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Research Article

An overview of drugs approved in India from 1999 through 2015

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ABSTRACT

Background: The drug approval regulations in India have changed since 2005 with new regulations for the conduct of clinical trials from 2013 onward. The present study was planned to see the number of drugs approved by Drugs Controller General of India (DCGI) and their trend over the last 16 years in view of new regulatory guidelines.
Methods: Data obtained from website of the regulatory authority, i.e., Central Drugs Standard Control Organization regarding DGCI approval of drugs in India from 1999 until May 2015 was noted for analysis.
Results: We identified 1716 drug approvals by the DCGI from 1999 to 2015, with a mean of 100.94±83.80 (standard deviation) approvals per year (median approvals per year: 57; range: 3-270). There is a rising trend for approval of drugs as a single agent, as well as in combination from 2004 showing a peak in 2008 with a decline from 2010 onward. Thus, very few drugs have been approved in last 3 years.
Conclusions: Thus, the present study highlights the changing scenario of drug approval, with few drugs being approved for clinical practice in the last 3 years.

Keywords: Drug approval, New drugs, India, Regulations

INTRODUCTION

The approval of a new drug by the regulatory authorities is a lengthy process in India. Research and development of new drugs are an ongoing process and it often takes more than a decade to launch a new drug in the market.[1] Whenever a new drug is innovated by a company or an individual researcher, the drug has to go through a series of mandatory procedures before it is actually available in clinical practice. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. In India, the responsibility of new drug approval is vested on Central Drugs Standard Control Organization (CDSCO).[2,3]

The new drug approval is a two phase process: the first phase of clinical trials and second phase of marketing of a drug. First, non-clinical studies of a drug are completed to ensure the efficacy and safety, and then an application for conduct of clinical trials is submitted to the competent authority of the concerned country. Thereafter, the clinical trials are conducted (Phase I-Phase IV). In India, the Drug and Cosmetic Act 1940 and Rules 1945 regulates the import, manufacture, distribution, and sale of drugs and cosmetics. The CDSCO works under the Drugs Controller General of India (DCGI).[4] In 1988, the Indian government added Schedule Y to the drug and cosmetics rules 1945. Schedule Y provides the guidelines and requirements for conducting clinical trials, which was further revised in 2005 to bring it at par internationally.

The drug approval process varies in different countries. In some, only a single body regulates the drugs and is responsible for all regulatory tasks such as approval of new drugs, providing a license for manufacturing and inspection of manufacturing plants. However, in other countries all these tasks are not performed by a single regulatory authority. In India, this responsibility is divided with central and state authorities. Also, a difference is seen in the time taken

for approval of Clinical Trial Authorization, evaluation of marketing authorization, registration process, and marketing of the new product.[5,6]

The regulatory scenario in India is changing very fast and DCGI is coming up with newer guidelines. Ever-changing laws and regulations are increasing the demand for regulatory affairs professionals to cater to the current needs of pharmaceutical companies who can help them to bring their medical products in the Indian market. In today's competitive scenario, the reduction in the time taken to launch a product is imperative and hence vital for the success of the pharmaceutical company.

Our study focuses on a number of drugs approved during the last 16 years from 1999 to 2015 along with an analysis of the changing trend over the years.[7-9]

METHODS

1. Data obtained from website of regulatory authority, i.e., The CDSCO regarding DGCI Approval of New Drugs
2. Drugs approved by DCGI from 1999 till 2015 were noted for analysis
3. Approvals included drug products for additional indications, additional dosage forms, additional higher or lower strengths, new salts, and combinations of previously approved drugs besides the products having a new molecule as a "drug" ("new drug")
4. Microsoft Excel 2013 was used for analysis
5. Values were expressed as total, mean ± standard deviation, median, and range
6. Drugs approved as a single, as well as in combination were considered for analysis
7. The trend of drug approval over the years was expressed as line diagram.

RESULTS

The present study identified a total of 1716 drug approvals in last 16 years, i.e., 1999 through 2015.

Table 1 shows the year-wise distribution of a total number of approvals in India, from 1999 to 2015 which are a total of 1716.

The highest number of approvals was seen in 2008 with 270 drug approvals which constituted 15.73% of total drug approvals over 16 years.

Table 2 compares the total drugs along with single and combination of drugs approved per year in terms of their mean, median, and range.

The total mean drug approvals were 100.94±83.80 with a median approval of 57 drugs in the range of 3-270.

Table 1: Total number of drug approvals in India, 1999-2015 (n=1716).

Year	Drug approvals	Percentage
1999	23	1.34
2000	28	1.63
2001	41	2.39
2002	57	3.32
2003	39	2.27
2004	78	4.55
2005	122	7.11
2006	162	9.44
2007	189	11.01
2008	270	15.73
2009	217	12.65
2010	224	13.05
2011	140	8.16
2012	44	2.56
2013	35	2.04
2014	44	2.57
2015	3	0.18
Total	1716	

Table 2: Drugs approved per year in terms of mean, median, and range; in various categories analyzed.

Parameter	Mean±SD	Median	Range
Total number of approvals (n=1716)	100.94±83.80	57	3-270
Single drug product approvals (n=1107)	65.12±43.77	57	3-148
Combination drug product approvals (n=609)	35.82±42.05	11	0-123

SD: Standard deviation

The single drug approvals were 65.12±43.77 with a median approval of 57 drugs in the range of 3-148.

The combination drug approvals were 35.82±42.05 with a median approval of 11 combinations in the range of 0-123.

Figure 1 shows the changing trend of total, single and combination drug approvals over the years.

DISCUSSION

Regulatory guidelines provide the basis for implementation of laws. Every country in the world have their own established pharmaceutical legislations and regulatory procedures. For worldwide regulatory dossier submissions, it is a pre-requisite to have knowledge of specific regulatory guidelines and norms in that country. Therefore, it is important to know the differences and similarities between

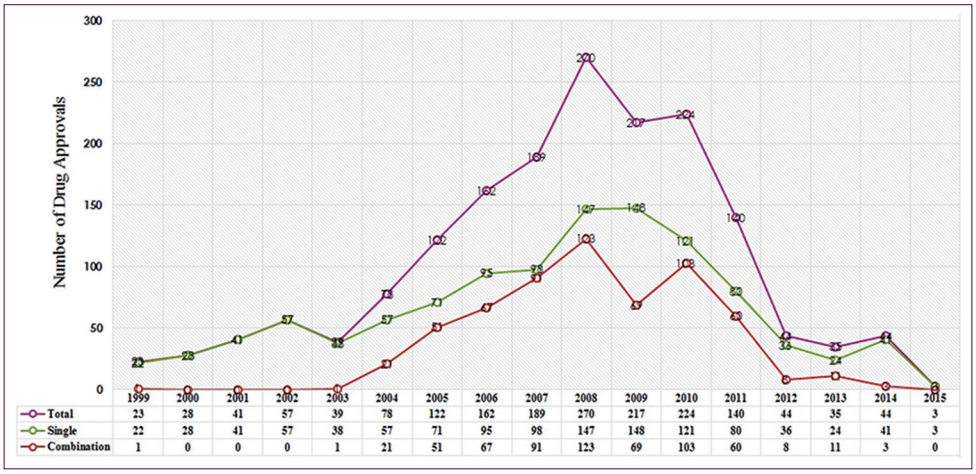

Figure 1: Trend of drug approvals in India from 1999 to 2015.

the regulatory requirements and pharmaceutical legislations in different countries of the world.[6]

A recent WHO report states that, drugs are expensive not because of lack of competition among research-based pharmaceutical companies, but because of time taken in the drug approval process. High drug development costs combined with low drug prices due to price control legislations eases the entry of generic products into the market which has resulted less pharmaceutical research and development. Estimates of the cost of developing a new drug show that these costs continue to increase, despite the recent efforts of regulatory agencies to speed up the drug-approval process. Between the years 1963 and 1975, the total cost of bringing a new drug to the market was estimated at $119 million. Recent estimates put the cost of having a drug approved over $802 million dollars.[2]

The price of pharmaceuticals is an issue of great concern for governments around the world. Soaring national health budgets and the fear that underprivileged populations have only limited access to life-saving medicines, have motivated policymakers to seek ways in which they can intervene to control the price of pharmaceuticals. In general, the drug approval process comprises mainly of two steps, application to conduct clinical trial, and application to the regulatory authority for marketing authorization of drug. The new drug approval process varies in different countries. In most countries, sponsor files an application to conduct clinical trial, and only after the approval of the regulatory authority, the applicant conducts the clinical studies and submits an application to the regulatory authority for marketing of a new drug. The fees and the time were taken for reviewing the process of conducting clinical trials and giving the marketing permission differs from country to country.

For the purpose of harmonization, the International Conference on Harmonization (ICH) has taken major steps for recommendations in the uniform interpretation and application of technical guidelines and requirements.[6] These steps reduce the need to duplicate work carried out during the research and development of new drugs. Therefore, harmonization of drug approval processes either by ICH or WHO have to be initiated at global level.

Our study highlights the low number of drug approvals in India after these regulations came into existence due to revised schedule Y of 2005 and recent regulations by DCGI in 2013.

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