ISSN–2230-7346
Journal of Global Trends in Pharmaceutical Sciences

AUTHORIZATION AND REGULATION FOR MEDICAL DEVICES MARKETING IN GULF CO-OPERATION COUNCIL MARKET

Mallikarjun Vasam[1], Raja Sridhar Rao[1], Tumma Hema Devi[1], Balaji Maddiboyina*[2]

[1]Department of Pharmacy, Chaitanya College of Pharmacy Education and Research Hanamkonda, Warangal-505009
[2]Department of Pharmaceutics, Vishwa Bharathi College of Pharmaceutical Sciences Perecherla, Guntur, Andhra Pradesh-522009

*Corresponding author E-mail: mbalaji113@gmail.com

ARTICLE INFO

Key Words
Medical Devices, Regulatory affairs, Gulf, Saudi Arabia, Oman, Qatar

Access this article online
Website: https://www.jgtps.com/
Quick Response Code:

ABSTRACT

The current scenario exhibit that the medical device market in the Gulf Cooperation Council (GCC) is predominantly import-based. Despite many local companies distributing the medical devices within the GCC only, there are individual active companies, such as the Qatari German Companies that disseminate to numerous countries within Europe, Africa, and North America. Understand marketing authorization procedures for Medical Devices in GCC, selection of the process and basic requirements are required for the Medical Devices to get registered in all the markets of GCC. To study the management of regulatory life cycle of Medical Devices in GCC, the patterns of the study, which it follows via specific pathways to conclude, are unique for each study. Thus, the scheme to be monitored plays an imperative role in influential the outputs as well as the concerns of study.

INTRODUCTION

According to WHO "Medical Devices" can be distinct as any instrument, apparatus, machine, appliance, implant, a reagent for in vitro use, software, substantial or other similar or related article envisioned to be used for human beings, unaccompanied or in accompanied, for any of the specific medical purposes of diagnosis, monitoring, prevention, treatment or alleviation of disease, diagnosis, treatment, compensation for an injury, investigation, replacement, modification, or support of the anatomy or a physiological process, supporting or sustaining life, control of conception, in vitro examination of specimens from the human body and which does not acts primarily by pharmacological, immunological or metabolic actions in or on the human body.

Medical Device Market in Gulf Cooperation Council (GCC)

GCC continues to spend actively in health care is expected to rise significantly. Health care expenditure as a percentage of gross domestic product is extensively lower in GCC as compared to that in Western nations despite their robust economies.[1] Saudi Arabia's expenditure was 5% associated with 16% in the United States in 2009. Among the GCC, the highest per capita health care spending of US$ 1,715 of Qatar is extensively lesser than in the United Kingdom and the United States, at US$3,285 and US$7,410, respectively. Saudi Arabia and the UAE have a combined expenditure of approximately US$1.4 billion in the

Market for medical equipment and provisions, which is 47% of the total GCC market. The total spending needs to be increased to meet the demand with ever-increasing disease burden in the GCC with an expected annual growth rate of 5% on Medical Devices.[2] The existing medical device market in the GCC is principally import-based, with 96% of medical equipment abounding by the United States and Germany and a total projected expenditure of US$819 million in the UAE unaided by the end of 2014. In Saudi Arabia, less than 3% of the total spending on medical equipment is for domestic products that are characteristically imperfect to low-technology consumables, such as syringes and catheters. Although many of these indigenous companies allocate within the GCC only, there are some active companies, such as the Qatar German Company for Medical Devices that disseminate to several countries within Europe, Africa, and North America. Again, the focus for the Qatar German Company for Medical Devices, which is the Middle East's prevalent medical device manufacturer, is on low expertise class 1 expedients. Still, it does embody the probable for the progress of a bigger market and device manufacturing in the province. Given the indigenous disease burden and demand, the essential subsectors within the GCC medical device market embrace cardiovascular devices (e.g., implantable stents, pacemakers, and implantable defibrillators), dialysis machines, rehabilitation equipment, diagnostic equipment, and surgical implants and correlated instruments.[3] Other than disease burden, there are surplus circumstances/progress within the health care infrastructure that subsidize to the cumulative mandate for medical technologies in the GCC.

Reimbursement pathways: Within the GCC, the role of payers and insurance is approximately 75% of health care disbursement is publically subsidized through the particular ministries of health, with the enduring spending assumed by the much slighter private health care systems with an anticipated advance of expenditure of as high as 14% per year. This escalation in spending is principally a consequence of an upward claim for amenities that necessitates investment in innovative infrastructure, medical technology acquisition, and hiring qualified medical professionals.[4]

Private health care: As an outcome of histrionic population progress, amplified disease burden, and escalating medical costs, governments in the GCC are embracing the private sector via public-private partnerships, in adding to private-only institutions.[5] For example, an effective public-private partnership (SEHA, The Abu Dhabi Health Services Company) has been executed in Abu Dhabi, whereby eight health systems are accomplished beneath one umbrella organization with private partners, comprising Johns Hopkins and the Cleveland Clinic from the United States. By alternative mechanism, promising the institution of private full-service health care amenities such as the Al Ahli Hospital in Doha serves to diminish capital investment requirements from the government purse and spur competition that will diminution prices and progress patient choice.

National health insurance:

At only 1.3% (gross premium as a percentage of gross domestic product), health insurance penetration in the GCC is ominously worse than the global average of 7%. Even midst emerging markets, insurance penetration is more than double that of the GCC. Many GCC governments have previously executed national insurance programs. Saudi Arabia, for example, has had a mandatory health insurance program in place for expatriates. Since 2006, the UAE has approximately 55% insurance penetration at current. Beneath this program, the plan is to have the entire Qatari national population concealed by the end of 2014, with the full resident population enclosed by the end of 2016.

Health care infrastructure: Although tranquil decisively in the advance phase, GCC member states are present in the practice of revitalizing their hospital systems in line with the collective health cognizance and potentials of their prosperous populace. Despite improved expenditure, GCC states trail overdue more advanced nations with esteem to the number of hospital beds and amount of diagnostic equipment, laboratory services, and trained medical personnel accessible.[6] This coordination was premeditated to sustenance

the National Health Strategy for the country, which provisions the subsequent key accomplishments: advance a world-class health care system with universal access, deliver high-quality medical care over an integrated network, focus exertions on the preclusion of disease, assemble a capable workforce adept of providing high- quality care, and sustenance research ingenuities that feedback into enhanced consideration.

Saudi Arabia [7, 8]: The Kingdom of Saudi Arabia is one of the prime markets for medical devices and associated products in the Middle East region. As part of the GCC, Saudi Arabia has experienced extraordinary growth, primarily due to its hydrocarbon-based economy. The Saudi Food & Drug Authority (SFDA) is the government agency that legalizes drugs and medical devices in Saudi Arabia.

Medical Device Overview

- The estimated size of Saudi medical Devices in 2014 is – 3billion USD
- Moderate growth between 2014-2019 (CAGR)- 7.6%
- Import of medical device grew at 8.7% reaching $2billion in 2014
- By 2019 the wound care management market is expected to reach $185 million growing at 6.6% (CAGR)
- $28 billion for healthcare & social development
- 8.4 million of the population are health insurance holders

Regulatory approval: As Kingdom of Saudi Arabia (KSA) is an active member of Asian Harmonization Working Party (AHWP), the most Medical Devices protocols are based on International Medical Devices Regulators Forum (IMDRF) and subsequently the Global Harmonization Task Force (GHTF) necessities. These regulations confirm that only Medical Devices that have been ratified by one of the institution IMDRF members have access to the Saudi Arabian market. SFDA was conventional in 2003 and is still erecting the regulatory infrastructure for Medical Devices registration. [9] The SFDA is valid through a Medical Devices Interim Regulations (MDIR) system.

Post-marketing surveillance:
The National Center for Medical Devices Reporting (NCMDR) accepts reports of suspected Medical Devices hostile trials, and inveterate product evokes from healthcare practitioners and Devices purveyors within the Kingdom of Saudi Arabia. SFDA personnel probe all submissions and, when probable, deliver technical and clinical guidance to consent all exaggerated revelries to elude or tenacity reported hitches that are associated with medical devices. NCMDR's predominant goal is enlightening patient and caregiver protection through the distribution of accurate, actionable evidence. Since the system's realization is best confirmed by active and ongoing participation, SFDA sturdily reassures all members of the medical community to take part.

Country Specifics

Enforcement of Medical Devices Marketing Authorizations: All Medical Devices & IVDs envisioned to be marketed in Saudi Arabia should have a valid Medical Devices Marketing Authorization (MDMA)

Regulatory Process Flow Chart
Fact Sheet
Competent Authority: Saudi Arabia Food and Drug Authority (SFDA)

Legal Basis: Medical Devices Interim Regulations (MDIR) from 2008

Device Classification: Classification within the reference country

Time to approval: For class I & II about 2-3 weeks and for class III about 5-10 weeks

Length of License: License issued in Saudi Arabia expire when either the GHTF license expires or after three years

UAE [10]
United Arab Emirates (UAE), a prominent GCC member nation, has an advanced healthcare system. Its market potential is proven and consistently on the rise. Medical

Devices Regulatory Services is governed by Drug Control Department of the Ministry of Health (MOH).

Medical Device Overview

- From $841m in 2014, the market is expected to reach $978.9m by 2020
- $747million imports of medical devices in 2013
- 7.3% projected CAGR for the medical device market
- 23.8% Increase in medical device imports from the year 2013 to 2014

The wound care market is primarily catered to by traditional wound care dressings manufactured by local players

Medical Devices Regulation: The UAE is like the KSA a member of the AHWP and the Medical Devices are delimited by the Ministry of Health (MOH) in the United Arab Emirates. UAE Medical Devices regulations are noticeably leaning towards GHTF guidelines as well as towards EU requirements. [11]

Country Specifics: After the consent of the claim, a registration number is given, which is sufficient for five years. A registration number can be rescinded, if

• The applicant appeals for it or

• Upon catastrophe to meet the standards based on assessment or monitoring evidencing that

Devices are unsafe and harmful,The quality of the Devices is substandard, The Devices differ from the approved labe

Pre-Owned Medical Devices

Used Medical Devices are not endorsed for ingress into and marketing in the UAE.

Fact Sheet

Competent Authority: Ministry of Health (MOH)

Legal Basis: Created on IMDRF as well as EU Medical Devices Directive (93/42/EEC) and USFDA

Devices Classification: Classes I, II, III, IV, IVD classes A, B, C, D

Time to approval: It takes approximately nine months to receive support in the UAE

Length of License: License issued in UAE expire when either the CE mark expires or after three years

Regulatory Process Flow chart: Qatar [10]

The Ministry of Public Health (MOPH) is liable for the regulation of the Healthcare Industry within Qatar. Medical Devices registration in Qatar is conducted through the Ministry of Economy and Commerce (MEC). The record is trailed by an application request to the Ministry of Municipal Affairs and Agriculture (MMAA) for an inspection of the shreds of evidence, because business deeds may not be undertaken in certain banned areas. An indigenous agent is vital and must be registered. As detailed in the National Health Strategy project update, it is renowned that "Qatar does not currently have an effective system to regulate the introduction and continued use of medical devices within the State." Even though Qatar has the least-developed regulatory system of the three leading economies in the GCC, there do exist specific general guidelines concerning medical device registration. [12]

Medical Device Overview

- Around the US $ 210mn medical device market in 2013 and is expected to be around the US $ 274.3 mn in 2018
- 97% of medical devices are imported products.
- Expected to 0.4bn by 2018
- <3% market share accounted by local medical devices

Medical Devices Regulation

The Ministry of Public Health (MOPH) is liable for the regulation of the Healthcare Industry within Qatar. Medical Devices registration in Qatar is steered through the Ministry of Economy and Commerce (MEC). The registration is tailed by a solicitation entreaty to the Ministry of Municipal Affairs and Agriculture (MMAA) for an inspection of the premises, because business accomplishments may not be assumed in assured prohibited areas. [13]

Furthermore, after June 30, 2011, only Qatar MEC-authorized medical Devices are endorsed to be used within Qatar, while Devices in use previously that date may remain to be exploited. Only Medical Devices that are authorized by one of the founding members of the Global Harmonization Task Force (GHTF) can smear for a MEC marketing authorization.

Fact Sheet: Competent Authority: Ministry of Public Health (MOPH)

Legal Basis: based on GHTF
Devices Classification: Classes I, IIa, IIb, III
Time to approval: Qatar does not specifically target approval times
Length of License: No particular length of License issued in Qatar

Regulatory Approval process Flow chart

Oman [10]

Medical products necessity is disclosed with the MOH. Oman consents all medical Devices classification systems. The listing practise is conducted by acquiescing a solicitation form and other pertinent documentation over an indigenous representative.

Medical Device Overview

- $111.6mn medical device market in 2013
- 95% of medical devices are imported products.
- Expected to expand by a CAGR of 11.4% to reach $191.4mn by 2018
- <5% market share accounted for by local medical devices

Medical Devices Regulation

Medicinal products must be registered with the MOH. Oman consents all medical Devices classification schemes. The registration practice is shown by acquiescing a tender form (Annex X) and added pertinent documentation over an indigenous representative. Bestowing to Ministerial Decision No. 109/2008, a pre-qualification of companies and factories of medical provisions is vital to register a Medical Devices in Oman. [14]

Pre-Owned Medical Devices

The ingress of used or renewed medical equipment has no restrictions, but the MOH does not buy them. The Ministry of Health is the leading buyer of medical equipment in Oman.

Fact Sheet

Competent Authority: Ministry of Health (MOH)
Legal Basis: Ministerial Decision No. 109/2008 under Ministry of Health
Devices Classification: Oman consents all classification schemes, and the type of product dictates the practice it must endure before receipt market authorization
Time to approval: No specific time
Length of License: License issued in Oman expire at the end of the approval in their country of origin

Regulatory approval process flow chart

Kuwait [15]

Kuwait is an associate of AHWP. Medical Devices are enumerated as products only within the Non-classified Produces Unit of the MOH Food & Drug Control Department. The medical devices market in Kuwait is entirely ingress driven subjugated by international brands. The medical devices market in Kuwait has perceived advance owed to the amplified participation of private players in the healthcare sector. Technological improvements and amplified focus on infrastructure development have also ensued in improved demand for medical devices in Kuwait. Heavy investments in infrastructure projects are driving the growth in Kuwait.

Medical Device Overview

- Domestic production principally involves the manufacture of essential items, such as surgical gloves, bandages, orthopaedic aids and hospital furniture
- Highly dependent on imports - 97.2% (2013)

Medical Devices Regulation

Kuwait is a member of AHWP. Medical Devices are enumerated as products only within the Non-classified Products Unit of the MOH Food & Drug Control Department.

Pre-Owned Medical Devices

It is sternly illicit to ingress pre-owned medical Devices into Kuwait. Kuwait's public health associations do not buy used or refurbished medical Devices. All tenders call for innovative Devices and equipment. Used or refurbished equipment does not have a market in Kuwait.[14]

Fact Sheet

Competent Authority: Ministry of Health (MOH)
Legal Basis: Kuwait has no formal medical device regulations and instead relies on the decisions made by the Gulf Cooperation Council on importation and registration

Devices Classification: There is no classification requirement or particular restriction for importing medical devices
Time to approval: within 1-2 months
Length of License: License issued in Kuwait expires with each import

Bahrain [16]

The Ministry of Health (MOH) is liable for the omission and regulation of the healthcare industry inside Bahrain. Medical Devices regulation in Bahrain is engaged by the Pharmaceutical Product Regulatory Office (PPRO) of the National Health Regulatory Authority (NHRA). Pharmaceutical products for which the principle envisioned action is pharmacological, metabolic or immunological are delimited as medicines or health products; although where the policy projected activity is physical or mechanical, then the product is delineated as a medical Device

Medical Devices Regulation

The Ministry of Health (MOH) is accountable for the lapse and regulation of the healthcare industry within Bahrain. Medical Devices regulation in Bahrain is engaged by the Pharmaceutical Product Regulatory Office (PPRO) of the National Health Regulatory Authority (NHRA). All medical equipment ought to conform with one of the international standards such as the CE mark or USA FDA principles and be sanctioned over the NHRA Medical Devices engineering department. [17]

Country Specifics

Rendering to the article (68) of the Legislative Decree No (18) from 1997, a product registration might be rescinded via a ministerial order.

Fact Sheet:

Competent Authority: National Health Regulatory Authority (NHRA)
Legal Basis: No separate legal basis is present
Devices Classification: Classes I, IIa, IIb, III
Time to approval: approximately six months
Length of License: License issued in Bahrain expire after two years

Yemen [18]

Yemen is a member of AHWP. Medical Devices in Yemen are enumerated through the Supreme Board for Drugs and Medical Appliances (SBDMA), the portion of the Ministry of Public Health and Population (MPHP). Many types of Medical Devices requisite are enumerated in Yemen, though the authorities reassure manufacturers to go over the registration development regardless.

Medical Devices Regulation

Yemen is an associate of AHWP. Medical Devices in Yemen are disclosed over the Supreme Board for Drugs and Medical Appliances (SBDMA), the portion of the Ministry of Public Health and Population (MPHP).

Pre-Owned Medical Devices

There are no limitations on the import of used equipment, excluding that it is in good form. The convention liabilities are relieved if the hospital is a speculation project, but the user equipment must not be more than eight years old. Public health institutions buy used or refurbished Medical Devices when assessed competitively with new material. [19]

Fact Sheet

Competent Authority: Ministry of Public Health and Population (MPHP)
Legal Basis: No separate legal basis is present
Devices Classification: Yemen follows a gradient of classification system relatively than a risk-based classification system, portrayal a distinction between invasive and non-invasive devices
Time to approval: 3-6 months
Length of License: Medical Devices in Yemen are valid for five years

Role of a local agent in the GCC market

All the GCC states necessitate an employee of an indigenous or authorized representative (LR) as a relationship between the regulatory body and the device manufacturer. Overseas device manufacturers prerequisite to recognize a representative based in the member country of interest who will be accountable for smearing for device authorization over the indigenous regulatory body, if present. [20] The manufacturer must deliver the LR with all the credentials that are desirable to gratify the requirements for solicitation to the regulatory body. Local device manufacturers do not necessitate any additional representation and can interconnect with the regulatory agency directly. [21] The notable events of the LR embrace communicating with the regulatory body, smearing for device consent through the regulatory body, cooperating with the

supervisory authority concerning post-market surveillance accomplishments where vital, informing the regulatory body of any confrontational events associated with a device, notifying the end-users of any contrary measures and taking educative action to diminish further events up, and cooperating with parties elaborate in the dissemination and deal of the device within the state. [22] The optimal of an indigenous representative is a decisive one for the device manufacturer, as it is this individual that epitomizes the company's face not only to the regulatory body but also to physicians, facilities procurement personnel, and other stakeholders. [23] Electing an LR that has well-established associations with the indigenous community and competent staff and who enables an operative resource chain to sustenance distribution and sale to indigenous institutions, is consequently critical. [24]

DISCUSSION

GCC

• Highly dependent on imports for medical devices (80-97%)
• Healthcare has been mostly public with private players entering the market in recent years
• Wound care market outside of Saudi Arabia ($134mn) is tiny
• Regulatory approvals are required mostly follow CE standards
• Timeframe 3-7months
• Local agent is required
• Competitors primarily operate through distributors

Saudi

• 80% of the healthcare sector of the country is highly dependent on imports.
• The wound care market accounts for $134mn within the medical devices segment expected to reach $185mn by 2019
• The local medical device market is focused on manufacturing small items like a bandage, medical disposables, surgical gloves and hospital furniture.
• Government has endorsed US$28 billion for healthcare and social development

UAE

• Government's share in total healthcare expenditure is 74%
• Import of medical devices reached to US$733.3 million in 2014 doubling from 2007
• 97% of the UAE medical device market is dependent on imports
• The local medical device market is focused on manufacturing small items like a bandage, medical disposables, surgical gloves, orthopaedic aids and hospital furniture.

Kuwait

• Medical device market has witnessed double-digit growth over the last decade
• Highly import-dependent 90% of the device registrations belong to foreign manufacturers
• Market of <5% is accounted for by local medical devices
• >80% of total investment in the healthcare sector is contributed by government
• Regional production is mostly focused on essential items like bandages, gloves and consumables

Oman

• Highly dependent on for its medical devices needs with imports accounting for ~95%
• The market for advanced wound care is small with a limited number of international manufacturers catering to demand
• Molnlycke healthcare, Hollister Pharma and Lohmann & Rauscher are the market leaders.
• Large distributors provide to the entire country and are clustered in Muscat

Qatar

• The medical devices market is expected to grow from $220mn (2013) to $400mn (2018) at a compounded growth rate.
• The market for advanced wound care is small with a limited number of international manufacturers catering to demand
• While Qatar is a small market for medical devices, Per capita medical device spending is high, ranking second in the region.
• Imports recorded a steep rise of 41.6% in 2013, reaching their highest ever level

The auxiliary coordination of the principles within the region would consequently have a positive sway on the co-operation between these countries as well as on the relation between these countries and the disseminating nations.

CONCLUSION

Notwithstanding a profusion of hydrocarbon-based wealth, the drivers of the medical device industry in the GCC are still in fluctuation, with advances yet to be made in areas of organization, regulation, and repayment. All indicators, always, advise robust enduring progress, in charge of surges in population growth, disease burden, health care infrastructure, and insurance penetration. Most nations have on the first aspect more or less comparable necessities for registration of Medical Devices, and they are ruthless to harmonize their principles with the regulations of the most imperative disseminating economies such as EU and US/Australia and their International Regulatory Organizations. The use of international standards enables harmonized regulatory developments and world trade, as technology progresses; it is much serene to update principles than to opposing regulations. Appropriate advancement and periodic adjustment by proficient groups mark medical device standards capable and competent tools for supporting health care. Standards Bodies emerging or reviewing rules for use with medical devices must contemplate the aptness of such measures for acquiescence with the Critical Principles and determine which of the Vital Principles they gratify. The use of standards should preferably replicate existing, broadly pertinent technology while not dispiriting the use of new technologies.

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