



CASE STUDY ON DRUG REGULATORY BODIES IN STATES OF INDIA: A NEED FOR UNIFORMITY

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ABSTRACT

The electronic Common Technical Document (eCTD) is an interface for the pharmaceutical industry to agency (regulatory body like FDA) pertaining to transfer of regulatory information. The content is based on the Common Technical Document (CTD) format of ICH. The regulatory bodies encountering NDA, ANDA and alike have to receive the respective documents which comprises a large amount of data in paper form. Sometimes the NDA application is like more than thousands of files. This amounts to usage of a paramount papers/stationary etc. Present case report is an attempt to study the aforementioned application of electronic transactions in regulatory affairs (import of drug, permission for marketing, permission to carry out clinical trials etc.) in different states in India pertaining to its similarities or dissimilarities. A survey was carried out on internet to look for websites of regulatory bodies of all states and to reveal whether the websites/webpage of the regulatory body is under the agencies of some ministry or a statutory body itself or some autonomous body. The objective was simply to know the harmony between regulatory bodies all the states. The case report is indicative of non uniformity amongst the Govt. sector with respect to drug control. The present situation demand the harmony in this matter.

Keywords: Common Technical Document, drug regulatory body, harmonization.

INTRODUCTION

The Internet is a worldwide collection of computer networks, cooperating with each other to exchange data using a common software standard. Through telephone wires and satellite links, Internet users can share information in a variety of forms.¹

The electronic Common Technical Document (eCTD) is an interface for the pharmaceutical industry to agency (regulatory body like FDA) pertaining to transfer of regulatory information. The content is based on the Common Technical Document (CTD) format of ICH. eCTD was developed by the International Conference on Harmonisation (ICH) Multidisciplinary Group 2 Expert Working Group (ICH M2 EWG). As of January 1, 2008, the U.S. Food and Drug Administration announced that the eCTD is the preferred format for electronic submissions². The New Drug Application (NDA) is the vehicle through which drug sponsors formally propose the FDA to approve a new pharmaceutical for sale and marketing³. An Abbreviated New Drug Application (ANDA) is an application for generic drug approval for an existing licensed medication or approved drug⁴.

The regulatory bodies encountering NDA, ANDA and alike have to receive the respective documents which comprises a large amount of data in paper form. Sometimes the NDA application is like more than thousands of files. This amounts to usage of a paramount papers/stationary etc.

Also to deal with such large amount of files and papers is a very tedious and difficult task for such offices.

With the advancement of information's technology and constraints of global warming it is the high time to

utilize/exploit these systems to replace paper work. Also another advantage of using electronic document is their retrieval system which is cumbersome in paper /file format.

IPR is another arena where this technology can be utilized to its full potential. Patent application requires being time bound and therefore they can be referred to the patent offices electronically.

Present case report is an attempt to study the aforementioned application of electronic transactions in regulatory affairs (import of drug, permission for marketing, permission to carry out clinical trials etc.) in different states in India pertaining to its similarities or dissimilarities.

METHODOLOGY

1. A survey was carried out on internet to look for websites of regulatory bodies of all states.
2. To reveal whether the websites/webpage of the regulatory body is under the agencies of some ministry or a statutory body itself or some autonomous body. The objective was simply to know the harmony between regulatory bodies all the states.
3. The survey included the modus operandi of these regulatory bodies regarding whether a single organization is responsible for matters related to manufacture, import, sale etc. relating to all system of medicine (allopathic, ayurvedic, homeopathy, unani etc) or separate organization for each system of medicines is operating.



- To see if all the information regarding permission for manufacturing, import, sale and distribution etc. along with the application to seek permission are available on the websites.

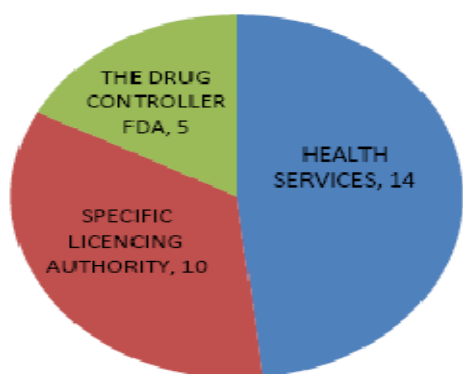
RESULTS AND DISCUSSION

The Drugs Controller General of India (DCGI) is a regulatory apex body under Government of India which oversees all clinical trials undergoing in India and also is governed by the rules in Amended Schedule Y. DCGI with CDSCO, DCGI heads the Central Drugs Standard Control Organization (CDSCO) and discharges the functions attached to the Central Government.

Figure 1 shows the status of regulatory bodies having websites and name by which these regulatory bodies are called. Out of 29 states only six states viz. Maharashtra, Uttar Pradesh, Madhya Pradesh, Goa and Gujarat are having their food and drug administration looking after all system of medicines also information regarding import/manufacture/sale/distribution is available on the websites. In these also Gujarat states was not having such downloadable application on its websites while Chhattisgarh don't have website.

On the other hand 14 states are dealing with this matter through health services department and information regarding permission for manufacturing/import/export/distribution was not clearly shown on the websites. These 14 states are Arunachal Pradesh, Assam, Bihar, Jammu & Kashmir, Manipur, Meghalaya, Mizoram, Nagaland, Punjab, Sikkim, Tripura, Tamilnadu, West Bengal, and Kerala.

Figure 1: Drug controller regulation according to ism/h at different state in India



Finally 9 states were found to have separate bodies to look after each system of medicines which is given in table no.1

Only six states viz. Uttar Pradesh, Maharashtra, Madhya Pradesh, Goa, and New Delhi are having the licensing facilities for manufacturing all system of medicines under one body.

In contrast very vague information is there, if any rest of the states.

Figure 2: Specific licensing facility on their websites

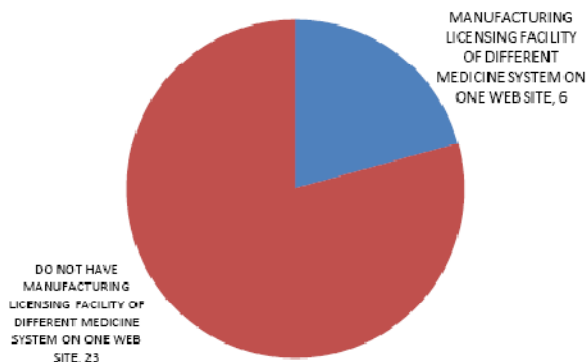
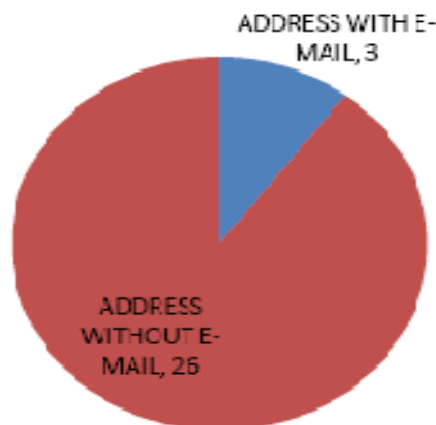


Table 1: States which have separate Regulatory Bodies

S.NO	NAME OF STATE	REGULATORY BODIES
1.	Andhra Pradesh	The Commissioner (ISM&H) & Licensing Authority
2.	New Delhi	The Director (ISM&H)
3.	Chandigarh	The Licensing Authority-cum-Director (Ayurveda)
4.	Himachal Pradesh	Director (Ayurveda) & Licensing Authority
5.	Jharkhand	Assistant Director (Ayurveda)
6.	Karnataka	The Licensing Authority, Directorate of ISM&H
7.	Orissa	Director & Licensing Authority, Directorate of Indian Medicine & Homoeopathy
8.	Rajasthan	Director of Ayurveda & Licensing Authority
9.	Uttaranchal	Director (Ayurveda)

Lastly, the official site drug controller of which gives a comprehensive list of regulatory bodies of all the states was searched and it is surprising that out of 29 Regulatory bodies only 3 bodies have their email address.

Figure 3: Drug controller licensing authority those have e-mail address on their address



CONCLUSION

The case report is indicative of non uniformity amongst the Govt. sector with respect to drug control. The present situation demand the harmony is this matter.

A pharmacy student learns about Licensing Authority under D&C ACT 1940 AND RULES 1945 as "Governing Body" the issue license for import/manufacture/sales/distribution of drug where as the present case report implies that this licensing authority is called by different names in different states ,this condition require attention from our constitution.

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