MEDICAL DEVICE INDUSTRY TRENDS TO WATCH

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INTRODUCTION

The healthcare and medical industry are growing at a fast speed. The demand and supply are increasing along with the latest technologies making space for themselves. Fortunately, it is getting a warm acceptance, too, due to the ease and convenience it brings along.

The medical industry has many branches. One is the service-providing sector, and another is the product developers. The medical device manufacturers (developing product sector) works towards producing medical equipment and tools designed to diagnose and treat patients at the global healthcare level.

These medical devices range from simple tongue depressors to bandages and sophisticated programmed pacemakers. The list is endless of what all medical devices are developed. The main product categories include surgical instruments and devices, medical supplies (pharmaceutical), electro-medical equipment, diagnostic devices, and dental goods.

There are various reasons for making an influence on the demand and supply of medical devices. Few of them are listed below:

POPULATION

Population plays a vital role in deciding the demand and supply of medical devices. The aging population is one of the major represents the uprising demand for medical devices. As per the estimation of the U.S.

Census Bureau, the older adults of the U.S. were 49 million in 2016 (15 percent of the population). It is roughly expected to double by 2060 to 95 million (23 percent of the total population of the country.) The elderly population demands one-third of the entire healthcare usage.

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According to the UN projections, the global population of older adults will rise from approximately 607 million (8.2 percent of the world's population) in 2015 to 1.8 billion (17.8 percent of the world's population) by 2060. Europe's elderly demography is expected to reach about 29 percent of the population by 2060, making it the world's oldest region. Although Asia and Latin America still hold a younger demographic, these regions are expecting a drastic transformation over the next few decades.

HEALTHCARE EXPENDITURE

With the growth in demand in healthcare devices, the expenditure takes a hike. Demographic shifts can witness anticipated growth in total U.S. healthcare expenditure from $3.5 trillion in 2017 to $6.0 trillion in 2027, which is an average annual growth rate of 5.5 percent.

Healthcare spending percentage of GDP is expected to rise from 17.9 percent in2017 to 19.4 percent in 2027. With the coming years, investment in the healthcare industry will spike due to the ongoing increase in demand. Medicare has recorded an increase in the proportion of the total U.S. healthcare estimate.

Basically, at present, it provides healthcare benefits to approximately 60 million elderly and disables people. It is the most significant portion of total healthcare costs and has specified estimation too. Medicare has accounted for 25 percent of hospital expenditure, 30 percent of retail drug sales, and around 23 percent of physician services.

Due to the growing impact of Medicare on average healthcare consumption, other developments can have a potential outsized effect on demand and pricing for medical products and services.

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REIMBURSEMENTS AND THIRD-PARTY COVERAGE CLAIMS

The maximum customers of medical device companies are physicians who need the instruments for their patients.

They select the equipment based on its utility for the patients. In the developed economies, the customers are interacting with the manufacturers and deciding the pricing of medical devices. Device producing companies finally receive payments from insurers, who reimburse the healthcare providers for routine procedures rather than for any specific components. According to that, the medical device purchasing decision is not dependent on the pricing factor.

The third-party payers be it private, or government is keen to re-evaluate the payment policies to avoid the rise of healthcare costs. There are various elements of the ACA that are estimated to limit reimbursement growth for healthcare clinics and hospitals, which is the largest market for medical devices across the globe.

Lower reimbursement growth will cause hospitals to scrutinize the medicinal buying decision by adopting higher standards to evaluate the benefits of new devices, and by having a more disciplined behavior towards bargaining instances.

The gradual change of the healthcare delivery form from fee-for-service (FFS) to value models is likely to lead to lesser hospital admissions and further procedures. It gives bandwidth to cost-effectiveness and efficiency. Many professionals showed concern for the shift towards value-based services would encounter difficulties with the current administration. In November 2017, the CMS partially canceled the piled up payment programs for joint replacement and cardiac rehabilitation process. But, some suggested that CMS supports value-based services and want pilot programs to progress. In the end, lower reimbursement rates and reduced procedure rate is likely to confine pricing for medical device and equipment.

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The medical device industry has faced the plight of reimbursement globally due to increasing healthcare pricing. Many countries have put up price ceilings on specific medical devices and procedures, which could pull down the reimbursement rates of third-party payors, forcing them to reduce the product prices.

Industry participants are required to report manufacturing price and medical device reimbursement rates that are set based on markets like Germany, France, Japan, Korea, China, and Brazil.

The third-party payors consider specific medical devices reasonable or essential for operational purposes, creates hindrance that device developers and manufacturers must overcome in launching their medical devices to the market.

COMPETITIVE AND REGULATORY FACTORS

Logically, it is thought that the growth of medical technology companies is based on continual product innovation. This makes devices readily available for doctors and convenient to be used. It improves human health, and the result has been witnessed. To make a product successful, you need a significant R&D layout and some fortune. However, viable latest medical devices can enhance average selling prices, market penetration, and share in the market.

Government regulations help cut down the pressurizing competition in two ways: the firms that launch a new product can benefit from patent protection, and second, medical device design and development regulation can be clinically tested and approved.

Regulatory factors within the U.S.

In the U.S., the FDA usually guides the implementation of the second set of regulatory norms. For many simple devices, there's a low risk of FDA exempting it. Chances of the remaining devices require marketing authority from the FDA, which comes in two folds.

The premarket notice process requires the manufacturing firm to demonstrate that a new device is substantially equivalent to an existing medical device that is already approved and marketed in the U.S.

With the due help of the FDA, we can find an alternative pathway to manufacture devices that well-understood and substantial performance criteria.

The premarket approval or PMA is a strict process that is time-taking and slightly on the expensive end. It must be supported by valid scientific proof that entitles the collection of extensive technical, clinical, and manufacturing data. Once the PMA is completed and submitted, the FDA goes in-depth review method, which takes time within 180 days. Though the process is slightly longer and may require years to complete.

Regulatory factor outside the U.S.

The European Union (EU), along with more countries like Japan, Canada, and Australia all have strict regulatory norms similar to the ones of FDA. A medical device producing companies face a regulatory body across the EU. To be allowed to run through the market, the medical device must meet the requirements set forth by the EU medical device directive.

The medical devices must be claimed with a Conformité Européenne (CE) Mark certification before they are allowed to be launched and sold in that market. The CE mark certification validates that a device abides by all regulatory norms, including the safety standards. A set of rules and regulations is applied to every medical device to seek its maximum potential through doctors, patients, and other medical professionals. It should stand by the set of standards laid by the government.

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EMERGING GLOBAL HEALTHCARE MARKETS

The developing economies are claiming they are witnessing an increasing share of global healthcare consumption, including the medical device industry and related proceduresthe relative economic growth and expanding medical awareness and an increase in the aging population. As the global healthcare expenditure is showing a steady rise, sales to countries outside the U.S. will represent a potential space for domestic medical device producing companies.

As per the International Trade Administration, the global medical device sales are expected to spike by 6.4 percent annually between the years 2016 to 2020, touching the estimate of $440 billion.

America will be the world's most significant medical device producing market. The Asian and European markets are anticipated to expand too in the coming years.

CONCLUDING NOTE

The population shift produces the long-term market opportunities for medical device producers. Although controlling the uncontrollable cost is part of the responsibility for the government. The government of the U.S. may limit future price hike for incumbent products. It will instead provide a comprehensive global market with opportunities and revenue generation procedures.

Developing new products and services is risky and more resource-consuming compared to other growing sectors of the economy. However, the hindrances to entering in the form of the existing body provide relief from outraging healthcare industry competition, especially for newly thought products.

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