ejpmr, 2024, 11(10), 511-515

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

REGULATORY REQUIREMETNS FOR CARDIOVASCULAR DISEASE IN INDIA AS PER CDSCO COMPERISION WITH UNITED STATES

Ashok Kumar P.*, Gagana K. N., Ganashree H., Kavana T. S., Madhu Charan D. M. and Puneeth K. M.

Regulatory Affairs Department, Sree Siddaganga Institute of Pharmacy, First Left Cross, Third Block of Mahalakshmi Nagar, Railway Gate, 80 feet Road Batawadi, Tumkur-572103, Karnataka (India).

***Corresponding Author: Dr. Ashok Kumar P.**

Regulatory Affairs Department, Sree Siddaganga Institute of Pharmacy, First Left Cross, Third Block of Mahalakshmi Nagar, Railway Gate, 80 feet Road Batawadi, Tumkur-572103, Karnataka (India).

Article Received on 28/08/2024 **Article Revised on 18/09/2024** **Article Accepted on 08/10/2024**

ABSTRACT

This review outlines the burden of cardiovascular diseases (CVDs) and risk factors in India compared to the United States, explains potential reasons for these variances, and discusses methods to enhance cardiovascular health systems, and policies in India. Over the last 20 years, there has been an increase in the occurrence of CVD in India because of an expanding population, aging inhabitants, and a consistent CVD mortality rate adjusted for age. During the same period, the United States has seen a decrease in age-adjusted CVD mortality rates, but the decline is starting to level off. The decrease in CVD mortality in the United States is mainly a result of positive trends in population-level risk factors like tobacco use, cholesterol levels, and blood pressure, alongside advancements in secondary prevention and acute care. India must implement population-wide policies while also enhancing and integrating its local, regional, and national health systems to achieve similar improvements in reducing premature death and disability related to CVD. Ensuring all Indians have access to health care coverage that safeguards them from financial risks is important in upholding their right to health.

KEYWORDS: CVD, Mortality, Cholesterol.

INTRODUCTION

Cardiovascular disease (CVD) is a board term that encompasses conditions impacting the heart and blood vessels. This involves stroke and health problems that impact the heart. For instance, a heart attack, heart failure, or issue with heart rhythm. CVDs are responsible for the highest number of worldwide deaths annually, claiming approximately 17.9 million lives per year. Cardiovascular diseases (CVDs) encompass various heart and blood vessel disorders, such as coronary heart disease, cerebrovascular disease, rheumatic heart disease, and other related ailments.

Main duties

CDSCO's main duties involve different areas of pharmaceuticals:

- **Safety monitoring:** CDSCO monitor and investigates adverse drug reactions (ADRs) and implements measures to reduce risks linked to drugs and medical devices.

- **Public awareness:** CDSCO provides education on regulatory requirements, safety concerns, and quality assurance to healthcare professionals, the pharmaceutical industry, and the general public.

- **Collaboration:** CDSCO works with international regulatory bodies, agencies, and organization to promote alignment, exchange knowledge, and improve regulatory effectiveness.

- **Objectives:** CDSCO aims to guarantee that the public can obtain pharmaceutical product and medical devices that are safe, effective, and of high quality.

Roles of CDSCO

- Authorization of new medications and medical research studies
- Registration and licensing of imports are necessary.
- Permission granted for Blood Banks, LVPs, Vaccines, r-DNA products, and certain Medical Devices.
- Modification to the D &C Act and Regulations
- Prohibited of drugs and beauty products.
- Issuance of Test Licences, Individual License, and Export NOCs granted.

Reasons for cardiovascular illness

- Elevated blood pressure levels.

Tobacco use

- Elevated levels of cholesterol.
- Condition characterized by high blood sugar level.
- Lack of movement.

Important details

Globally, CVDs are the primary reasons for mortality. In 2019, approximately 17.9 million individuals passed away from cardiovascular diseases, accounting for 32% of total worldwide deaths. Out of all the fatalities, 85% resulted from heart attacks and strokes. More than 75% of deaths from CVD occur in low and middle-income countries. In 2019, 38% of the 17 million premature deaths (under 70) from noncommunicable diseases were attributed to cardiovascular disease. Preventing cardiovascular disease primarily involves targeting behavioural and environmental risk factors like tobacco use, unhealthy eating habits, obesity, lack of physical activity, excessive alcohol consumption. Detecting cardiovascular disease early is crucial to starting management with counselling and medications promptly.

Nations with Elevated CVD Rates

- The primary cause of deaths in the United States is cardiovascular disease. Elevated rates are attributed to a significant presence of risk factors such as obesity, hypertension, and diabetes.
- Russia has a high prevalence of cardiovascular disease due to elevated levels of smoking, alcohol consumption, and hypertension.
- India is experiencing a surge in cardiovascular diseases, mainly in urban regions, due to the rising prevalence of diabetes and hypertension.
- China is experiencing a rise in cardiovascular disease, particularly among the elderly, due to fast lifestyle changes and urbanization.
- Eastern European nations: Several countries in this area experience elevated levels of cardiovascular disease as a result of issues such as unhealthy eating habits, tobacco use, and alcohol intake.

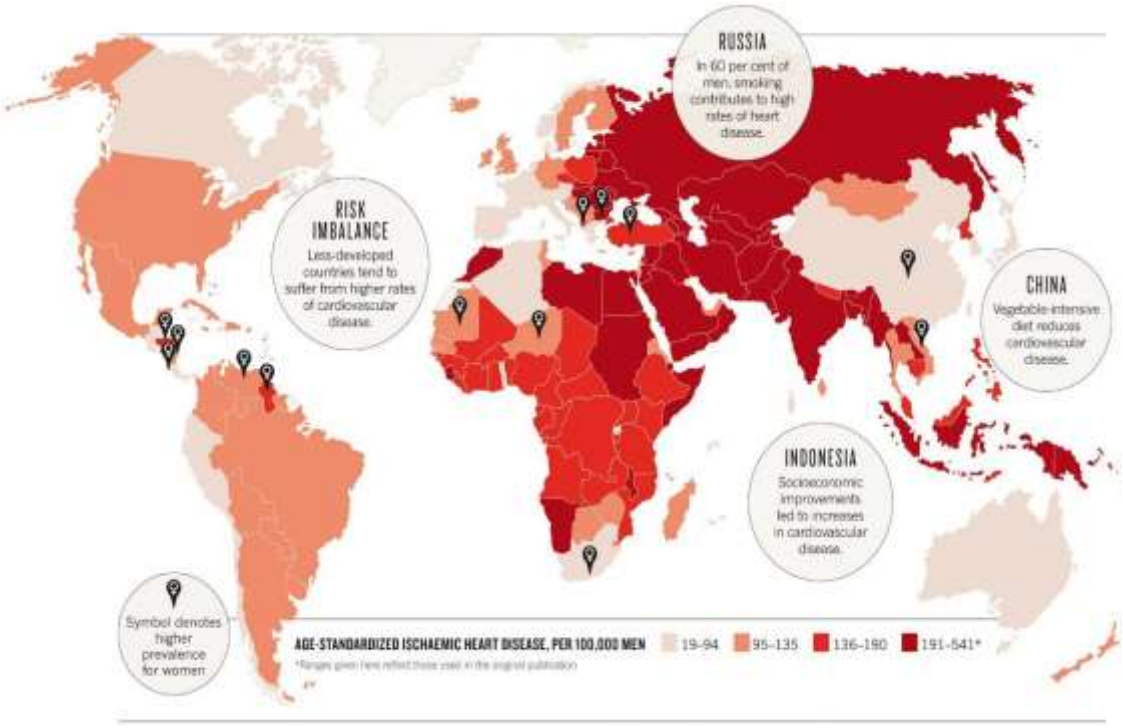

Figure no. 1: Global heart disease burden.

Main distinctions

Beginning age: CVD typically impacts younger people in India, in contrast to the US where it is prevalent among older demographics.

- Access to healthcare in the United States is typically superior in terms of advanced medical treatment however, affordability may still be a hindrance. In India, accessibility varies greatly based on where you are your socioeconomic standing.

Lifestyle and Diet: The problems with unhealthy diets and lifestyle are present in both countries, but they differ in specific because of cultural variations. The US consumes more processed food, while India struggles with traditional diets rich in facts and carbs.

Current Trends and Obstacles

United states: Continuing attempts to lower risk factors such as smoking, enhance diet, and boost physical activity. Nevertheless, the increasing rates of obesity continue to be a worry.

- India is continuously working to enhance healthcare accessibility and preventive measure, focusing on

tackling the increasing rates of diabetes and hypertension.
- Both nations are focused on enhancing knowledge, preventive strategies, and treatment choices for CVD however they encounter different obstacles due to their individual social, economic, and healthcare environments.

Medications prescribed for cardiovascular disease

1. Drugs for lowering high blood pressure
- ACE inhibitors such as Enalapril and Lisinopril lower blood pressure by relaxing blood vessels and decreasing the burden on heart.
- Angiotensin II leading to a decrease in blood pressure.
- Beta-Blockers like Metoprolol and Atenolol decrease the heart rate and the amount of blood pumped by the heart.
- Diuretics such as Hydrochlorothiazide and Furosemide aid in reducing blood pressure by assisting the body in removing salt and water.

2. Medications that inhibit platelet aggregation
- Aspirin prevents platelet aggregation, decreasing the chance of blood clot formation.
- Clopidogrel is frequently administered in combination with aspirin for patients who have had a stent placement or a heart attack.

3. Medications for blood thinners
- Warfarin hinders clotting factors to stop blood clot formation.
- Direct Oral Anticoagulants (DOACs) such as Dadigatran and Rivaroxaban are newer anticoagulants that need less monitoring compared to warfarin.

4. Medications for angina
- Nitrates, such as Nitroglycerin and Isosorbide Mononitrate, widen blood vessels and enhance blood circulation to the heart.
- Ranolazine is utilized to treat chronic angina by enhancing blood flow, thereby aiding the heart in functioning more effectively.

5. Medications for treating heart rhythm disturbances
- Class I medications such as Flecainide and Quinidine are considered sodium channel blockers
- Class II (Beta –Blockers, such as Propranolol): Diminish the impacts of adrenaline on the heart.
- Class III drugs such as Amiodarone and Sotalol fall under the category of potassium channel blockers.
- Class IV drugs, such as Verapamil, decrease heart rate by impacting the AV node.

Comparison of regulatory requirements of cardiovascular disease

	India	**United States**
Power of control	Central Drugs Standard Control Organization	Food and Drug Administration
Function	The CDSCO oversees the regulation of pharmaceuticals, medical equipment, and clinical studies India	The FDA oversees drugs, medical devices, and biologics to guarantee they are safe and efficient
Instructions	The CDSCO abides by the Drugs and Cosmetics Act, along with its corresponding rules	Regulated by the FDAC (Federal Food, Drug, and Cosmetic Act).
Process of obtaining consent	The authorization procedure involves Phase I-III Clinical Trials, followed by an evaluation. A new drug application (NDA) is necessary for introducing new medications. The duration of the process varies from several months to years, depending on the level of efficacy and safety shown in the trial data.	Before new cardiovascular drugs can be approved by the FDA, they must undergo thorough clinical trials in Phase I-III. The submission of the New Drug Application (NDA) initiates a review process that involves inspections and feedback from an conclusion within 10 months for regular application or 6 months for priority application
Surveillance after product is on market	The CDSCO oversees the safety of authorized medications, but the system is evolving. Encouragement of reporting adverse events is done through different channels, yet there may limitations in collecting comprehensive data.	The FDA possesses a strong monitoring system after products are on the market, which includes REMS for specific drugs and Medwatch for reporting adverse events.
Analysis of risk and benefits	The CDSCO assesses risks using clinical trial data there may be constraints on resource for	The FDA performs a thorough evaluation of risks and benefits of drugs, utilizing a wide range of data

	comprehensive analysis.	from trials, real-world evidence, and scientific sources to determine their safety and efficacy.
Difference in structure	CDSCO falls within the purview of the Ministry of Health and Family Welfare	While FDA operates as a separate agency. The regulatory system in the US is more decentralized
Chronological order	Half a year to a year	1-2 years
Financial support	While CDSCO depends on financial support from the government	The FDA sustains itself financially by collecting user fees.
Timelines for Approval	In general, the approval process may take longer because of bureaucratic procedures, but there are new reforms in place to speed it up.	The FDA often has more efficient process, especially for innovative therapies and devices, which results in quicker approval.

METHODOLOGY

1. Recognize regulatory framework

- Recognize regulatory agencies such as CDSCO in India and FDA in US.
- Familiarize yourself with regulations Comprehend laws and guidelines for drug and device approval.

2. Studies conducted before clinical trials

- Perform experiments in a controlled lab setting to evaluate the biological effects.
- Animal research conduct toxicology and pharmacokinetics experiments to assess safety and effectiveness.

3. Clinical trial design

- **Phase I Trials:** Involves testing safety, tolerability, and pharmacokinetics in either healthy subjects or small groups of patients.
- **Phase II Trials:** Evaluate the effectiveness and best dosage for patients with heart-related problems.
- **Phase III Trials:** Carry out extensive research to validate effectiveness and over see negative outcomes in comparison to usual therapies.

4. Management and Analysis of data

Utilize uniform techniques for collecting data on clinical outcome measures such as heart function and blood pressure.

- **Statistical analysis:** Establish statistical techniques in advance to assess trial outcomes and guarantee credibility.

5. Gathering of information

- **Qualitative information:** Conducting interviews and focus groups to collect in-depth patient viewpoints.
- Quantitative data encompasses surveys, medical records, biomarker analysis, and imaging studies such as echocardiograms and MRIs for researching.

6. Collaborative teamwork across disciplines

- Cardiovascular disease is a multifaceted health issue that necessitates a collaborative approach to tackle its numerous risk factors. This strategy may involve self-care assistance, local services, and medical data platforms.

Summary for heart disease

Compliance with regulations for treating and intervening in cardiovascular disease (CVD) is vital for safeguarding patient safety, effectiveness, and excellence. These rules, usually monitored by health agencies like the U.S. FDA, EMA, and other international regulatory organizations, concentrate on thorough testing and authorization of drugs, devices, and therapeutic procedures.

The process involves conducting preclinical studies, clinical trials, and post-market surveillance to consistently monitor results and negative reactions. Moreover, the changing landscape of CVD treatments, such as personalized medicine and advanced technologies (for example, medical devices or gene therapies), has resulted in a more flexible regulatory framework.

This guarantees that advancements in CVD treatment keep progressing to benefit patients, while upholding quality care and public health standards. In general, regulations for treating cardiovascular disease are crucial for improving care and reducing dangers, guaranteeing that treatments are secure, efficient, and available to patients who require them. Governmental bodies such as the FDA, EMA, and other global health authorities create these regulations to support patient safety and public health.

ACKNOWLEDGEMENTS

In performance our project work we needed the assistance and guidelines of the one deserving of our sincere gratitude. We are very happy that this mission has been completed, and we would like to thank you, Sir Dr. P Ashok Kumar, Professor Department of Pharmaceutical regulatory science, Sree Siddaganga College of Pharmacy, Tumkur for assigning this task to us, with the intention of expanding our knowledge.

Discloser of conflict of interest:

No conflict of interest to be disclosed.

REFERENCE

1. Key facts and overview of cardiovascular disease is:Available from: URL: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)
2. Types of cardiovascular disease and other risk factors: Available from: URL: https://www.nhs.uk/conditions/cardiovascular-disease/
3. Cardiovascular diseases according to 2023:Available from: URL: https://world-heart-federation.org/wp-content/uploads/World-Heart-Report-2023.pdf
4. Functions and Flow chart of CDSCO: Available from: URL: https://www.slideshare.net/slideshow/cdsco-ppt/162059242
5. Cardiovascular drugs that are Imported from other countries to US: Available from: URL: https://www.exportgenius.in/blog/us-top-import-source-of-cardiovascular-medicaments-remains-india-2021-553.php
6. Countries with high Cardiovascular Disease [CVD] rates: Available from: URL: https://www.nature.com/articles/493S2a
7. Risk factors of Cardiovascular Disease [CVD] Available from: URL: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09298-w
8. Introduction to cardiovascular disease: Available from: URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6994761/
9. Cardiovascular disease treatments: Available from: URL: https://g.co/kgs/vYEga3Y