

## **REVIEW**

### **Accessing the medical devices market in Egypt and Saudi Arabia: a systematic review of policies and regulations**

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## **Abstract**

Despite the significant medical devices market size in Egypt and Saudi Arabia, information regarding policies and regulations for medical devices market access is highly deficient. The aim of this paper is to provide a systematic review on market access policies and regulations in both countries, to allow safe and timely access to medical technology. The following databases were searched: PubMed, Science Direct, Scopus, and Al Manhal Arabic database. Additionally, the web portals of regulatory authorities of both countries were searched. There are 34 records included in the qualitative synthesis of this review. Main findings include; adopted regulatory framework from reference countries, and interim main regulatory documents, In conclusion, the market access schemes are relatively structured. However, some recommendations are put forward to navigate towards a more comprehensive policy framework in both countries.

**Keywords:** Medical device, Medical technology, Egypt, Saudi Arabia, Middle East, Market Access, Health Technology Regulation, Health Technology Assessment

## **1. Introduction : Health Systems & the four phases of the medical devices life-cycle**

According to the World Health Organization (WHO), medical devices have a life-cycle that consists of four phases (Figure 1). When effectively implemented, these phases enable improved access to safe, high quality, and cost-effective medical devices [1]. The research and development phase is guided by input parameters like identified population needs. Nevertheless, another important parameter is the national policy on health technology research and development. According to the WHO, national policy should incentivize manufacturers to innovate solutions to those needs in the form of health technologies [1]. The regulations phase is in place to protect the public. It ensures that the health technology in question meets the minimum safety and effectiveness standards prior to placement on the market, as well as offering continuous supervision over its safe use [2]. Consequently, the assessment phase which includes Health Technology Assessment (HTA) is in place to inform potential payers with clinical outcomes and cost-effectiveness when selecting medical devices for procurement. Finally, the management phase, which refers to Health Technology Management (HTM), covers a wide range of functions. This includes; procurement, completing inventory of assets , maintenance, and matching timely the safe high quality devices with their users and with health services provided (see figure 1) [1].

Insert Figure 1 phases of medical devices

## **2. Rationale**

Despite the significant market size of medical devices in the Middle East, and its substantial potential for growth, information regarding policies and regulations for accessing this market is highly deficient. Consequently, the state and the progress level of the region's respective regulatory systems and their abilities to provide safe, timely, and effective access to medical technology remains unclear.

Egypt and Saudi Arabia are considered to be pivotal states in the Middle East that continue to hold a notable role in the region of the Middle East. Egypt has been taking on the role of political and cultural leadership in the Arab world, while Saudi Arabia remains a main dominant economic power within the region. Deep political and economic ties are strongly present between the two countries [3].

From the industrial perspective, Egypt and Saudi Arabia hold substantial medical devices market size (Table 1) [4-7]. Both countries have numerous market features in common - mainly the fact that both are heavily relying on medical devices importation. From the economic perspective, such countries' selection allowed taking into consideration the different country income levels and their effect on establishment of market access policies and regulations. Considering the leadership role held by the two countries in the region, their extensive economic relationship, and their considerable market size, one can highlight their significance in terms of impact on the Middle East medical devices market. The authorities' health policy choices can widely impact the choices of other developing authorities in the region, and may eventually have a trickle-down effect towards the development of the region's regulatory ability to guard patient's safety and allow timely access to medical technology.

Insert Table 1 countries' profiles comparison

### **3. Aims and objectives**

This review is an attempt towards exploring the regulatory systems of Egypt and Saudi Arabia as two major exemplars of the regulatory systems in the Middle East region. The goal of this review is to study the market access processes, their governance and implementation in in the context of medical devices. The main focus is on the

regulations phase (phase 2) (see figure 1). The paper's scope is on the pre-market access process. Although some information highlighted in this report relate to the post-market surveillance, yet such information remains within the context of the initial market access framework. An in-depth focus of the post-market stage is beyond the scope of this review.

The intention is to provide analysis based on the findings and put forward some recommendations for strengthening the regulatory phase, hence paving the way towards proper integration of the upcoming phases to achieve a more comprehensive medical devices policy framework. According to the WHO, a comprehensive policy framework is one that is able to fully implement official national policies on access, quality, and use of health technologies. This is done throughout the entire phases of the medical devices lifecycle [1]

The core value of this review is emphasized through two main angles. The first is a descriptive focus that attempts to explore and collate in a systematic manner the information on market access policies and regulations in these countries. Such information is currently highly fragmented and in some cases available in Arabic language only. This is done to allow more informed market access process by the interested stakeholders.

The second angle is an analytical focus, which allows critical visualization of the status quo of the regulatory schemes. This offers a unique opportunity for corrective actions towards current insufficiencies, and lays a foresight on how the regulatory schemes are likely to develop over time, in light of regional and international changes as well as knowledge transfer in the healthcare policy field.

The collective approach of this review offers the advantage of identifying the challenges faced by both systems, since both belong to similar market and geo-political conditions. Additionally, this approach identifies opportunities in the context of regional and global harmonization efforts of medical devices regulations. To our knowledge, several reviews on different medical devices regulatory systems have been carried out [8, 9], yet no previous systematic reviews have attempted to explore and analyze any of the medical devices regulatory systems of the Middle East.

#### **4. Methods**

Following PRISMA guidelines for systematic reviews [10], a systematic search was performed in academic journals and relevant regulatory authorities' web portals. The following databases were searched; PubMed (Medline), Science Direct, Scopus, and the Arabic database Al Manhal, which is a full-text searchable databases of scholarly and scientific publications from the Arab and Islamic world. Furthermore, the web portals of both the Egyptian Drug Authority (EDA) and the Saudi Food and Drug Authority (SFDA) were searched. In addition, a rigorous hand search was carried out on; country data from the WHO medical devices portal, and the WHO Eastern Mediterranean Health journal (all volumes from 1995-2015) [11, 12]. Additional articles were found via citation snowballing and grey literature search. Due to the draft nature of some of the data retrieved from the EDA sources, a supplementary phone interview was conducted with EDA medical devices sector personnel to verify the validity of the retrieved information.

English and Arabic Keywords were used in the search with no date restrictions. The search protocol including the selection criteria was in line with the CRD's guidance for undertaking systematic reviews in healthcare. (Further details on the methodology can be found in the supplementary material). The following are the search criteria;

**A. Inclusion Criteria:**

- Focus on Egypt and/or Saudi Arabia.
- Medical device context.
- Sufficient details about regulatory, approval, or pre-market process.
- No search date restrictions were imposed.
- Articles in English or Arabic languages.

**B. Exclusion Criteria:**

- Focus on other countries.
- Highlighting the case of a specific technology only.

## **5. Results**

This review identified a total of 160 documents that were potentially relevant, of which 116 papers are from scientific databases - six studies from PubMed, 104 from Science Direct and EMBASE, and six from SCOPUS. There were 42 records identified from authorities' web portals; websites, repository portals, and documentations, and two additional records through snowball citation and grey literature.

No matching records were retrieved from country data of medical device profiles provided by the WHO medical devices portal, the WHO Eastern Mediterranean Health journal, or Al Manhal database.

After removing duplicates, a total of 54 records were screened by reviewing the abstracts. After which, a total of 37 articles were retrieved for full text screening. The full text assessment excluded three articles with reasons including; article that was focusing on specific technology only, an article with exclusive emphasis on patency, and an article focusing on Middle Eastern culture in regulatory environment.

Finally the review included a total of 34 records for qualitative synthesis. Four studies from scientific databases, 28 records from authorities' databases, and two from grey literature and snowball citation [29,41] (Figure 2) (Results references: [13- 46]).

Insert Figure 2 PRISMA flow diagram

For clarity, result details are divided in two main parts:

- (1) Governance; highlighting main topics related to regulatory authorities, type of regulations, and main elements of regulatory system.
- (2) Process and Implementation; involving details relating to the actual process of market access, and implementation of regulations in Egypt and Saudi Arabia.

## ***5.1 Governance***

### ***5.1.1 Regulatory Bodies***

The EDA is the pharmaceutical regulatory body of the Ministry of Health and Population (MOHP) in Egypt. Medical devices unit is included within the spectrum of this pharmaceutical regulatory body as a sub function [13]. The main bulk of regulatory processing is done through the Central Administration for Pharmaceutical Affairs (CAPA) [14]. CAPA handles a whole range of activities including; premarket authorization, customs release, post-market inspection, and licensing and registration of;

importers, Authorized Representatives (ARs), and establishments. CAPA is assisted by the National Organization for Drug Control and Research (NODCAR), and other specific technical committees for checking the technical specifications of medical devices facilities and products [15].

Similarly, the SFDA is an independent authority with a primary function of ensuring safety, quality, effectiveness and performance of medical devices according to their intended purpose [16]. The SFDA has an entire sector dedicated solely for the regulation and organization of medical devices. Unlike the EDA, the SFDA uses electronic databases to handle the entire processes of medical devices registration, post-market surveillance, custom release, and listing/licensing of establishments and ARs [17]. (Further information on regulatory bodies can be found in the supplementary material).

### *5.1.2 Medical Devices Classification*

The EDA fully adopts the European Directive of the Medical Devices 93/42/EEC and its amendment 2007/47 in defining and classifying the medical devices [18, 19].

Accordingly, medical devices are classified into four Classes; I, IIa, IIb, and III. The classification depends on the duration of usage, invasiveness, and special rules [19].

Despite adopting the European classification system of medical devices, the Egyptian MOHP reserves the right to modify any classification based on the technological progress of devices. In cases of disputes on classification between MOHP and the manufacturer, the MOHP refers to decisions of committee on standards and technical regulations [20].

On the Other hand, SFDA doesn't have a specific medical device classification system. Nevertheless, using its Medical Devices Classification (MDC) e-system, the classifications are set according to the medical device's country of original authorization. This has to be within the jurisdictions of one or more of the International Medical Device Regulators Forum (IMDRF) countries namely; European Union (EU), United States of America (USA), Australia, Canada, and Japan [21]. A unique regulatory governance advantage in this case is the fact that the majority of medical devices (70%) in Saudi Arabia are imported from IMDRF members, namely USA and Germany [22].

### *5.1.3 Regulatory Documents*

The Main regulatory policy documents are interim in both countries; the Egyptian Regulation for Medical Devices (ERMD), issued in 2010, and the Saudi Medical Devices Interim Regulations, issued in 2008 [20, 23]. The ERMD is further aided by a regulatory document called, updates of provisions in the rules of registration of medical supplies (issued in 2014) and by The Egyptian Guideline for Medical Device Vigilance system. The latter outlines the concept of post-market surveillance vigilance system, in context of responsibilities of the manufacturers, distributors and users of medical devices [24, 25].

The SFDA has a more extensive set of documents expanding on the main regulatory one. This includes a set of eight Implementing Rules (IRs) documents. These documents have been issued to specify and refine the provisions of the Medical Devices Interim Regulation [26, 27]. Additionally, the SFDA has National Provisions and Requirements for Medical devices. This is a unique regulatory document that mandates

some Saudi specific national provisions to ensure safety of medical devices. This includes provisions related to; electrical safety, electrical coding, medical gases, electromagnetic compatibility, labelling and packaging requirements [26, 28]. Such parameters are tested against standards set by the Saudi Arabian Standards Organization (SASO), International Organization for Standards (ISO), and International Electrotechnical Commission (IEC)[28] . This regulatory feature is deficient in the Egyptian system, which has developed only standards for measuring devices [29]. Furthermore, there are ten guidance documents aimed at manufacturers, ARs and distributors. Thereby, ensuring coherent application of the IRs and the interim regulations specially in the processes of market authorization, post-market surveillance, licensing, and listing purposes of medical devices [30].

#### *5.1.4 Authorized Representatives (ARs)*

According to the SFDA, the AR is any natural or legal person, who is established within the state and has received a written mandate from the manufacturer to act on his behalf for specified tasks [31]. Both countries necessitate the presence of ARs for manufacturers who have no local establishments within their territories. Regulatory documents of both countries necessitate this legal obligation [20, 31].

#### *5.1.5 Medical Devices National Registry*

SFDA has a comprehensive database for all establishments, products and devices in the field of medical devices. This database is called the Medical Device National Registry (MDNR). The aim of the MDNR is to obtain a profile of the Saudi medical devices industry, and to measure the readiness of medical devices and establishments to comply with medical devices regulation [32]. Other databases exist for reporting of medical

devices and importation. However, the MDNR is considered to be a medical devices database rather than a medical devices patient registry [33]. No similar databases were found for the EDA.

## ***5.2 Process & Implementation***

### ***5.2.1 Premarket Authorization (PMA)***

Insert Figure 3 Premarket Authorization Process in Egypt

According to the EDA, the PMA process takes seventy working days before a final decision is made. The full process is described in details in Figure 3 in accordance with official EDA registration flowchart [34].

According to consultations with a medical device expert from the EDA, non-sterile devices of Class I from reference countries are granted direct entry into the Egyptian market. In order for all the other classes of medical devices to be granted PMA, they have to be manufactured in a reference country or certified by notified bodies of a reference country. In addition, the device has to be freely sold in one of the reference countries. Certificate of Conformité Européenne (CE), ISO and free sale are the main mandatory documentations required by the EDA. The US Food and Drug Administration (FDA) certificate is considered enough as a certification and waives the requirements of the 3 previous main documents. Declaration of Conformity (DOC) is provided by manufacturers in all cases. In some cases, the sterile and non-sterile devices that are not from reference countries, or non-sterile devices in dosage form require a specialized scientific committee consultation [35].

The fee for the process of medical devices registration was not obtainable via the website or any other source on the EDA web-portal. However, according to correspondence with an EDA personnel, a unified set fee is indicated for all types of medical devices, amounting to 3,500 Egyptian pounds (\$458.6) [35].

Insert Figure 4 Premarket Authorization Process in Saudi Arabia

Regarding Saudi Arabia, the SFDA as specified by a royal decree regulates the pre-market authorization of all medical devices on the national level, irrespective of the classes of the product or their level of safety [36]. Manufacturers or ARs apply through the electronic Medical Device Market Authorization system (MDMA). The PMA process is guided by articles of Implementing Rule of Market Authorization (MDS-IR6) [37]. The lead time for such a process is 35 working days irrespective of the medical device type [38]. The full process is described in Figure 4.

The SFDA applies a four tiered fee system for medical device marketing authorization. The processing fees depends on the class and the type of the device ranging from 15,000 Saudi Riyals (\$3,999.7) to 23,000 Saudi Riyals (\$6132.9) [38].

#### *5.2.1.1 Products Standards & testing*

Neither the EDA nor SFDA have their own local product standards for medical devices, or carry out clinical trials for PMA. Instead, both authorities adopt PMA systems of reference countries. (Reference countries can be found in the supplementary material).

The EDA assesses both local and imported product standards and risks through the CE, ISO 13485, and the FDA certificates. All medical devices require a proof that they are

freely sold in the country of origin. Devices which are from a non-referenced country are required to obtain a documentary proof stating that it is currently being freely sold in one of the reference countries [39]. Other reports like stability study, sterility and test reports are also mandatory documents in the dossier [13]. (The full documents checklist are in the supplementary material).

On the other hand, SFDA recognizes the product standards of medical devices that have been granted PMA by at least one of the IMDRF members. Obtaining a CE mark alone would be sufficient for market access. However SFDA and all regulatory bodies within the Gulf Cooperation Council (GCC) require safety data, including; information on intended use, warnings, precautions, and potential adverse events associated with this use [40]. Some of these requirements are mandated by the National provisions of Saudi Arabia which have to be complied with in addition to the IMDRF member requirements. (Further information on the checklist for the documentary evidence can be found in the supplementary material).

#### *5.2.1.2 Scientific Committee*

In some cases the EDA consults a scientific committee as a third party to further examine the applicant's dossier and may even test the device if necessary. Accordingly, the scientific committee issues a recommendation to the EDA and a final decision on PMA is issued [20]. This committee consists of leading medical professors (approximately ten in number) from various medical specialties in addition to pharmacist managers from CAPA and the NODCAR [41].

Similarly, the SFDA holds the right to designate a third-party organization known as Conformity Assessment Body (CAB), for assistance in the process of PMA [42]. The role of the CAB is specialized examination of the documents to verify conformity with the IMDRF and Saudi National provisions [31].

#### *5.2.1.3 Local Manufacturers*

Local medical device production is relatively limited in both countries. In Egypt, the medical device industry is largely confined to the production of consumables, and other medical devices such as furniture and basic dialysis products. It is estimated that only 10% of medical device market is supplied by local production. Complex technology as diagnostic imaging is a large import product area due to the low local production capabilities [4].

Local manufacturers have their facilities licensed by both the Industrial Ministry and the MOHP, to control the quality from both public health and industrial quality control perspectives. Application of local medical devices is subjected to another modified checklist. However, in terms of medical devices' technical requirements, the same regulations apply [39].

In Saudi Arabia, less than 3% of the total expenditure on medical equipment is for local products [40]. Local manufacturers in Saudi Arabia are expected to comply with the relevant regulatory requirements of one or more of the IMDRF member's jurisdictions, in addition to the National Saudi provisions. However, It is not required for medical devices designed and constructed by health facility staff for internal use within that facility to acquire a PMA [16].

#### *5.2.1.4 Customs Release*

In Egypt, the General Directorate of Pharmaceutical Monitoring for Custom Release on Medical Devices is the entity in charge of custom releases [43]. Custom release is granted for registered medical devices. It is also possible to approve unregistered free samples of medical devices for registration and research purposes. Normally, this is requested by universities, research centers, and central laboratories of the MOHP [43]. (More information on custom release checklist is available in the supplementary document).

Similarly, medical devices presented to the Saudi customs have to be accompanied by all the necessary documentation to be released from the port of entry. This includes; DOC and Market Authorization issued by the SFDA. It is noted that charities, diplomatic, and military institutions are normally exempted from custom tariffs on medical devices [44].

#### *5.2.1.5 Refusal of PMA*

Refusal of PMA by the EDA can occur pursuant to applications not satisfying the ERMD. Any refusal should be communicated without delay to the manufacturer or the AR. According to article seventeen of the ERMD, corrective actions should be presented to the manufacturer or the AR, as well as time allowed for such corrective actions to be implemented. The manufacturer or the AR is allowed to put forward their views as a part of a consultation process. However, consultations on the decision may depend on the urgency of the measures being taken and their impact on the public health [20].

In Saudi Arabia, applicants getting refusals on their PMA are entitled to know the reasons and the means of appeal by the SFDA. There are no further clarification on means of appeal demonstrated in the regulatory documentation [26].

### *5.2.2 Placing on the Market*

A unified clear regulatory document illustrating the specific labelling requirements of the medical devices was not retrievable for Egypt. However, labelling requirements are derived as separate provisions from various regulatory sources. Generally, the regulatory threshold of labelling and packaging requirements is set in accordance with their relevant adopted legislations. These are the legislations adopted by the EDA from reference countries including their respective ISO, CE, or FDA standards systems. As such, a master label of the device from the country of origin is required by the EDA [45]. According to the labelling provisions in the ERMD, labelling and packaging of the medical devices must be made available to the user and the patient in Arabic language [19, 20].

On the other hand, the SFDA has an established system for labelling of medical devices. SFDA requires copies of all labelling that were submitted and approved by the relevant authority in the country of origin of the medical device. In terms of content, all information of the device name and data, power supply, environmental factors, and any precautions, warnings or limitations has to be clearly placed on the label of the medical device. The Information For Use (IFU) should indicate the intended purpose, performance, and handling conditions according to the Saudi National Provisions [46].

### *5.2.3 Post-market Surveillance*

The Medical Device Safety Department (MDSD) of the EDA is the entity responsible for handling the post-market medical device vigilance system. The MDSD handles the medical device vigilance data in a way compatible with the IMDRF and the European commission guidelines for medical devices [24].

Incidents reported are normally related to malfunctions, unanticipated adverse events, interactions with other substances or products and degradation of the device. Incidents caused by patient conditions or abnormal use are not required to be reported. Reporting is the responsibility of manufacturer, user, and the MDSD [24].

Post-market surveillance system is done via random inspection carried out by EDA on the medical devices, and the manufacturers' establishments. The MDSD responsibilities include receiving incidents reports, risk evaluation, and monitoring of manufacturers' subsequent actions. Consequently, the MDSD gather further information, consult with a relevant notified body or medical devices registration department, and then issue recommendations to users and manufacturers. updated information is disseminated accordingly within the EDA [24].

The manufacturer on the other hand, is required to have suitable vigilance systems in place for their devices. They are responsible for notifying the MDSD with incidents when the reporting criteria are met according to the Egyptian guidelines for pharmacovigilance. This is in addition to submitting trend reports, periodic summary reports, and notifying the MDSD with the field safety corrective actions of their products. The manufacturer is responsible for keeping ARs, and any other agents on the market informed [24].

The SFDA maintains a web-based system for medical device reporting, called the National Center for Medical Device Reporting (NCMDR). The purpose of which, is to execute key aspects of the SFDA's post-market activities, and allow dissemination of information reducing the likelihood of adverse events [26].

Reportable adverse events are divided into two main categories; those occurring within Saudi Arabia and others occurring outside. In case of incidents occurring outside, measures have to be taken to assess whether such incidents are liable to occur in Saudi Arabia as well. A field safety notice is issued to the users and manufacturer to take precautionary actions.

On the other hand, for incidents occurring within Saudi Arabia; a similar procedure takes place with a corrective action that is agreed by the SFDA. Corrective Actions include; notifying the IMDRF country of origin, as well as drafting and completing a field safety corrective action plan. The reported incidents can happen as sporadic events or during the post-marketing surveillance process [26].

Insert Table 2 Comparison of regulatory frameworks of Egyptian and Saudi Systems

## **6. Discussion**

### ***6.1 The Need for a Comprehensive Regulatory Framework***

Aiming for a comprehensive medical devices regulatory framework can impose immense financial burden on regulatory authorities [47]. However, ensuring safety of medical devices entails the presence of such regulatory framework that leaves no room for regulatory gaps. Both EDA and SFDA have their main policy framework for

medical devices regulation still labelled draft or interim, since 2010 for Egypt and 2009 for Saudi Arabia. Moreover, both rely on adoptive regulatory framework from reference countries [20, 26]. However, this does not waive the need for legislating national provisions, to adapt these frameworks accordingly to fit within the local environments of both countries.

The EDA regulatory system shows some degree of vagueness concerning the regulations of medical devices. This is probably pertaining to; the draft nature of the ERMD, the relatively low number of implementation policy documents, and the lack of transparency in dissemination of regulations via regulatory databases and web portals. On the other hand, the SFDA has already taken an initial step by issuing the national provisions regulating; electrical safety, electrical coding, medical gases, electromagnetic compatibility, and labelling and packaging of medical devices[28].

It is also noted that the EDA's interim regulation only deals with medical devices generally and inspires its legislation from the EU directive 93/94/EEC. Nonetheless, there is no indication of adoption of other legislative work with respect to active implantable medical devices or in vitro diagnostic medical devices, both of which formally have separate directives in the EU. The EDA specifies that the ERMD policy document is not applicable on these two types of devices, yet does not mention other alternative regulative schemes for them or clarify sources for regulations of such devices [20, 24].

## ***6.2 Centralized Governance***

Both EDA and SFDA centrally handle the registration of any kind of medical devices prior to granting access to the markets. This model is in contrast to less centralized regulatory systems such as China, a system that has delegation of authority to provincial authorities on the regulation of some classes of medical devices [8].

Centralized governance can greatly burden both regulatory systems from the financial and the organizational perspectives given both system's developing nature. This raises the question of whether these developing regulatory systems are capable of effectively handling such rapidly expanding markets [5] [4].

### ***6.3 Harmonization***

Despite the similarities between the EDA and the SFDA regulatory systems like relying heavily on medical devices importations and adoption of foreign regulatory frameworks, regional harmonization on the Eastern Mediterranean level is still relatively low [48]. Pooling the financial, knowledge, and the human resources can alleviate the regulatory burden at a single country level and unify the market access process for the manufacturers.

On the international level, adopting regulatory framework from the IMDRF countries allows a great level of harmonization, since these countries are also major manufacturers of medical devices worldwide [47].

### ***6.4 Patient's Safety***

Medical devices regulations are in place to guarantee medical devices safety for patients. Whether the product will be safe to use and perform in an effective way

depends on three elements that need to be covered comprehensively in the relevant regulations. These elements are; the product itself in terms of its standards, the use of the product and the product representation to the user [47].

With regards to product standards, PMA pathways in Egypt and Saudi Arabia recognize products standards of PMA from reference countries' systems. According to the WHO, adopting standards of PMA allows the governments to establish low cost programmes that promote safety performance of medical devices. This is done by taking advantage of what other more experienced systems have already achieved on the level of product standards [47]. Nevertheless, a certain degree of threat to patient's safety in Egypt and Saudi Arabia relatively persist in the light of the current market access regulatory framework.

Two main PMA reference systems as revealed by this review are the ones from the US and the EU [20, 26, 47]. These two systems present greatly different approaches to approving devices for use in patients [9]. Devices subject to the EU process may be available to patients sooner compared to the US, although with less clinical experience prior to use [49]. This consequently means, devices accepted and allowed access to Egypt and Saudi markets are resultants of varying degree of scrutiny of different approval systems. Such heterogeneous adoptive approach does not allow a uniform overall impact assessment on patient's safety. Furthermore, both the US and the EU systems are faced with variable dissatisfaction and criticism levels [50-52] . For instance, since 2012 the EU have been forced to revise the medical directives in place after being faced with scandals of medical devices safety issues [53]. A famous 2012 US FDA report cited twelve examples of high risk medical devices that were approved

in the EU and then later deemed ineffective or dangerous [54]. On the other hand, quality problems in pre-market submissions in the US have been evidently found by several studies. There are several claims of lack of hallmarks of well-designed clinical trials, and unfair results reporting, raising questions on the empirical basis for device approval in the US [49]. As such, in the light of these developments, serious questions can be raised on the current state of heavy reliance on US and EU standards by Egyptian and Saudi PMA systems.

Although a full analysis on patient's safety is not possible given the scope of this review, the advantages of regulations adoption by regulatory systems as stated by the WHO do not come risk-free. Patient's safety in such systems can be highly dependent on understanding the nature of the adopted systems, and their main challenges. Moreover, a robust post-market system that takes into account the heterogeneity of the approved medical devices, can be of great significance in guarding patient's safety. Judging by the more advanced e-system of Saudi Arabia compared to the Egyptian counterpart, threats on patient's safety can be more eminent in Egypt.

Finally, the lack of national provisions on labelling and on environmental related mandates in Egypt is another limiting factor that further hinders the safe representation, and usage of medical devices. Based on this review's findings, an in-depth analysis of post-market surveillance in both countries is highly encouraged, this is to assess how patient's safety in both countries can be guarded based on their current market access systems.

### ***6.5 Electronic-databases & Medical Devices Registries***

There is considerable gap between Egypt and Saudi Arabia in terms of electronic database services (e-services). Such capabilities are significant to both the manufacturers and the regulatory authorities alike. Manufacturers can view regulatory requirements clearly and can interact better with regulatory authorities in the presence of such e-services [30]. Saudi Arabia has a five year National e-Health Strategy, aiming to position e-Health as a primary transformation agent and enabler towards improving standards, availability, and quality of care in the Kingdom [55]. On the Other hand, the EDA services are comparably traditional in nature. The application for the Medical Devices PMA is initiated by manual procedures. This could be related to the longer procedural time by the EDA [56].

On another note, establishing medical devices registries should be considered. Medical device registries are used for the study of medical devices outcomes. They can be used to bridge the gap between the devices' performance in clinical trials and their use in regular practice, in addition to laying preliminary grounds for HTA of medical devices [33].

### ***6.6 Fee Systems & Sustainable Financing***

Sustainable financing is one of the main sources of maintaining a strengthened National Regulatory Authority (NRA). Governments need to revise their legislation and introduce fee systems in addition to other funding mechanisms that reflects the real costs of the NRA activities [57].

One of the interesting findings of this review is the huge discrepancy between fees charged in Egypt and Saudi Arabia for PMA. The SFDA charges a fee which is roughly

eleven times greater than the EDA's [35, 38] . This substantial discrepancy is an interesting point for further investigations and research. More resourceful regulatory authorities are more able to provide tools like e-services databases, possibly leading to more effective and less bureaucratic PMA processing. Moreover, the lack of tier-based fee system that reflects devices classification is a major weakness in the EDA compared to the SFDA. This is because high risk devices may require more regulatory work done for their assessment than lower risk ones.

### ***6.7 Time to Market***

From a manufacturer's point of view, time needed to access the Egyptian and Saudi markets is dependent on several factors. Initial selection of the EU PMA regulatory process as a reference system may make devices available on the market sooner compared to the US's PMA system [49]. This fact may encourage international manufacturers to pursue faster referenced PMA systems to gain faster access to the Egyptian and Saudi markets.

An interesting finding of this review is the time discrepancy between the two regulatory systems. Although both the EDA and SFDA carry out similar PMA processes, the time to market in Egypt is much longer compared to that of Saudi Arabia. The official SFDA timeframe of application reviews are typically 35 business days. while, the EDA timeframe can take up to five months for application reviews [56].

## **7. Expert Commentary**

The findings of this review highlight the significant association between the expanding market and the developing regulatory infrastructure of the Egyptian and Saudi Arabian

systems. A desirable market growth entails a simultaneous proportionate development of regulatory systems. Regulatory programs for health technologies, more specifically for medical devices can be developed in stages, as suggested by the WHO's Global Overview of Medical Device Regulation [47]. Recommendations for developing further the regulatory infrastructure of both countries can encompass long and short term actions (Figure 5). Long term actions can be done through strengthening and capacity building of the existing NRAs. However, the notion of patient's safety cannot be withheld until NRAs are fully strengthened. This is why short term actions are highly significant.

Short term actions include imposing import planning and control strategy, since both systems are heavily reliant on importation. This can ensure that imported devices are of required standards, and of priority to the healthcare needs. Customs authorities and medical devices regulatory authorities may need to cooperate more effectively to successfully meet these objectives. This includes a clearer display of regulatory requirements to interested stakeholders overseas. Moreover, the establishment of databases and medical devices registries, especially in the Egyptian system can help ease the burden on the centralized governance structure adopted by the authorities. This allows better handling of data and minimizes unnecessary delays in the market access process, as well as laying foundation for HTA and HTM capabilities.

Advertising control is essential in maintaining a proper presentation of medical devices, which is one of the main critical elements of medical devices safety suggested for developing regulatory systems [47]. Post-market surveillance and problem reporting needs further research to allow proper enforcement mechanisms. This is needed to

ensure that the post-market vigilance system is in coherence with the heterogeneous nature of the adopted PMA regulatory frameworks.

On the other hand, long term strategies to strengthen NRAs shouldn't be omitted. Active stakeholders' engagement is a key factor to stronger NRAs. Regulations that result from inclusive stakeholder involvement will likely yield better implementation [47]. Other strategies include re-assessing organizational structure of current governing bodies, and aiming for human resources empowerment. These provide the means for highly alert and responsive regulatory systems. Having the perfect regulations in place will not guarantee patient's safety unless such regulations are executed skilfully by the proper workforce [57]. Last but not least, sustainable financing mechanisms need to be set to empower all these corrective measures. Strategies for fee systems are needed, to allow a sustainable effective function of regulatory enforcement and supervision.

Insert Figure 5 Summary of Recommendations

## **8. Five-year view**

The medical devices markets in both Egypt and Saudi Arabia are expected to grow tremendously. In Saudi Arabia, the market's expected growth is estimated to exceed US\$ 1.6 billion by 2018, with a Compound Annual Growth Rate (CAGR) of 9% [5]. Similarly, the Egyptian market is expected to double in size by the year 2018, it is forecasted to reach an estimation of US\$ 1.009 billion [4].

The main findings highlighted in this review indicate a relatively fast regulatory track for market access of medical devices. These findings when combined with deficient national strategies for HTA and HTM may lead to uninformed procurement strategies.

On the large scale this may lead to unplanned industrial influx of medical devices into both markets. From the industrial perspective, this can be a good market opportunity. Nonetheless, the risk of influencing the market towards a supply induced demand exists under the current circumstances [58]. Consequently, problems of resources allocation in the public or private sector may arise, reducing their ability to respond to population needs in the longer term. Therefore, governments are urged to formulate as appropriate, national strategies and plans for the establishment of systems for the; assessment, planning, procurement and management of health technologies as per the 60<sup>th</sup> World Health Assembly's resolution WHA60.29 [58].

## **9. Limitations**

Available data on market access of medical devices in the Middle East is highly limited. An extensive database search was performed, in addition to hand searching relevant web portals, institutions, and grey literature. Although all efforts were done to undergo this complex research in a systematic and accurate manner, the authors cannot rule out the possibility of missing some data, especially in the complex hand search segment.

## **10. Conclusion**

Market access policies of both Egyptian and Saudi Arabian regulatory systems are relatively structured. There are major similarities between the two countries including; adopting regulatory frameworks of reference countries, interim nature of regulatory documents, centralized governance, and necessitating the presence of ARs. However, regarding process and implementation more progress is seen in Saudi Arabia, due to the presence of national provisions of medical devices regulations, faster processing time of PMA, and more established e-system capabilities.

The status quo of both regulatory systems poses several implications. Both markets are not directly accessible by new technologies that are unauthorized in reference countries. Furthermore, the growing market potential highlights the need for developing more comprehensive national strategies, which eventually may need to encompass the other phases of medical devices lifecycle. This includes HTA, and HTM of medical devices.

Finally, further research work is needed by both systems to assess the compatibility of post-market strategies within the context of the current regulatory frameworks. Further work is needed by both regulatory systems to look for means of strengthening their NRAs collectively to allow safe, timely, and effective access to medical technologies.

## **11. Key Issues**

- Despite the significant market size of medical devices in Egypt and Saudi Arabia, and its substantial potential for growth, information regarding policies and regulations for accessing this market is highly deficient.
- The Egyptian Drug Authority fully adopts the European Directive of the Medical Devices 93/42/EEC and its amendment 2007/47, while the Saudi Food and Drug Authority adopts the regulatory frameworks of the founding members of the International Medical Device Regulators Forum.
- The main regulatory documents are interim in both countries; the Egyptian Regulation for Medical Devices, issued in 2010, and the Saudi Interim regulations for medical devices, issued in 2008.

- Both countries necessitate the presence of ARs for manufacturers who have no local establishments within their territories.
- There is a substantial discrepancy in Premarket Authorization fees between Egypt and Saudi Arabia. The Saudi Food and Drug Authority charges a fee which is roughly eleven times greater than that of the Egyptian Drug Authority.
- Neither the Egyptian Drug Authority nor the Saudi Food and Drug Authority have their own local product standards for medical devices, or carry out clinical trials for Premarket Authorization. Instead, both authorities check documentary evidence which proves access to a reference country.
- The time to market in Egypt is much longer compared to that of Saudi Arabia. The official Saudi Food and Drug Authority timeframe of application review is typically 35 business days. Meanwhile, the Egyptian Drug Authority timeframe can take up to five months.
- Although a full analysis of patient's safety is not possible given the scope of this review, serious questions can be raised on the current state of heavy reliance on the US and EU regulatory frameworks by the Egyptian and Saudi Premarket Authorization systems.
- The status quo of the Egyptian and Saudi systems offer a relatively fast regulatory track for market access of medical devices. These findings when combined with deficient national strategies for health technology assessment

(HTA), and health technology management (HTM), may lead to unplanned industrial influx of medical devices into both markets.

- A desirable market growth entails a proportionate development of regulatory systems. Short term actions are needed to guard patient's safety, while long term ones are needed to strengthen existing national regulatory authorities.

### **Declaration of Interest**

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\*\* Of considerable interest

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# 1. Research and development

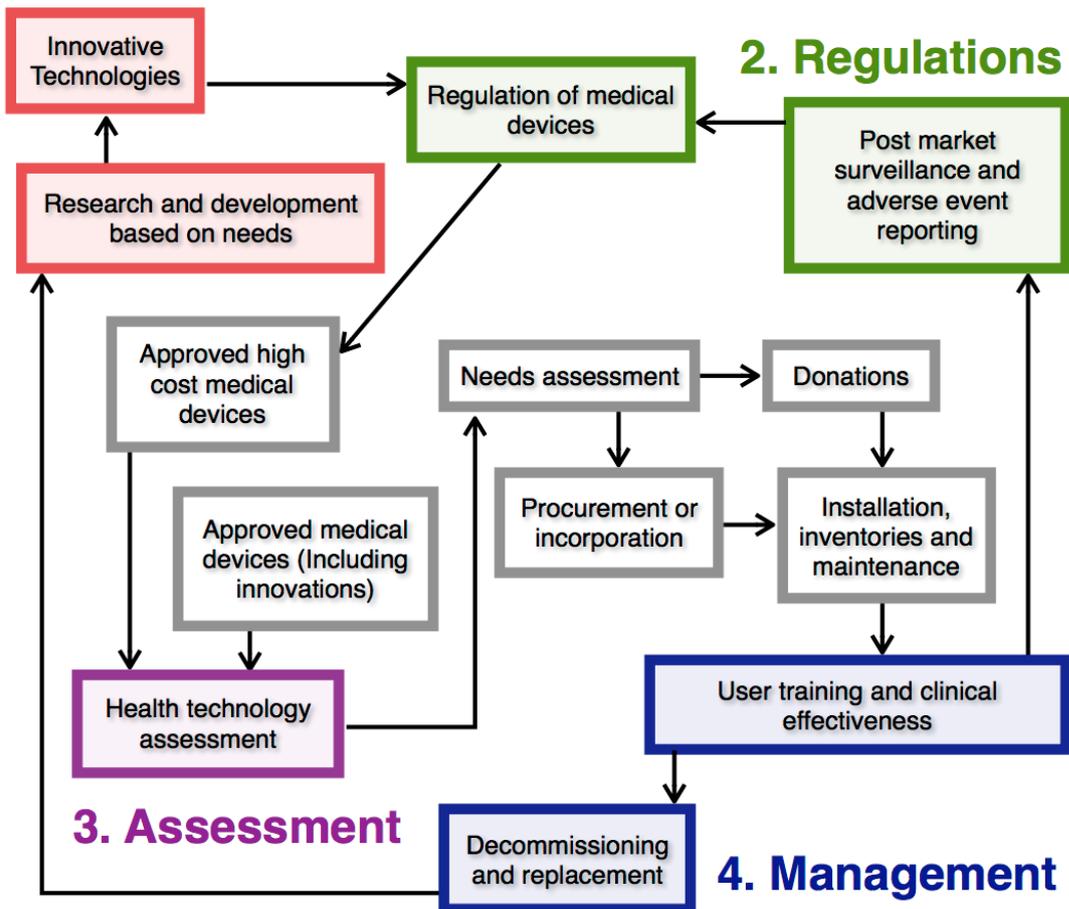
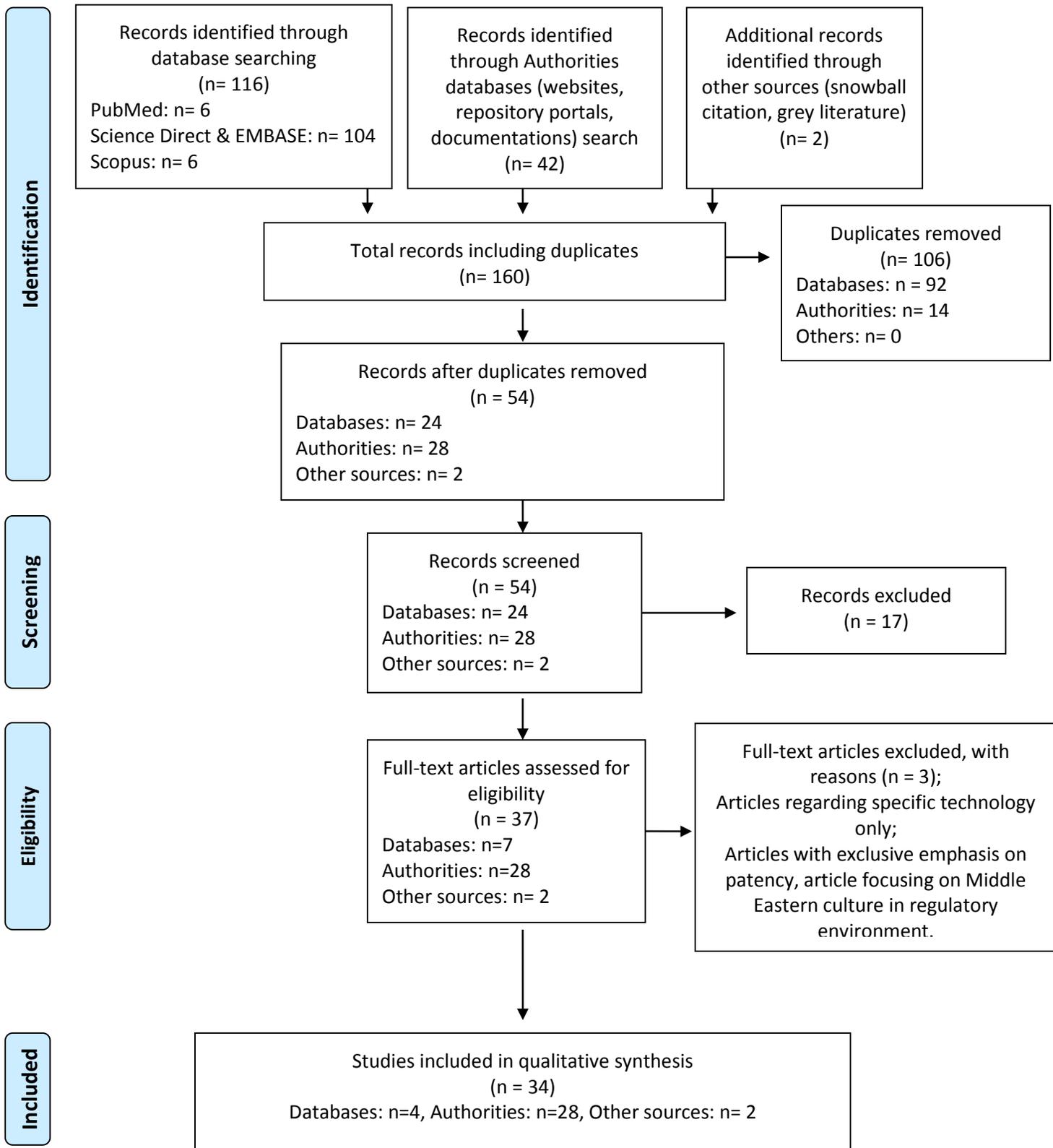


Figure 1 Phases of Medical Devices Life Cycle. Reproduced with permission from [1].

**Figure 2 Flow Diagram**



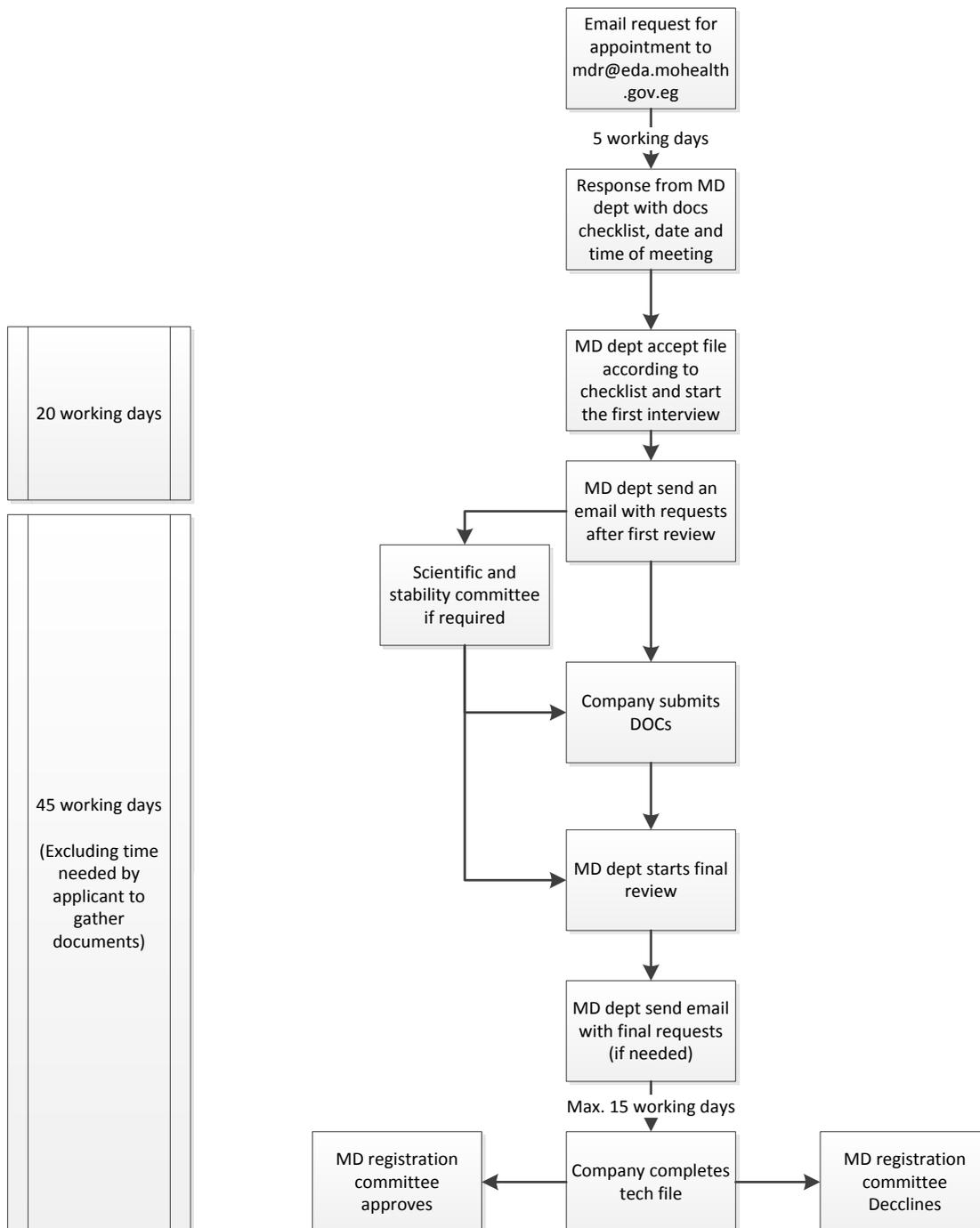


Figure 3 Premarket Authorization Process in Egypt

Information based on Egyptian Regulation for Medical Devices (ERMD), (Central Administration of Pharmaceutical Affairs (CAPA). *The Egyptian Regulation for Medical Devices*. 2010)

**Abbreviations:**

**MD dept:** Medical Device department

**DOC:** Declaration Of Conformity

**MD:** Medical Device

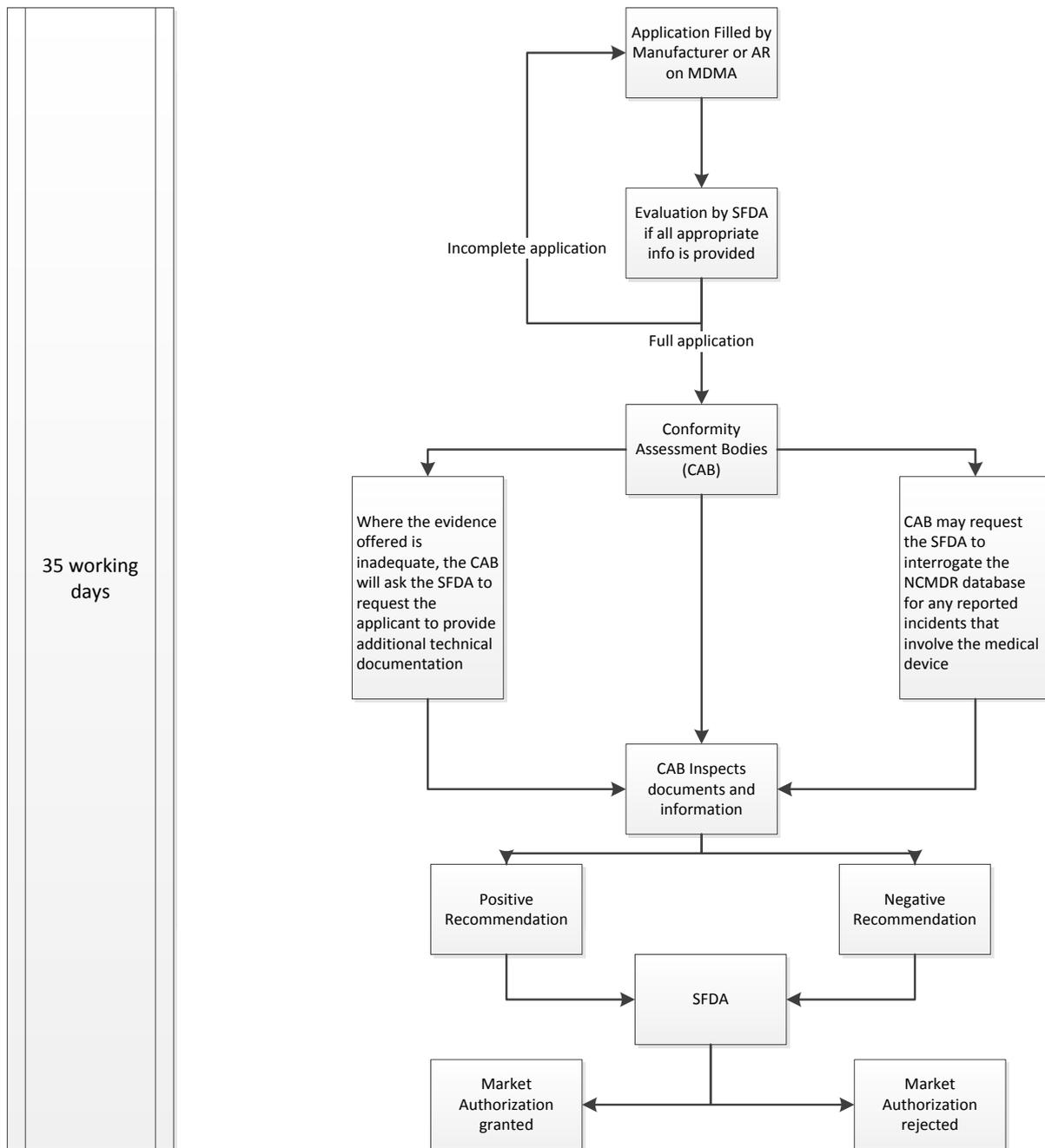


Figure 4 Premarket Authorization Process in Saudi Arabia

Information based on the Saudi Medical Devices Interim Regulations (Saudi Food and Drug Authority (SFDA). *Medical Devices Interim Regulations*. 2009 )

**Abbreviations:**

**AR:** Authorized Representative

**MDMA:** Medical Device Market Authorization System

**SFDA:** Saudi Food and Drug Authority

**CAB:** Conformity Assessment Body

**NCMDR:** National Center for Medical Device Reporting

### **A-Strengthening National Regulatory Authorities (Long term)**

- Regulatory Framework Development
- International Engagement
- Stakeholder Involvement
- Re-assessing Organisational Structure
- Human Resources Empowerment
- Sustainable Financing

### **B- Direct Actions to ensure patient safety in current process (Short term)**

- Import Planning and Control Strategy
- Establishment of Databases and Medical Devices Registries
- Advertising Control
- Enforcing Problem Reporting and Post Market Surveillance

Figure 5 Summary of Recommendations

	Egypt	Saudi Arabia
Population	82.6 million	29.9 million
GDP (2013)	\$272.0 Billion	\$748.4 billion
GDP per Capita (2013)	\$10,850	\$53,780
Total expenditure on health per capita (2012)	\$323	\$1,004
Total expenditure on health as % of GDP (2012)	5.0%	3.2%
Healthcare facilities	5,000	4,225
Beds	80,000	45,110
Medical Devices Market Size	\$595.0 Million	\$1.1 Billion

Table 1 Comparison between Countries' Profiles

**Source:** Author's illustration  
**Abbreviations:**  
**GDP:** Gross Domestic Product

Point of Comparison	Egypt	Saudi Arabia
<b>I-Governance</b>		
Regulatory body	EDA	SFDA
Basis of regulation	EU Directive 93/42/EEC and its amendment 2007/47	IMDRF founding members jurisdictions
Need for AR	Yes	Yes
Medical Devices Classification	EU medical devices classification system	According to pre-existing approval IMDRF member
<b>II-Process &amp; Implementation</b>		
Product standards	Assessed through Documentary evidence of CE, ISO 13485 & free sale certification or FDA approval	Assessed through Documentary evidence of complying with conformity assessment requirements of at least one of the IMDRF jurisdiction
Process time	70 working days (approx.)	35 working days
National Medical Devices Registry	Absent	Present
Local manufacturers	Limited capacity, required to be licensed and obtain CE and ISO 13485 certification	Limited capacity, required to obtain establishment license and comply with requirements of at least one of the IMDRF jurisdiction
Provisions for labeling and advertising	No specific national provisions were found	Specific National provisions are in place
Post market Surveillance	Required to maintain vigilance system, databases of safety and performance info (not yet fully developed), mechanism for corrective actions as necessary	Required to maintain a database of safety and performance info: mechanism for corrective actions as necessary
Fees for PMA	\$458.6	\$3999.7- \$6132.9
Clinical Investigations	Present for medical devices intended for clinical investigations	Present for medical devices intended for clinical investigations

Table 2 Comparison of Regulatory Frameworks of Egyptian and Saudi Systems

Abbreviations:

**EDA:** Egyptian Drug Authority

**SFDA:** Saudi Food and Drug Authority

**EU:** European Union

**IMDRF:** International Medical Device Regulator Forum

**FDA:** US Food and Drug Administration

## Supplementary Material

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# 1. Table of Abbreviations:

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<b>ARs:</b>	Authorized Representatives
<b>CAB:</b>	Conformity Assessment Body
<b>CAGR:</b>	Compound Annual Growth Rate
<b>CAPA:</b>	Central Administration for Pharmaceutical Affairs
<b>CE:</b>	Conformité Européenne
<b>DOC:</b>	Declaration of Conformity
<b>EDA:</b>	Egyptian Drug Authority
<b>ERMD:</b>	Egyptian Regulation for Medical Devices
<b>E-services:</b>	Electronic database services
<b>EU:</b>	European Union
<b>FDA:</b>	US Food and Drug Administration
<b>GCC:</b>	Gulf Cooperation Council
<b>HTA:</b>	Health Technology Assessment
<b>HTM:</b>	Health Technology Management
<b>IEC:</b>	International Electro-technical Commission
<b>IFU:</b>	Information For Use
<b>IMDRF:</b>	International Medical Device Regulators Forum
<b>IRs:</b>	Implementing Rules
<b>ISO:</b>	International Organization for Standards
<b>MDC:</b>	Medical Devices Classification
<b>MDMA:</b>	Medical Device Market Authorization system
<b>MDNR:</b>	Medical Device National Registry
<b>MDSB:</b>	Medical Device Safety Department
<b>MOHP:</b>	Ministry of Health and Population
<b>NCMDR:</b>	National Center for Medical Device Reporting
<b>NODCAR:</b>	National Organization for Drug Control and Research
<b>NRA:</b>	National Regulatory Authority
<b>PMA:</b>	Premarket Authorization
<b>SASO:</b>	Saudi Arabian Standards Organization
<b>SFDA:</b>	Saudi Food and Drug Authority
<b>USA:</b>	United States of America
<b>WHO:</b>	World Health Organization

## 2.Elaborate Methodology

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This study performs a systematic review of the literature, applying two methodologies to search for potentially relevant data; one through a systematic literature research in academic journals, and the other by searching for medical devices regulatory information in relevant regulatory authorities' data sources. As such, the Egyptian Drug Authority [1] and the Saudi FDA web portals [2] were searched. In addition, country data from medical device profiles provided by the WHO medical devices portal was searched [3]. The search methodology employed was in line with PRISMA guidelines [4].

The following journals were searched: PubMed (Medline), Science Direct, EMBASE, Scopus and the Arabic database Al Manhal, which is a full-text searchable databases of scholarly and scientific publications from the Arab and Islamic world, including in the areas of health and social sciences. A hand search was undertaken for the WHO Eastern Mediterranean journal (all volumes from 1995-2015).

The search protocol including the selection criteria have been in line with the CRD's guidance for undertaking systematic reviews in healthcare [5].

The search language was limited to English and Arabic. A comprehensive search strategy has been developed, using appropriate search terms. The following search terms were used (list in English and Arabic).

### **English:**

**Keywords:** Medical device, medical product

**In combination with:** regulatory, approval, regulation, HTA, and registration

**In combination with:** Middle East, Egypt, Saudi Arabia

### **Arabic:**

**Keywords:** المنتج الطبي, الاجهزة الطبية

**In combination with:** تسجيل, تقييم التكنولوجيا الصحية, قانون, موافقة, التنظيمية

**In combination with:** المملكة العربية السعودية, مصر, الشرق الاوسط

Data has been extracted with no exclusion of publication dates, with the following criteria applied:

### **Inclusion Criteria:**

- Focus on Saudi Arabia, and Egypt

- Medical Device Context
- Articles publication date is open
- Articles in English or Arabic

**Exclusion Criteria:**

- Focus on other countries
- Highlighting the case of a specific technology only

The English search results were identified from the viewed records title and were independently reviewed and screened by two researchers. The Arabic Search results were only reviewed and screened by the lead researcher.

Additional articles were found in the references and citations of the retrieved articles (citation snowballing) and grey literature search was undertaken. In addition, experts were consulted via telephone interviews to verify the validity of the documents and search findings.

## 3. Countries' profiles

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### ***3.1 Egypt***

The most populous country in Northern Africa and the Arab world with a population amounting to 82.6 million in 2013 [6]. This Transcontinental country is a lower middle income country with a GDP of \$272.0 billion in 2013[6]. 5.0% of the GDP was the total expenditure on health in 2012 [7]. The Egyptian Medical devices and supplies market is considered to be one of the largest in the Middle East. However the per capita consumption is considered to be low by regional and world standards [8]. This indicates the enormous market potential for medical devices on the long term. In 2013 the market was estimated at \$595.0 million (EGP 4,090.7 million) and is forecasted to reach \$1.009 billion in 2018 [8].

The Ministry of Health and Population (MOHP) is a major provider of primary, preventive, and curative care in Egypt. Capacity includes 5,000 health facilities (of which there are 539 hospitals) and more than 80,000 beds spread nationwide [9]

### ***3.2 Saudi Arabia***

Saudi Arabia is one of the main Arabic states with a total population of 29.99 million in 2013 [10]. It occupies the main bulk of the Arabic Peninsula. This world's largest producer and exporter of oil is a high income country with \$53,640.0 GNI per capita [11]. GDP is estimated to be \$748.4 billion in 2013 [11]. 3.2 % of the GDP was dedicated to Healthcare expenditure in 2012 [12]. The Saudi medical devices market accounts for 50% of the total Middle Eastern market, with a medical devices market amounting to US\$ 1.1 Billion in 2013, with estimated expected growth exceeding US\$ 1.6 Billion by 2018 and a Compound Annual Growth Rate (CAGR) of 9% [13]. Owing to these figures, Saudi Arabia remains a very attractive destination if not the most attractive destination for medical device companies in the Middle East.

The MOH is the major provider and financer of Health in Saudi Arabia providing 60% of total health services [14]. Saudi Health capacity includes 244 hospitals (33 277 beds) and 2037 Primary Healthcare Centers (PHCs) of governmental origin, and 125 hospitals (11 833 beds) and 2218 dispensaries and clinics.

## 4. Further Results details:

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### 4.1.1 Further info on Regulatory bodies:

#### i. Medical Devices Regulatory bodies:

##### 1) Egyptian Drug Authority (EDA)

MOHP is the final decision maker for market authorization, and drug reimbursement in the public sector. Headed by the Minister of Health, the MOHP is responsible for the overall health policy as well as Health Insurance Organization (HIO). It issues ministerial decrees and executes the legal and regulatory framework for all health interventions. These different functions are done through three sub-organizational structures (figure 1)

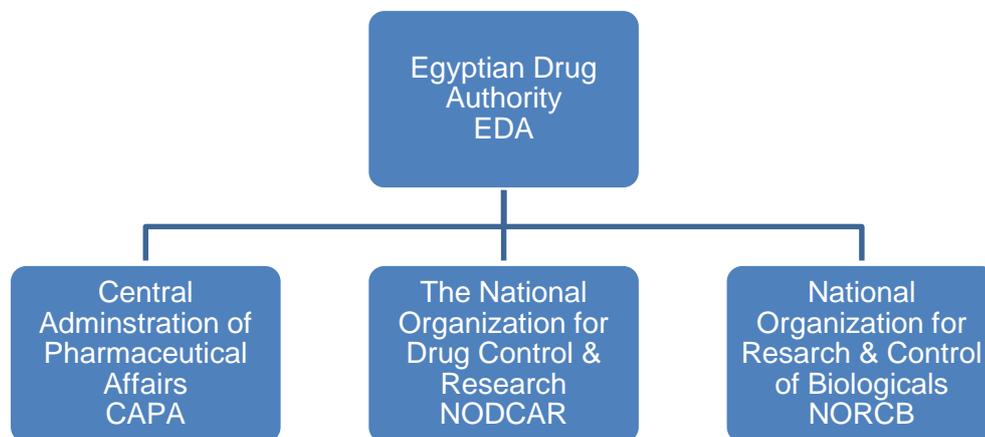
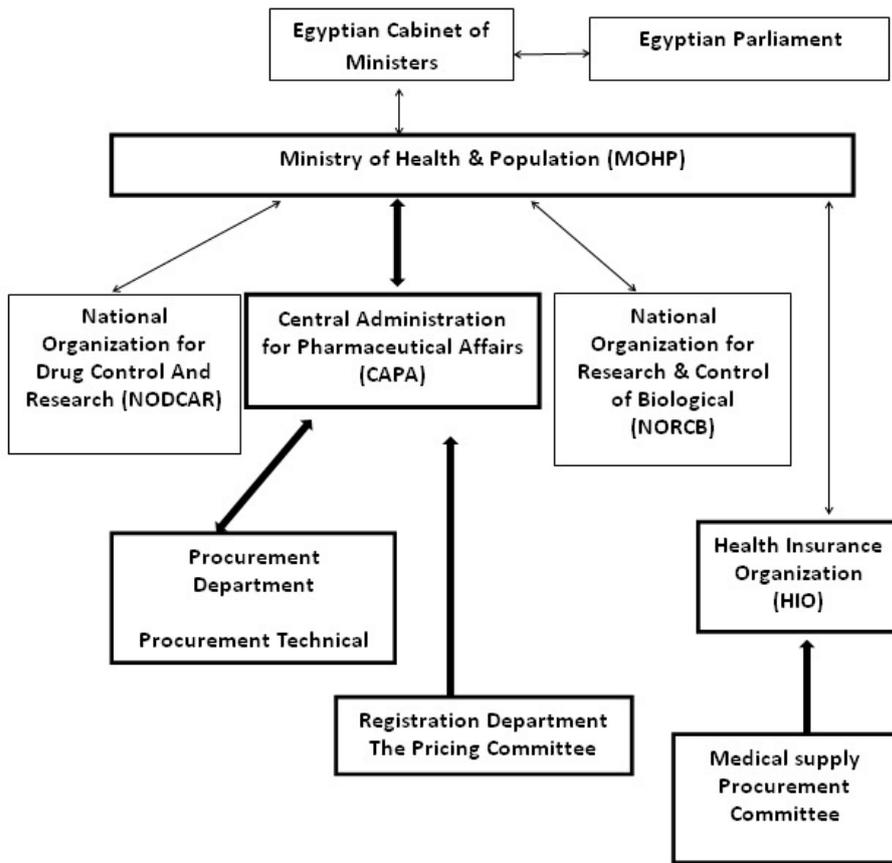


Figure 1 EDA structure

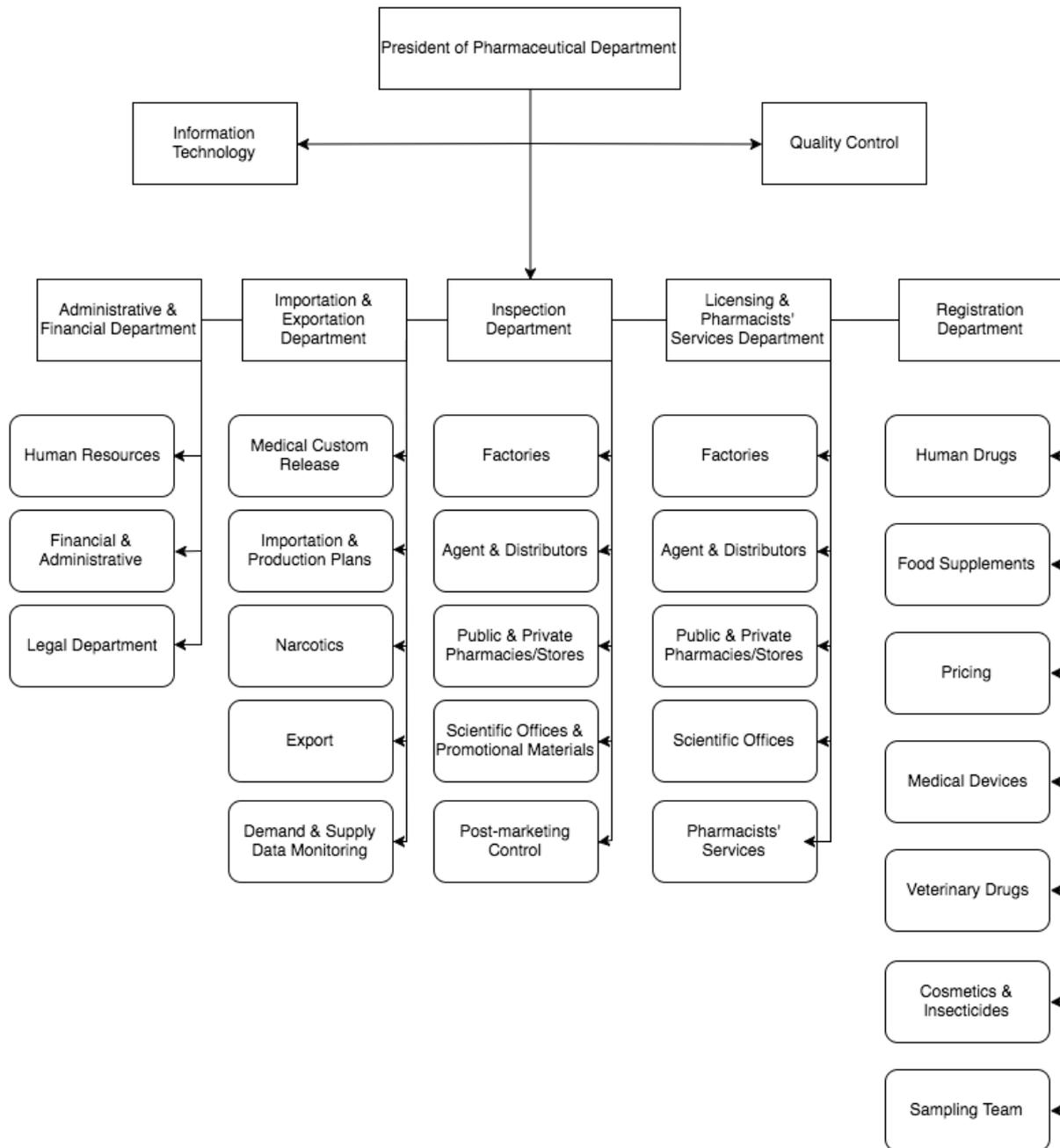
The three structures together constitute the Egyptian Drug Authority (EDA). The EDA is the pharmaceutical regulatory body of the MOHP. Medical devices unit with all its sectors (Registration, Custom Release, and Inspection) are included within the spectrum of this pharmaceutical regulatory body as a sub function. This is in addition to other disciplines like biological, cosmetics, dietary supplements and pesticides [15].

Figure 2 shows a brief overview of the Egyptian healthcare governance with respect to medical devices and other aspects. The main bulk of regulatory processing is done through the CAPA[16]. CAPA handles a whole range of activities including premarket authorization, customs release, post market inspection, and licensing & registration of importers, Authorized Representatives (ARs), and factories. CAPA is assisted by NODCAR and other specific technical committees for checking the technical specifications of medical devices facilities and products [17].



**Figure 2 Overview of Egyptian Healthcare governance. Reproduced with permission from Dr. Gihan El Sisi**

It is notable to state that the EDA relies mainly on bureaucratic functions, and has minimal use of electronic systems in the process of medical devices market access regulations. CAPA has a very dense structure (figure 3) and is considered to be the central hub for most of the pharmaceutical and medical devices work.



**Figure 3 CAPA Structure**  
Based on Egyptian Drug Authority structure

## 2) Saudi Food and Drug Administration (SFDA)

SFDA was established in 2003 after the Council of Ministers issued a resolution in March 2003 [18]. SFDA was established as an independent Authority that reports directly to the Council of Ministers of Saudi Arabia [19].

SFDA primary function is to ensure the safety of food, along with ensuring safety, quality, and effectiveness of drugs, and ensuring safety, quality, effectiveness and performance of medical devices according to their intended purpose [18]. Organized into sectors, The SFDA has an entire

sector dedicated solely for the regulation and organizing of medical devices. This is beside three other sectors that handles food, drug, and information technology [20].

Unlike the EDA, the medical device sector of the SFDA handles the entire process of Medical devices registration, post market surveillance, custom release, listing and licensing of establishments and ARs with the help of electronic databases. This powerful comprehensive electronic system (e-services) includes Medical Devices Marketing Authorization (MDMA) system, Medical Devices Importing License (MDIL) system, and Medical Devices Establishment License (MDELS) system, Medical Devices National Registry (MDNR), National Center for Medical Devices Reporting (NCMDR), Medical Devices Databases (MDDDB), and Medical Device Classification (MDC) system.

The SFDA's entire medical device sector shows automated e-services and e-records. The entire medical devices lists, establishments, imports, and error reporting is visible through a uniform portal that includes all these e-Systems [21].

#### **4.2.1.1.2 Reference Countries:**

**Egypt: List of reference countries approved by technical committee 2009:** (devices coming from the following countries, are approved for registration on receipt of EMEA or ISO certificate)[22]

- Australia
- Austria
- Belgium
- Canada
- Denmark
- Germany
- Finland
- Iceland
- France
- Ireland
- Luxemburg
- Holland
- Newzeland
- Norway
- Sweden
- Switzerland
- USA
- UK
- Japan
- Italy
- Spain
- Portugal

**For Saudi Arabia:**

- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia, and
- United States of America.

## 5. Checklists

**Table 1 EDA Checklist for imported medical devices. Based on Egyptian Drug Authority, *Regulatory Checklist for Imported Medical Devices*, M.D. Sector, Editor**

### **Checklist for Imported devices PMA:**

1. Application form Signed and stamped by AR
2. AR's importer license
3. Agreement between Manufacturer and AR
4. Free Sale issued by Ministry of Health in the country of origin
5. CE certificate issued from an accredited notified body
6. Certificate for Foreign Government issued from FDA
7. ISO 13485 certificate
8. Test report certificate issued from Quality control lab (signed and stamped by manufacturer)
9. Sterility certificate (signed and stamped by manufacturer)
10. Composition certificate acc. To international standards (signed and stamped by manufacturer)
11. Shelf Certificate (Signed and stamped by manufacturer)
12. Stability study (signed and stamped by manufacturer)
13. Packaging material certificate (signed and stamped by manufacturer)
14. Sketch diagram and dimension of product (signed and stamped by manufacturer)
15. Sample
16. Internal and External label of product (signed and stamped by manufacturer)
17. Catalogue and inner leaflet
18. Declaration of conformity mentioning (product name, classification, CE certificate number, a statement that the declaration is issued under the sole responsibility of the manufacturer) (signed and stamped by manufacturer and legalized by chamber of commerce)

### **Regulatory Checklist for Local devices:**

1. Application form Signed and stamped by AR



**Checklist for Customs release:**

1. Delivering medical stamp.
2. Request for release on company letterhead signed by the Director of the company and stamped by the company.
3. Pledge not to disengage or release the product unless in the presence of a pharmacist from the Central
4. License registration in importers record and add the company supplied the license.
5. Administration inspector.
6. Commercial invoice origin or certified bank image + 2 copies.
7. Bill of lading original + image.
8. Approval policies originally directed to release medical + 2 copies.
9. Image of medical device registration notification.
10. Certificate of ISO for quality in the case of supplies from the country registered non-reference.
11. License registration in importers record and add the company supplied

**Table 3 EDA Checklist for custom release. Based on Egyptian Drug Authority, General Directorate of Pharmaceutical Monitoring For Custom Release On Medical Devices and Kits. 2010.**

**Checklist for Documentary evidence of compliance with regulations of a GHTF founding member:**

1. The classification of the medical device according to the regulations that apply.
2. Evidence of complying with the conformity assessment requirements of one IMDRF jurisdiction, including any registration or listing requirements.
3. Evidence, where such is required, that the manufacturer's quality management system is in place
4. An attestation that the medical device complies with the provisions of the medical device regulations that apply within the GHTF Founding Member jurisdiction that has been selected as the basis of the application.

**Table 4 SFDA Checklist for documentary evidence. Based on Saudi Food and Drug Authority, Implementing Rule On Market Authorization (MDS-IR6). 2008**

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