Law No. 151 for Year 2019

Promulgating law establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and the Egyptian Drug Authority (EDA)

In the Name of the People
The President of the Arab Republic of Egypt,
The House of Representatives approved the following law, and hereby enacted by us:

Article (1)

The provisions of the annexed law shall enter into force with regards to the establishment of the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management **(AUPP)** and Egyptian Drug Authority (**EDA**), each provision contradicting the provisions of this law shall be nullified.

Article (2)

EDA, established pursuant to the provisions of the annexed law shall replace each of the National Organization for Drug Control and Research (NODCAR), established pursuant to Presidential Decree No. 382 for Year 1976, and the National Organization for Research and Control of Biologicals (NORCB), established pursuant to 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 this law and the accompanying law, namely in every jurisdictions provided for under the laws or decrees stipulating their establishment.

EDA shall also replace the Ministry of Health and Population, and the chairman of the board of EDA shall replace minister of health and population in the jurisdictions stipulated under Pharmacy Profession Practice 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.

NODCAR Fund created by virtue of Presidential Decree No. 404 for Year 1983, as well as the Planning and Drug Policies Fund shall be transferred to EDA established pursuant to the provisions of this law bearing all rights and liabilities therein.

The Executive Regulations of the accompanying law shall determine the phases for the transfer of the organizational and regulatory jurisdictions to EDA, and the jurisdictions of each phase, and the time schedule needed for such transfer, by coordinating with the Ministry of Health and Population and other relevant entities. All of which by ensuring EDA full replacement in the aforementioned jurisdictions no later than one year from the date of the enforcement of this law, this term may be renewed once by a Prime Minister decree.

Article (3)

Personnel working at ministries, public authorities, government departments, local administrative units and others in regulatory entities with supervisory jurisdiction over medical products and devices subject to this law and the accompanying law, and as specified by virtue of a decree from the prime minister pursuant to the proposal of EDA chairman, and after coordination with the ministers concerned in the manner described in the executive regulation of this law and the accompanying law; shall be transferred to EDA without prejudice to the employment positions and the financial benefits of the transferred personnel as of the date of the transfer.

Personnel not included in the above said prime minister's decree shall be transferred to the State's administrative units or research centers in accordance with regulations and procedures set by the Central Agency for Organization & Administration.

Article (4)

The Prime Minister shall issue the executive regulation for the accompanying law within six months as of the publication of this law in the official gazette.

Article (5)

The last paragraph of Article No. 23 of the Comprehensive Health Insurance Law promulgated by Law No.2 for Year 2018 shall be replaced by the following text:

Procuring medical products and devices needed to render health care services, provided that AUPP shall be in charge of the procurement process, and the care authority, in order to achieve its purposes, may set up pharmacies inside hospitals and execute contracts with public or private pharmacies in accordance with the provisions of Law No. 127 for Year 1955 regarding Pharmacy Profession Practice.

Article (6)

This law shall be published in the official gazette and shall enter into force the next day after the lapse of six months of its publication.

This law shall be stamped by the State's Seal, and shall be enforced as one of its laws.
Issued at the presidency of the republic on Zul Hija 24, 1440 AH
(Corresponding to Aug. 25, 2019, AD).
Abdulfatah Al Sisi

Law Establishing the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management (AUPP) and the Egyptian Drug Authority (EDA)

(Chapter One)
Definitions

Article (1)

In the application of this law; each of the following words and phrases shall have the meaning assigned thereto:

1. **Medical Technology:** the application of knowledge and structured skills in the form of pharmaceuticals, radioactive materials, serums, human vaccines, medical appliances, medical or visual aids, or any means of transportation that have a medical role, procedures and systems developed in order to solve a health problem.

2. **Medical Products:** Any product of formula containing a substance or a group of substances used for the purpose of treatment or prevention or diagnosis in humans or animals or which can be described as having another medical effect or which aims to restore, correct or modify physiological functions through having a pharmacological, immunological, or metabolic effect on general health in accordance to the applicable references and standards, as well as, any formulae or substances that may be invented through advances in science and/or international references and standards.

3. **Medical Device:** Any device, instrument, medium, machine, or application, including what is being implanted, or any *laboratory reagent used in the laboratory,* or electronic program, or substance or any other similar or related manufactured by the manufacturing company for the purpose of human use, whether used alone or in combination for one or more of the following medical purposes:
Diagnosis, prevention, monitoring, treatment, alleviation of disease
Diagnosis, monitor, treatment, alleviation, compensation for an injury

Investigation, replacement, modification, or support of the anatomy or of a physiological process.
Supporting or sustaining life.
Control of conception.
Disinfection of medical devices.
Providing information by means of *in vitro* examination of specimens derived or taken from the human body.

Provided that it does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

4. Biological Products: Products containing one or more active ingredients produced or derived from a biological source, including but not limited to, human vaccines, serums, blood and plasma products and derivatives, also products manufactured using biotechnology and the like, as well as, any products or substances that may be created based on science updates and/or international standards and references.

5. Plasma Derivatives: Biological products derived from human blood plasma components, for example albumin and clotting factors and other plasma derivatives.

6. Raw Materials: Active or inactive substances used to manufacture medical products and devices that are subject to the provisions of this law, other than materials used for packaging and wrapping.

7. Cosmetic Products: Products intended for use on external parts of the human body, teeth, or oral cavity membranes for cleaning, perfuming, protection, preservation, or changing and improving appearance, purposes, or any other existing or newly created products classified as cosmetic products in accordance with international standards.

8. Medicinal Plants Extracts: Botanical Extracts containing one or more medical substances, capable of treating a certain disease or reducing infection, or contain raw materials used in the preparation of medical substances.

9. Disinfectants: Products or formulations that contain substances with disinfecting properties without any therapeutic purposes, bearing in mind international references classifications.

10. Pesticides: Substances or products intended to combat insects that pose danger to public health either by killing, inhibiting its growth, or ousting away.

11. Circulation of Medical Products and Devices: Any process or more from the processes of producing medical products and devices subject to the provisions of this law, or its distribution, possession, market release, offering for sale, storage, use, preserving, wrapping, transport, delivery, import or export of the same.

12. Medical Technology Assessment: it is a systematic assessment process of the characteristics, effects, and reflection of a medical technology so as not conflict with the terms of reference of policy-making related to health care of the relevant authorities.

13. Medical Technology Management: all medical technology management processes from the management stage, during its life expectancy or its disposal, that includes a wide range of stages, starting with the inputs such as management, manufacture and evaluation to the outputs or results that support clinical medical research services effectively and safely such as:

- Grouping the procurement needs & properties
- Preparing a complete inventory of existing medical technology assets

- Maintenance and training programs for risk reduction and safe operation.
- Monitoring the medical effectiveness of the medical technology and controlling its performance.
- Decommissioning and safe disposal of medical waste.

14. Unified Procurement: all of procurement &management processes of the needs of the state and governmental bodies and authorities or any other body that the board of directors of the Egyptian Authority for Unified Procurement agrees upon their request for pharmaceuticals &medical appliances that are subject to provisions of law.

15. Government Bodies: The Ministry of Health and Population (MoHP), and bodies & hospitals thereof, also government universities and Its hospitals, and any hospitals affiliated to ministries or other bodies, and finally the educational institutions and government research institutes.

16. Requesting Entities: government bodies that are subject to provisions of law. Other entities, whether private or multinational, may apply, based on their desire and choice, to purchase and manage their needs of pharmaceuticals &medical appliances that are subject to provisions of law, provided that the board of directors of the Egyptian Authority For Unified Procurement agrees upon.

17. Cases of Emergency: Rare, sudden, unexpected, or forecasted-at-short-notice events, which cannot be dealt with by ordinary response, and which may cause financial or human losses; thus, requiring urgent intervention and prompt decisions.

18. Recall of a Medical Product: The process of eliminating a product from the supply chain. During such process, consumers or users are advised to take the appropriate action.

19. The Pharmacopeia: A volume published by official health institutions in countries, contains medical products permitted for use, its properties, characteristics, methods of preparation, and analysis, used as an essential reference for such medical products.

20. Medical Supply: activities that must be carried out to obtain sufficient quantities of medical quality assured products, pharmaceuticals & appliances and devices that are subject to the provisions of law at competitive prices and in accordance to national laws and international standards in a reliable and timely manner.

Chapter Two

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

Article (2)

An economic public authority, called the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management ("AUPP") shall be established. It shall have a legal personality and shall be under Prime Minister Office. Chairman Head office shall be determined by virtue of a decree from prime minister. By a decision of the authority's board of directors, other headquarters may be established and shall be referred to in law by the Egyptian Authority for Unified Procurement.

Article (3)

The Egyptian Authority for Unified Procurement, exclusively, shall undertake procurement processes for pharmaceuticals & human medical appliances for all government bodies & authorities, in return for paying a purchase fee that does not exceed 7% of the net value of what the authority purchases for the aforementioned bodies, authorities, and companies without adding custom duties or tax charges on VAT or other costs. Purchase fee shall be collected in cash or by any other payment

method, the executive regulation of LAW determines the rules for calculating the fee, not exceeding the prescribed maximum, and the conditions of exemption from paying thereof in whole or in part.

The authority, in accordance with the international rules and standards related to unified procurement, shall prepare plans, programs, rules of management, and unified procurement, from inside or outside, and shall prepare the estimated annual budget required for procurement in coordination with Ministry of Finance and the beneficiaries, thus it has to perform, in particular, the following:

1. Implementing plans and policies for medicines and medical technology and taking the necessary measures to activate them or work out them, or include them within the state plan, finally following up their implementation in accordance with the applicable laws and local and international health systems.

2. Establishing indicative specifications and criteria for the requisitioners in order to prepare their needs of pharmaceuticals and medical supplies subject to the provisions of this Law.

3. Coordination with pharmaceuticals and medical supplies companies subject to the provisions of this Law whether these companies were governmental, private or foreign, and governmental, local and international entities, to reinforce the medical strategic stock of the state in order to face any extraordinary circumstances, which requires rapid intervention that necessitate providing resources exceeding the regular needs in stable conditions.

4. Establishing inventory and aggregation systems for the requirements of the requisitioners concerning pharmaceuticals and medical supplies subject to the provisions of this Law annually.

5. Contracting with all companies, entities and private medical institutions inside or outside the Arab Republic of Egypt to purchase pharmaceuticals and medical supplies subject to the provisions Law in favor of the requisitioners

6. Laying down rules of customs clearance for pharmaceuticals and medical supplies to emerging situations after coordination with the Minister of Finance. The prime minister decree on these rules based on the Minister of Finance presentation.

7. Setting a system for medical technology assessment according to the latest global systems in order to benefit from efficient modern technology, in coordination with the requisitioners.

8. Regular reviewing of the stock of pharmaceuticals and medical supplies subject to the provisions of this Law with the requisitioners.

9. Development of electronic registration programs and systems for local and foreign companies working in the field of pharmaceuticals subject to the provision of this law, and the medical services according to the rules and proceedings established by the board of directors.

10. Setting an integrated database of medical technology in centers, hospitals, storages and all public health facilities in order to follow up requirements, usage, maintenance and training.

11. Management storage, transportation and distribution system regarding pharmaceuticals and medical supplies, reviewing the stores of the concerned authorities, managing and monitoring examination and reception process, beside applying the highest international standards, without prejudice to the right of such authorities in establishing and managing the stores of pharmaceuticals and medical supplies subject to the related provision of this law.

12. Administration of the unified maintenance system of the medical equipment in order to improve after sales service.

13. Accepting pharmaceuticals and medical supplies subject to the provision of this law coming from abroad in form of grants and donations according to the rules organizing such.

14. Determining the needs of the staff working in the aforementioned fields, in respect of the development and training the employees in such field.

Article (4)

The Egyptian Authority for Unified Procurement shall have a board of directors chaired by the chairman of the authority, recruited at the minister degree. A decree by the president shall be issued concerning the formation of the board of directors and amendment thereupon and the determining of the financial transaction of the chairman and members. The membership term shall be renewable for four equal years.

Article (5)

The board of directors shall be the dominant power over the Egyptian Authority for Unified Procurement and shall take all the necessary steps whatsoever in order to achieve the goals of the Authority. The Board shall in particular undertake the following:

1. Developing and approving planes concerning the unified procurement according to international standards and rules.

2. Establishing the functional structure of the Authority to ensure the achievement of its goals, and approving the necessary plans for achieving the authority goals and following - up its implementation.

3. Issuance of the internal regulations concerning the financial and administrative affairs, procurement, warehouses, human resources and other by laws in respect of regulating the Authority business without complying with the governmental rules and systems.

4. Offer proposals of establishing joint stock companies independently or with third parties or contributing in existing companies, within the goals, objectives and competencies of the Authority, according to the controls set forth in law no, 127 of 2015 concerning permitting subjects of public law to establish joint stock companies.

5. Reviewing and evaluating the governmental bodies needs from pharmaceuticals and medical supplies subject to provisions of this law, also the manufacturing of such.

6. Approving the providence of pharmaceuticals and medical supplies subject to provisions of this law, which are intended to be provided based on reviewing them, follow up their validity, updating them, creation of a database for them.

7. Setting necessary procedures and measures to cope with emergencies in coordination with the relevant authorities.

8. Intervention to cope with cases of shortage of pharmaceuticals and medical supplies in a specific area by providing them from warehouses of the governmental bodies and public business sector, and coordination with competent authorities to face and prevent the illegal practices violating the law on the Protection of Competition and the Prohibition of Monopolistic Practices, issued by law no 3 of year 2005.

9. Approving the quarterly report of the Authority business, which specifically includes its activities, future planes, and what have been achieved concerning previous planes.

10. Approving providence of pharmaceuticals and medical supplies subject to this law to third parties inside or outside the Arab Republic of Egypt and contracting thereof.

11. Accepting grants, gifts and donations according to the regulating laws.

12. Adoption of the annual budget draft and the balance sheet of the Authority.

Article (6)

The board of directors shall convene a meeting at least once every month on an invitation from the chairman of the board or whenever necessary.

Resolutions of the board shall pass with a majority vote, and if the votes are tied, the side for which the chairman votes shall prevail.

The board may invite experts to attend the meetings to assist the board without those experts having the right to vote.

Article (7)

Chairman of the board is in charge of managing AUPP **in accordance with resolutions passed by the board of directors, and is in charge of execution of the general policy in place to achieve the purposes of** AUPP**. The Chairman of the Board may particularly tend to do the following:**

1. Run the technical, financial and administrative day-to-day affairs of AUPP and follow up on the progress of its operations.
2. Execute the resolutions adopted by the board of directors.
3. Supervise AUPP personnel in accordance with its regulations.
4. Approve the reports referred to the board of directors and issue circulars on the implementation of applicable regulations and rules.

5. Execute purchase contracts with third parties subject to the approval of the board of directors.
6. Prepare internal regulations on financial, administrative, procurement, storage and human resources affairs and all other regulations pertaining to organizing AUPP operations.
7. Prepare the draft budget and closing financial statements and refer the same to the board of directors on the due time.

Article (8)

The Chairman of the Board shall represent AUPP before the law and any third parties.

Article (9)

Except for the bodies funded by the State public budget, the purchase requisitioners shall pre-pay for their orders, however the transaction shall be settled based on the actual purchase value.

In any case, the Egyptian Authority for Unified Procurement shall be exempted from payment of primary and final insurance upon purchasing.

Article (10)

Neither the Egyptian Authority for Unified Procurement nor any other administrative body subject to the provisions of the law hereof may conclude credit contract to purchase any pharmaceuticals and medical supplies subject to provisions of the law hereof, unless the cabinet approve such and the established procedures are being followed. Also, any administrative body may only purchase pharmaceuticals and medical supplies via the Authority, except in the extreme circumstances, prior opinion of the Authority's board of directors and cabinet's approval. Every action performed in violation of the jurisdiction of the Egyptian Authority for Unified Procurement void and null.

Article (11)

The Egyptian Authority for Unified Procurement shall have an independent budget modelled on the public economic authorities. The authority's fiscal year begins with the State's fiscal year and ends with such. The authority shall have a private account in the Central Bank in the unified treasury account. The distribution percentages of the authority's budget surplus shall be annually determined in agreement with the minister of finance.

Article (12)

The Egyptian Authority for Unified Procurement funds are public funds. In order to proclaim its rights, the authority may take the administrative sequestration procedures according to the provisions of law no. 308 of year 1995 on administrative sequestration, and according to the controls and limits established in any other law.

Article (13)

The financial resources of the Egyptian Authority for Unified Procurement consist of:

1. Financial appropriations allocated by the State in, its public budget, in order to purchase and maintain pharmaceuticals and medical supplies.
2. Fees collected by the authority in accordance with the law thereof.
3. Consideration of services preformed to third parties according percentages determined by the board of directors
4. Return on investment of the Authority's funds.
5. Grants, gifts and donations, which the board of directors resolves to accept by majority of its members, in a manner consistent with the authority's goals and according to rules and regulations organizing such.

(Chapter Three)
Egyptian Drug Authority (EDA)

Article (14)

A Public service authority called "Egyptian drug authority" (EDA) shall be established, having legal personality, affiliated to the prime minister, and shall have a head office determined by a prime minister decree, other premises may be established by a decision from the authority board of directors.

Article (15)

EDA shall exclusively take over, excluding others, the jurisdictions of the Ministry of Public Health and Population and other public authorities and government departments with regards to regulating the registration, circulation and supervision of the products defined in Article (1) herein and the raw materials in its manufacture whenever stated in relevant laws, regulations and regulatory decisions, in addition to EDA's jurisdictions as stipulated under this law.

Article (16):

EDA's objective is to regulate, implement and supervise the quality, efficacy and safety of medical products and devices stipulated under this law, and shall enforce the applicable Pharmacy Profession Practice Law provisions without prejudice to this law provisions. EDA shall take over all necessary competences, jurisdictions and legal actions needed for this purpose, in particularly it may:

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

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 in this law.

Fourth: Boost community medicinal awareness and education, also communicate documented and trustworthy health information 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 on draft laws, regulations and resolutions pertaining to medical products and devices and raw materials, as well as relevant regulatory issues.

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

Article (17):

EDA shall exercise all regulatory, executive, and supervisory jurisdictions necessary to achieve its assigned purposes, and desired objectives, in accordance with regulatory authorities' international standards, in so EDA may take the following:

First: The 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 regulatory 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.

5. Set the rules and procedures that regulate the process of examination of medical products and devices and raw materials subject to this law.

6. Set the rules and procedures that regulate the processes of import, export, registration, pricing, circulation, supervision and inspection of medical products and devices subject to this law and raw materials used in its manufacture, through coordination with relevant entities and in accordance with international standards.

7. Set binding regulations that guarantee the safety of medical products and devices subject to this law, and their tracking and monitoring throughout all stages of circulation and apply such regulations on producers and manufacturers of these products, the same applies to the circulation of these products and devices and take the necessary action to withdraw the product from circulation, such regulations are passed by a resolution from EDA board of directors.

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

Second: The Executive Jurisdictions:

EDA shall implement frameworks and regulations related to medical products and devices subject to this law, and follow-up on 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 facilitating licensing of industrial establishments promulgated by Law No. 15 for Year 2017, EDA shall have jurisdiction to issue operation licenses but not the rest of licensing procedures for factories that produce medical products and devices and raw materials subject to the provisions of this law and as defined in Article (1) thereof.

2. License Private Laboratories relevant to EDA's scope of work and set licensing rules for such establishments.

3. Inspect and analyze medical, biological products, plants, and herbs with medical claim, 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 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 analyses.

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

9. Handle emergency situations in the field of medicine and take adequate precautions and preventive measures.

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

11. Collaborate with research centers to perform research and applied studies on all that is related to EDA scope of work.

12. 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.

13. 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.

14. Increase consumer awareness regarding medical products and devices subject to the provisions of this law and all that falls within the jurisdictions of EDA.

15. Represent the State in regional and international organizations in relation to the scope of EDA jurisdictions.

16. Evaluate the results of different stages of clinical trials for medical products and devices subject to the provisions of this law.

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.

Third: The Supervisory Jurisdictions

1. Monitor the application of frameworks, regulations, and the procedures for remunerating activities by factories that produce medical products and devices 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) in the manner contemplated in the executive regulation of this law.

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 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 validity and compliance to the specifications 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.

Article (18)

EDA shall have a board of directors chaired by the chairman of EDA, who shall be appointed with the rank of Minister. The formation and amendment of the board of directors and the determination of the financial rights of the chairman and members of the board shall be decided pursuant to a presidential decree. The term of board membership shall be four years renewable for an equal term.

Article (19)

The board of directors is the body that has a dominant authority to decide on and run the 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 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 of 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.

5. Form specialized committees as required by EDA's operations; including the scientific and technical committees, and specify the jurisdictions and work mechanisms and remuneration of the members of these committees.

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.

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 governmental rules and regulations.

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



Article (20)

The board of directors shall convene a meeting at least once every month on an invitation from the chairman of the board or whenever necessary.

Resolutions of the board shall pass by virtue of a majority vote, and if the votes are tied, the side for which the chairman votes shall prevail.

The board may invite experts to attend the meetings to render assistance to the board without those experts having the right to vote.

Article (21)

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

2. Execute the resolutions adopted by the board of directors.

3. Supervise EDA personnel in accordance with the regulations.

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

5. Prepare internal regulations pertaining to financial, administrative, procurements, storages and human resources affairs and other regulations related to EDA operations.

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

7. Prepare the quarterly annual report on EDA operations, which shall particularly cover EDA activities, future plans and a review of completed plans.

Article (22)

EDA Chairman represent EDA before Courts and third parties.

Article (23)

EDA shall collect all prescribed charges in consideration for its activities while taking into consideration the maximum limits stated in the charges schedule attached to this law. EDA shall collect the charges in cash or through any means of payment thereby acceptable. The executive regulation of this law shall specify the categories for the charges, which may not exceed the maximum limit for each category in the said schedule. The board of directors may double these maximum limits.

Article (24)

EDA shall have an independent budget having the same pattern as the general state budget. 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. The annual budget surplus shall be carried forward from one year to the other.

Article (25)

EDA funds are public funds, EDA may execute administrative attachment in accordance with administrative attachment Law No. 308 for Year 1955 and in accordance with the controls and limits stipulated under any other law to settle its rights.

Article (26)

EDA Financial Resources consist of the following:

1. The financial provisions allocated by the state.
2. The consideration for services rendered by EDA to third parties in accordance with rates and rules as set by the board of directors.
3. The charges collected by EDA in accordance with the law.

Article (27)

EDA chairman of the board shall establish one or more grievance committees, The Grievance Committees are chaired by an EDA board member and its membership consists of a physician nominated by the minister acting in his/ her capacity as the minister of health and population, a deputy to the president of the council of the state appointed in accordance with State Council Law No. 47 for Year 1972, the executive regulation for this law shall specify the formation of these committees.

The committee is mandated to contemplate grievances submitted by stakeholders against administrative decisions rendered by EDA regarding supervision of medical products and devices subject to the provisions of this law and its executive regulation, all of which for a charge not exceeding Five Thousand Egyptian Pounds.

The executive regulations for this law shall specify due dates for the submission and ruling on the grievance motions and charges categories.

Article (28)

EDA personnel specified by virtue of a decree from the minister of justice following an agreement with EDA chairman shall have the capacity of judicial police with respect to crimes described under the Pharmacy Profession Practice Law No. 127 for Year 1955.
To achieve their role, they may have access to the manufacturing and storage sites or any facilities subject to EDA supervision and to search these sites and to examine any equipment, products and devices and to review records, ledger and all documents and papers required to enforce this law. Officials at those sites are required to produce these statements, extracts and copies of documents required for that purpose in the manner described under the executive regulation of this law.

The Official Gazette – Issue 34 Bis (A) dated Aug. 25th, 2019

Schedule of Charges
First : Pharmaceutical Registration Charges

Sr.	Type of Charges	Maximum Limit
1	Registration of medical products	EGP 250,000[1]
2	Application for the registration of medical devices	EGP 50,000
3	Application for the registration of Pesticides	EGP 20,000

Second: Charges for Pricing of Medical Products

Sr.	Type of Charges	Maximum Limit
1	New application for product pricing	EGP 10,000
2	Application for pricing of a new package	EGP 5,000
3	Charges for issuance of a pricing certificate for a product for export	EGP 1,000
4	Charges for the issuance of a 'Free Sale' certificate	EGP 1,000

Third: Licensing Charges for Import of Medicines, Medicinal Raw Material and Production Plans

Sr.	Type of Charges	Maximum Limit
1	Approval to import medicinal raw materials- per invoice	EGP 400
2	Approval to import cosmetic raw materials- per invoice	EGP 400
3	Approval to import pesticides raw materials- per invoice	EGP 400
4	Approval to import narcotics + import permit	EGP 1,000
5	Import approval issued to El Gomhouria Company for the purpose of trade	EGP 200
6	The annual import approval for bulk imported products	EGP 5,000
7	The annual import approval for finished imported products	EGP 7,000
8	The import approval for an annual production plan	EGP 30,000
9	License to import medical products and devices	EGP 10,000

[1] Prime Minister rectification, the Official Gazette – Issue no. (7) dated February 13th, 2020

Fourth: License and Costing Charges
(A) Charges for Licensing of Plants

Sr.	Type of Charges	Maximum Limit
1	License to add a new production line	EGP 10,000
2	License for a scientific office	EGP 50,000
3	License for an agent's warehouse	EGP 40,000
4	License for a storage or a distribution company	EGP 20,000
5	License for bioequivalence research center	EGP 40,000

(B) Pharmacy licensing charges

Sr.	Type of Charges	Maximum Limit
1	Charges for the certificate to open a new pharmacy or charges for the transfer of a title of a pharmacy	EGP 500

Fifth: Inspection Charges

Sr.	Type of Charges	Maximum Limit
1	For each production line. The charge in consideration of monitoring the plant's compliance with Good Manufacturing Practices (GMP)	EGP 10,000

Sixth: Analysis and calibration charges

Sr.	Type of Charges	Maximum Limit
1	Custom clearance of consignment per invoice	EGP 1,000
2	Analysis of products and studies of products and devices	EGP 100,000

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