

CORRELATION OF REGULATORY AFFAIRS OFFICER WITH DIFFERENT DEPARTMENT OF PHARMACEUTICAL INDUSTRY IN INDIA AND IMPACT OF GST

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Article Received on
23 June 2017,

Revised on 13 July 2017,
Accepted on 03 August 2017

DOI: 10.20959/wjpr20179-9194

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ABSTRACT

Drug Regulatory Affair (DRA) is an important part of the organizational structure of Pharmaceutical companies. Now days it's necessary to have DRA department in companies for fast growth and development of the company. There are different departments in pharmaceutical company such as Research and Development, Quality Assurance, Production, and Quality Control. RA officer having different roles in these departments. They are involved in the development of new medicinal products from the primary stage, preparing the dossier and documentation to till end stage, submitting the relevant regulatory dossiers to health authorities. Marketing is the process of planning and executing the design, pricing, promotion and

distribution of ideas, goods, and service to create relations that satisfy person and organizational goals. Various regulatory authority such as United States Food and Drug Administration (USFDA), Therapeutic drug administration Australia (TGA), Central Drug Standard Control Organization (CDSCO), Health Canada these are responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing of the pharmaceutical products in their respective countries. In this review we discussed that the role of RA officer in different areas discussed and impact of Goods Service Tax on Pharmaceutical industries also concisely deliberated.

KEYWORDS: Goods Service Tax, DRA, CDSCO, Medical Devices.

INTRODUCTION

Regulatory affairs Department (DRA) is a comparatively new profession which developed from the hankering of governments to protect public health by monitoring the safety and efficacy of products in areas including pharmaceuticals products, medical devices, pesticides, agrochemicals, cosmetics.^[1] The Pharmaceuticals companies responsible for the discovery, testing, manufacture and marketing of these products also want to confirm that they supply products that are safe and make a valuable contribution to public health and welfare. Role of RA officer increasing day by day in different departments of pharmaceutical industries Fig.1. RA officer playing a vital role in bringing new product to market, there are different responsibilities for them from primary stage to till end stage.^[2]



Fig. 1: Contribution of Regulatory Affairs in different departments.

Regulatory guidelines changes regularly, so its duty of the RA officer to update with new regulatory guidelines. This is the responsibility of RA officer that what they making in Pharmaceutical company complying with latest regulatory guidelines or not. RA officer will make sure that they making quality product as there is safety of the consumers is major concern. Its RA officer duty to ensure compliance with regulation in all regions in which a company wishes to distribute its drug.^[3] Working with Central, state and local regulatory agencies and personnel on specific issues affecting their business. Guiding companies on the regulatory aspects and climate that would affect their planned activities.

Regulatory Affairs officer role in Different Department**1. Raw material department**

RA plays vital role in this department, for manufacturer a pharmaceutical drug, companies' required active pharmaceutical ingredient (API). For import and export of API Company has to take permission from regulatory authorities' state regulatory authority or central authority. RA officer will take care of the documentation part for getting permission from these authorities. After getting the permission RA officer will verify the quantity of the API, Storage condition, approved or unapproved status of the API also will cross verify.^[4]

2. Research and Development department

Research and Development department (R&D) having the responsibilities to bring a new drug to the market after lots of research and investigation, testing on different compounds. It is the duty of the R&D department to develop innovative products which beneficial and safe for public health. RA officer having the role in providing fast regulatory approval for test and analysis of the new drugs from State Food and Drug Control Administration (FDCA).^[5] Company has to take approval in FORM 30 application and license in FORM 29 (Test licence is issued for the purpose of examination, test or analysis). Drugs those not approved from Drug Controller General of India (DCGI) Company has to take No Objection Certificate (NOC) for form 29.^[6] Using new clinical trial strategies, gaining quick approval from regulatory authorities and avoiding drawbacks in processes can fast-track the development of new products which will reduce shortage of the drugs.^[7]

3. Production department

Production department having different responsibilities, first one is to establish standards in regard to the quality and the quantity of the products being made. Usually, these standards are placed all over the process, not just at the beginning or end. The second function of the department is to work with the purchasing department to ensure sufficient materials are on the production line and to ensure replacement of any damaged equipment. The purchasing department works with other departments to make sure purchased equipment and materials are all stocked and available.^[8] Next function is to work with the design and technical department to ensure the product is built to the correct specifications and to place any new designs or changes to the product onto the line. Finally, the production department collaborates with the works department to ensure there is a proper workforce available to check the quality of the product and make any necessary repairs to any equipment that

breaks. RA officer will check in between that, proper Good Manufacturing Process guidelines (GMP) following by production department and proper production permission they have or not. Full process is done according to Standard testing procedures (SOPs) and Batch Manufacturing Record (BMR). After proper verification by RA or In-process quality assurance (IPQA) material will transfer to next stage.^[9]

4. Medical Devices department

This is most sensible department in Pharmaceutical industry, the regulation of Medical Devices is overseen by both, the central government and the state governments. For manufacture, import, distribution and sale of medical devices require licenses or permissions from State FDCA and DCGI as the case may be. There is different forms available for import, export and manufacture of medical devices. Certificate of registration of the foreign manufacturer and the medical devices to be imported (Registration Certificate) approval will obtained in Form 41.^[10] For Import of Notified Medical Devices in India license will obtained in Form 10. License to manufacture Notified Medical Devices will obtained in Form 28 from DCGI. It is the duty of the RA officer to make sure that labelling and packaging is done according to proper guidelines given by DCGI. During manufacturing, GMP guidelines are the key portion in medical devices.^[11]

5. Quality Control department

Quality Control (QC) department having the duty to testing of raw materials, packaging materials and carried out in process controls. In QC highly trained and experienced personnel will done testing with modern analytical techniques. QC also undertake reference standard certification in compliance with GMP regulations. RA department role is to collect the certificate of analysis, Stability studies, Analytical method validation reports (AMV) and AMV Protocol for submit the dossier for registration of the product.^[12]

6. Quality Assurance Department

Quality Assurance department (QA) is responsible for the maintenance, compliance and further development of our internal quality management system (QMS). The QA group assurances that the pharmaceutical ingredients and other products comply with the respective requirements and are developed, produced, tested and released according to GMP demands.^[13] RA officer will collect Master Formula Record, Process validation Protocol, Process validation report from QA department. RA department have to review these documents for submitting the dossier to regulatory authorities to get marketing approval or

register the product. It is the duty of the RA officer to check that QA department comply with regulatory guidelines or not.^[13]

7. Packaging Department

After manufacturing process material will transfer to packaging department for packing and dispatch. QA officer will play vital role here to check the packing material and proper packaging of the medicines. Leak test will perform by QA officers for blisters and sachets, if leak test fail than material will reject and will not dispatch to market. RA will require packing material samples and strips, blisters for documentation as a proof for submitting to the regulatory authorities for getting the drug registration approval.^[14]

Impact of the Goods Services Tax

The Indian pharmaceutical industry is the major supplier of generic drugs all over the world, with 80% of all AIDS drugs produced in India. The United Nation has provided licenses to six Indian pharmaceutical labs to make generic anti-AIDS medicine for all the developing nations. Indian pharmaceutical companies manufacture 20% of all generic drugs used around the world.

Now it is the duty of the RA official to take care of the quality of the products manufactured by Indian pharmaceutical companies.^[15]

There is no huge impact of GST on medicines, but a tax rate of 5% on life-saving drugs that treat diseases like malaria, HIV-AIDS, tuberculosis, and diabetes is predictable to slightly increase prices of these drugs.

Earlier these drugs were exempted from excise and customs duties. However, a few states were charging 5% on these drugs which will now be subsumed under GST. Under GST, there will be a 12% on formulations and 18% on APIs (active pharmaceutical ingredients) – the bulk drugs that go into the making of final pills and tablets.^[16]

Earlier, Ayurvedic drugs or medicines were available at an average VAT of 4% and excise of 1.5% due to the excise free manufacturing zone benefit. Under GST, Ayurvedic medicines could get costlier as they would be taxed at the rate of 12%.

CONCLUSION

From this review we concluded that there is correlation between Regulatory affairs and different departments of pharmaceutical industry. For register a new drug in market RA department is the main key. It is the duty of all departments that they should follow updated regulations in their departments provided by regulatory authorities for faster growth and availability of medicines in the market. After GST came into force price of medicines increased and shortage of medicines occurs. Advantage of GST is that the medicines will be available on same price in whole country, no inter-state taxes will charge.

ACKNOWLEDGMENT

In this article I want to acknowledge my Parents Mr. **Suresh Chand** And Mrs. **Tarsem Devi**, who supported me throughout my studies.

REFERENCES

1. What is a regulatory affair, https://www.topra.org/TOPRA/TOPRA_Member/What_is_regulatory_affairs.aspx.
2. Regulatory Affairs: an Overview, <http://www.pharmatutor.org/articles/an-overview-of-regulatory-affairs-and-its-importance-in-pharmaceuticals-other-industries>.
3. The Scope of Regulatory Affairs in the Pharmaceutical Industry, <http://hygeiajournal.com/downloads/554336197subash%20,ansa.pdf>.
4. CMC Regulatory Affairs — Insights and Career Advice from an Expert, <http://www.cmcregaff.com/files/94137004.pdf>.
5. Food and Drug Control Administration http://xlnindia.gov.in/SOS/xln_RP_Working_At.aspx?ST=MH.
6. NOC FOR FORM 29, <https://cliniexperts.com/india-regulatory-services/biologicals/form-manufacturers/noc-for-form-29/>.
7. Department of Biochemistry, http://biochem.iisc.ernet.in/research_areas.php.
8. Role of regulatory affairs in the pharmaceutical industry, https://www.omicsgroup.org/journals/2167-7689/2167-7689_S1.008_052.pdf.
9. ROLE OF REGULATORY AFFAIRS IN A PHARMACEUTICAL INDUSTRY, [http://www.ijpr.com/File_Folder/127-131\(ijpr\).pdf](http://www.ijpr.com/File_Folder/127-131(ijpr).pdf).
10. The Indian Medical Device Industry, http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/The_Indian_Medical_Device_Industry.pdf.

11. The New Role of Regulatory Affairs in Medical Device Manufacturing, http://www.mpo-mag.com/issues/2014-11-01/view_features/the-new-role-of-regulatory-affairs-in-medical-device-manufacturing.
12. Quality and Regulatory Overview, <http://www.dishmangroup.com/quality-assurance.asp>.
13. Quality, http://www.biocon.com/biocon_aboutus_certification.asp?subLink=quality.
14. Role of packaging material on Pharmaceutical product stability, <http://www.ipapharma.org/events/stability/jbhat.pdf>.
15. Impact of GST Rate on Life-Saving Drugs and Other Pharma, <https://cleartax.in/s/impact-of-gst-rate-on-pharmaceutical-industry>.
16. Impact of GST on Pharmaceutical Industry, <https://www.legalraasta.com/gst/impact-gst-pharmaceutical-industry/>.