Overview of The New Law & National Regulatory Authorities

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PREPARATION FOR THE LAW

- As the examination and preparation for such national project take place, it has become clearly obvious that there is a legislative vacuum in the Law no. 178 of 1960 on Collecting, Storing and Distributing Blood and its Compounds in the Southern Territory .

- Moreover, it was necessary to take into consideration the privacy of the Egyptian situation. Hence, the Egyptian national standards of blood and its derivatives transfusion are complied with.

PRESIDENTIAL ASSIGNMENT

- Accordingly, an assignment was given by the President to make comparative legal studies to compare our legislation with those of the other countries in relation to blood donation within our National Project for Self-Sufficiency of Plasma Derivatives .

STANDARDS AND UPDATES

- Such national standards were set by a committee comprised of all bodies acting as blood service providers in Egypt in collaboration with WHO, within the general layout of international rules in this regard. Such rules governing the foundation to be relied on in all work phases of blood and its derivatives.

- In light of the foregoing, a bill has been proposed with its target to correct the legal defects and keep pace with the latest developments that came into prominence since the long period elapsed after the passing of the previous legislation. The bill is organized into five chapters.

LEGAL TARIFFS

- The First chapter included the law defined terms.

For example,

The Competent Ministry: The ministry concerned with health affairs

- Blood processes: Collection, examination, storing, distribution or transfusion of blood, its compounds and derivatives, other than plasma for manufacturing.

- Plasma derivatives: Bio products derived from human blood plasma components, including

for example, albumin, coagulation factors and other plasma derivatives.

REGULATING BLOOD PROCESSES

The second Chapter included:

- All matters pertaining to blood processes organization Collecting, storing, distributing of blood, its compounds and derivatives;

- Granting licenses to blood processes centers in accordance with the specifications and requirements that must be met by such centers depending on the review of the Blood Processes Observation Council.
  - A statement of fees to be paid by a license applicant, with such fees to be paid out by any e-payment methods prescribed by law. The governmental bodies will be exempted from such fees.
  - Blood donation is voluntary and free of charge.

BLOOD OPERATIONS MONITORING BOARD

In the Competent Ministry, a council for the blood processes observation to be created and chaired by the Competent Minister or its deputy with those persons

PLASMA CENTERS LICENSING

The Third Chapter included

- all matters associated with “Plasma collection for manufacturing and exporting its derivatives”
- Only a licensed center may collect plasma for the purpose of manufacturing its derivatives.
- Only a licensed factory may manufacture plasma derivatives.
- All of such practices must be introduced while seeking guidance from the applicable international standards.
  - The examination fees to be paid by a license applicant
  - The blood donation requirements and frequency according to the internationally recognized standards, the donor's health condition and age

PLASMA COLLECTION CONTROLS

- A blood transfusion and plasma collection center has the right to dispose and dispatch such collected plasma to any factories governed by this Law, and export, after achieving self-sufficiency, fully manufactured plasma derivatives pursuant to the controls imposed by the Egyptian Drug Authority (EDA) in coordination with the Egyptian Authority for Unified Procurement (UPA).
- All such practices to be adopted according to the provisions, rules and procedures for which a resolution to be issued by EDA upon coordination with UPA following the achievement of self-sufficiency of plasma derivatives.
- A blood plasma collection center shall be liable for the damages suffered by a donor during or because of the donation process.

GENERAL PROVISIONS

The Fourth Chapter: “General provisions”

- A blood or blood plasma donor must be a volunteer; i.e., donation is for free.
- If a potential donor is disqualified, disqualification, upon medical exams and analyses, must be for medical reasons, not for any other discrimination issues.
- No imported or given blood units, blood components, or plasma or its derivatives may be released until after a verification process to ensure they are free of all infectious diseases and viruses.

- The blood or its components and plasma shall be dispensed for a therapeutic purpose, free of charge, for those enrolled in free treatment sections of all government-owned hospitals according to the controls for which a decision to be issued from the Competent Minister.

PENALTIES

The Fifth Chapter: “Penalties”

- Without prejudice to any tighter penalty, whoever commits any of the following acts will be subject to a fine of at least EGP100,000 and no more than EGP1 Million:
- Management of blood plasma collection center or plasma derivatives manufacturing factory without a permission, which is a contravention of this Law and its executive regulation.
- Actual or attempted import or export of blood plasma in contravention of this law provisions and the resolutions issued for enforcing hereof.

NATIONAL REGULATORY AUTHORITIES

On 25 August 2019, Law No. 151 of 2019 was issued for the establishment and regulation of two new public authorities in the pharmaceutical sector, namely, the Egyptian Drug Authority ("EDA") and the Egyptian Authority for Unified Procurement, Medical Supply and Technology Management ("AUPP").

The Egyptian Drug Authority (EDA) is established as a public service authority affiliated to the Prime Minister to be responsible for all drug related matter.

EDA is responsible solely for the registration, licensing, inspection and supervision of all pharmaceutical and cosmetic products, medical equipment and raw materials used in their manufacturing.

EDA has replaced following entities:

- National Organization for Drug Control and Research (NODCAR).
- National Organization for Research and Control of Biological (NORCB).
- Central Administration of Pharmaceutical Affairs (CAPA) in relation to the registration and licensing or pharmaceutical products.

EDA RESPONSIBILITIES

The main responsibilities of EDA will be, among others, the following:

- Issuance of the necessary licenses for all pharmaceutical entities.
- Issuance of the operation licenses for factories of pharmaceutical products and medical equipment.
- Licensing private laboratories that are working in the pharmaceutical field.
- Examination of all pharmaceutical, biological products like medicines, cosmetics, insecticides, vaccines, serums, pharmaceutical devices, tools, medical lenses, diagnostic indicators in order to insure their quality, safety, effectiveness and compliance with the approved.
- Setting the rules and procedures for importation, exportation and pricing of all pharmaceutical products and medical equipment.
- Customs release of all imported pharmaceutical products and medical equipment.
- Licensing locally manufactured products and equipment.
- Issuance of the Egyptian Pharmacopeia.
- Inspection of all pharmaceutical entities and their officers and taking necessary

Thank You