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Recent advancement in regulatory requirements on hypertension in India as Per CDSCOIN comparison with Australia

Ashok Kumar P *, Dhanush K P, Darshan G V, Vikas S, Rakshith B M and Manoj Kumar M C

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st left cross, 3rd Block, Mahalakshmi Nagara, Batawadi, Tumakuru-572103, Karnataka, India.

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Abstract

Hypertension is a significant health issue in India and Australia, and it is associated with a considerable reduction in adverse cardiovascular disease outcomes. To decrease the prevalence of hypertension by 25% by 2025 and expedite access to treatment services, The India Hypertension Control Initiative (IHCI) was established. To enhance hypertension management in public sector clinics, the IHCI project was introduced in 2018-2019 in 26 districts in five Indian states: Punjab, Madhya Pradesh, Kerala, Maharashtra, and Telangana.

Both India and Australia, face significant public health issues related to hypertension, with 28.1% of adults suffering from the condition. With 28.1% of adults in both India and Australia suffering from hypertension, the two countries face serious public health challenges. India has made great strides toward controlling hypertension and improving regulatory policies. The prevalence in both countries varied significantly between urban and rural areas as well as between specific demographic groups. Men's awareness, treatment, and control in rural areas were substantially lower than women's. All of the national studies reported that the prevalence is lower in urban areas when compared to rural areas in Australia, but contrastingly prevalence is higher in urban areas when compared to rural areas. In rural areas, treatment and awareness are especially crucial. With a greater percentage of people suffering from hypertension, it is a serious problem in both countries. This paper examines and compares the regulatory requirements concerning hypertension in the two countries.

Keywords: Regulatory requirements; IHCI; Hypertension management; Awareness; Prevalence

1. Introduction

1.1. Regulatory body of India: Central Drugs Standard Control Organization (CDSCO)

The National Regulatory Authority (NRA) of India is the Central Drugs Standard Control Organization (CDSCO), which is housed within the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

Its headquarters are located at FDA Bhawan, Kotla Road, New Delhi, 110002, and it has seven laboratories, thirteen Port offices, six zonal offices, and four sub-zonal offices dispersed throughout the nation. and in charge of several regulatory obligations about medications, clinical trials, medical equipment, and vaccinations.

According to the Drug and Cosmetics Act, state authorities are primarily in charge of regulating the production, sale, and distribution of drugs, while the Central Authorities are in charge of approving new drugs, overseeing clinical trials conducted nationwide, setting standards for drugs, maintaining control over the quality of drugs imported, coordinating

* Corresponding author: Ashok kumar P

the work of State Drug Control Organizations, and offering expert advice to ensure uniformity in the enforcement of the Drug and Cosmetics Act. The Indian Drug Controller General approves licenses for certain drug categories, including blood and blood products, Fluids, Immunization, and Sera.

Figure 1 CDSCO Logo

1.1.1. Organization of CDSCO:

The Drugs and Cosmetics Act assigns the Central Government the authority to oversee the Central Drug Authority, which is the Central Drugs Standard Control Organization (CDSCO). Under its jurisdiction are multiple offices and laboratories. The primary duties of CDSCO are as follows.

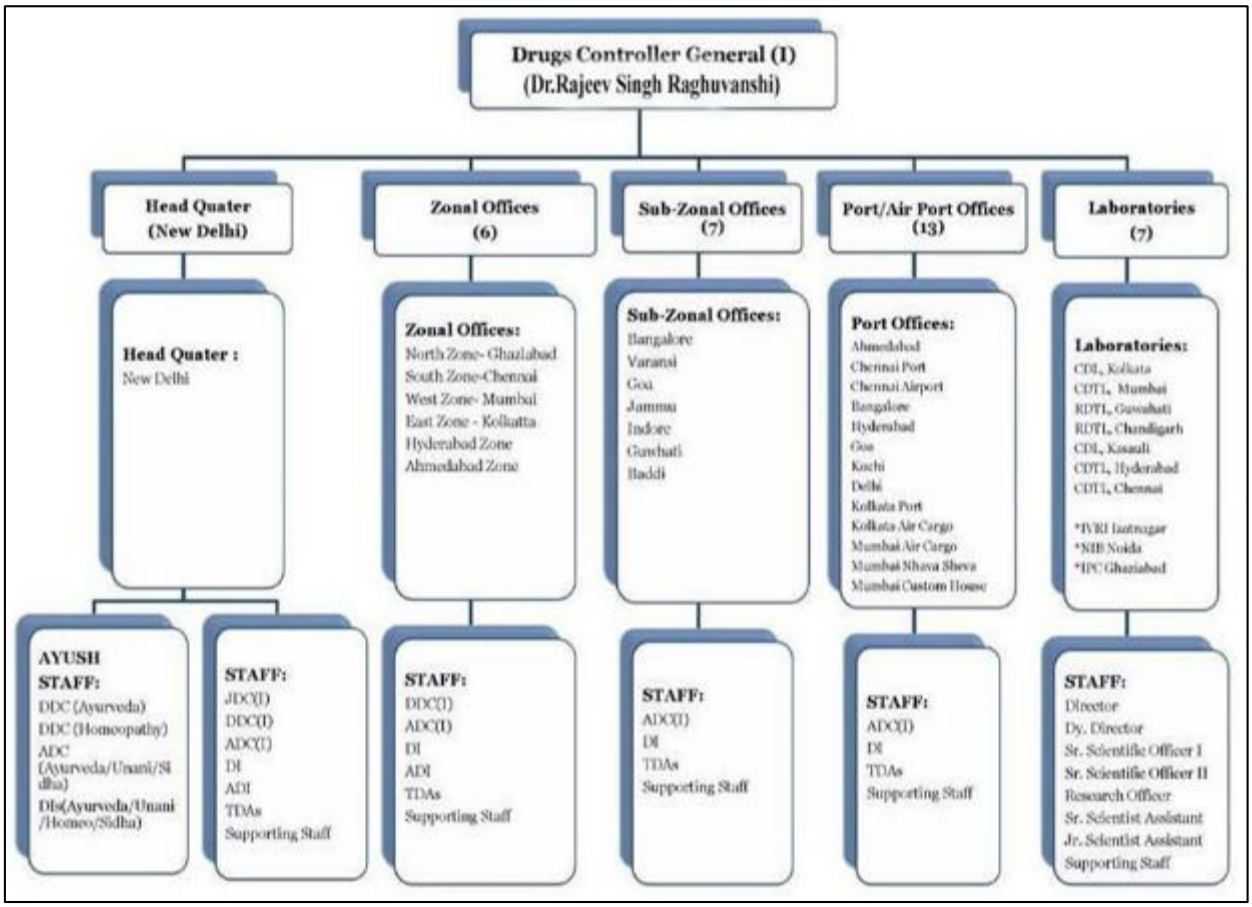

Figure 2 Organization of CDSCO

1.1.2. Functions of CDSCO:

The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for squaring functions assigned to the Central Government under the Drugs and Cosmetics Act CDSCO has several offices and laboratories under its control. The major functions of CDSCO include:

- Regulatory control over the import of drugs: CDSCO exercises regulatory control over the quality of drugs, cosmetics, and notified medical devices imported into the country Approval of new drugs and clinical trials: CDSCO is responsible for approving new drugs and clinical trials.
- Meetings of Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB): CDSCO convenes meetings of DCC and DTAB.
- Approval of certain licenses: CDSCO headquarters exercises the authority to approve certain licenses as Central License Approving Authority.
- Grant of licenses of specified categories of drugs: CDSCO is responsible for approving licenses of specified categories of drugs such as blood and blood products, I. V. Fluids, vaccines, and sera.
- Coordination of activities of State Drug Control Organizations: CDSCO provides expert advice to State Drug Control Organizations to bring about homogeneity in the enforcement of the Drugs and Cosmetics Act. Approval of Drugs: CDSCO is responsible for the approval of drugs, including new drug substances, additional strengths, additional indications, and modified release forms. The industry is required to submit comprehensive and rational documents to facilitate the review process by CDSCO.
- Licensing and Registration: CDSCO, along with state regulators, is responsible for conceding licenses for specialized categories of critical drugs, such as blood and Blood products. The organization also oversees the registration of bulk drugs and finished formulations.
- Control over Imported Drugs: CDSCO is responsible for certifying the quality of imported drugs in the country. This includes the requirement for a Free Sale Certificate, GMP Certificate of WHO guideline, or Certificate of Pharmaceutical Product (COPP) for imported drugs.
- Clinical Trials: CDSCO is responsible for the approval of clinical trials in India. Institutions conducting biomedical and health research are required to have an Ethics Committee (EC) that reviews and superintends the research. CDSCO must confirm the EC approvals for each participating site before approving the initiation of the study.
- Medical Devices: CDSCO is involved in various regulatory aspects of medical devices, including the grant of Certificate of Registration for a Notified Body for the audit of Class A and Class B Medical Devices. The organization also processes applications for the issuance of Market Standing Certificates, and Non-Conviction for Medical Devices, and handles post-approval changes and inspections of manufacturing sites for compliance with Quality Management Systems (QMS).
- Vaccine Development: CDSCO has specific regulatory guidelines for the development of vaccines, with special consideration for COVID-19 vaccines. These guidelines outline the thorough requirements and guidelines for the conduct of nonclinical and clinical studies and the approval of new vaccines.

1.2. Regulatory body of Australia: Therapeutic Goods Administration (TGA)

Figure 3 TGA Logo

The Australian government's Therapeutic Goods Administration (TGA), a branch of the Department of Health and Ageing, is in charge of policing therapeutic goods, which include prescription drugs, medical equipment, and blood and blood products. The TGA is the regulatory authority in Australia tasked with guaranteeing the efficacy, safety, and quality of medicinal products. It is an internationally respected industry regulator of therapeutic goods. The regulatory

framework within which the TGA operates is based on a risk management approach Therapeutic goods are evaluated before they are marketed by TGA. Monitoring of the products once they are in the market is also done by TGA. It also considers whether pharmaceuticals and medical equipment are appropriate for export from Australia. Therapeutic goods manufacturing units are also regulated by TGA to ensure they meet acceptable standards of manufacturing quality. An international team of manufacturing inspectors conducts audits of manufacturing facilities to guarantee the high quality of products supplied to Australia.

1.2.1. TGA Structure

It comes from the Health Product Regulating Group (HPRG) in the Australian Government Department of Health.

The TGA Regulatory offices are grouped into:

- TGA Executive Group
- Market Authorization Group
- Monitoring and Compliance Group
- Regulatory Support Group
- Office of Regulatory Integrity

TGA Executive Group:

The TGA Executive group has overall responsibility for the management of the TGA regulatory functions

The executive comprises of:

- TGA National Manager
- Principal Medical Adviser
- Principal Legal Adviser
- Chief Regulatory Officer
- Chief Operating Officer

Market Authorization Group:

The Market Authorization Group is responsible for the evaluation and authority of therapeutic goods to ensure they meet appropriate standards of quality and efficacy. It makes decisions on whether to approve or reject market authorization of medicines, medical devices, and blood and tissues that are imported, exported, manufactured, and supplied in Australia.

Monitoring and Compliance Group:

The Monitoring and Compliance Group is responsible for monitoring therapeutic goods on the Australian market to ensure that they comply with the requirements. Standards of quality, safety, and efficacy.

Regulatory Support Group:

It provides whole-of-agency regulatory support services to the TGA, this includes legal, finance, information technology and information management, communications, parliamentary, and human resource management services.

The Office of Regulatory Integrity (ORI):

It provides an independent and objective review and advisory service to assure the National Manager of the TGA that the TGA's financial and operational controls are operating in an efficient, effective, and appropriate manner and that its regulatory controls are operating in an efficient, effective and appropriate manner and are consistent with relevant legislative requirements.

1.2.2. Elements regulated by TGA

- Licensing and audit of manufacturers: Regulate the manufacturer licensing of medicinal products for human use. License holders are required to be compliant with the manufacturing principles of the act including compliance with GMP.
- Pre-Market assessment: This includes the study of toxicity and dosage form of medicines. The product risk is determined by the side effects, inappropriate self-medication, and adverse effects of prolonged use.

- Post-market regulatory authority: The essential elements of this risk-based approach include:
    - Monitoring of adverse reactions to medicines.
    - Targeted and random surveillance in the market.
    - An effective, responsible, and timely recall procedure.
    - Audit of GMP.
    - Effective controls for advertising of therapeutic goods.

1.3. Hypertension:

When your blood vessel pressure is excessively high (140/90 mmHg or higher), you have hypertension or high blood pressure. Although common, if left untreated, it can become a serious issue. High blood pressure sufferers might not experience the symptoms. The only way to find out is to get your blood pressure checked.

Different ranges of Blood Pressure are as follows:

- Normal blood pressure: Blood pressure is 120/80 mm Hg or lower.
- Elevated blood pressure: The top number ranges from 120 to 129 mm Hg and thebottom number is below, not above, 80 mm Hg.
- Stage 1 hypertension: The top number ranges from 130 to 139 mm Hg or the bottomnumber is between 80 and 89 mm Hg.
- Stage 2 hypertension: The top number is 140 mm Hg or higher or the bottom numberis 90 mm Hg or higher.

According to the World Health Organization (WHO), hypertension is currently the leading cause of death worldwide, accounting for 7.5 million fatalities annually. As a major risk factor for cardiovascular illnesses, hypertension accounts for about 30% of deaths worldwide, making it a widespread health problem affecting millions of people. Revision of the prevalence of hypertension in Australia and India, The Indian government has set a goal to reduce the prevalence of hypertension (high blood pressure) by 25% relative to 2025. To achieve this, the Indian Hypertension Control Initiative (IHCI) was launched to fast-track access to treatment services for over 220 million people in India who have hypertension. Hypertension is a significant health issue in Australia too, and is linked with a substantial reduction in cardiovascular disease outcomes. In Australia, a study was carried out in 2023 to examine the socioeconomic correlates of hypertension prevalence, awareness, treatment, and control at the individual and area levels. The study's findings revealed that the prevalence of hypertension was higher in less educated people, who had lower incomes and lived in rural areas. The study highlights how important it is to address socioeconomic disparities to enhance the region's ability to control hypertension. According to the studies, better blood pressure control and a decline in the prevalence of hypertension in the area depend on improving adherence to treatment regimens and addressing socioeconomic disparities.

2. Comparative Analysis of Hypertension Prevalence and Management Strategies, and Regulatory Requirements, in India and Australia

2.1. Hypertension Prevalence and Management Strategies

Firstly, the prevalence of hypertension differs significantly between the two countries, India and Australia. According to a study, the hypertension prevalence in India is around 28.1%, while in Australia, it is 36.5%. These rates are equivalent to those reported in high-income countries. In 2020, elevated blood pressure was responsible for 8% of the Australian total burden of disease and is one of the most prevalent risk factors for cardiovascular disease. Rural Australians have higher rates of hypertension (38.5%) compared to metropolitan areas (34.5%). Rural residents are more likely to have risk factors such as obesity, physical inactivity, and smoking [8].

Second, initiatives have been put in place in Australia and India to improve hypertension patients' access to medications. The governments of Australia and India have both undertaken initiatives to improve medication accessibility, and both have developed cutting-edge protocols for the diagnosis, management, and goals of hypertension. According to these guidelines, healthcare providers should be given evidence-based guidelines for managing hypertension. It is recommended by both Australia and India that all patients with hypertension make the necessary lifestyle changes. This covers dietary adjustments, consistent exercise, and stress reduction methods. There are, however, some variations in the rates at which hypertension switches between the two nations. Although the information provided does not specify the exact control rates, it is mentioned that Australia has lower levels of blood pressure control and awareness than India.

According to a 2015–2021 study, 58% of current cases of hypertension in India are undiagnosed; these cases are more common in middle-aged and male individuals, those with lower levels of education, those in lower wealth quintiles, people who are STs, and those who live in rural areas. In order to decrease the prevalence of hypertension by 25% by 2025 and expedite access to treatment services, the India Hypertension Control Initiative (IHCI) was established[2]. A nationally representative study found that at least one in four adults in India have hypertension, but only 12% of the population has their blood pressure under control. Uncontrolled blood pressure is a major risk factor for cardiovascular diseases. A 2019 study conducted in Australia discovered that patients with hypertension had high morbidity and insufficient blood pressure control as a result of their poor adherence to treatment plans. According to a 2023 study, people who live in rural areas, have lower incomes, and have less education are more likely to have hypertension. With 28.1% of adults in both Australia and India having hypertension, these two countries have serious public health issues. Significant progress has been made in recent years in India and Australia regarding the regulatory frameworks pertaining to hypertension. The Central Drugs Standard Control Organization reports that India has improved regulatory actions and addressed hypertension with notable progress. Recognizing the high prevalence of hypnosis is one of the main improvements in regulatory requirements in India[1].

2.2. Regulatory requirements:

2.2.1. Regulatory requirements for manufacturing drugs for hypertension in India:

Manufacturing drugs for hypertension in India comes with several regulatory requirements. The Central Drugs Standard Control Organization (CDSCO) is the primary regulatory body overseeing the pharmaceutical sector.

Key Regulations:

- Drug Price Control Order (DPCO): The National Pharmaceutical Pricing Authority (NPPA) controls prices of essential medicines, including those for hypertension.
- Good Manufacturing Practices (GMP): Compliance with GMP guidelines ensures quality standards in manufacturing.
- Bioavailability and Bioequivalence Studies: Mandatory for certain drugs to demonstrate efficacy and safety.
- Labelling and Packaging: Regulations require printing generic names in larger font sizes than brand names.

Licensing and Approval:

Manufacturers must obtain licenses from state or central authorities, depending on the type of drug. The CDSCO has streamlined regulatory procedures, introducing an online licensing system called SUGAM.

Medical Devices Rules: Separate rules govern medical devices used in hypertension treatment, requiring registration and compliance with safety and performance standards.

Pricing and Marketing:

- Price Controls: The NPPA regulates prices of essential medicines, including hypertension drugs.
- Uniform Code of Pharmaceutical Marketing Practices (UCPMP): Guidelines govern marketing practices, including gifts, hospitality, and claims.

These regulations aim to ensure the affordability, quality, and safety of hypertension medications in India.

2.2.2. Regulatory requirements for sales of drugs for hypertension in India:

Regulatory requirements for selling hypertension drugs in India are quite comprehensive. The India Hypertension Control Initiative (IHCI) has adopted standardized treatment protocols recommended by the World health Organization.

Key Regulatory Requirements:

- Mandatory Registration: Blood pressure monitoring devices require registration in India, effective January 1, 2021.
- Standard Treatment Protocols: The IHCI has standardized drug- and dose-specific hypertension treatment protocols.
- Good Manufacturing Practices (GMP): Compliance with GMP guidelines ensures quality standards in manufacturing.

- Labelling and Packaging: Regulations require printing generic names in larger font sizes than brand names.

Additional Guidelines:

- National List of Essential Medicines (NLEM): Lists essential medicines, including those for hypertension.
- Drugs and Cosmetics Act, 1940: Regulates the import, manufacture, distribution, and sale of drugs in India
- National Pharmaceutical Pricing Authority (NPPA): Controls prices of essential medicines.

Banned and Prohibited Drugs:

- The Drugs Controller, India, prohibits the manufacture and sale of certain drugs.
- These regulations aim to ensure the safe and effective management of hypertension in India.

2.2.3. Regulatory requirements for importing drugs for hypertension in India:

Importing drugs for hypertension into India comes with several regulatory requirements. To start, you'll need to obtain an import license from the Central Drugs Standard Control Organization (CDSCO). This license ensures that the imported drugs meet India's safety, efficacy, and quality standards.

Required Documents and Forms:

To obtain the import license, you'll need to submit the following documents and forms:

- Covering Letter.
- Original Power of Attorney.
- Copy of Import Permission for new drugs (Form 45 for formulations or Form 45A for new bulk drug substances).
- Copy of Wholesale License (20B/21C) or Manufacturing License of the Indian agent/corporate office address.
- Authorization Letter
- Schedule D (I) and Undertaking.
- Schedule D (II) and Undertaking
- Copy of Original Notarized/Attested/Apostilled documents.

Registration Certificate:

It is mandatory to obtain a Registration Certificate from the CDSCO, which is valid for three years and must be renewed before expiration. This certificate confirms that the imported drugs meet India's regulatory standards.

Additional Requirements

- New Drug Approval: If the drug is new, you'll need to obtain approval from the CDSCO before importing.
- Clinical Trials: If required, you'll need to conduct clinical trials and submit the data in Form 44.
- Fee Payment: You'll need to pay the required fees for registration, import license, and testing.

Authorized Agent:

- As an overseas supplier, you'll need to appoint an authorized agent in India to facilitate the import process. The agent must have a valid wholesale license to sell and distribute the imported drugs.
- By following these regulatory requirements, you can ensure a smooth and compliant import process for hypertension drugs into India.

2.2.4. Regulatory requirements for manufacturing drugs for hypertension in Australia:

To manufacture hypertensive drugs in Australia, you must comply with the Therapeutic Goods Administration's (TGA) regulatory requirements. Here's an overview:

Licenses and Approvals:

- Manufacturing License: Obtain a license from the TGA to manufacture therapeutic goods, including hypertensive drugs.
- Good Manufacturing Practice (GMP) Certification: Comply with TGA's GMP standards for medicinal products.

- Therapeutic Goods Registration: Register your hypertensive drug with the TGA's Australian Register of Therapeutic Goods (ARTG).

Quality and Safety Requirements:

- Active Pharmaceutical Ingredient (API) sourcing: Ensure API quality and authenticity.
- Finished Product Testing: Conduct testing for identity, purity, and potency.
- Stability Testing: Demonstrate product stability over time.
- Labelling and Packaging: Comply with TGA labelling and packaging requirements.

Regulatory Compliance:

- TGA's Therapeutic Goods Act 1989: Comply with the Act and associated regulations.
- TGA's Therapeutic Goods Regulations 1990: Adhere to regulations governing manufacturing, testing, and labelling.
- Australian Standard AS 4082: Comply with standards for GMP in medicinal product manufacturing.

Documentation and Reporting:

- Product Information Document: Provide detailed information about the product.
- Consumer Medicine Information (CMI): Supply CMI leaflets with product packaging.
- Adverse Event Reporting: Report adverse reactions to the TGA.

Inspections and Audits:

- TGA Inspections: Undergo regular inspections to ensure compliance with GMP and regulatory requirements.
- Audits: Conduct internal audits to maintain quality and compliance.

2.2.5. Regulatory requirements for sales of drugs for hypertension in Australia:

To sell hypertensive drugs in Australia, you must comply with the Therapeutic Goods Administration's (TGA) regulatory requirements:

Prescription Medicine Requirements:

- Registration: Hypertensive drugs must be registered on the Australian Register of Therapeutic Goods (ARTG).
- Schedule: Ensure the medicine is classified correctly under the Poisons Standard (e.g., Schedule 4, Prescription Only Medicine).
- Labelling: Comply with TGA labelling requirements, including warnings and precautions.

Over-the-Counter (OTC) Medicine Requirements:

- Listed or Registered: OTC hypertensive medicines must be listed or registered on the ARTG.
- Labelling: Comply with TGA labelling requirements for OTC medicines.
- Advertising: Ensure advertising complies with the Therapeutic Goods Advertising Code.

Pharmacy and Sales Requirements:

- Pharmacy License: Retailers must hold a pharmacy license.
- Trained Staff: Ensure staff are trained on hypertensive drug use and safety.
- Dispensing: Dispense prescription medicines by TGA and state/territory regulations.

Safety and Monitoring Requirements:

- Adverse Event Reporting: Report adverse reactions to the TGA.
- Recall Procedures: Establish recall procedures.
- Quality Defect Reporting: Report quality defects to the TGA.

2.2.6. Regulatory requirements for importing drugs for hypertension in Australia:

To import hypertensive drugs into Australia, you must comply with the Therapeutic Goods Administration's (TGA) regulatory requirements:

Pre-Import Requirements:

- Sponsorship: Appoint an Australian-registered sponsor (company or individual) responsible for the importation and compliance.
- Therapeutic Goods Registration: Ensure the hypertensive drug is registered on the Australian Register of Therapeutic Goods (ARTG).
- Import License: Obtain an import license from the TGA for each shipment.

Documentation Requirements:

- Import Declaration: Submit a declaration to the TGA for each shipment.
- Commercial Invoice: Include product information, quantity, and country of origin.
- Certificate of Analysis: Provide certificates for each batch.
- Product Information Document: Include detailed information about the product.
- Labelling and Packaging: Comply with TGA labelling and packaging requirements.

Regulatory Compliance:

- Therapeutic Goods Act 1989: Comply with the Act and associated regulations.
- Therapeutic Goods Regulations 1990: Adhere to regulations governing importation, testing, and labelling.
- Australian Standard AS 4082: Comply with standards for Good Manufacturing Practice (GMP).

Testing and Certification:

- Testing: Conduct testing for identity, purity, and potency.
- Certification: Obtain certification from the manufacturer or a recognized testing authority.

TGA Clearance:

- Electronic Entry Processing: Submit import declarations through the TGA's Electronic Entry Processing (EEP) system.
- TGA Assessment: The TGA assesses the import declaration and documentation.

Post-Import Requirements:

- Storage and Distribution: Store and distribute products by GMP.
- Adverse Event Reporting: Report adverse reactions to the TGA.
- Recall Procedures: Establish recall procedures.

2.3. General Comparison of Hypertension in India and Australia:

Table 1 General Comparison of Hypertension in India and Australia

Comparison	**India**	**Australia**
Regulatory body	Central Drugs Standard Control Organization (CDSCO)	Therapeutic Goods Administration (TGA)
Regulated under	Drugs and Cosmetics Act,1940	Therapeutic Goods Act,1940
Focuses on	Product approval, Licensing, and Monitoring	Risk-based evaluation and Post-market surveillance
Clinical Trials	Required for certain products	Required for all products
Approval Process	Centralized	Decentralized
Fees	Lower (INR 50,000 – 5,00,000)	Higher (AU$1,500 – 10,000)
Post-market surveillance	Limited	Comprehensive
Product Registration	6-12 months	4-6 months

Clinical trial approval	3-6 months	1-3 months
Hypertension prevalence	29.8% (Urban) 25.3% (Rural)	34.5%(Urban) 38.5%(Rural)
Hypertensive individuals	200 million	6.5 million
Prevalence comparison	Higher prevalence in urban areas than in rural areas	Higher prevalence among Indigenous Australians than in Rural Australians
Health care system	Limited access to healthcare, particularly in rural areas	Well-established healthcare system
Treatment rates	Low treatment and awareness rates	High treatment rates
Medicines used	Traditional medicines	Emphasis on lifestyle modifications and medication adherence

3. Conclusion

- Hypertension is a significant health issue in Australia, associated with reduced cardiovascular disease outcomes. Usually, hypertension goes unnoticed due to improper knowledge. The major reasons include lacking improved management strategies and regulatory improvement. The symptoms and risk factors associated with the Hypertension are studied.
- The regulatory bodies of India and Australia that are CDSCO and TGA with their organization, functions and regulatory requirements for the sale, manufacture and import of antihypertensive drugs are studied.
- The prevalence is higher in rural areas and specific demographic groups than urban areas in Australia but contrastingly lower in rural areas when compared to urban areas in India. The Indian Hypertension Control Initiative (IHCI) implements certain strategies such as standard treatment, consistent drug supply, team-based and patient-centered care, and an information system.
- The drugs which are used to treat hypertension and how to control the occurrence of higher blood pressure is studied.
- Different kinds of the schemes that are brought out by the different governments and the regulatory bodies to reduce the occurrence of hypertension and providing the basic to advanced knowledge regarding hypertension.
- This paper highlights the importance of improved hypertension management, including screening diagnosis, treatment, lifestyle modification, and patient education.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest to be disclosed.

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