticides and disinfectants to verify their quality, efficacy, safety, and compliance with the mandatory standard specifications approved by EDA.

7. Permit the circulation of locally produced medical products and devices subject of this law and other products and devices subject to the jurisdiction of EDA, provide conducting the required examinations and analysis.

8. Provide clearance for imported medical products and devices subject to the provisions of this law and any other products and devices related to EDA scope of work after conducting the necessary examinations and analyses.

9. Create accurate and updated databases related to EDA's scope of work and exchange information with domestic, regional, and international entities.

10. Collaborate with Egyptian and foreign universities and research centers to perform research and applied studies on all that is related to EDA scope of work.

11. Carry out research and studies related to EDA's work and activities and collaborate with companies, authorities, scientific entities, universities and research centers and other entities engaging in similar scope of work.

12. Implement training programs that ensure boosting efficiency of EDA personnel and others working in the same field and approve entities that provide training courses and qualification programs for personnel in the medicinal service scope of work.

13. Increase consumer awareness regarding medical products and devices subject to the provisions of the law and all that falls within the jurisdictions of EDA and coordinate with relevant entities and authorities in this regard.

14. Represent the State in regional and international organizations in relation to the scope of EDA jurisdiction.

15. Evaluate the results of different stages of clinical trials for medical products and devices subject to the provisions of this law and adopt the necessary regulatory procedures to supervise all various stages and relevant facilities under the jurisdiction of EDA in accordance with the norms and procedures determined by the board of directors and issued by a decision from the chairman of the board.

The chairman of the board, subject to the approval of the board of directors, may establish a reference laboratory and examination laboratories at EDA's headquarters to cover all EDA's specializations or create specialized secondary laboratories.

The Supervisory Jurisdictions
Article (17)

EDA shall exercise the following Supervisory Jurisdictions:

1. Monitor the application of frameworks, regulations, regulatory decisions, norms, and the procedures for remunerating activities by factories that produce medical products and devices and raw materials subject to the provisions of this law, and all other activities and issues subject to the jurisdiction of EDA and verify the correct application of Good Manufacturing Practices (GMP) within and outside the republic. All of which by EDA adoption of the standards and requirements of World Health Organization for the norms and requirements of Good Manufacturing Practices (GMP) as a scientific reference, as well as, other international references, provided issuing explanatory and interpretative decisions based on the nature, requirements and needs of the Egyptian pharmaceutical market and consistent with the standards and references of international regulatory authorities.

2. Supervise, monitor, and inspect all types of pharmaceutical establishments and their personnel and take legal action against violators by application of the standard specifications for production, or storage or

circulation through cooperating and coordinating with the relevant entities.

3. Supervise medical products and devices subject to the provisions of this law and all fields related to EDA's scope of work to ensure quality, efficacy, safety, and validity compliance to the specification of the manufacturer with the mandatory standard specifications approved by EDA.

4. Supervise import, export, distribution, storing and circulation of medical products and devices subject to the provisions of this law.

5. Identify and monitor any adverse effects that may result from the circulation of medical products and devices subject to the provisions of this law.

6. After-sale follow-up and pharmacovigilance for medical products and devices subject to the provisions of this law.

EDA Board of Directors (BoD)
Article (18)

The board of directors is the body that has a dominant authority to decide on and run EDA affairs and to take whatever actions it deems necessary to achieve its purposes. The board of directors may particularly carry out the following:

1. Set the functional, structure of EDA in a manner that ensures achieving its objectives for which it was established and adopting necessary plans to achieve such objectives and follow-up on the progress made towards achieving them.

2. Issue the Egyptian Pharmacopeia.

3. Take the necessary actions to approve the standard specifications for medical products and devices subject to the jurisdictions of EDA.

4. Set standards for the registration, pricing, import, export, production and circulation of medical products and devices subject to the provisions of this law, in addition to the conditions, standards and GMP requirements; all of which in accordance with the proposals presented by the chairman of the board and EDA's technical and specialized divisions.

5. Form specialized committees as required for EDA's operations; including the scientific and technical committees and specify the jurisdictions and work mechanisms and remuneration of the members of these committees, all of which in accordance with the proposals by the chairman of the board and EDA's specialized divisions.

6. Approve the quarterly annual report on the works of EDA, which particularly includes EDA's works and future plans and the works actually completed from previous plans.

7. Determine the consideration for the services offered by EDA and to continuously update these prices, in accordance with scientific and market updates.

8. Issue the internal regulations on financial, administrative, procurements, stores, human resources, and others related to EDA's operational organization, without the need to strictly act according to the government rules and regulations.

9. Approve the annual Draft budget and the closing financial reports.

The Chairman of the Board
Article (19)

Chairman of the board shall oversee managing EDA in accordance with resolutions passed by the board of directors and is responsible to implement the general policy in place to achieve the purposes of EDA. The chairman of the board may Particularly carry out the following:

1. Manage all headquarters and assets previously owned by entities replaced by EDA in accordance with Paragraph One of Article Two of the abovementioned Law No. 151 for Year 2019, and manage the day-to-day affairs of these entities, as well as manage all the headquarters and assets previously owned by the Pharmaceutical Affairs Central Administration affiliated to the Ministry of Health and Population.

2. Run EDA's technical, financial, and administrative affairs and follow up on the progress of its operations.

3. Implement the resolutions adopted by the board of directors and take the necessary actions and issue the required decisions to achieve the purposes of EDA and its establishment objectives and ensure its proper operation.
4. Implement strategies and work plans that are necessary to supervise EDA personnel in accordance with laws and regulations.

5. Approve the reports referred to the board of directors and issue circulars on the implementation of applicable regulations and rules.

6. Set and update internal regulations pertaining to financial, administrative, procurement, storages and human resources and other regulations related to EDA operations and its jurisdictions to achieve its objectives.

7. Prepare the draft budget and closing financial statements and refer them to the board of directors in due time.

8. Prepare the quarterly annual report on EDA operations, which shall particularly cover EDA activities, future plans and a review on works actually completed from previous plans.

The Scientific and Technical Committees
Article (20)

Chairman of the board, and after the approval of the board of directors, shall issue decisions to form specialized technical and scientific committees. Members of these committees may be EDA members or personnel or other experts and specialists, all of which; to perform some tasks within the jurisdiction of the EDA, *inter alia*:

Registration of medical products and devices subject to the provisions of the law, and raw materials involved in their production.

Pricing of any medical or biological products subject to the provisions of the law, in accordance with the norms and standards approved by the board of directors.

Technical licensing to operate various pharmaceutical establishments.

Inspection of various pharmaceutical establishments in Egypt and abroad in accordance with the norms and standards approved by EDA board of directors and international standards and references recognized by regulatory authorities.

Analysis and monitoring of the quality, efficacy and safety of medical products and devices subject to the provisions of the law, and raw materials involved in their production.

The decision to form these committees shall determine their jurisdictions, work mechanisms, and methods of challenging their decisions. The resolutions rendered by these committees shall not be final except after approval in accordance with the regulations, norms and regulatory procedures approved by EDA board of directors.

Financial Resources and Budget

Article (21)

NODCAR fund created by virtue of the aforementioned Presidential Decree No. 404 for Year 1983, as well as the Planning and Drug Policies Fund shall be transferred to EDA bearing all their rights and liabilities. Also, the account of NORCB shall be transferred to EDA bearing all its rights and liabilities.

Article (22)

The internal regulations related to the financial affairs, procurements, storages, human resources, and other regulations related to organization of EDA operations shall be issued by virtue of a decision rendered by the chairman of the board of directors after the approval of the board without complying with government rules or regulations.

Article (23)

EDA Financial Resources consist of the following:

1. The financial provisions allocated by the state.
2. The consideration for the services rendered by EDA to third parties, rendered by EDA's Chairman, provided the previous board of directors' approval.
3. The charges collected by EDA in accordance with the law.

Article (24)

EDA shall have an independent budget having the same pattern as the general state budget and shall be subject to the government accounting system. The fiscal year shall commence with the fiscal year of the state and ends with it. EDA shall have a special account at the Egyptian Central Bank within the unified treasury account and the surplus shall be carried over from one fiscal year to the another.

Article (25)

EDA may conclude contracts for works that its execution requires contracting for more than one fiscal year but within the limits of the total costs for contracts and works and provided that, the amount payable during the fiscal year is within the credit limit included in the budget.

Article (26)

Payments may be made from the budget in accordance with the disbursement procedures as determined by the financial regulations and in accordance with the provisions of abovementioned Law No. 127 for Year 1981.

Article (27)

EDA shall collect all charges prescribed in consideration for its activities in accordance with the charges categories stipulated under Schedule 1 attached to this regulation, in cash or through any means of payment.

The Chairman of the board shall issue a decision to determine the consideration for the services provided by EDA after the approval of the board of directors.

Grievance Committee
Article (28)

Chairman of the board shall render a decision to form one or more grievance committee, as follows:

A member of the EDA board of director (Chairman)
A Vise president of State Council
A physician nominated by the Minister of Health and Population.
An expert in EDA scope of works who is not an EDA personnel and nominated by the Minister of Higher Education.
An expert from EDA personal (Committee Rapporteur).

The committee Rapporteur shall prepare the meeting agenda and provide committee members with copies of the same at least one week prior to convening the committee meeting. The committee Rapporteur shall record minutes of the meeting and sign the same by committee members and notify stakeholders by the committee's resolutions.

The committee may appoint any experts in EDA scope of works as the committee deems fit without having voting rights.
The committee shall convene upon an invitation from the committee chairman whenever necessary. The committee's resolution shall pass with majority voting; when the votes are tied, the side for which the chairman of the committee voted shall prevail. The applicant shall be notified with the resolution of the committee no later than fifteen days after its issuance.

Article (29)

The Grievance Committee shall contemplate grievances filed by stakeholders against administrative decisions rendered by EDA regarding regulation of medical products and devices subject to the provisions of the law, and in accordance with charge categories stated in Schedule 2 herein attached.

Article (30)

Grievances shall be referred to the office of EDA chairman or his delegate within sixty days from the date of the issuance of the challenged decision. The grievance shall include all supporting documents and statements. A ruling on the grievance shall be rendered within sixty days from the date the grievance is submitted.

The Power of Judicial Police
Article (31)

Without prejudice to the jurisdictions prescribed for judicial police officers with general jurisdiction, only EDA personnel in charge of enforcing the provisions of the law and laws and regulations within the scope of EDA work and who are identified by a decree by the minister of justice as agreed with the chairman of EDA may act as judicial police officers to substantiate crimes in violation of the provisions of these laws and their executive regulations.
When exercising their jurisdictions related to relevant legislations; judicial police officer with general jurisdiction shall act in observance of EDA operations and shall coordinate with EDA.

Article (32)

EDA personnel vested with the capacity of judicial police officers may have access to the sites used for the production, storage and use in medical products and supplies subject to the provisions of the law and sites for the production of raw materials used in the production of the above, as well as, the facilities used for conducting various research and studies and sites at any facilities subject to EDA regulation, and to search such sites and inspect equipment, products or supplies and to inspect records, ledgers, documents, papers required for enforcement of the law. Officials in charge of these sites shall produce data, extracts, copies of documents required for this purpose. EDA judicial police officers may

substantiate crimes commissioned within their scope of work using all modern means and technologies.

Article (33)

EDA chairman, and after deliberating with the board of directors, shall issue the engagement rules of judicial police officers with facilities subject to the provisions of the law.

Article (34)

The judicial police capacity shall remain attached to the judicial police officers during leaves, vacations and official holidays and shall only terminate upon the termination of the employment relationship with EDA or suspension from work by virtue of a judicial or an administrative decision.

Article (35)

EDA personnel with judicial police capacity shall act in observance of the judicial police cards and the definitions and information of this capacity and the scope of exercise of their jurisdictions, and they must disclose their identity to stockholders upon carrying out the inspection.

Interim Phase and Transfer of Jurisdictions
Article (36)

The timeframes for the transfer of jurisdictions to EDA as stipulated under the law commence from the next day after the enforcement of these regulations, as follows:

1. The creation of the organizational structure for EDA divisions and departments within the following three months, provided however, this

is simultaneous with the identification of the human resources to be recruited by EDA and in coordination with the relevant entities.

2. Training of human resources within the following six months to be screened in accordance with the consecutive screening lists of these human resources.

3. Determination of the EDA expert human resources to be qualified – in coordination with the ministry of justice –who are to be vested with the judicial police capacity within the following three months after the issuance of these regulations.

4. Completion of the review of all the regulatory laws and regulations related to the EDA operations within the following six months in prelude to the issuance of the same in accordance with applicable methods and procedures.

5. Formation of the expert scientific and technical committees required by EDA within three months after the issuance of these regulations.

6. Issuance of the internal regulations for financial, administrative affairs, procurement, funds, and accounts transferred to EDA within one month from the issuance of the executive regulations.

7. Issuance of the human resources regulations within three months from the issuance of the executive regulations.

8. Creation of the draft for the Egyptian pharmacopoeia within six months following the issuance of the executive regulations and the publication of the Egyptian pharmacopoeia within the next six months.

9. Creation of guidelines for administrative operations and the issuance of organizational decisions within three months from the issuance of these regulations.

10. Tackling the creation of an integrated database no later than one year after issuance of these regulations.

11. Evaluation and screening of existing entities that provide training courses and personnel qualification programs in pharmaceutical services within six months from the issuance of these regulations.

12. Approval of sound foundations and technical and health requirements that must be available in pharmaceutical establishments and its personnel within six months from the issuance of these regulations.

All of the above is to ensure complete and smooth migration during the interim phase and to avoid any shortcomings or shortages in the domestic pharmaceutical market, and to provide EDA with comprehensive solutions in all of its jurisdictions no later than a year after the enforcement of the law. This term may be extended for another term only once by virtue of a decree from the prime minister pursuant to a proposal from the EDA chairman.

Article (37)

Chairman of the board may issue a decision to form a technical coordination committee specializing in inventory and review of operations rules and procedures for all of EDA's tasks and specializations in all different divisions; and to propose a system of operations through the preparation of work manuals for all procedures and plans for all operations and determining the required timeframes for the same.

Existing rules and procedures shall continue to be applicable until chairman of the board issues controls, rules and procedures to regulate EDA's various tasks, jurisdictions and divisions.

Human Resources
Article (38)

Personnel working at ministries, public authorities, government departments, local administrative units and others in regulatory entities with jurisdiction over medical products and supplies subject to the law and who are determined by a decree by the prime minister pursuant to a proposal by EDA authority; shall be transferred to EDA after coordination with the concerned ministers as follows:

Chairman of the board of EDA, and after consulting with various relevant entities, shall be tasked with determining the human resources needed for operations in each EDA division in accordance with their jurisdictions and in terms of numbers, qualifications and experiences and any other indicators that meet EDA human resources requirements and EDA organizational and administrative structure, while taking into consideration the interim phase transferring the regulatory, executive and supervisory jurisdictions to EDA.

EDA chairman of the board renders its decisions form specialized committees to set controls, standards and mechanisms for screening of qualified human resources who are necessary for EDA operations, as well as, the necessary training and evaluation programs. Lists of names and grades of personnel to be transferred shall be referred to the chairman of the board for approval and coordination with the concerned ministers after the approval of the prime minister without prejudice to the employment status, financial benefits of transferred personnel as of the date of the transfer.

Serialized lists of the names of personnel to be transferred, during the interim phase, shall be served to EDA to transfer regulatory, executive and supervisory jurisdictions to EDA until the complete transfer of all these jurisdictions to EDA.

Personnel in entities replaced by EDA pursuant to Paragraph One of Article Two of above said Law No. 151 for Year 2019 and who are not included in the prime minister's decision shall be transferred to state's administrative units or research centers in accordance with the decision of the Central Agency for Organization & Administration.

(Chapter Four)
General and Common Provisions
Article (39)

The Supreme Committee for Medicine shall be formed and shall be chaired by the prime minister comprised of the following members:
Minister of higher education and scientific research.
Minister of planning and economic development.
Minister of finance.
Minister of health and population.
Chairman of AUPP.
Chairman of EDA.
Secretary General for the council of ministers (committee rapporteur).
Director of the Armed Forces Medical Services Administration.
Representative from the Administrative Control Authority nominated by chairman of the authority.

The Supreme Committee for Medicine shall have the jurisdiction to monitor the work of AUPP and EDA and coordinate between them to resolve any interference in jurisdictions that may appear during actual operations. The prime minister shall issue a decree on the other jurisdictions of this committee.

The Supreme Committee for Medicine shall convene every three months or whenever necessary and may appoint any person for the purpose of completing its mandate, and the committee shall serve the president with quarterly reports on the operations of AUPP and EDA.

Article (40)

A joint committee shall be formed between AUPP and EDA. The membership of this joint committee shall consist of the vice chairman of AUPP, EDA counterpart, and an EDA sector director elected by the EDA Chairman.

In addition to the provisions of these regulations regarding coordination between AUPP and EDA, the joint committee shall be concerned with unification of concepts on issues of common interests, including without limitation the following:

1. Informing AUPP, after coordination with EDA, on the volume of raw materials imported, the production capacity of factories, size of inventory of medical products at stores maintained by the state and the private sector.

2. Monitoring and evaluating the performance and effectiveness of medical products and devices and application of the results of the evaluation of medical technologies.

3. Setting coordination plans to correlate scientific research and innovation in the field of pharmaceutical sciences or relevant sciences within AUPP scope of work and encourage the use of applied research in universities or research centers to introduce advanced technology and the indigenization of these industries and technology in the domestic market.

4. Implement plans to encourage Egyptian exports in terms of medical products and devices and raw materials used to produce the same subject to the provisions of the law.

5. Take the necessary actions to ensure the availability of medical products and devices and raw materials used to produce the same in the domestic market subject to the provisions of the law.

6. Implementing the necessary actions and measures to deal with emergencies and emergency situations related to medicines, and to take appropriate precautions and measures.

The committee shall convene every month or whenever necessary and may appoint any person to assist in completion of its mandate. The committee shall present the Supreme Committee for Medicine with a report on the progress of operations of AUPP and EDA, and the Supreme Committee for Medicine shall escalate this report to the President of the Republic.

Article (41)

EDA and AUPP shall implement a system to expedite the process of registration and trade in medical products and devices, with regards to the processes carried out by AUPP, for FDA, EMA, EMEA approved medical products and devices that are being traded in the country of origin or as agreed by EDA and AUPP in light of developments in international references on medical products and devices.

Article (42)

EDA shall entrust experts to be in charge of medical custom clearance inside airports and ports to inspect consignments, spare parts and medical devices that are within AUPP scope of work and EDA shall exempt earlier stated consignments from waiting lists for analyses, inspection and clearance.

Article (43)

AUPP, EDA, General Authority for Investment and Free Zones, and other relevant entities may develop a strategy for the indigenization and development of medical products and devices industry by benefiting from and counting on the results of unified procurement and with the objective of achieving self-sufficiency, providing incentives to investment, encouraging exports, realization of the considerations of modern technology, while taking into account geographical distribution. This plan shall be presented to the prime minister for inclusion in the investment map.

Furthermore, AUPP, EDA and the General Authority for Investments and Free Zones shall also implement a plan for indigenization and development of industry of medical products and devices and take the necessary actions to actualize the plan and monitor its execution. The three entities shall present the Supreme Committee for Medicines stipulated under Article No. 39 of these regulations with periodic reports on monitoring the executive situation of the investment map with regards to the indigenization and development of the industry for medical products and devices in order to take the necessary action.

Article (44)

The Armed Forces Medical Services Administration shall inform AUPP of the required medical products and devices and the AUPP shall undertake the tender procedures and the technical evaluation of bids and issue an award letter to the winning bidder to eventually achieve the best prices and contractual conditions, then AUPP shall notify the Armed Forces Armament Authority and the Armed Forces Medical Services Administration of the award results so that each of the latter, according to its jurisdiction, shall sign contracts with the winning bidder and take necessary action to give effect thereto.

Schedule No. 1

Sr.	Type of the Charges	Category of the Charges
First: Pharmaceutical Registration Charges		
1	Application to register a locally produced medical product (pharmaceutical/ biological/ veterinary/ herbal)	EGP 15,000
2	Application to register an imported medical product (pharmaceutical/ biological/ veterinary/ herbal)	EGP 20,000
3	Application to register a locally produced cosmetic product	EGP 2,500
4	Application to register an imported cosmetic product	EGP 5,000
5	Application to register a locally produced medical device	EGP 5,000
6	Application to register an imported medical device	EGP 7,000
7	Application to register a locally produced disinfectant/ pesticide	EGP 3,000
8	Application to register an imported disinfectant/ pesticide	EGP 4,000
Second: Pricing Charges for Medical Products		
1	Application for pricing of a medical product	EGP 5,000
2	Application for pricing of a new package	EGP 3,000
3	Charges for issuance of a pricing certificate for a product prescribed for export	EGP 500
4	Charges for the issuance of a 'Free Sale' Certificate	EGP 500
Third: Licensing Charges for Import of Medical Products And Medical Raw Materials and Production Plans		
1	Approval to import medical raw materials	EGP 300
2	Approval to import raw materials for cosmetic products	EGP 300
3	Approval to import raw materials for pesticides	EGP 300
4	Approval to import narcotic materials	EGP 500
5	Permit to procure/ withdraw narcotic materials	EGP 1,000
6	Import permit issued to El Gomhoria Company for the purpose of trade	EGP 200
7	Import permit for a medical product (bulk/ finished product)	EGP 2,000
8	Annual import plan for a medical product (bulk/ finished product)	EGP 3,000
9	**Application to approve the annual production plan:**	
A	Annual production plan for raw materials less than 20 sources of raw materials	EGP 5,000
B	Annual production plan for raw materials from 20 to 50 sources of raw materials	EGP 10,000
C	Annual production plan for raw materials from 51 to 100 sources of raw materials	EGP 15,000
D	Annual production plan for raw materials for more than 100 sources of raw materials	EGP 25,000

Sr.	Type of the Charges	Category of the Charges
10	**License to Import Medical Devices**	
A	If the value of the invoice is less than EGP 10,000	EGP 500
B	If the value of the invoice is between EGP 10,000 and until EGP 50,000	EGP 1,000
C	If the value of the invoice is more than EGP 50,000	EGP 2,000
	Fourth: Charges for Licensing and Assignment	
1	**Charges for licensing of factories:**	
A	License to add a new production line	EGP 5,000
B	License for scientific offices	EGP 50,000
C	License for an agent's warehouse	EGP 30,000
D	License for a storage or a distribution company	EGP 20,000
E	License for bioequivalence research center	EGP 40,000
2	**Pharmacy licensing charges**	
A	Charges for the certificate to open a new pharmacy	EGP 500
B	Charges for the transfer of a title of a pharmacy	EGP 350
	Fifth: Inspection Charges	
	For each production line. The charge in consideration of monitoring the factory's compliance with Good Manufacturing Practices (GMP):	
1	**The charge in consideration of monitoring the factory's compliance with Good Manufacturing Practices (GMP) for the production line**	EGP 5,000
2	**The charge in consideration for monitoring the factory's compliance with GMP for production lines approved by FDA, EMA, WHO, PIC/S**	EGP 3,000
	Sixth: Custom clearance charges	
	Custom clearance charges for consignment per invoice:	
1	Application for medical custom clearance for medical products	EGP 500
2	Application for medical custom clearance for medical raw materials and packing and wrapping material	EGP 250
3	Application for medical custom clearance for samples and standard materials	EGP 200

Sr.	Type of the Charges	Category of the Charges
	Seventh: Analysis and calibration charges	
1	Application to register locally produced medical products (pharmaceutical/ veterinarian/ herbal/ pesticide or disinfectant/ medical devices) for products or medical devices containing a maximum of three substances to be analyzed.	EGP 12,000
2	Application to register imported medical products (pharmaceutical/ veterinarian/ herbal/ pesticide or disinfectant/ medical devices) for products or medical devices containing a maximum of three substances to be analyzed.	EGP 15,000
3	Application to analyze locally produced cosmetic products	EGP 5,000
4	Application to analyze imported cosmetic products	EGP 8,000
5	Application for inspection/ analysis of samples for locally produced medical products or devices including: (pharmaceutical/ veterinarian/ herbal/ pesticide or disinfectant/ medical devices) for medical products or devices containing a maximum of 3 substances to be analyzed.	EGP 2000
6	Application for inspection/ analysis of samples for imported medical products or devices including: (pharmaceutical/ veterinarian/ herbal/ pesticide or disinfectant/ medical devices) for medical products or devices containing a maximum of 3 substances to be analyzed.	EGP 3,000
7	Application for analysis of materials for government tenders or bids	EGP 1,000
8	Application for analysis of a raw material	EGP 2,000
9	Application for analysis of any added substance to a medical product or device	EGP 2,000
10	Application for analysis of any product containing a hazardous material	EGP 750 per material
11	Application for analysis for registration of a locally produced biological product	EGP 30,000
12	Application for analysis for registration of an imported biological product	EGP 50,000
13	Application for analysis of a locally produced biological product for clearance of formulae	EGP 3,000
14	Application for analysis of an imported biological product for clearance of formulae	EGP 5,000

Schedule 2

Sr.	Type of the Charges	Category of the Charges
Charges for submission of a grievance to the Grievances Committees		
1	Grievance against a general administrative decision (for all pharmaceutical establishments or for a specific type of pharmaceutical establishments)	EGP 5,000
2	Grievance against an administrative decision specific to a pharmaceutical establishment	EGP 4,000