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Review Article

A comprehensive review on registration requirements for Drug Approval in India, South Africa and US

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Abstract

The drug approval process is country-specific. The regulatory framework of all the national regulatory agencies differ from one another in terms of administration and product specific guidelines for registration of drug and drug products in a particular country. Every national regulatory authority provides regulatory guidelines for drug or drug product registration and the pharmaceutical industries which rely upon these guidelines prepare drug applications along with all the required administrative, non-clinical and clinical data in the form of a technical dossier which is known as Common Technical Document. This Dossier is prepared either in an electronic format or in the paper submission format. This review focuses on the comparative study of the registration requirements for getting a drug approval in India, South Africa and United States of America. The significant differences between the technical requirements of these three markets have been discussed in detail.

Keywords: Central Drug Standard Control Organization (CDSCO), South African Health Products Regulatory Authority (SAHPRA), United States Food and Drug Administration (USFDA), Drug approval, New Drug Application (NDA), Common Technical Document (CTD), Dossier

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1. Introduction

The pharmaceutical industries rely upon the registration requirements that are set forth by the National Drug Regulatory Authority. The regulatory requirements for obtaining a marketing authorization or marketing licensure for a particular drug, drug product, medical device or biologic vary from country to country and their respective regulatory agencies. In order to maintain the uniformity and to streamline the process of dossier submission, the regulatory agencies provide product-specific guidelines for the industry. This article will discuss the latest regulatory requirements for obtaining drug approval in three countries, namely India, South Africa and USA.

Introduction to National Regulatory Authority of India, South Africa and USA (1-4)

A. Central Drug Control Standard Organization (CDSCO)

The Central Drugs Standard Control Organization (CDSCO) established under the Ministry of Health & Family Welfare, Government of India is recognized as the National Regulatory Authority (NRA) of India. CDSCO works in a streamlined fashion following the laid legislative norms in order to ensure safety, efficacy and quality of the medicinal products that are manufactured, imported and distributed throughout the country. Under the Drug and Cosmetic Act, 1940 and Rules, 1945 the CDSCO is responsible for approving of marketing applications of Drugs, monitoring and regulating the clinical trials and laying down the standards for maintaining the quality of drug and drug products throughout the nation. (1)

B. South African Health Products Regulatory Authority (SAHPRA)

South African Health Products Regulatory Authority (SAHPRA), a part of the National Department of Health of South Africa, is the drug regulatory authority established by the Government of South Africa with a view of developing a safe and effective healthcare system for human as well as animal life. SAHPRA is entitled with the responsibility of regulating the registration, inspection, manufacture, distribution and sales of medicines, related medicinal products, medical devices and IVDs (in-vitro devices) across the African region. (2)

The Medicines Control Council (MCC) is a part of SAHPRA which looks over the regulatory framework of drug registration and approval in South Africa. MCC reviews all the types of drug applications for marketing. Three types of product review assessments are used by regulatory authorities:

- Verification review (Type 1)
- Abridged review (Type 2)
- Full review (Type 3)

The MCC conducts a type 3 full assessment in the review of all applications, including New Active Substance (NAS) and generics for medicinal products. A full independent assessment of quality, efficacy, and safety data is performed. (3)

C. United States Food and Drug Administration

The United States Food and Drug Administration (USFDA) is a regulatory agency of United States which is authorized to regulate the manufacture, distribution and sale of food supplies, medications, cosmetics and veterinary medicines, including those that emit radiation. The USFDA works primarily to ensure the security of the health of the people of United States (US) by evaluating the quality, safety and effectiveness of medicines, biologics, cosmetic products, medical devices and other such drugs. The Center for Drug Evaluation and Research (CDER) works in the direction of approving all the marketing applications related to drugs and drug products. The FDA also maintains strict vigilance in the manufacture and sale of tobacco products, taking into account the protection of public health and the goal of eliminating the use of tobacco products by children or underage citizens. (4)

Common Technical Document (Error! Bookmark not defined.)

The International Council for Harmonization of Technical Requirements of Pharmaceuticals for Human Use (ICH) prescribes a common dossier format for drug product registration and approval across the world. ICH has developed a harmonized Common Technical Document (CTD) format that contains all data on the quality, safety and effectiveness of drugs and drug products. This convergence has led to a rapid assessment of the technical requirements for the approval of pharmaceuticals. In addition, the common electronic format of CTD, known as electronic Common Technical Document (eCTD) has contributed to the reduction of paper documents and reduced the timeframe for lengthy reviews. By July 2003, the CTD format was compulsion for drug applications in Europe and Japan and was widely adopted in the USA.

The ICH CTD is divided into 5 modules.

Module 1: Regional Administrative Information

Module 2: Quality Overall Summary

Module 3: Quality

Module 4: Non-Clinical Study Reports

Module 5: Clinical Study Reports (5)

Electronic Common Technical Document (eCTD)

Electronic Common Technical Document is the interface of industry to agency transfer of regulatory information with due consideration to enhance the creation, review, lifecycle management and archiving of electronic submission. (6)

Organization of contents in eCTD

Table 1. Organization and contents of Module in eCTD (7)

Module/Section in CTD	Name of Module/Section	Naming of Module/Section in eCTD
Module 1	Administrative Information and Prescribing Information	*m1*
Module 2	Summaries	*m2*
Section 2.2	Introduction	*22-intro*
Section 2.3	Quality overall summary	*23-qos*
Section 2.4	Nonclinical Overview	*24-nonclin-over*
Section 2.5	Clinical Overview	*25-clin-over*
Section 2.6	Nonclinical Written and Tabulated Summaries	*26-nonclin-sum*
Section 2.7	Clinical Summary	*27-clin-sum*
Module 3	Quality	*m3*
Section 3.2	Body of Data	*32-body-data*
Section 3.2.S	Drug Substance	*32s-drug-sub*
Section 3.2.P	Drug Product	*32p-drug-prod*
Section 3.2.A	Appendices	*32a-app*
Section 3.2.R	Regional Information	*32r-reg-info*
Section 3.3	Literature References	*33-lit-ref*
Module 4	Nonclinical Study Reports	*m4*
Section 4.2	Study Reports	*42-stud-rep*
Section 4.2.1	Pharmacology	*421-pharmacol*
Section 4.2.2	Pharmacokinetics	*422-pk*

Section 4.2.3	Toxicology	*423-tox*
Section 4.3	Literature References	*43-lit-ref*
Module 5	Clinical Study Reports	*m5*
Section 5.2	Tabular Listing of all Clinical Studies	*52-tab-list*
Section 5.3	Clinical Study Reports	*53-clin-stud-rep*
Section 5.4	Literature References	*54-lit-ref*

Benefits of eCTD

- ✓ Ease of accessing computer based tools like searching, copy and paste.
- ✓ Enhances efficiency of the review of the submitted data in less time compared to paper submissions Streamlines review process for regulatory agencies.
- ✓ Reuse of documents and submission components
- ✓ Allows easy data preparation, organization and its submission management.
- ✓ Collaborates the working processes of development, regulatory and marketing departments.
- ✓ Reduction in storage cost of paper submissions
- ✓ Allows easy navigation between documents and contents of the dossier.
- ✓ Electronic submission via ESG helps in avoiding data transmission errors.
- ✓ Dossier lifecycle management is possible with eCTD thereby providing an easy track of the history of electronic submissions.
- ✓ The regulatory agency can incorporate multiple reviewers for a single dossier submitted electronically, thereby assuring a thorough and peer review of the dossier and the drug application. (8)

2. Regulatory Framework for Drug Approval in India (9-11)

Central Drug Control Standard Organization is the national drug regulatory authority of India. Within CDSCO, the Drug Controller General of India (DCGI) is responsible for the regulation of registration and approval of pharmaceuticals and medical devices. The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). Licensing and classification of medical devices are handled by the Central Licensing Approval Authority (CLAA). The CLAA is also responsible for setting and enforcing safety standards, conducting post market surveillance and issuing warnings and recalls for adverse events. (9-10) In India, the Drug Controller General of India (DCGI) looks after the entire framework of registration, import, export and sales of drug and drug products in India. In order to obtain a marketing authorization approval in India, a pharmaceutical manufacturer needs to seek an approval from the Central Licensing Authority (i.e. DCGI) by submitting the Form number 44 and providing all relevant data related to clinical trials as per the norms and provisions mentioned in Schedule Y of the Drug and Cosmetic Act, 1940 and Rules, 1945.

The rules to be followed while seeking an approval from CDSCO includes:

Rule 122-A: Application for permission to import new drug

Rule 122-B: Application for approval to manufacture new drug other than the drugs specified under Schedule C and C (1) of D&C Act, 1940 ad Rules, 1945.

Rule 122-D: Permission to import or manufacture fixed dose combination.

Rule 122-DA: Application for permission to conduct clinical trials for New Drug/Investigational New Drug.

Rule 122- DAB: Compensation in the case of injury or death during the clinical trials.

For New Drug Application approvals, demonstration of safety and efficacy of the drug product for use in humans is a preliminary and mandatory requirement before the drug product can be approved for marketing for commercial use. The specific and detailed information required for approval of a marketing authorization application is described under Rules - 122A, 122B and 122D and further in Appendix I, IA and VI of Schedule Y of the Drug and Cosmetic Act, 1940 and Rules, 1945.

The commonly adopted format for submission of the marketing authorization application is Dossier, i.e. Common Technical Document (CTD). Even, for manufacturing or importing licensure for India, CDSCO has adopted the CTD format for submission of technical requirements via SUGAM Portal. (11)

Format of CTD as per CDSCO (12):

Table 2. CTD Format as per CDSCO (12)

Module	Name of the Module	Remarks
Module 1	General Information	Should contain Form 44, Treasury Challan Fee and the proposed Label
Module 2	CTD Summaries	Should contain Quality Overall Summary
Module 3	Quality	Should contain information on Quality
Module 4	Non-clinical Study Reports	Must contain all animal study data
Module 5	Clinical Study Reports	Must contain all human study data

Drug Approval Process in India (13,14)

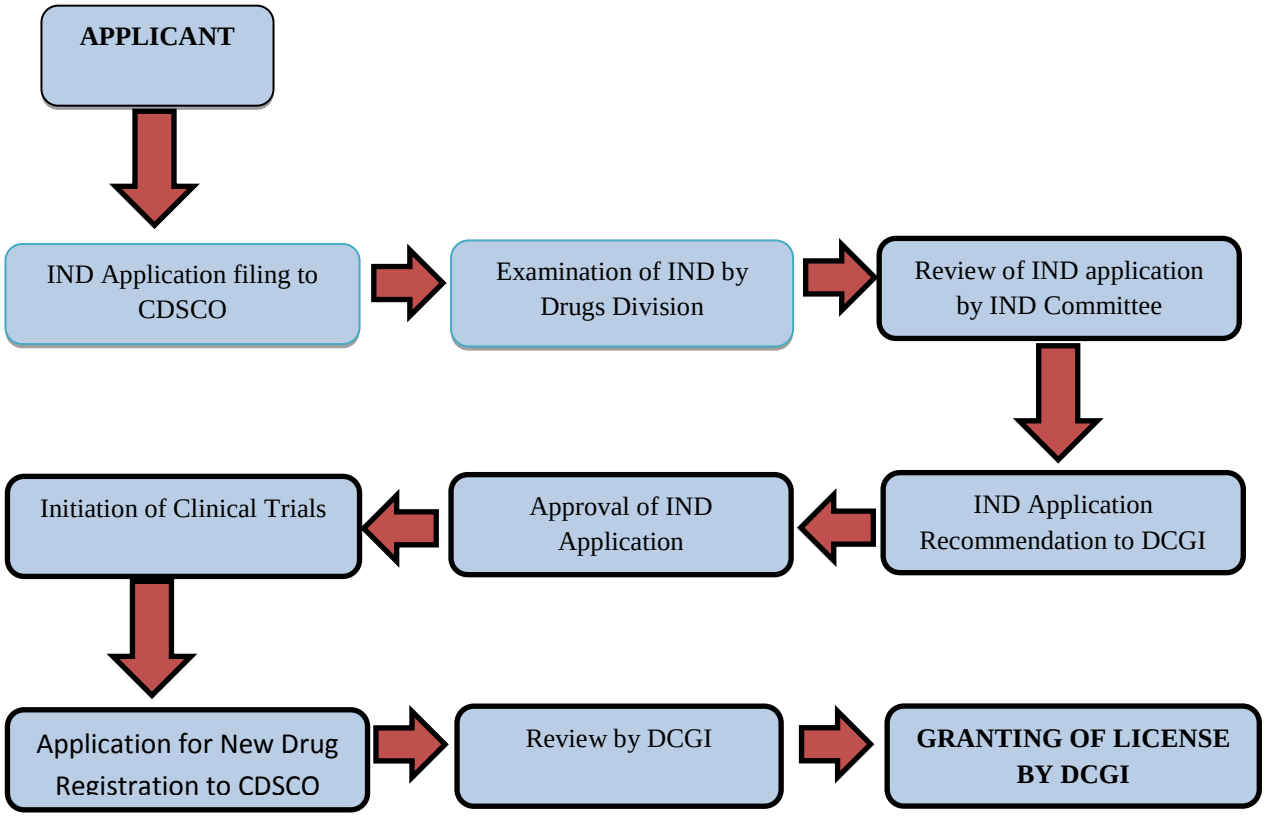

Figure 1. Drug Approval Process in India (13,14)

Contents of Dossier for Drug Approval in India as per CDSCO (12)

Module 1: General Information

1.1 Covering Letter & Comprehensive Table of Contents

1.2 Administrative Information

1.3 General Information on Drug Product

1.4 Summary of Testing Protocol(s) for Quality Control Testing together with a complete impurity profile and release specifications for the product should be submitted.

1.5 Regulatory Status in other countries

1.6 Domestic Price of the Drug followed in the Countries of Origin in INR.

1.7 Manufacturer's Research Activity Profile

1.8 Manufacturer's Business Activity Profile

1.9 Information regarding involvement of Experts

1.10 Samples of Drug Product

1.11 Promotional Materials

Module 2: CTD Summaries

2.1 Table of Contents of Module 2

2.2 Introduction

2.3 Quality Overall Summary (QOS)

2.3.S Summary of Drug Substance

2.3.P Summary of Drug Product

2.3.A Appendices

2.4 Non-Clinical Overview

2.5 Clinical Overview

2.6 Non-Clinical Written and Tabulated Summaries

2.7 Clinical Summary

Module 3: Quality

3.1 Table of Contents of Module 3

3.2 Body of Data

3.2.S Drug Substance(s)

3.2.P Drug Product (Name, Dosage Form)

3.2.A Appendices

3.3 Literature References

Module 4: Non-Clinical Study Reports

4.1 Table of Contents of Module 4

4.2 Study Reports

4.2.1 Pharmacology

4.2.2 Pharmacokinetics

4.2.3 Toxicology

4.3 Literature References

Module 5: Clinical Study Reports

5.1 Table of Contents of Module 5

5.2 Tabular Listing of All Clinical Studies

5.3 Clinical Study Reports

5.3.1 Reports of Biopharmaceutical Studies

5.3.2 Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials

5.3.3 Reports of Human Pharmacokinetic (PK) Studies

5.3.4 Reports of Human Pharmacodynamic (PD) Studies

5.3.5 Reports of Efficacy and Safety Studies

5.3.6 Reports of Post-Marketing Experience

5.3.7 Case Report Forms and Individual Patient Listings

5.4 Literature References (12)

3. Regulatory Framework for Drug Approval in South Africa (15)

South Africa has developed a national regulatory authority with a council of international significance named as Medicines Control Council (MCC). MCC is a part of the drug regulatory authority – South African Health Products Regulatory Authority (SAHPRA). The registration of medicine in South Africa is governed by the provisions and statutory requirements of the Medicines and Related Substances Control Act, 1965. It is a legal requirement that data submitted for evaluation should adhere to the guidelines laid down by MCC and must fulfil the technical requirements of quality, safety and efficacy of the product for the purposes for which it is intended.

Under the Medicines and Related Substances Act, 1965 the MCC is entrusted with the responsibility of monitoring and functioning the control over regulation of medicines, scheduled substances, clinical trials, medical devices, etc. in South Africa. The pharmaceutical company which wishes to seek an approval for marketing their drug in South Africa, needs to submit the Dossier with Medicines Registration Form (MRF1) along with the application of Proposed Holder of the Certificate of Registration (PHCR). (15) The dossier is to be submitted in the South African Common Technical Document (ZA CTD) format the overview of which is discussed below.

Format of ZA CTD as per SAHPRA (16)

Table 3. ZA CTD Format as per SAHPRA (16)

Module 1	Name of the Module	Remarks
Part 1	Administrative information	Relevant administrative documentation should be submitted
Part 2	Basis for registration and overview of application	Contains the summaries and overviews for the quality, non-clinical and clinical sections of the dossier. The Clinical Overview should include a statement regarding GCP compliance.
Part 3	Pharmaceutical and Analytical	Contains the chemical, pharmaceutical and biological data relevant to the application.
Part 4	Pre-clinical studies	Contains the non-clinical (pharmaco-toxicological) data relevant to the application
Part 5	Clinical studies	Contains international studies used to establish the pharmacodynamics, pharmacokinetics, safety and efficacy of the medicine across an international patient population.

Contents of Dossier for Drug Approval in South Africa as per SAHPRA (16)

Part 1: Administrative Information

1.0 Letter of Application

1.1 Comprehensive Table of Contents

1.2 Application

1.2.1 Application Form

1.2.2 Annexes to Application Form

1.3 South African Labeling and Packaging

1.4 Information about the Experts

1.5 Specific Requirements as per type of Application

1.6 Environmental Risk Assessment

1.7 Good Manufacturing Practice

1.8 Details of Compliance

1.9 Individual Patient Data – Statement of Availability

1.10 Foreign Regulatory Status

Part 2: Basis for Registration and Overview of Application

Part 2A: Pharmaceutical and Biological Availability

Part 2B: Summary Basis for Registration Application (SBRA)

Part 2C: Pharmaceutical Expert Report (PER) / Quality Overall Summary (QOS)

Part 2D: Pre-Clinical Expert Report

Part 2E: Clinical Expert Report

Part 3: Pharmaceutical and Analytical

Part 4: Pre-Clinical Studies

Part 5: Clinical Studies (16)

Drug approval process in South Africa (3, 15)

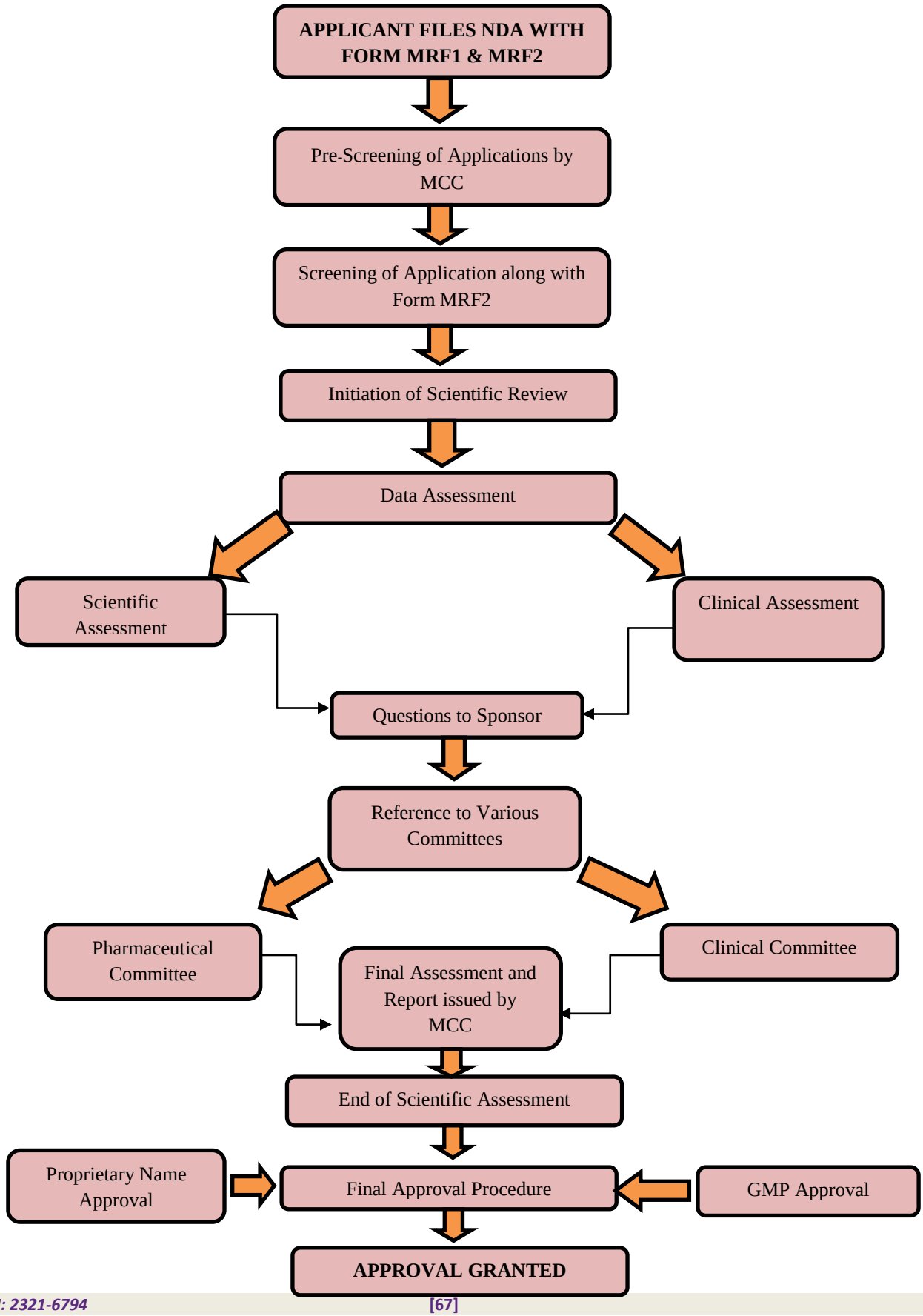

Figure 2. Drug Approval Process in South Africa (3,15)

4. Regulatory Framework of Drug Approval in USA (14,17)

United States of America (USA) has the most specific and stringent guidelines for importing, exporting and sales of drugs and medical devices and other related substances. The United States Food and Drug Administration (USFDA) is the national drug regulatory authority of United States having the key functions over the administration of manufacture, distribution and sales of drugs and medicinal products in the entire country. Under the Federal Food Drug and Cosmetic Act (FFD&C), a new drug cannot enter the interstate commercial market until and unless the USFDA has approved the New Drug Application (NDA) filed by the sponsor of the new drug.

Drug Approval Process in United States of America (11)

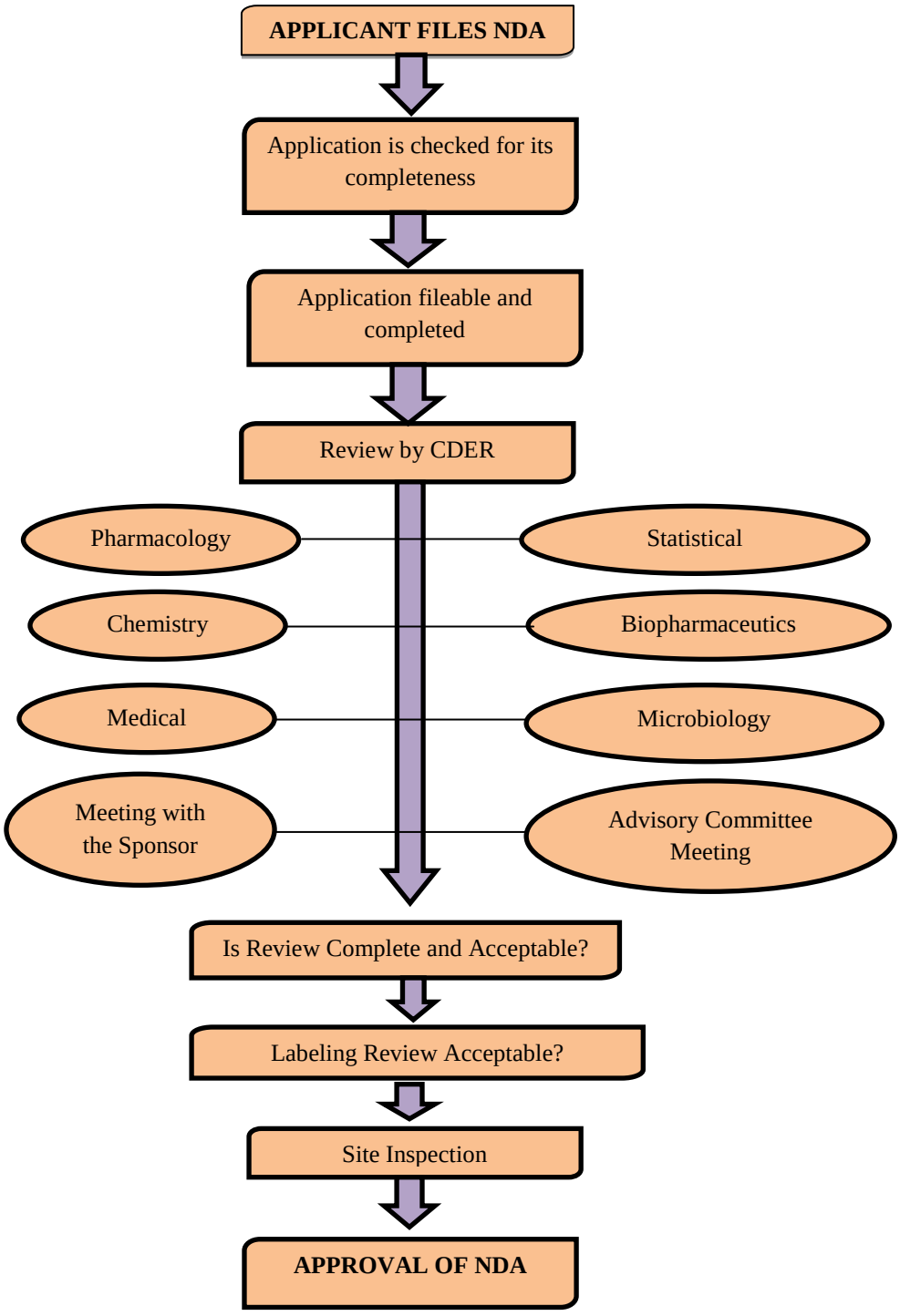

Figure 3. Drug Approval Process in USA (11)

Format of CTD as per USFDA (17)

Table 4. CTD Format as per USFDA (18)

Module No.	Name of the Module
1	Administrative Information and Prescribing Information
2	CTD Summaries
3	Quality
4	Nonclinical Study Reports
5	Clinical Study Reports

A pharmaceutical company can file a new drug application (NDA) in USA only after the drug successfully passes all three phases of clinical trials and the sponsor has retained all records of animal and human study of drug and its manufacturing and proposed labelling. The documentation required in an NDA is supposed to provide an in-depth about the drug's entire story, right form the clinical tests to the ingredients of the drug product; from the results of the animal studies up to the details regarding the steps involved in manufacturing, processing and packaging the drug product. All these data are reviewed at the Centre for Drug Evaluation and Research (CDER). Only after successful validation and confirmation of the drug's safety and efficacy reports, the manufacturer can file a NDA which is the actual request to manufacture and market the drug in the United States. The manufacturer can file an application to market a new drug by filling Form FDA 356h along with the technical dossier. USFDA has adopted the commonly recommended format of CTD for dossier submission which is harmonized and provided by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Currently the marketing applications for drugs are accepted for review only in the CTD format. (14, 17)

Contents of Dossier for Drug Approval in USA as per USFDA (19)

For a New Drug Application the content of the regulatory submission as per USFDA is as under:

- Cover Letter
- FDA Form 356h
- Index (Table of Contents)
- Labeling
- Summary
- Technical Section: Chemistry, Manufacturing and Controls (CMC)
- Non-clinical pharmacology and toxicology
- Human pharmacokinetics and bioavailability
- Clinical Microbiology section
- Clinical data
- Safety Update
- Statistical section
- Case Report Tabulations
- Case Report Forms
- Patent Information
- Patent Certification
- Debarment Certification
- Field Copy Certification
- User Fee Cover Sheet (19)

5. Comparative Study of Regulatory Requirements for New Drug Approval in India, South Africa and USA (11, 14, 15, 20)

Every country has it's specifications regarding new drug or drug product registration and approval for being able to enter into the commercial pharmaceutical market of the nation. The following table highlights the significant differences between the registration requirements of the three countries selected for this study.

Table 5. Comparison of registration requirements for drug approval in India, South Africa and USA (11, 14, 15, 20)

Comparative Parameter	India	South Africa	United States of America
Regulatory Agency	Central Drug Standard Organization (CDSCO)	South African Health Products Regulatory Authority (SHAPRA)	United States Food and Drug Administration (USFDA)
Regulatory Department working for Drug Approvals	Drug Controller General of India (DCGI)	Medicines Control Council (MCC)	Center for Drug Evaluation and Research (CDER)
Name of Application	Marketing Authorization Application (MAA)	Application for New Active Substance (NAS)	New Drug Application (NDA)
Registration Process	Single Registration Process	Single Registration Process	Single Registration Process
Braille Code on Labeling	Not required	Required	Not Required
Debarment Classification	Not required	Not required	Required
Number of Copies	1	1	3
Approval Timeline	2 – 18 months	48 months	18 months
Fees	50,000 INR	23,980 ZAR (equivalent to	Under USD 2 Million

		USD 2000)	
Presentation Format of Technical Requirements	Paper Submission (CTD)	ZA CTD , Electronic Submission (eCTD)	Electronic Submission (eCTD), Paper and NeeS (Non-eCTD Electronic Submission)
Form for New Drug Approval	Form 44	MRF1 (Medicines Registration Form – 1) & MRF2	FDA 356h
Modules of CTD	**Module 1:** General Information **Module 2:** CTD Summaries **Module 3:** Quality **Module 4:** Non-clinical Study Reports **Module 5:** Clinical Study Reports	**Part 1:** Administrative information **Part 2:** Basis for registration and overview of application **Part 3:** Pharmaceutical and Analytical **Part 4:** Pre-clinical studies **Part 5:** Clinical studies	**Module 1:** Administrative Information and Prescribing Information **Module 2:** CTD Summaries **Module 3:** Quality **Module 4:** Nonclinical Study Reports **Module 5:** Clinical Study Reports
Post-approval Changes	Scale up and Post approval changes in the approved drug: ▪ Minor ▪ Moderate ▪ Major	Post variation in the approved drug: ▪ Type IA ▪ Type IB ▪ Type II	Post approval changes: ▪ Major ▪ Moderate

6. Conclusion

This study was conducted to give a regulatory review on the drug approval framework and registration requirements for new drug approval in three different markets, namely India, South Africa and USA. All of these three markets are well established in the pharmaceutical sector and they contribute to a major extent in the global revenue from pharmaceutical market. Country-specific technical requirements set by the national regulatory authorities of the respective countries have been studied and compared in detail. A pharmaceutical industry, when applying to get a new drug approval, must strictly adhere to the specified technical requirements in order to achieve greater level of regulatory compliance. This will quicken the review process and maximize the chances of getting approval within minimum possible time. (21-26)

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. CDSCO. About CDSCO [Internet]. Ministry of Health and Family Welfare, Government of India; 2021 [cited 2021 Mar 04]. Available from: https://cdsco.gov.in/opencms/opencms/en/Home/#
2. SAHPRA. About Us [Internet]. South Africa: SAHPRA; 2021 [cited 2021 Mar 03]. Available from: https://www.sahpra.org.za/who-we-are/
3. Keyter A, Gouws J, Salek Sand Walker S. The Regulatory Review Process in South Africa: Challenges and Opportunities for a New Improved System [Internet]. 2018 [cited 2021 Mar 03]; 20(1): 1-10. Available from: https://journals.sagepub.com/doi/full/10.1177/2168479018776649
4. USFDA. What We Do [Internet]. US FDA; 2018 Mar 28 [cited 2021 Mar 06]. Available from: https://www.fda.gov/about-fda/what-we-do
5. ICH. M4: The Common Technical Document [Internet]. ICH; 2021 [cited 2021 Mar 08]. Available from: https://www.ich.org/page/ctd
6. Sama R, Swarna Latha K, Sathish M, Gowthami Krishna M and Santhosh P. Electronic Common Technical Document (eCTD): A Review of History, Benefits of implementing, challenges, modules, risks involved in eCTD publishing and Quality Control [Internet]. 2016 [cited 2021 Mar 04]; 6(2): 133-149. Available from: http://ijpcbs.com/files/12-04-2016/04-620.pdf
7. ICH. ICH M2 EWG – Electronic Common Technical Document Specification [Internet]. ICH; 2008 Jul 16 [cited 2021 Mar 05]. Available from: https://admin.ich.org/sites/default/files/inline-files/eCTD_Specification_v3_2_2_0.pdf
8. eCTD 247. Benefits of Electronic CTD Submissions [Internet]. ectd247; 2021 [cited 2020 Dec 12]. Available from: https://ectd247.com/benefits/
9. N. Vishal Gupta, C. Mohan Reddy, K. Pradeep Reddy, R. Ajay Kulkarni, H.G. Shivakumar. Process of Approval of New Drug in India with Emphasis on Clinical Trials. International Journal of Pharmaceutical Sciences Review and Research [Internet]. 2012 [cited 2021 Mar 05]; 13(2): 17-23. Available from: https://www.globalresearchonline.net/journalcontents/v13-2/004.pdf
10. S.D.Mankar, V.D. Gholap, T.P. Zende, R.S.Dighe. Drug Regulatory Agencies in India, USA, Europe and Japan - A Review. International Journal of Institutional Pharmacy

and Life Sciences [Internet]. 2014 [cited 2021 Mar 05]; 4(2): 288-297. Available from: http://www.ijipls.com/archives.php?archid=18

11. Sawant AM, Mali DP and Bhagwat DA. Regulatory Requirements and Drug Approval Process in India, Europe and US. Pharmaceutical Regulatory Affairs [Internet]. 2018 [cited 2021 Mar 05]: 7(2): 1-10. Available from: https://www.hilarispublisher.com/open-access/regulatory-requirements-and-drug-approval-process-in-india-europe-and-us-2167-7689-1000210.pdf
12. CDSCO. Guidance for Industry on Preparation of Common Technical Document for Import/Manufacture and Marketing Approval of New Drugs for Human Use (New Drug Application - NDA) - Draft Guidance Document [Internet]. CDSCO FDA Bhavan Kotla Road, New Delhi; 2010 Oct 28 [cited 2021 Mar 06]. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadGazette_NotificationsFiles/CTD%20Guidance%20Final.pdf
13. Krishnasis Chakraborty, Kavita Yadav. Drug approval process in US, Europe and India and its regulatory requirements: A Review. International Journal of Drug Regulatory Affairs [Internet]. 2018 [cited 2021 Mar 05]: 6(3): 31-39. Available from: http://ijdra.com/index.php/journal/article/view/332
14. Jawahar.N, Vidhya Lakshmi. T. Regulatory Requirements for the Drug Approval Process in US, Europe and India. Journal of Pharmaceutical Sciences and Research [Internet]. 2017 [cited 2021 Mar 06]: 9(10): 1943-1952. Available from: https://www.jpsr.pharmainfo.in/Documents/Volumes/vol9Issue10/jpsr09101759.pdf
15. Pharmexcil – Pharmaceuticals Export Promotion Council of India. Regulatory & Market Profile of South Africa [Internet]. Ministry of Commerce & Industry, Government of India [Internet]. Pharmexcil; 2017 [cited 2021 Mar 06]. Available from: https://pharmexcil.com/uploadfile/ufiles/South_Africa_Regulatory_Market_Profile.pdf
16. SAHPRA. Guidance for the submission of the South African CTD /eCTD - General & Module 1 [Internet]. South Africa: SAHPRA; 2019 May. [cited 2021 Mar 05]. Available from: https://www.sahpra.org.za/wp-content/uploads/2020/02/2.01-Guidance_General_Module_1_May19_v6-1.pdf
17. USFDA. New Drug Application (NDA) [Internet]. US:US FDA; 2019 Jun 10 [cited 2021 Mar 06]. Available from: https://www.fda.gov/drugs/types-applications/new-drug-application-nda
18. ICH. M4Q: The CTD – Quality – Guidance for Industry [Internet]. US: US FDA; 2001 Aug [cited 2021 Mar 05]. Available from: https://www.fda.gov/media/71581/download
19. USFDA. Providing Regulatory Submissions in Electronic Format-NDAs – Guidance for Industry. US: US FDA; 1999 Jan [cited 2021 Mar 06]. Available from: https://www.fda.gov/media/76482/download
20. ClinRegs. India v/s South Africa [Internet]. National Institute of Allergy and Infectious Diseases; 2020 Jul 23 [cited 2021 Mar 06]. Available from: https://clinregs.niaid.nih.gov/country/india/south-africa#_top
21. Ananth L, Gurbani NK, Kumar S, Gujavarti B. A retrospective study of Warning Letters issued by US FDA over 2015-2017. Int J Drug Reg Affairs [Internet]. 2018Jun.15 [cited 2021Mar.06];6(2):48-3. Available from: http://ijdra.com/index.php/journal/article/view/242
22. Budhwar V, Singh AK, Choudhary M. REGULATIONS OF ORPHAN DRUGS IN USA, EU AND INDIA-A COMPARATIVE STUDY. Int J Drug Reg Affairs [Internet]. 2018Feb.13 [cited 2021Mar.05];4(3):30-7. Available from: http://ijdra.com/index.php/journal/article/view/187
23. Gupta S, Popli H. Regulation of Blood and Blood products in India, USA and EU. Int J Drug Reg Affairs [Internet]. 2018Jun.15 [cited 2021Mar. 06];6(2):72-4. Available from: http://ijdra.com/index.php/journal/article/view/246
24. Budhwar V, Yadav S, Choudhary M, Nitesh,. A Comprehension Study on Regulation of Herbal Drugs in USA, European Union and India. Int J Drug Reg Affairs [Internet]. 2017Dec.7 [cited 2021Mar. 06];5(4):8-17. Available from: http://ijdra.com/index.php/journal/article/view/205
25. Rani A, Shukla VK. Impact of rules for New Drug and Clinical Trial in India. Int J Drug Reg Affairs [Internet]. 2020Mar.16 [cited 2021Mar. 03];8(1):25-0. Available from: http://ijdra.com/index.php/journal/article/view/379
26. Rampal A, Kanti SPY. Cosmetics in US and India: Overview of Regulations and Registration process. Int J Drug Reg Affairs [Internet]. 2020Dec.15 [cited 2021Mar. 04];8(4):20-4. Available from: http://ijdra.com/index.php/journal/article/view/430