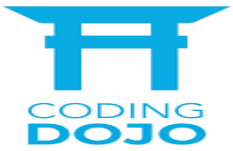


Medical Devices Licensed Non-Local Based on Hadoop Ecosystem

Prepared by:

Anfal Almohaimeed

Hajer Alhoqail

Norah Alamri

Nouf Almuwaisheer

Renad Alahmadi

Zainab Alhejji

27/11/2022

Content

1. Introduction

The Saudi Food and Drug Authority (SFDA): was established under the Council of Ministers in 2003, as an independent body corporate that directly reports to The President of the Council of Ministers. SFDA assumes the procedural, executive, and supervisory, which is carried out by the currently existing agencies. The main objectives of the SFDA are to ensure the safety of food, a drug for humans and animals, the safety of biological and chemical substances as well as electronic devices related to human health.

The medical devices Sector at Saudi Food and Drug Authority plays a pivotal role in ensuring the safety, efficacy, and performance of medical devices under comprehensive legislation and regulation. Medical Devices Regulation covers the entire lifecycle of medical devices starting from the idea, concept, and manufacturing process and ending by reaching the product to end users in addition to monitoring the performance and safe use of medical devices.

The sector performs a series of regulatory activities including reviewing the technical file of medical devices, clinical trials, postmarket surveillance plan, quality, and other technical documents prior to granting the marketing authorization. Moreover, monitoring the approved devices via a well-designed model of post-market surveillance focuses on the risk-based approach. analyzing field safety notices, adverse events, and other safety signals to ensure a high degree of safety and efficacy of Medical devices. Also, communicating effectively with the healthcare providers, and sharing a series of updated safety communication recommendations and vigilance reports. In addition, the sector oversight and monitors the medical radiation emitting devices, medical radioactive material, and radiation protection and safety at healthcare providers ensuring the compliance of these radiology departments, nuclear medicine, radiotherapy, dermatology, and dental clinics with SFDA regulatory requirements.[1]

Problem Statement: The Saudi health sector is the largest in the Gulf countries in terms of government spending, according to a report issued by Ardent Advisory and Accounting. The amount of import of medical devices is large in Saudi Arabia because KSA Medical Devices Market is a highly price-sensitive market relying heavily on imports due to the underdevelopment of the domestic medical device industry.

The problem that Saudi Arabia suffers from importing medical devices is the high cost and dependence on other countries. There are locally manufactured devices,

40% of locally manufactured devices are single-use devices made from plastic. Other products are reusable surgical instruments, detergents, solutions, general IVD, hospital furniture, and dental and ophthalmic products.

The reason why the lower share of domestic production is due to a lack of capabilities and fewer numbers of local manufacturing companies in the KSA. The investors in the medical industry need clarity of laws and regulations so that they can study risks better and more effectively.

2. Data Review

The medical devices licensed non-local dataset which was used in this case study has been taken from Saudi Arabia Open Data Portal for Saudi Food & Drug Authority [2]. It includes importing medical devices from 2014 to 2021. At the start of the project, we are going to have a clear and only one data frame to study. We have 10 variables and 75233 observations on the dataset.

Variables and Explanations :

Variable	Meaning
Trade Name	The brand name of a device medical
Generic Name	Rather than the brand name
Issue Date	The date when the original device is produced
Expiry Date	The date after which the device is no longer in effect
Manufacture Country	Name of Manufacture Country
Is Local Manufacturer	The medical device is manufactured locally or not
Jurisdiction	Name of legal Jurisdiction Country

Device Type	The device is Medical Device or IVD or AIMD
Classification	Classification risk of medical devices
Accessories	Are medical devices including accessories or not include

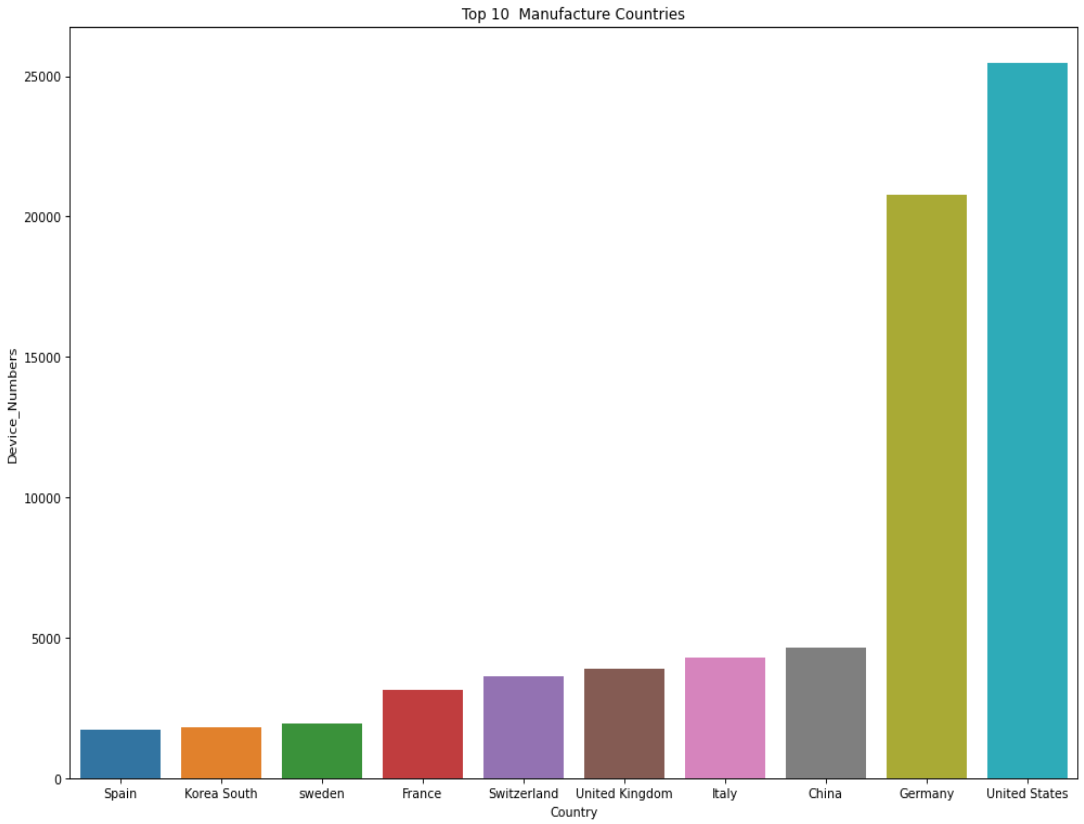
3. MapReduce Program

The goal of the case study: To build a MapReduce program that helps to count how many times the Manufacturer's Country and Jurisdiction Counties for medical devices were seen.

- First, we installed packages for running MapReduce jobs with Python.
- Second, we create the Mapper function and the Reducer function.
- Third, run the code as a terminal command in python.
- Fourth, run the code as a terminal command in Hadoop.
- Fifth, create a dictionary for countries and sorted via the top ten countries.
- Six, create a new data frame for the country and the number of devices they produce and sorted via the top ten countries.

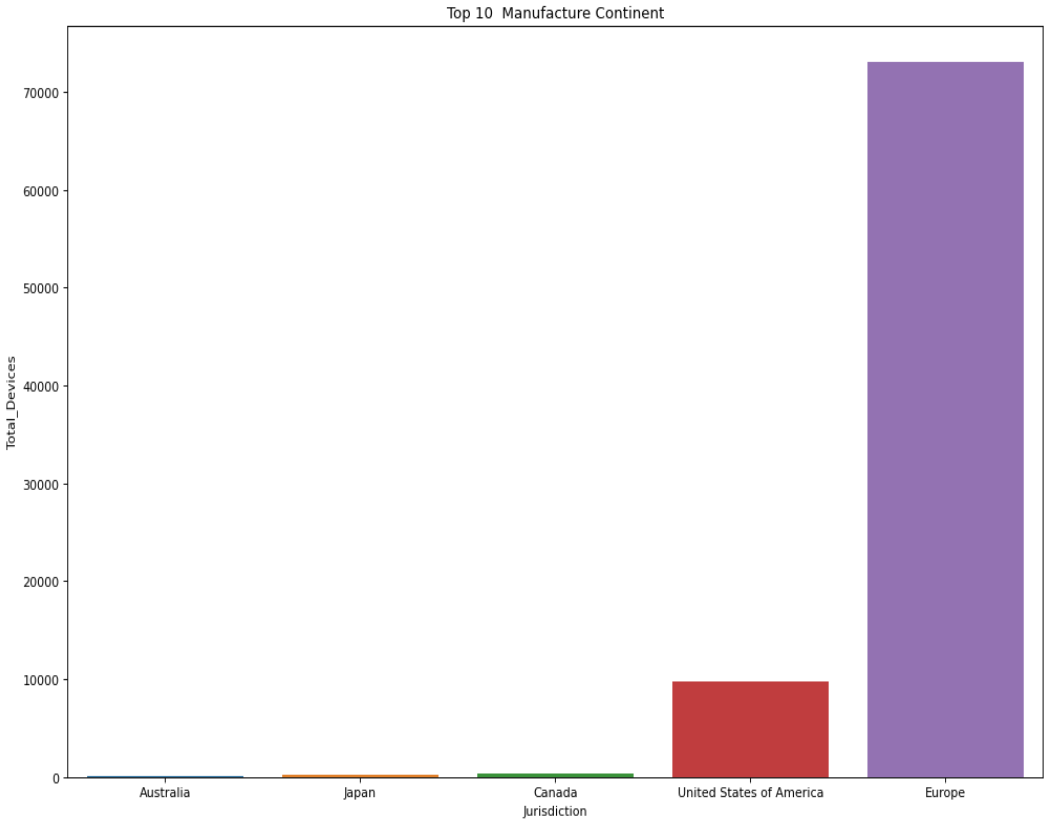
4. Result

- Top 10 Manufacture Countries



As we can see in the above chart, the United States, Germany, and China are the most country that Saudi Arabia imported medical devices from it.

- Top 5 Jurisdiction Countries



As we can see in the above chart, the Europe and United States are the most countries that have jurisdiction to allow to use of medical devices.

5. Conclusion

In the year 2022, Saudi Arabia signed a joint agreement to localize the medical device industry, which moves to the Kingdom of Saudi Arabia with 3 companies from Finland, Spain, and China, in the field of medical manufacturing, technical solutions, and health care. This agreement comes in support of “Made in Saudi Arabia” endeavors [3].

Saudi Arabia's efforts in the medical devices industry, setting executive regulations to be clear to investors and workers in the medical device sector. It aspires to develop the medical devices and supplies industry up to 15٪ , which includes consumer medical supplies, and simple, medium, and high sterilization devices. Increasing the rate of localization of the device industry transferring information in the field of medical supplies [4].

References

[1] https://www.sfda.gov.sa/

[2] https://data.gov.sa/Data/organization/general_authority_for_food_and_drug_administration

[3] https://www.spa.gov.sa/viewfullstory.php?lang=ar&newsid=2324080

[4] https://istitlaa.ncc.gov.sa/ar/health/sfda/MDSuppliesSystem/Pages/default.aspx