Journal of Pharmaceutical and Biological Research

Journal Home Page: www.pharmaresearchlibrary.com/jpbr

Research Article

A Study on medical devices as per EU and CHINA

Gudapati Sirisha*, Yarra Sai Phanindra, Adapa Haritha Naga Vara Lakshmi, Doonaboyina Raghava, Kavala Nageswara Rao

Department of Pharmaceutical Drug Regulatory Affairs, K.G.R.L College of Pharmacy, Bhimavaram-534201, Andhra Pradesh, India

ABSTRACT

Medical devices are used in many diverse settings, for example, by laypersons at home, by paramedical staff and clinicians in remote clinics, by opticians and dentists and by health-care professionals in advanced medical facilities, for prevention and screening and in palliative care. Such health technologies are used to diagnose illness, to monitor treatments, to assist disabled people and to intervene and treat illnesses, both acute and chronic. According to the current medical devices legislative framework, the EMA mainly provides scientific opinions to notified bodies through consultation procedures. The EU revised the laws governing medical devices and in-vitro diagnostics to align with the development of the sector over the last 20 years to ensure transparent and regulatory framework and maintain a high level of safety, while supporting innovation. The reason behind the changes of regulations is to strengthening of post-market surveillance requirements for manufacturers, improved coordination mechanisms between EU countries on vigilance and market surveillance. The reason behind the changes of regulations is to strengthening of post-market surveillance requirements for manufacturers, improved coordination mechanisms between EU countries on vigilance and market surveillance. The Chinese government has promulgated the New Regulations, which covers various perspectives of the regulatory regime of medical devices, such as device classification and registration, supervision of production and distribution, etc. The recent update is particularly comprehensive, with nearly every kind of device affected. Between this update from the NMPA and their recent electro-medical safety update, it is absolutely imperative for manufacturers marketing products in China to stay informed of which standards are changing. So they can take immediate action to comply with the new requirements. The new changes further specify the definition of a Market Authorization Holder and explain its responsibilities. The new 2018 draft amendment also explains the creation of a Unique Device Identification (UDI) system by the NMPA. By 2030, according to a 2018 KPMG report China is expected to have more than 25 percent share of the global medical device industry. Prior to Covid-19, China medical devices market was growing at twice the pace of the overall market, driven by the healthcare reform and overall rising demand for healthcare. Driven by the more powerful regulatory requirements under the New Regulations, the Chinese medical device market will become increasingly dynamic in the future.

Keywords: Medical devices, Regulations, MDR, NMPA, EMA, CFDA, PRC, Conformitte European

ARTICLE INFO

Corresponding Author
Gudapati Sirisha
Department of Pharmaceutical Drug Regulatory Affairs, K.G.R.L College of Pharmacy, Bhimavaram-534201, Andhra Pradesh, India.

Journal QR-Code

ARTICLE HISTORY: Received 7 July 2023, **Accepted** 10 Aug 2023, **Available Online** 25 Sept 2023

Citation: *Gudapati Sirisha, et al. A Study on medical devices as per EU and CHINA. J. Pharm. Bio. Res., 2023, 11(1): 29-33.*

C O N T E N T S

1. Introduction

- A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.
- Medical devices are used in many diverse settings, for example, by laypersons at home, by paramedical staff and clinicians in remote clinics, by opticians and dentists and by health-care professionals in advanced medical facilities, for prevention and screening and in palliative care. Such health technologies are used to diagnose illness, to monitor treatments, to assist disabled people and to intervene and treat illnesses, both acute and chronic.
- The Global Harmonization Task Force (GHTF) is proposing a harmonized scheme for medical device classification
- People rely on these devices every day and expect them to be safe and incorporate the latest progress in science and innovation. The current rules on the safety and performance of medical devices in the EU were harmonized in the 1990s. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the Commission proposed to update the rules to improve the safety of medical devices for EU citizens, create the conditions to modernize the sector and to consolidate its role as a global leader.
- Activities related to medical devices in the People's Republic of China (PRC), including their manufacturing, marketing, distribution, and sale, are mainly regulated by the Regulations on Supervision and Administration of Medical Devices (the Regulations) promulgated by the State Council and most recently amended in May 2017. The National Medical Products Administration (NMPA) is the governmental authority principally responsible for the supervision and administration of medical devices in the PRC.

2. Materials and Methods

Medical Device Regulation in Europe:

- Medical devices are products or equipment intended for a medical purpose. In the European Union (EU) they must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended. They are regulated at EU Member State level, but the European Medicines Agency (EMA) is involved in the regulatory process.
- Manufacturers can place a CE (Conformitte European) mark on a medical device once it has passed a conformity assessment.
- EMA regulatory role is limited to the assessment of certain categories of medical devices and in-vitro diagnostics, and in the context of medicinal products used in combination with a medical device.
- The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device.
- The length of proposed conditional extension of the transition periods depends on the type of device.
- The EU MDR came into force on May 26, 2021. The regulation places restrictions and reporting requirements on substances used in the design and manufacture of medical devices, excluding IV medical devices, in order to reduce the potential risks posed by some 2,000 substances

Medical device regulations in china:

- Medical devices are defined as any instrument, apparatus, material, or other article whether used alone or in combination, including the software necessary for its proper application.
- The **National Medical Products Administration (NMPA),** previously the **China Food and Drug Administration (CFDA),** is the institution responsible for pharmaceuticals and medical devices regulations in China.

3. Results and Discussion

Market Authorization Holder (MAH)

The new changes further specify the definition of a Market Authorization Holder and explain its responsibilities. Based on the new information put forth in the 2018 draft amendment, MAHs must ensure the quality of their products, show that their products meet all applicable requirements, submit self-inspection reports to relevant authorities every year, and maintain their products'

information in the NMPA's Unique Device Identification (UDI) database. For example, By 2030, according to a 2018 KPMG report China is expected to have more than 25 percent share of the global medical device industry. Prior to Covid-19, China medical devices market was growing at twice the pace of the overall market, driven by the healthcare reform and overall rising demand for healthcare.

Unique Device Identification

The new 2018 draft amendment also explains the creation of a Unique Device Identification (UDI) system by the NMPA. Main goal of this system is to improve the monitoring of medical devices and allow the tracking of these devices from the point of their manufacture to their distribution and use. The NMPA's UDI database will store the following information: the expiry and production dates of the device, the device model, and the alphanumeric UDI code placed on the device or its packaging.

Prioritization of Innovative Devices

The NMPA's new regulations clearly prioritize innovative medical devices. According to the 2018 draft amendment, foreign manufacturers will be allowed to import innovative devices into China without having to provide market entry approval certificates from the country the device was manufactured in.

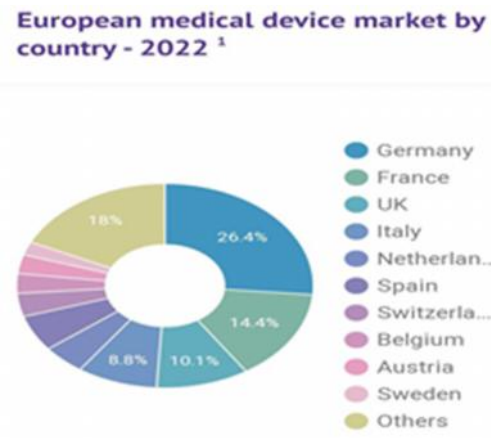


Fig.1

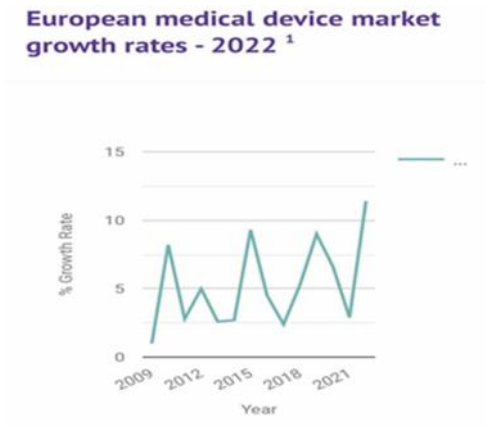


Fig.2

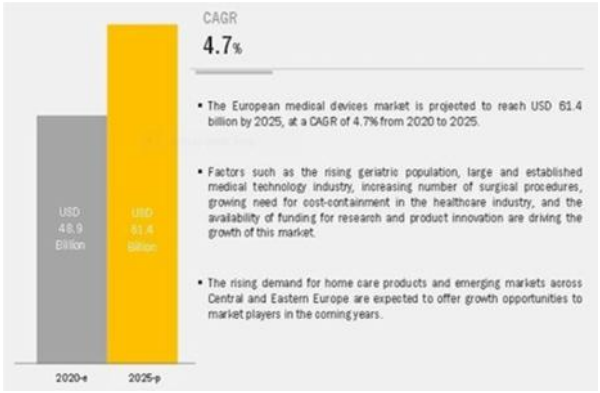


Fig.3

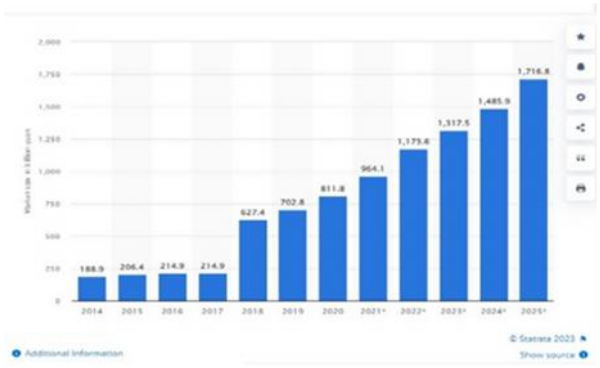


Fig.4

- At present moment, China's medical products market is rated second in the world. The market has been rising at around 20% per year since 2009, driven by both and increase in discretionary money and a population that is aging quicker than any other country's population.
- In China, rising prosperity is accompanied by an increase in the incidence of cancer, heart disease, diabetes, and other chronic illnesses among the population. As per a WHO estimate, China had almost three million newly diagnosed cancer cases in 2012, accounting for over 22% of the worldwide total, and 2.2 million cancer deaths, accounting for 27% of the global total.

Table 1: Registration of Medical Devices in Europe (EU)

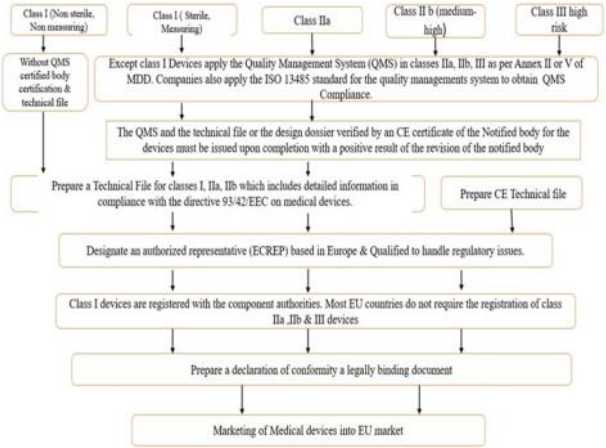
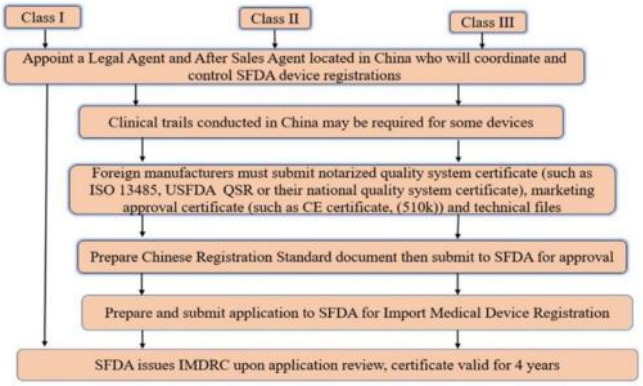


Table 2: Registration Process of Medical Device in China



4. Conclusion

- The Chinese government has promulgated the New Regulations, which covers various perspectives of the regulatory regime of medical devices, such as device classification and registration, supervision of production and distribution, etc.
- By 2030, according to a 2018 KPMG report China is expected to have more than 25 percent share of the global medical device industry. Prior to Covid-19, China medical devices market was growing at twice the pace of the overall market, driven by the healthcare reform and overall rising demand for healthcare.
- Driven by the more powerful regulatory requirements under the New Regulations, the Chinese medical device market will become increasingly dynamic in the future.
- In September 2022, the state council announced a loan incentive policy of CNY 1.70 trillion (US$246.40billion) as part of its economic stimulus package.
- This package is designed to renovate equipment in public buildings, universities, and medical facilities.
- According to the current medical devices legislative framework, the EMA mainly provides scientific opinions to notified bodies through consultation procedures.
- The reason behind the changes of regulations is to strengthening of post-market surveillance requirements for manufacturers, improved coordination mechanisms between EU countries on vigilance and market surveillance.
- In article 120.3 of the EU MDR the EU commission proposal contains suggested amendments to the EU MDR and In vitro diagnostics regulation (IVRD).
- High risk devices (Class 3 and 2b) will be required to conform to the EU MDR by 2027 in the near future.
- Medium and low risk devices (Class 2a and class1) will be required to conform to the MDR by 2028 in the near future.
- The EU revised the laws governing medical devices and in-vitro diagnostics to align with the development of the sector over the last 20 years to ensure transparent and regulatory framework and maintain a high level of safety, while supporting innovation.

5. References

[1] Press corner. European Commission - European Commission. New EU rules to ensure safety of medical devices. (5 Apr 2017). https://ec.europa.eu/

[2] Wilkinson B, van Boxtel R. The Medical Device Regulation of the European Union intensifies focus on clinical benefits of devices. Their Innov Regul Sci [Internet]. 2019; 2168479019870732.

[3] Times of Malta. Enhancing medical devices safety [Internet]. Times of Malta - Malta's Leading News Service since 1935. 2017 [cited 2022 Dec 12]. https://timesofmalta.com/articles/view/Enhancing-medical-devices-safety.645603

[4] Toshiko K. China's concern over population aging and health, 2006, https://www.prb.org/chinasconcernoverpopulationagingandhealth/#:~:text=Because%20chronic%20health%20problems%20becomeneed%20for%20long%2Dterm%20cae

[5] Woo J, Kwok T, Sze F, et al. Ageing in China: health and social consequences and responses. Int J Epidemiol 2002; 31(4): 772–775.

[6] Sciences CAoM. China's health care development report (2009-2014). Beijing, China: Sciences CAoM, 2015. [Google Scholar]

[7] https://www.morganlewis.com/pubs/2020/02/overview-of-medical-device-regulation-in- China

[8] Migliore, Antonio (2017). On the new regulation of medical devices in Europe. Expert Review of Medical Devices, 1–3.

[9] Lakshmi US, Sowjanya K, Revathi K, Shailaja P, Ratna JV, Daniel BA, Prashanth S. A Review on European Union New Medical Device Regulations-2017. Pharma Tutor. 2018 Feb 1; 6(2):9-14.

[10] The Medical Device and In Vitro Diagnostic Regulations (MDR and IVDR): Changes and Impacts. (19 Apr 2017). https://lne-america.com

[11] Katru S, Majety RPD, Veluchuri JP, Yallabandi SPD, Juturi RKR. New regulations on Medical Devices in European Union. International Journal of Drug Regulatory Affairs [Internet]. 15 Sept 2020 [cited 15 Sept 2020]; 8(3):11-21. Available from: http://ijdra.com/index.php/journal/article/view/394

[12] https://ryortho.com/2019/08/europe-dumps-its-regulatory-system-confusion-reigns/2/.

[13] https://chinameddevice.com/medical-device-regulations-in-china/.

[14] An overview of medical device regulations in China [Internet]. Reg Desk, Inc. 2019 [cited 2022 Dec 13]. https://www.regdesk.co/an-overview-of-medical-device- regulations-in- China/.