

**REGULATORY REQUIREMENTS FOR THE APPROVAL OF ANTICANCER DRUGS AS
PER CDSCO IN INDIA COMPARISON WITH AUSTRALIA****Dr. Ashok Kumar P.*, Pallavi J., Punya K. S., Rakshitha B. R., Priyanka M., Sharanya J.**

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batawadi, Tumkur-572103. Karnataka, India.

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

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block, Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road, Batawadi, Tumkur-572103. Karnataka, India.

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ABSTRACT

In India, cancer is a significant and growing public health concern, with the number of new cases projected to rise substantially in the coming years. The country's pharmaceutical industry mainly focused on developing affordable generic drugs which includes a range of chemotherapeutic drugs and targeted treatments. This has been an important technique for increasing access to vital cancer treatments for a large population. The Indian anti-cancer drug market is experiencing rapid growth, due to increasing prevalence of cancer, enhancing government programs to lower drug costs and healthcare infrastructure. The Central Drug Standard Control Organization (CDSCO) is the major regulator of medications, particularly anticancer therapies. The CDSCO is in charge of approving new drugs and clinical studies as per the Drugs and Cosmetics Act and the New Drugs and Clinical study Rules 2019.^[1] In Australia, cancer is still the biggest reason to death where its survival rates have increased to around 71%. The nation's approach to treatment is shifting from traditional chemotherapy to targeted and personalized therapies, including advanced immunotherapies and hormonal treatments. The "Pharmaceutical Benefits Scheme" (PBS) frequently provides incentives for the availability of specific pharmaceuticals, hence boosting patient access. The Therapeutic Goods Administration (TGA) is Australia's regulating body. TGA thoroughly evaluates novel anticancer medications for safety, quality, and efficacy before they are listed on the 'Australian Register of Therapeutic Goods' (ARTG).^[2]

KEYWORDS: India, CDSCO, TGA, Anticancer, Australia, ARTG.**1. INTRODUCTION**

Uncontrolled proliferation and spread of aberrant cells are the cause of cancer, a complicated set of disorders.

These cells can form tumors, invade surrounding tissues and metastasis or spread to other parts of the body. There are over 100 types of cancer, which are broadly categorized based on the type of cell they originate from. There are various types of cancers. It includes: Carcinoma, Sarcoma, Leukemia, Lymphoma and Myeloma, Brain and Spinal Cord Cancers. Cancer treatment depends on the type and stages of Cancer. A type of treatment that uses drugs or other substances to treat cancer and most of the people receive combination of treatment some are "local" treatment like surgery, radiation therapy which are used to treat a specific tumor. Systemic treatment such as chemotherapy, immunotherapy, or targeted therapy etc.^[3]

An anticancer drug is a medication used to treat cancer by targeting and destroying, shrinking, or slowing the growth of cancer cells. These drugs are a cornerstone of

cancer treatment and are often used in combination with other therapies like surgery or radiation.

Anticancer treatments, also known as oncology. The goal of this study is to destroy cancer cells, preventing their growth and /or manage the symptoms of the disease. They work by targeting the unique characteristics of cancer cells, such as their rapid division, their ability to evade the immune system and their altered metabolism. Many patients use natural supplements as a form of complementary and alternative medicine (CAM) to help manage the side effects of conventional treatments and improve their overall well-being. Under the direction of your oncology team, it is important to utilize them as an adjuvant therapy rather than a substitute. Nutrients including zinc, ginseng, glutamine, and ginger are utilized to counteract the side effects of treatment. The supplements with potential anticancer properties include curcumin, green tea, zeaxanthin, flavonoids and isoflavones. Some of the precautions and Dangers involved in this like: - The use of supplements during cancer treatment is not without risks. It is essential to discuss any and all supplements with your doctor before

taking them, some supplements can interfere with the way chemotherapy drugs are metabolized in the body, making them less effective or more toxic, Antioxidants

like vitamins A, C, and E may protect cancer cells from the damage intended by chemotherapy and radiation.^[4]

2. CLASSIFICATION OF ANTICANCER DRUGS

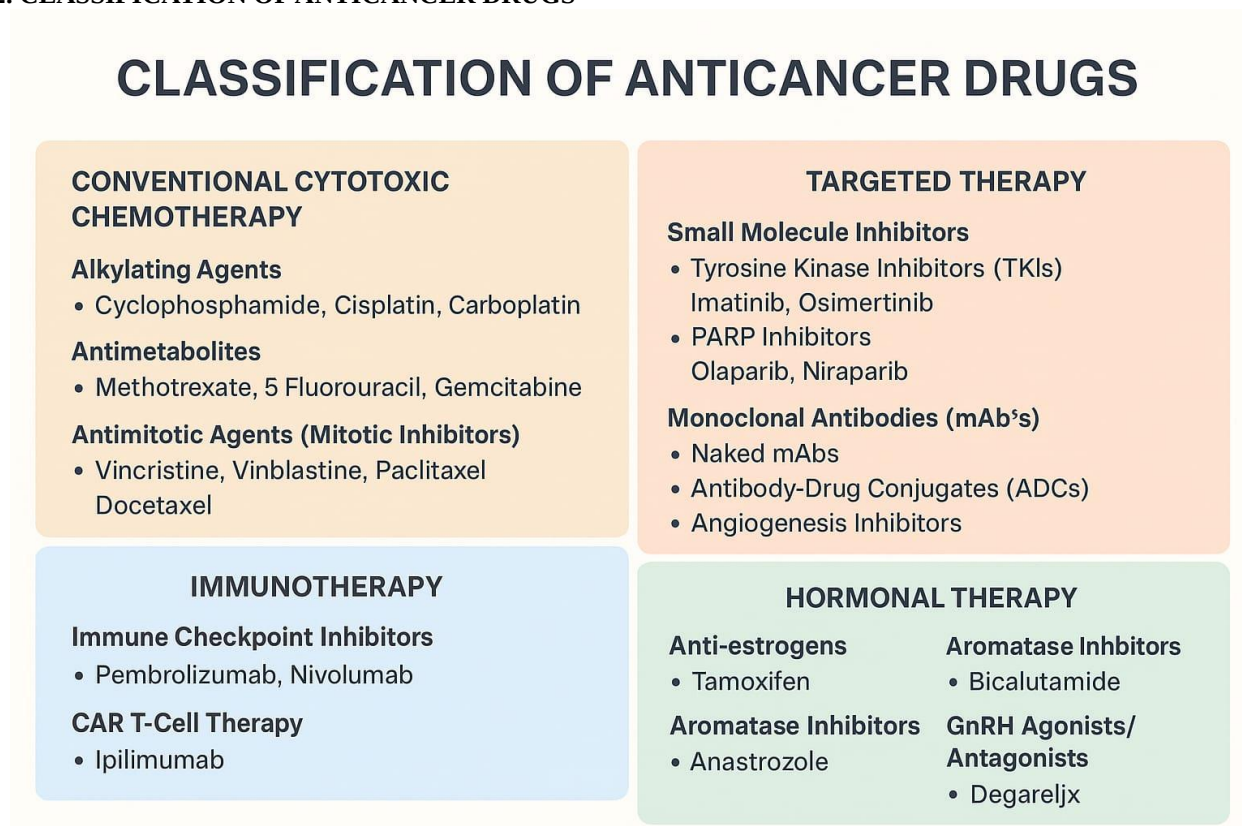


Fig. no 1: Anticancer Drugs.

1. Conventional Cytotoxic Chemotherapy

Alkylating Agents: These drugs work by adding an alkyl group to DNA, which creates cross-links within the DNA strands. The cell dies as a result of this damage since it prevents the DNA from being correctly duplicated and the cell from replicating. They are not cell-cycle specific, meaning they can affect cells at any stage of the cell cycle.

Common Examples: Cyclophosphamide, cisplatin, and busulfan.

Antimetabolites: These agents are structural analogues of essential cellular building blocks, such as purines, pyrimidines, or folic acid. They interfere with DNA and RNA synthesis by either directly incorporating into the genetic material or by inhibiting the enzymes required for their synthesis. This effectively starves the cell of the necessary components for division.

Common Examples: 5-fluorouracil (5-FU), methotrexate, and gemcitabine.

Antimitotic Agents (Mitotic Inhibitors): These drugs specifically target the M-phase (mitosis) of the cell cycle, which is when the cell divides. They work by disrupting

the function of microtubules, which are essential for forming the mitotic spindle.

Vinca Alkaloids: These drugs, like vincristine and vinblastine, prevent the polymerization of tubulin, thereby inhibiting the formation of microtubules. As a result, cell division is stopped.

Taxanes: In contrast, these drugs, such as paclitaxel and docetaxel, stabilize microtubules and prevent their breakdown. The resulting stable, non-functional microtubules also halt cell division.

2. Targeted Therapy

Small Molecule Inhibitors: These are small enough to enter cells and block specific intracellular signalling pathways that drive cancer growth.

Tyrosine Kinase Inhibitors (TKIs): Tyrosine kinases are enzymes that act as "on/off" switches for many cellular functions. In many cancers, these enzymes are overactive. TKIs block these signals, halting cancer cell growth. Imatinib, for example, is a TKI used for chronic myeloid Leukemia (CML) that target the BCR-ABL fusion protein.

PARP Inhibitors: These drugs block poly ADP-ribose polymerase (PARP), an enzyme involved in repairing DNA damage. By inhibiting PARP, these drugs prevent cancer cells from fixing DNA breaks, leading to cell death, especially in cancers with existing DNA repair defects (e.g., BRCA1/2-mutated breast or ovarian cancers).

Monoclonal Antibodies (mAbs): These are lab-made antibodies that are designed to target specific proteins on the surface of cancer cells or in their microenvironment.

Naked mAbs: These antibodies work by binding to cancer cells, thereby flagging them for destruction by the immune system. For example, rituximab targets the CD20 protein on B-cell lymphomas.

Conjugated mAbs: These antibodies are attached to a cytotoxic drug, a radioactive particle, or a toxin. By acting as a "homing device," the antibody minimizes harm to healthy cells by delivering the payload straight to the cancer cell. An example is trastuzumab emtansine (T-DM1), which combines an anti-HER2 antibody with a chemotherapy drug.

Angiogenesis Inhibitors: These mAbs, such as bevacizumab, block the growth of new blood vessels (angiogenesis) that tumors need to get nutrients and grow. This effectively starves the tumor.

3. Immunotherapy: - This class of drugs works by boosting the patient's immune system to recognize and attack cancer cells.

Immune Checkpoint Inhibitors: Cancer cells can evade the immune system by activating "checkpoints" that act as brakes on immune cells. Inhibitors like pembrolizumab and nivolumab block these checkpoints (PD-1 or CTLA-4), releasing the brakes and allowing the immune system's T-cells to mount a strong anti-tumor response.

CAR T-Cell Therapy: This is a highly specialized form of immunotherapy where a patient's own T-cells are genetically modified in a lab to express a **chimeric antigen receptor (CAR)** that specifically recognize and binds to a protein on the surface of their cancer cells. To eradicate the malignancy, the patient is given the altered T-cells again.

4. Hormonal Therapy: This treatment is used for cancers that are driven by hormones, such as breast cancer (Estrogen-receptor positive) and prostate cancer (androgen-receptor positive).

Estrogen Receptor Modulators (SERMs): Drugs like tamoxifen block Estrogen from binding to its receptors on breast cancer cells, preventing them from growing.

Aromatase Inhibitors: These medications, which include anastrozole, prevent the production of estrogen in postmenopausal women by inhibiting the enzyme aromatase. Breast cancer growth can be slowed or stopped by reducing Estrogen levels.

Androgen Deprivation Therapy (ADT): For prostate cancer, ADT aims to reduce the level of androgens (like testosterone) in the body. This can be achieved with drugs that block androgen receptors (e.g., bicalutamide) or with agents that stop the production of androgens (e.g., leuproli).^[5]

3. REGULATORY BODY OF INDIA CENTRAL DRUG STANDARD CONTROL ORGANISATION(CDSCO)

The Ministry of Health and Family Welfare oversees the Central Drugs Standard Control Organization (CDSCO), which is India's primary regulating body for pharmaceuticals and medical devices.

Objective: To guarantee the quality, safety, and effectiveness of medications, cosmetics, and medical equipment in India. In India, the Drugs Controller General of India (DCGI), a CDSCO officer, has the last say over whether clinical studies are approved. The DCGI receives input from the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).^[6]

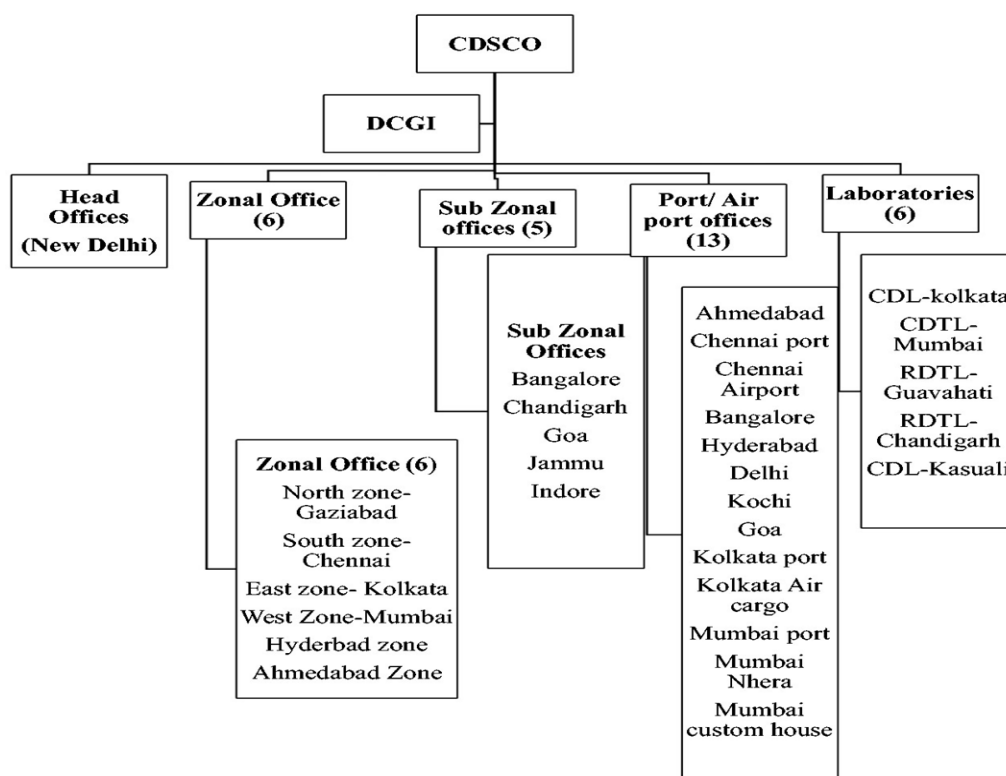


Fig.no 2: Organization of CDSCO.

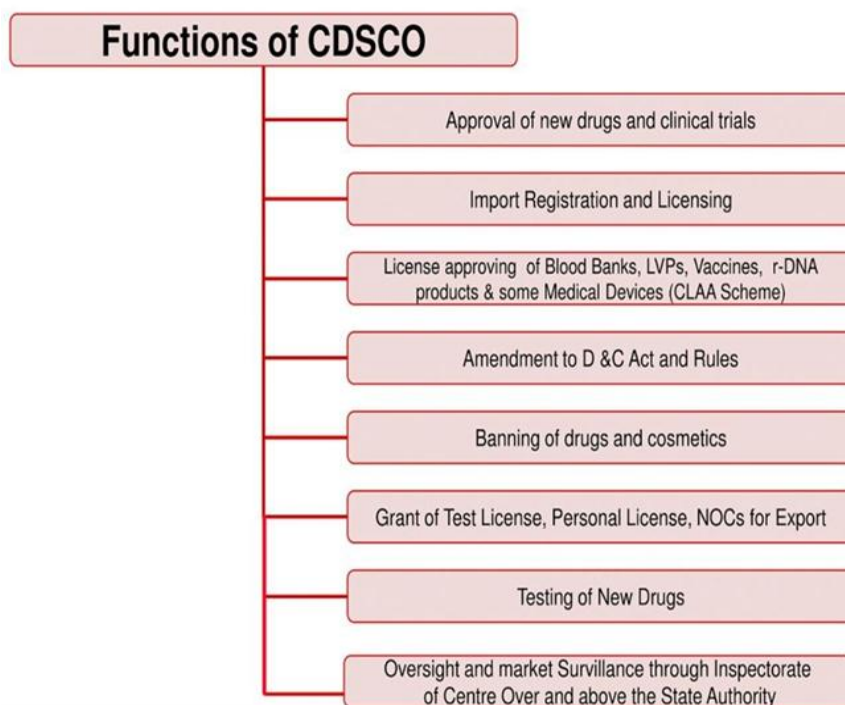


Fig. no 3: Functions of CDSCO.

4. REGULATORY REQUIREMENTS FOR ANTICANCER DRUGS AS PER CDSCO

The Drugs and Cosmetics Act of 1940 and the Rules of 1945 regulate the regulatory requirements for anticancer medications in India according to the Central Drugs Standard Control Organization (CDSCO).

1. Drug Classification

Due to differences in approval processes, the applicant must first classify the anticancer medication into one of the following categories before applying.

New Drug (ND): A drug substance or product that has never been offered for sale in India for the treatment of cancer.

Subsequent New Drug (SND): A new dosage form, strength, route of administration, or new indication for an already approved anticancer drug.

Fixed Dose Combination (FDC): A novel mix of two or more anticancer medications in a predetermined proportion.

Investigational New Drug (IND): A substance that is still being researched or tested and has not yet been given commercial approval.

2. Pre-clinical Studies (for Anticancer drugs)

Before testing in humans, the following studies are performed.

- Toxicological studies (acute, sub-acute, chronic – in two mammalian species).
- Pharmacology studies (mechanism of action, pharmacodynamics, anticancer activity).
- Animal models (efficacy, special cancer models, dose-ranging studies).

3. Clinical trial application (CTA) Approval

- Submit Clinical Trial Application (CTA) with Form CT-04 to CDSCO.
- Conduct trials as per New Drugs and Clinical Trials Rules, 2019.

Clinical Trial Phases.

- Phase I: Safety & tolerability in healthy volunteers or patients (dose-ranging).
- Phase II: Efficacy and dose optimization in patients with cancer.
- Phase III: Confirmatory efficacy & safety in larger cancer patient populations.

- Phase IV: Post-marketing surveillance.

4. New Drug Application (NDA)

Submit Form CT-21 after successful completion of clinical trial.

It should include.

- Complete clinical trial data.
- CMC (Chemistry, Manufacturing & Controls) data.
- Risk Management Plan (RMP).
- Labelling information.
- Details on manufacturing, packaging, and quality control as per **Schedule M** guidelines.

5. Review and Evaluation: Relevant Subject Expert Committees (SEC's) evaluate applications

Applications are reviewed by relevant Subject Expert Committees (SECs), which comprise medical and scientific experts. The SEC provides recommendations to the DCGI.

DCGI Approval

The DCGI provides marketing approval (Form 45 for import, Form 46 for production) based on the SEC's recommendations and a careful examination of the data supplied.

Post Manufacturing Approval

Manufacturers are required to submit periodic safety update reports (PSURs) and conduct post-marketing surveillance to continually monitor the drug's safety profile.

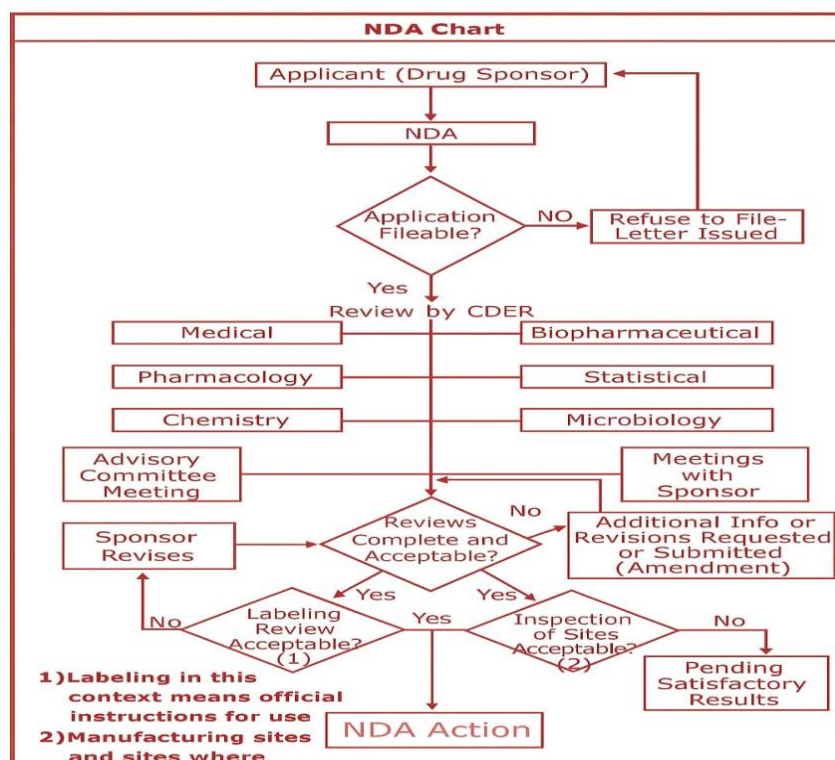


Fig no 4: NDA chart.

6. Fixed Dose Combination (FDC)

Must comply with CDSCO FDC guidelines.

An FDC is a formulation containing two or more active pharmaceutical ingredients (APIs) in a fixed ratio of doses, combined into a single dosage form.

Regulatory Pathway for anticancer FDCs (as per CDSCO)

CDSCO classifies FDCs into **four types**. Here's how they apply to anticancer drugs:

I: FDCs of Already Approved Drugs (new combination)

II: FDC where one or more APIs is a new drug.

III: FDCs for convenience (already marketed together abroad)

IV: FDCs for convenience (all APIs used together in clinical practice)

Some of the Examples of Anticancer FDCs (CDSCO-approved globally)

- Capecitabine + Oxaliplatin (CAPOX)
- Bortezomib + Lenalidomide + Dexamethasone
- Palbociclib + Letrozole

7. Post-Marketing Surveillance (PMS) Phase IV research may be required.

Phase IV studies may be mandated.

Periodic Safety Update Reports (PSURs) must be submitted every 6 months for the first 2 years and annually for the next 2 years.

Adverse Drug Reaction (ADR) monitoring is required.

8. Labelling and Packaging

As per Drugs and Cosmetics Rules, include.

- Drug name, strength.
- Manufacturer details.
- Warnings.
- Storage conditions.^[7]

Regulatory Requirements for Manufacturing of Anticancer Drugs in INDIA

The manufacturing of anti-cancer drugs in India is governed by a comprehensive regulatory framework, primarily overseen by the Central Drugs Standard Control Organization (CDSCO), which falls under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. The overarching legislation is the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, along with subsequent amendments and specific guidelines.

The key regulatory requirements

1. Primary Legislation and Regulatory Body: Drugs and Cosmetics Act, 1940: This act regulates the import, manufacture, distribution, and sale of drugs and cosmetics in India, ensuring their safety, efficacy, and quality.

2. Manufacturing Licence: Manufacturers of anti-cancer drugs must obtain a manufacturing license from the respective State Drug Control Authority, adhering to the requirements laid down in the Drugs and Cosmetics Rules.

3. Good Manufacturing Practices (GMP): strict compliance with Schedule M of the 1945 Drugs and Cosmetics Rules, which describes the extensive GMP specifications for operations, plant, facilities, and equipment.

4. Quality Risk Management (QRM): A robust QRM system is essential. Manufacturers must conduct a comprehensive risk assessment to identify, evaluate, and mitigate potential risks throughout the entire product lifecycle, from raw material procurement to final product distribution.

5. Personnel Training and Protection: All personnel involved in the manufacturing process must undergo specific and regular training on the safe handling of highly potent compounds. This includes the proper use of personal protective equipment (PPE), such as specialized gowns, gloves, respirators, and eye protection.

6. Approved Facilities: Manufacturing premises must meet specific design and environmental control standards to prevent contamination and ensure product integrity.

7. Raw Material Control: Stringent control over sourcing, testing, and release of all raw materials and excipients, including adherence to pharmacopoeia standards.

8. In-process Controls: the use of designated in-process controls to monitor and control important parameters during various stages of manufacturing.

9. Finished Product Testing: Comprehensive testing of finished products for identity, purity, potency, and dissolution as per pharmacopoeia specifications.

10. Comprehensive Stability Studies: Manufacturers must conduct extensive stability studies to determine the drug's shelf life and recommended storage conditions. This data is critical for ensuring the drug's quality and efficacy throughout its intended lifespan.

11. Full Traceability: Every step of the manufacturing process must be fully documented and traceable. This includes detailed batch records, a complete audit trail of all materials used, and records of all personnel involved in each stage.

12. Process Validation: All critical manufacturing processes—such as mixing, sterilization, and filling—must be validated to consistently produce a product of the intended quality. This is particularly important for sterile injectable anticancer drugs.

13. Cleaning Validation: Due to the risk of cross-contamination, a rigorous cleaning validation program is required to demonstrate that the cleaning procedures effectively remove all traces of the previous product from the equipment.

14. Change Control: A documented system for managing and approving any changes to processes, equipment, or materials.

15. Recall Procedures: Established procedures for rapid and effective recall of defective products from the market.

16. Pharmacovigilance: procedures for keeping track of and informing CDSCO about adverse medication reactions once they occur.

5. REGULATORY BODY OF AUSTRALIA THERAPEUTIC GOODS ADMINISTRATION

The Australian government's Therapeutic Goods Administration (TGA) is a branch of the Department of Health and Ageing. It is the regulatory authority in

Australia tasked with guaranteeing the efficacy, safety, and quality of medicinal products. Therapeutic goods manufacturing units are also regulated by TGA to ensure they meet acceptable standards of manufacturing quality.^[8]

Organization of the TGA

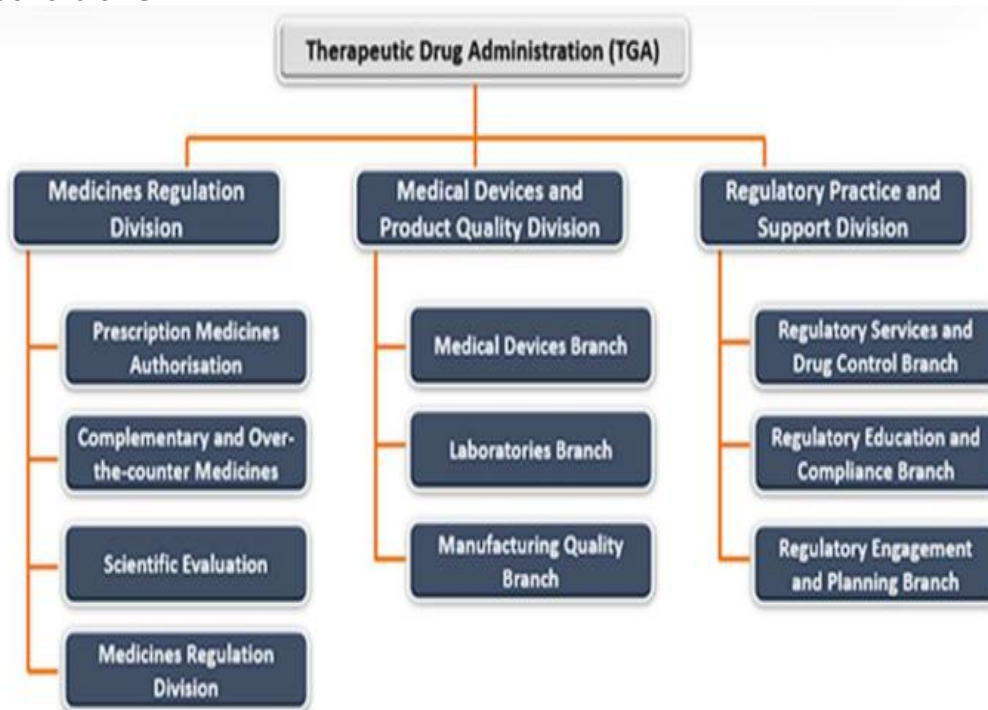


Fig. no 5: Organization structure of TGAs.

Functions of TGA

- Evaluation & Approval of Therapeutic Goods.
- Maintaining the ARTG (Australian Register of Therapeutic Goods)
- Post-Market Monitoring & Compliance.
- Licensing & Manufacturing Standards.
- Enforcement & Regulatory Action.
- Safety Alerts & Product Recalls.
- Public & Industry Guidance.
- International Collaboration.
- Policy Advice to Government.

6. REGULATORY REQUIREMENTS FOR ANTICANCER DRUGS AS PER TGA

The regulatory requirements for anticancer drugs in the Australia are primarily governed by the Australia's Therapeutic Goods Administration (TGA). These requirements ensure the safety, efficacy, and quality of the drugs before and after they reach the market.

3. Clinical Trials (Human Studies)

Clinical trials must follow Good Clinical Practice (GCP) and are conducted in 4 phases.

Phase	Purpose	Participants
Phase I	Safety, dosage range and identify side effects	20-100 advanced cancer patients
Phase II	Preliminary efficacy and safety	100-300 with target cancer type
Phase III	Confirm efficacy, monitor side effects	300-3000 + Patients
Phase IV	Post-marketing surveillance	Thousands of patients

1. Regulatory Authority

Australia's Therapeutic Goods Administration (TGA)

- Australian Register of Therapeutic Goods (ARTG) maintains the list of approved anticancer drugs.

2. Preclinical Requirements

TGA's pre-clinical requirements for anticancer drugs aligned with international guidelines, such as European Medicines Agency (EMA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH).

Before testing in humans, the drug sponsor must

- Perform studies on toxicity, pharmacodynamics, and pharmacokinetics in animals and in vitro studies
- Follow Good Laboratory Practices (GLP).

4. New Drug Application (NDA)

If trials show safety and efficacy.

- Sponsor submits full CTD dossier via the TGA Business Service portal, including.
- Clinical data
- Chemistry, Manufacturing and Controls (CMC)
- Labelling
- Risk Management Plan (RMP) specific to Australia

5. Labelling Requirements

- Must include clear indications, dosage, warnings, and instructions.
- For combination cytotoxic, list each active with exact amount.
- Must include brand name and active ingredients using Australian Approved Name (AAN).
- Hazardous or Cytotoxic drug statements are mandatory.

6. Manufacturing Compliance

- Manufacturing must follow Current Good Manufacturing Practices (cGMP) under PIC/S Guide.
- Facilities are subject to TGA inspection.

7. Post Marketing Surveillance

- Detect rare or long-term adverse effects not seen in clinical trials.
- Monitor real-world effectiveness and patterns of use.
- Identify off-label use or misuse.
- Ensure ongoing quality and supply chain integrity.
- Support regulatory decisions such as label changes, restrictions, or recalls.

8. Special Considerations for Anticancer Drugs

- These drugs require careful handling and administration by trained healthcare professionals.
- Patients receiving anti-cancer drugs require close monitoring for side effects, toxicity, and treatment response, as well as supportive care to manage adverse effects.
- Patients and caregivers should receive education on safe handling, administration, and potential side effects of anti-cancer drugs.
- Some anti-cancer drugs are cytotoxic, requiring special precautions to prevent exposure and minimize risk to patients, healthcare workers, and the environment.^[9]

REGULATORY REQUIREMENTS FOR MANUFACTURING OF ANTICANCER DRUGS IN AUSTRALIA

Manufacturing anti-cancer drugs in Australia is subject to stringent regulatory requirements primarily overseen by the Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health and Aged Care. The goal is to ensure the quality, safety, and efficacy of these critical medicines. the key regulatory requirements.

1. Registration on the Australian Register of Therapeutic Goods (ARTG)

- Before any anti-cancer drug can be imported, manufactured, or supplied in Australia, it must generally be included in the Australian Register of Therapeutic Goods (ARTG).
- The TGA assesses the quality, safety, and effectiveness of the product to determine if it meets the necessary standards. This assessment is based on scientific and clinical data.

2. Good Manufacturing Practice (GMP)

- GMP describes a set of principles and procedures that ensure therapeutic goods are consistently produced and controlled to quality standards appropriate to their intended use.
- The TGA's GMP code is based on the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to GMP for Medicinal Products.
- For Australian manufacturers, the TGA issues a manufacturing licence after a successful on-site inspection.
- For overseas manufacturers, the TGA requires GMP certification, which can also be obtained through an on-site inspection by the TGA or a reliance on a comparable overseas regulator.

3. Clinical Evidence and Evaluation

- Clinical Data: The TGA requires extensive clinical data to demonstrate the efficacy and safety of anti-cancer drugs. This involves a rigorous assessment of clinical trials.
- International Guidelines: Australia often adopts international scientific guidelines, such as those from the European Medicines Agency (EMA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), particularly for the clinical evaluation of anticancer medicinal products (e.g., ICH S9 for non-clinical evaluation).
- Risk Management Plans: Sponsors are often required to submit risk management plans for medicines and biologicals to address potential risks associated with their use.

4. Analytical method validation

- All analytical tests (e.g., assay, dissolution, impurities) must be validated for accuracy, precision, specificity, and robustness.

5. Documentation and Record

All manufacturing activities must be recorded in:

- Batch Manufacturing Records (BMR)
- Batch Packaging Records (BPR)
- Equipment logs

6. Packaging and Labelling Controls

Packaging materials must be tested and approved.

Packaging must be sealed, leak-proof especially for parenteral preparations.

Labelling of anti-cancer drugs ensures the correct identification, safe handling and proper administration. It includes dosage, warnings, expiry, etc.

7. Biological Anti-Cancer Drugs

- For anti-cancer drugs that are classified as "biologicals" (made from or containing human cells or tissues), a specific Australian Regulatory Guidelines for Biologicals (ARGB) framework applies.
- This framework employs a tiered, risk-based approach, with Class 4 biologicals (highest risk) requiring the most comprehensive data submission, including safety, efficacy, and quality data, and strict GMP compliance.

8. Specific Requirements for Anti-Cancer Drugs

- Sterility and Quality: Anti-cancer drugs, particularly those for parenteral use (e.g., injections, infusions), must be manufactured in sterile environments to prevent microbial contamination.

- Safety and Handling: Due to their cytotoxic nature, there are strict rules for handling and disposal.
- Documentation and Control: The manufacturing process must be precisely defined and controlled.
- Documentation and investigation of any deviations from the established procedures.

9. Stability Studies

- Determines the product's shelf life under various conditions.
- Supports the expiry date and storage conditions.

10. Post-Market Surveillance and Reporting

- The TGA's role doesn't end after a drug is registered. It also monitors the product after it is on the market to ensure its continued safety and quality.
- Manufacturers and healthcare professionals are required to report any adverse events or problems with the product to the TGA. The TGA investigates these reports and takes necessary regulatory action.

7. COMPARISION BETWEEN REGULATORY REQUIRMENTS FOR ANTICANCER DRUGS IN INDIA AND AUSTRALIA



Fig. no 6: India and Australia.

Table No 1: Comparison between Regulatory Requirements for anticancer drugs in INDIA and AUSTRALIA.

SL. NO	FEATURES	INDIA	AUSTRALIA
1.	Regulatory Bodies	The Central Drug Standard Control Organization (CDSCO)	The Therapeutic Goods Administration (TGA)
2.	Role	The CDSCO Regulates the approval, quality, safety, and import of drugs, medical devices, and cosmetics in India.	Regulates the safety, quality, and efficacy of therapeutic goods (medicines, medical devices, vaccines) in Australia.
3.	Guidelines	The CDSCO Provide standards and procedures for approval, manufacture, import, sale, and clinical trials of drugs,	Outline requirements for licensing, registration, quality, safety, efficacy, and post-market monitoring of therapeutic goods.

		medical devices, and cosmetics.	
4.	Regulatory department working for drug approval	Drug approval is handled by the Office of the Drugs Controller General of India (DCGI).	Drug approval is handled by the prescription medicines Authorisation Branch of the Therapeutic Goods Administration (TGA).
5.	Fees	Anticancer drugs follow the same fee structure as new drugs: roughly ₹ 4-8 lakh INR for registration/import plus inspection charges.	Anticancer drugs are treated as prescription medicines, with application + evaluation fees typically around 20,000-80,000+ AUD depending on submission type.
6.	Approval Process	The CDSCO regulates anti-cancer drug approval. The process includes preclinical studies, approval for clinical trials (via Form CT-04), and conducting Phases I–III trials under the New Drugs and Clinical Trials Rules, 2019. After successful trials, a New Drug Application is submitted for marketing authorization (Form CT23). Post-marketing surveillance (Phase IV) ensures ongoing safety.	The TGA oversees the process. Trials begin after preclinical studies and ethics approval, mainly under the Clinical Trial Notification (CTN) scheme. After trials, a Market Authorization Application is submitted using the Common Technical Document format. If approved, the drug is listed on the Australian Register of Therapeutic Goods (ARTG). Post market monitoring ensures long-term safety.
7.	Approval Timelines	Anticancer drug approvals typically take about 6–12 months depending on data completeness and priority review.	Anticancer drug approvals usually take around 9–12 months under the standard prescription medicine evaluation pathway.
8.	Clinical Trial	Anticancer drug trials need DCGI approval, Ethical clearance from an Institutional ethics Committee, and follow Indian GCP & CDSCO's Drugs and Cosmetics Rules, especially Schedule Y, with mandatory registration on CTR-I.	Anticancer drug trials run under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes, require HREC ethics approval, and must comply with ICH-GCP guidelines.
9.	Funding	In India, funding for anti-cancer drugs is supported through government schemes like Ayushman Bharat (PMJAY) and NPCDCS, offering free or subsidized treatment in public hospitals. Several state health insurance programs, NGOs, and CSR initiatives also contribute to drug access, especially for low-income groups.	In Australia, the Pharmaceutical Benefits Scheme (PBS) plays a major role in funding anti-cancer drugs, making them affordable for patients through federal subsidies. Additionally, Medicare covers diagnostic and treatment services, ensuring broad access to cancer care across the country.
10.	Handling and Administration of Hazardous Drugs	While the CDSCO sets the standards for drug approval, specific guidelines for the safe handling and administration of cytotoxic (hazardous) drugs are often a matter for individual, hospitals and state health departments, following national and international best practices.	Australia has detailed guidelines and standards for the safe handling of anti-cancer medicines. For example, the Clinical Oncological Society of Australia (COSA) provides comprehensive guidelines for the safe prescribing, dispensing, and administration of cancer chemotherapy.
11.	Recent Amendments	Anti-cancer Medicines Now Covered Under Schedule-H2 (Aug 2023) NPPA's Ceiling Price Fixes & Tax Fixes (Feb 2025).	Genetic Discrimination & Life Insurance (Sep 2024) Private Health & Medicare Benefits Changes (Effective 1 July 2025) Cancer Screening & Diagnostic Protocol Changes (Jun 2025) Cancer Notification Laws in Queensland (from 3 May 2025)
12.	Special Consideration for Anticancer drugs	Allows expedited approval, waivers of local Phase III trials, and compassionate use for anticancer drugs treating serious or life-threatening conditions.	Offers priority review, provisional approval, and Special Access Schemes for anticancer drugs to speed up patient access to life-saving therapies.

8. CONCLUSION

While both India and Australia have stringent regulatory frameworks for anticancer drugs, their approaches differ

significantly. India, through the Central Drugs Standard Control Organization (CDSCO), emphasizes a decentralized process with local ethics committee

approvals for clinical trials. In contrast, Australia's Therapeutic Goods Administration (TGA) employs a more centralized and often expedited system, including pathways like Priority Review and Provisional Approval to fast-track access to critical oncology medicines.

Unlike India, which may require local clinical trial data for new drugs, the TGA often leverages data and assessments from comparable overseas regulators to streamline its evaluation process. This focus on international cooperation in Australia's regulatory framework can lead to faster market access for innovative therapies compared to India's more independent and comprehensive review process. As a result, while both countries prioritize safety and efficacy, Australia's system is generally seen as more flexible and quicker for certain life-saving oncology treatments.

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