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Colombia Country Facts:

- Colombia is the third largest Latin American country by population (49.8m) and the fourth largest by GDP.
- Colombia has had an average economic growth of over 4% between 2001 and 2017 and grew 2.7% in 2018.
- Colombia was ranked number 3 in Latin America and the Caribbean for “Ease of doing business” in 2017 behind Mexico and Peru, and 59th in the world – according to the World Bank and the IMF.
- Colombia has access to 60 countries and more than 1.5 billion consumers through its network of trade agreements. Some of these agreements include the US, Canada, the EU, and South Korea
- Fixed investment is playing an important role in the economy, as it increases from 18.8% of GDP in 2008 to 29.0% in 2017.
- It is a country characterized by the expansion of the middle class and increasing foreign direct investment, due to improvement in the security environment.
- The approval of the peace deal in particular will improve Colombia's reputation amongst investors.
- Disposable incomes are rising, with the portion of households expected to be earning above the USD10,000 mark reaching almost 29.0% by the end of 2020. - According to BMI Forecast 2017.
- Colombia has continuously decreased its poverty levels, and the percentage of people considered to be middle class has doubled in the last 15 years.
- Colombia is the 37th member of the OECD – this means that public institutions in Colombia will meet standards of the developed world which gives more confidence to investors.
- Colombia was recognized as the first country in the region that best protects investors, obtaining the sixth worldwide position – World Bank.

Healthcare Market Overview:

The Colombian healthcare sector has developed rapidly over the last two decades. Strong investment in public sector healthcare and the country's growing non-communicable disease burden have driven growth in this sector.

- Colombian main health norms are the Health Statutory Act (Law 1751, 16 February 2015), establishing healthcare as a fundamental right for all citizens and Law 100 of 1993 that regulates social security system.
- Today 98% of the population has access to healthcare.
- Total healthcare expenditure as a percentage of GDP will be 8% (approx.) in 2019, while as a percentage of the National Development Plan budget will be 15%.
- Private healthcare spending accounted for 28.61% of total healthcare spending in 2018.
- There is an increasing burden of non-communicable diseases such as cardiovascular diseases, cancer, diabetes, and pulmonary affections.
- Colombia is the third largest medical device market and fourth largest pharmaceutical market in Latin America.
- In 2018, Colombia's per capita spending for pharmaceutical sales was \$75, while pharmaceutical spending as a percentage of GDP was 1.1%.
- The main medical devices sold in Colombia are of the consumable type (bandages, sutures, syringes, needles, first aid kits, gloves, etc.) accounting for 22.0% of total sales. The market relies on imports, despite strong domestic production focused on consumables.
- BMI predicts that the medical devices market in Colombia will reach £937 million by 2019. The market will register a growth of 9.8% 2017-2022.

Specific Market Opportunities:

- Colombia's x-ray technology market is expanding at 40% per year and is worth \$31 million USD.
- The implementation of tighter regulations on bioequivalence is driving rapid growth in the bioequivalent generic drug market.
- Health tourism in Colombia is growing rapidly at over 30% per year, bolstering private health spending.

Medical Device Sector in Colombia:

Colombia is the third largest medical device market in Latin America and the seventh most attractive market in the region in which to commercialise a medical device. This market represents around 5.0% of health expenditure, though per capita expenditure is considered low and consequently there is considerable growth potential. It is expected that the market record high single-digit market growth in 2019.

The market key drivers are the improving economic growth, as the FARC peace deal signed in November 2016, will offer long-term economic benefit, the strengthening of the Colombian peso and the consolidation of trading connections.

This market also benefits from the increasing burden of chronic diseases and the increasingly universal health coverage as Colombia has the third largest population in Latin America. In addition, the government continues to work on a healthcare reform, in the widening of the POS benefits and in healthcare infrastructure projects as the country's health system is in need of modernisation and expansion.

The medical devices market was import reliant in 2018, despite strong domestic production focused on consumables and the devaluation of the Colombian peso. The US is the dominant leading supplier in all major product ranges and the European Union accounted for USD259.4mn, equal to 25.7% of the total imports.

The Colombian medical device market will benefit from moderate economic growth. Medical device imports will be slower over this decade than in the last, while exports will remain low and continue to target neighboring Latin American markets. Multinationals will further consolidate the market, while stronger market competition will keep prices lower.

According to Business Monitor International, the Colombian medical device and equipment market is the fourth largest in Latin America, but it also has the second most growth in the region. It is expected that the medical devices market in Colombia will reach GBP 937.0 million by 2019. Medical devices and equipment are considered a key component to the provision of health services, representing about 60.0% of the elements used in hospitals. There are approximately 5,000 different types of medical devices and equipment, including products ranging from a needle or syringe to high-tech equipment such as CT scanners and implantable pacemakers.

The main medical devices sold in Colombia are of the consumable type (bandages, sutures, syringes, needles, first aid kits, gloves, etc.). This market segment accounts for 22.0% of total sales of medical devices, followed by the segment of orthopedic products and prostheses with 19.0%.

The participation of imports from the UK is minimum. The most important international supplier is the US. More than 80.0% of imports for this sector are represented by equipment and medical devices. Other products represent less than 15.0% of total imports. Again, the main supplier in this area is the US with a market participation of 32.0%, followed by China (12.0%) and Germany (10.0%).

Medical Device Registration and Approval in Colombia

Marketing medical devices in Colombia requires registration with the National Food and Drug Surveillance Institute (INVIMA), the country's medical device regulator. INVIMA is often seen as one of the most efficient yet strict registration bodies in the region. Once a product is registered with INVIMA, a process that, in many cases, can take as little 3 months, it is then easier to register with other registration bodies in other regional markets.

The first step towards INVIMA regulatory approval is to determine the correct classification of your medical device. Device classification in Colombia follows a four-tiered risk model (Class I, Class IIa, Class IIb and Class III) that is similar to the classification scheme used in Europe and Global Harmonization Task Force (GHTF) system. Classification of devices in Colombia follows a four-tiered risk model (Class I, Class IIa, Class IIb and Class III). If the device falls into a lower-risk category in Colombia (Class I or IIa), the importer may qualify for

an expedited review and achieve market entry in a shorter time. It is strongly recommended that companies process the registration under their name and not under the local distributor name, as if it is listed under the local distributor name, the UK company will not be able to change or add distributors, during the lifetime of the registration, which is 10 years.

Access to this market is not easy for newcomers. The market is mature and competitive, with many foreign firms selling medical equipment and medical products. It should be noted that registration procedures can often be challenging and may pose a barrier to entry into this market. U.S. imports make up the largest share of the Colombian market, accounting for around one-third of all medical equipment imports. Currently the strongest competitors are China, Germany, Mexico and Japan. China has been quickly increasing market share. Since the implementation of the FTA, tariffs on 96 % of U.S. medical equipment exports to Colombia went from an average of 7.6 % (ranging from zero up to 15 %) to zero. Colombia has FTAs with leading medical device producers such as the European Union and Canada, and is in negotiations of an FTA with Japan.

According to INVIMA, as of 2018, Colombia has 254 certified medical equipment manufacturers and 1,445 certified importers of medical equipment between national and international companies.

According to a study by America Economia Intelligence, seven of the 20 best hospitals and clinics in Latin America in 2017 are located in Colombia (followed by Brazil with five). In third place is Fundación Valle del Lili in Cali, in fifth is Fundación Cardiovascular de Colombia in Bucaramanga, in seventh Fundación Cardioinfantil in Bogota, in ninth Hospital Pablo Tobon in Medellin, in twelfth Centro Medico Imbanaco in Cali, in fifteenth Hospital Universitario de San Vicente in Medellin, and in seventeenth FOSCAL in Bucaramanga.

The best approach to enter this market is through distributors, as companies prefer to buy from someone located in Colombia that can provide after-sales services when needed. Although distribution and sales of imported medical equipment in Colombia is handled principally through importers, distributors, representatives, and agents, an increasing percentage of materials, supplies, and equipment, is imported directly by end-users. Manufacturers should maintain close contact with end-users and provide training and demonstrations so end-users can familiarize themselves with the equipment. This strategy is being used effectively in Colombia by European and Japanese manufacturers.

The Colombian watchdog authorities have been looking more closely at the claims in advertising for OTC products, dietary supplements and weight management products, as a consequence of a series of controversial products that promise amazing results in a short time and promote claims without having technical or scientific support. During 2016 companies such as Jorge Hane Laboratories and Genomma Lab Colombia were sanctioned by the Superintendencia de Industria y Comercio for misleading advertising.