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Research Article

Comparison of new drug approval by regulatory agencies of US, EU and India

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ABSTRACT

Background: As per World Trade Organisation (WTO), from the year 2005, India granted product patent recognition to all new chemical entities (NCEs). This may affect the new drug approvals in India. The purpose of this study was to compare the new drug approvals in India with the United States (US) and the European Union (EU) regions.
Methods: We obtained information about regulatory approval of new drugs in the US, EU, or India of last 5 years (from 2011 through 2015) from the publicly accessible databases of three regulatory agencies. For the drug products identified, the drugs were classified into fourteen main Anatomical Therapeutic Chemical (ATC) groups, review classification and approval date.
Results: There were 509 new drugs approved from 2011 through 2015 by one or more of the three regulatory agencies. Total 182 new drugs were approved in US during the period of 2011 to 2015, with an average of 36.4 new drugs approved per year. For the same period a total of 257 new drugs were approved in the EU, with an average of 51.4 new drugs approved per year and in India a total of 70 new drugs were approved, with an average of 14 new drugs approved per year. There were more number of new drug approvals in antineoplastic and immunomodulating agents (L) ATC group in all the three regions (US= 66; EU= 61 and India= 17).
Conclusions: For new drugs approved between 2011 and 2015, India has lagged behind the US and the EU in approval of new drugs. There was no difference in the patterns of new drug approvals with respect to the therapeutic areas.

Keywords: Priority review, CDSCO, EMA, FDA, ATC group

INTRODUCTION

In most countries, the regulatory agencies authorize drugs for marketing. The main regulatory body for the Indian pharmaceutical industry is the Central Drugs Standard Control Organization (CDSCO). The Drug Controller General of India (DCGI) is the controlling body for the CDSCO. The office of the Drug Controller General of India is responsible for the approval of new drugs and clinical trials in India. In the European Union (EU), the European Medicines Agency (EMA) began operating in 1995.[1] The EMA is a decentralised agency of the EU, located in London. The EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. The United States (US) Food and Drug Administration (FDA), founded in 1906, is one of the oldest federal regulatory agencies.[2]

There are many local and multinational pharma companies selling their drug products in India. Most of the local pharma companies are mainly in generic drug business. There is a change in the regulatory environment after a system of product patents in India since 2005. After a system of product patents, it's not possible for the Indian companies to launch patented new drugs. Indian physicians and patients mainly depend on multinational pharma companies for novel drugs.

The average number new drug approval by the Indian drug regulatory authority was 34.46 per year from 1999 through 2011 and U.S. FDA averaged about 28 new drug approvals per year from 2006 through 2014.[3,4] It's

interesting to see the trend of new drug approvals after a system of product patents in India. Therefore, identifying the actual status of the new drug approvals in India would provide important information. The purpose of this study was to compare the new drug approvals in India with the US and the EU regions and assess the patterns of new drug approvals with respect to therapeutic areas.

METHODS

We obtained information about regulatory approval of new drugs in the US, EU, or India between 2011 and 2015 from the following publicly accessible databases:

1. The US: The Center for Drug Evaluation and Research (CDER), New Molecular Entity (NME) and New Biological Approvals, US Food and Drug Administration (FDA),[5]
2. The EU: The European Public Assessment Report (EPAR), Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA),[6]
3. India: The Central Drugs Standard Control Organization (CDSCO), List of approved drug.[7]

Information about name of approved drug, indication and date of issue of marketing approval was retrieved from the above sources. The definition of "new drug" included new molecular entities (NMEs) and new biologics. These analyses don't include generic drugs, biosimilar and supplemental approvals (e.g. additional indication, additional strength, new dosage form etc.) to new drugs. The information from the regulatory agencies online databases was entered and analysed using a Microsoft Excel worksheet (Microsoft Office 2010).

For the drug products identified the following features were recorded: International Non-proprietary Names (INN), the ATC code as per WHO Anatomical Therapeutic Chemical (ATC) classification, single or combination product, review classification (priority review drug, standard review drug, orphan drug) and approval date.[8]

RESULTS

We identified 509 new drug approvals between 2011 and 2015 that were approved by one or more of the three regulatory agencies. Total 182 new drugs were approved in US during the period of 2011 to 2015, with an average of 36.4 new drugs approved per year. For the same period a total of 257 new drugs were approved in the EU, with an average of 51.4 new drugs approved per year and in India a total of 70 new drugs were approved, with an average of 14 new drugs approved per year. The year wise distribution of new drug approvals in the US, EU and India is shown in Figure 1.

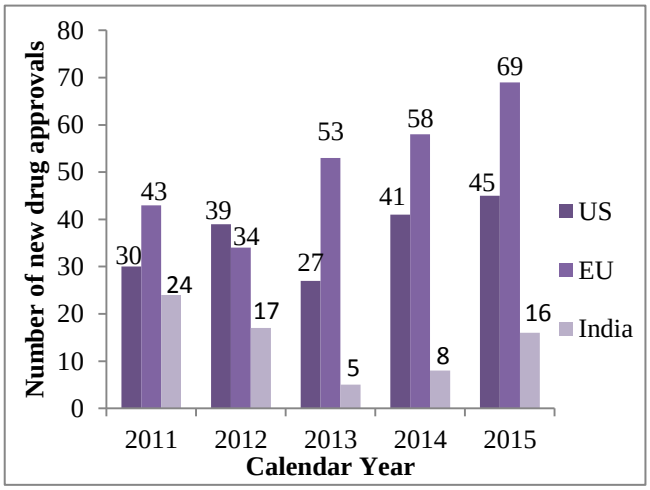
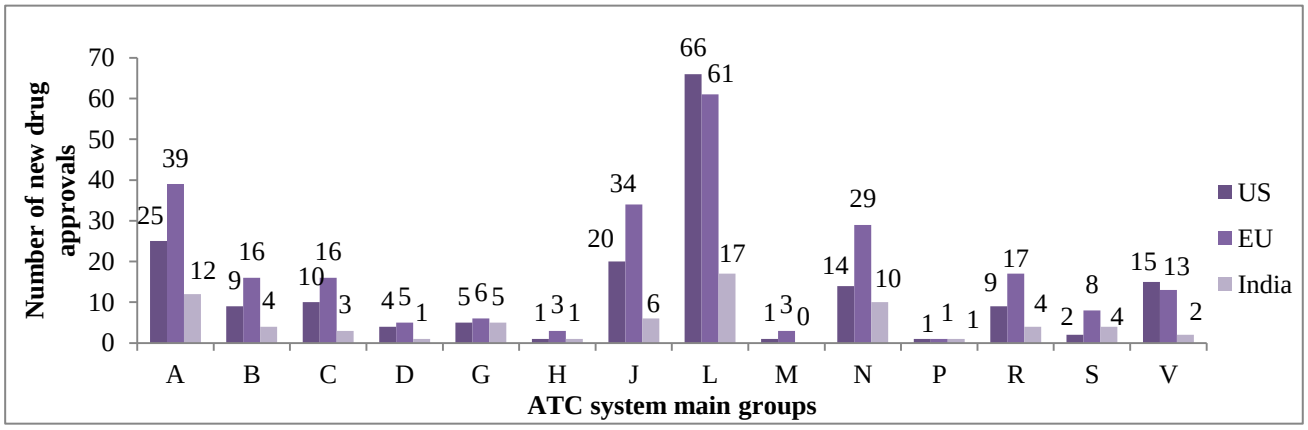


Figure 1: Number of new drug approvals per year for US, EU and India, 2011-2015.



ATC Group: A (Alimentary tract and metabolism), B (Blood and blood forming organs), C (Cardiovascular system), D (Dermatologicals), G (Genito urinary system and sex hormones), H (Systemic hormonal preparations, excluding sex hormones and insulins), J (Antiinfectives for systemic use), L (Antineoplastic and immunomodulating agents), M (Musculo-skeletal system), N (Nervous system), P (Antiparasitic products, insecticides and repellents), R (Respiratory system), S (Sensory organs), V (Various).

Figure 2: Number of new drug approvals as per ATC classification in US, EU and India, 2011-2015.

Figure 2 shows the new drug approvals for each group of ATC classification in US, EU and India. There were more number of new drug approvals in antineoplastic and immunomodulating agents (L) ATC group in all the three regions (US= 66; EU= 61 and India= 17). The total number of new drug approvals was higher in EU (n= 257), but new drug approvals for antineoplastic and immunomodulating agents (L) ATC group was higher in US (66 in US and 61 in EU). New drug approvals for alimentary tract and metabolism (A) ATC group was second highest in all the three regions (US= 25; EU= 39 and India= 12).

The information regarding orphan versus nonorphan status was not available for India. The FDA approved a larger proportion of orphan-designated new drugs than the EMA (39.44% versus 20.23%) (Table 1). The FDA approved 90 new drugs under priority review and 92 new drugs under standard review. The information with respect to priority or standard review was not available for EU and India.

Table 1: Characteristics of new drugs approved in US, EU and India from 2011 through 2015.

Variable	US (*n*= 182)	EU (*n*= 257)	India (*n*= 70)
Average approval per year	36.4	51.4	14
Therapeutic class			
Alimentary tract and metabolism	25	39	12
Antiinfectives for systemic use	20	34	6
Antineoplastic and immunomodulating agents	66	61	17
Nervous system	14	29	10
Respiratory system	9	17	4
Other	48	77	21
Orphan status#			
Orphan designation	71 (39.44%)	52 (20.23%)	-
Nonorphan designation	111 (60.56%)	205 (79.77%)	-
Review status*			
Priority	90	-	-
Standard	92	-	-

#: Central Drugs Standard Control Organization (CDSCO) India does not designate orphan versus nonorphan status.
*: Status with respect to priority or standard review was not analyzed for EU and India because the information regarding review classification was not available from EMA and CDSCO databases.

DISCUSSION

This study shows that the number of new drug approvals in India between 2011 and 2015 is less as compared to the US and the EU. As most of the pharmaceutical and biopharmaceuticals companies are more interested in the developed markets like the US and EU for their novel drugs, there may be less regulatory submission in India for new drugs. Our previous analysis showed substantial drug lag in approval of new drugs in India compared with the United States and European Union.[9-11]

This study has not explored the disease burden of all three regions. However, the pattern of new drug approvals shows similar upward trends for oncology drugs in all three regions. This trend shows more commercial interest in drug development then healthcare needs of specific region. As drug development cost is very high, small local pharmaceutical and biopharmaceuticals companies cannot afford developing new drugs. As per World Trade Organisation (WTO), from the year 2005, India granted product patent recognition to all new chemical entities (NCEs). Many Indian origin pharmaceutical and biopharmaceuticals companies are taking interest in drug development now. One of the examples of novel drug developed by Indian origin pharmaceutical company is saroglitazar (Lipaglyn). Saroglitazar is the first glitazar to be approved in the world and is the first new chemical entity (NCE) discovered and developed indigenously by an Indian Pharma Company (Cadila Healthcare Ltd).[12] Saroglitazar has been approved for marketing in India for treating diabetic dyslipidemia or hypertriglyceridemia in type 2 diabetes, not controlled by statins alone.

In last decade (from 2006 through 2014) U.S. FDA averaged about 28 novel drug approvals per year.[4] The annual number of novel drug approvals in India is not comparable with the US and the EU regions. Regulatory processes differ widely in different countries. However, there is a need to improve the regulatory processes in India to enhance the clinical trial and new drug approvals. The Indian regulatory authority has to initiate some measures to reduce the delay in approval.

In conclusion, our analysis of new drugs approved in the US, the EU and India between 2011 and 2015 shows that India has lagged behind the US and the EU in approval of new drugs. There was no major difference in the patterns of new drug approvals with respect to therapeutic area as in all the three regions proportionately more number of drugs approved in the antineoplastic and immunomodulating agents ATC group.

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