

Pharmaceutical Good Distribution Practices – A Review of Global Scenario

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ABSTRACT

In order to manage medicine distribution in an appropriate manner, there is a necessity of deep understanding of its management. The challenges of the pharmaceutical products supply chain are its specified shelf life and specified storage conditions. Managing quality of medicines during distribution is a critical operation. There are various dosage forms of medicines eg tablets, syrups, injectables etc. Each of them are to be stored at different environmental conditions defined on the basis of stability of drug products. For cold chain products, more care is required because of the fear of failures during testing. The desired features have high requirements for supply chain management and planning to achieve the goal of ensuring availability in retail stores without increasing the quantity of wasted products in different supply chain phases. In UK, USA and Europe significant amount of control is exercised during medicine distribution as compared to Pacific region.

Key Words: Good Distribution Practices, Pharmaceutical Supply Chain, GMP, GDP, Quality

INTRODUCTION

World Health Organization (WHO) described Good Distribution Practice (GDP) as a part of quality assurance which ensures that products are consistently stored, transported and handled under suitable condition as required by the marketing authorization (MA) or product specification.

Managing quality of medicines during distribution is a challenging operation. The challenges of the pharmaceutical products supply chain is and due to its specified shelf life and storage conditions. The various dosage forms (eg tablets, syrups, injectables etc) are to be transported and stored at different environmental conditions hence all medicines cannot be handled with a general rule. viz the requirement of handling tablets, syrups and injectables shall widely vary.

Cold chain product range of medicines are stored at temperature between 2 to 8 ° C. For cold chain products, therefore the degree of carefulness shall be more due to the fear of product failures during quality control testing by customers.

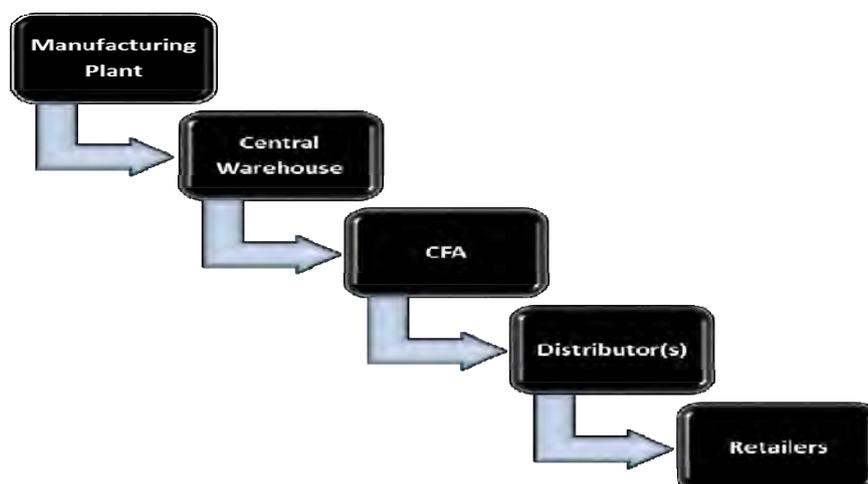


Figure-1 : Pharmaceutical distribution Process

The efficiency and performance of the whole supply chain is essential in minimizing the environmental effects. Thus, producing only the volumes that have been demanded can significantly reduce the waste caused in perishable supply chains.

DISCUSSION

A review of worldwide literature's availability on GDP reveals that the awareness about GDP is maximum in United States of America (USA) followed by United Kingdom and Europe.

In western countries the use of vehicle with controlled temperatures (also called Reefer containers) are mandatory but in countries of Indian subcontinent neither use of such vehicles nor temperature controls at retail counters are given importance. Waste reduction of medicines, particularly in medicine in liquid form has become an important goal in order to implement sustainable performance of supply chains.

Public health crises caused by shortages of medicinal products usually require centralized assessment by multi-disciplinary teams from within the Network, require the engagement of all stakeholders in the Network, frequently require the engagement of actors/experts inter-linked with, but not operating within the Network, usually need rapid and sophisticated communication of appropriate risk management measures, and may require an implementation that is customized to the national situation.

The effects of these crises can be more enduring after the initial shock to the system and they may require short, medium and long term remediation measures to be taken both by industry, by the Network and by patients/healthcare providers.

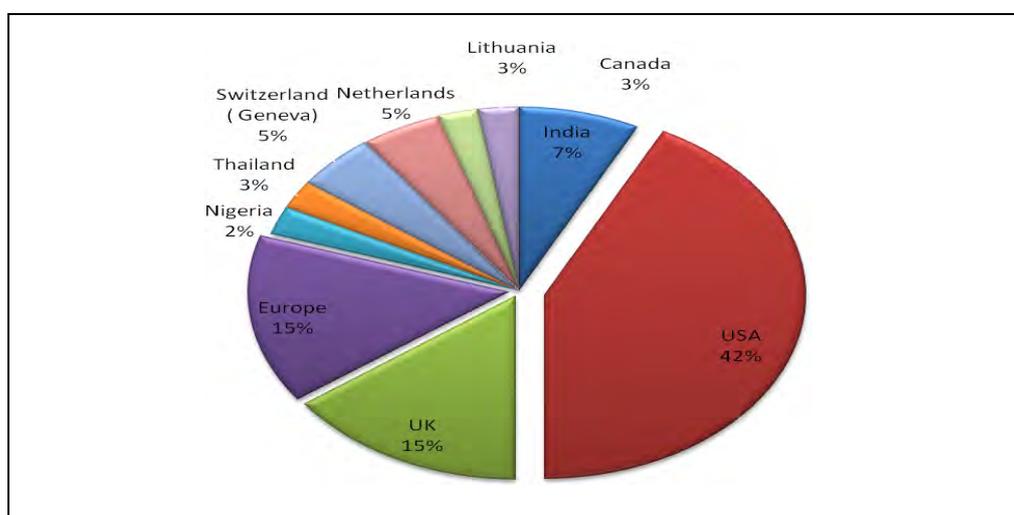


Figure-2, Survey of countrywide literature's availability on GDP

During literature survey, it was observed that very less work has been carried out on studying the status of GDP in India.

The GDP guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent.

GLOBAL SCENARIO OF 'GDP' IMPLEMENTATION

With the incidents of counterfeiting, theft and diversion increasing steadily, the industry needed to continuously evolve its methods and controls to rapidly manage these risks and preemptively shift practices to avoid incident. This study explores this global issue and best practices to help ensure supply chain security to provide both patient and brand protection.

Scenario in UK

In UK, a national body has been established for ensuring the interest common patients, but grossly an absence of a structured mechanism to address overall problems of patients has been observed. The problem of counterfeit medications in United Kingdom has been assessed by independent hospitals.

GMP/GDP Consultative committee meets at a regular quarterly interval under the aegis of national regulatory body Medicinal Health and Regulatory Agency (MHRA). The Consultative Committee is an informal committee established to provide a dialogue between the MHRA and other Governmental departments, the Devolved Administrations, and relevant trade associations on matters relating to the manufacture and wholesale distribution of medicinal products for human use.

This committee comprises of a group of experts drawn from government, regulators, British Association of Research Quality Assurance, industry, and the academic and third sector communities meet to discuss healthcare regulation issues, including the development of new initiatives and innovations. In

September 2012, a meeting was held to discuss various issue and was attended by regulator MHRA. The MHRA considered that the key objective is to establish how all stakeholders can work together. It was observed that there is hardly any discussion about the status of GDP, although the purview of committee covered GDP as well as GMP.

The drugs regulatory agency of UK has quality noticed problems arising during distribution of medicines. In UK, medicine supply problems can occur for various reasons, such as manufacturing problems, difficulties in obtaining raw materials, regulatory issues, changes to manufacturers' distribution systems and fluctuations in parallel trade.

Scenario in Europe

European Medicines Agency (EMA) published a Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems. This Reflection Paper is concerned with public health crises that arise due to unforeseen disruptions within the manufacturing process, caused by manufacturing/GMP compliance problems and affecting medicinal products for human use, independent of their route of authorization, where a need for co-ordination of the assessment and risk reducing actions at a Community level has been identified.

While control and supervision of the national market remains a national responsibility, Member States may experience difficulties in acting in a purely national way when faced with a pan-European crisis during distribution network. The network is increasingly looking to the European Medicines Agency (EMA) by coordinating the development and communication of appropriate risk management measures arising from unexpected shortages in supply. This coordination may be through informal cooperation and information sharing or formally through the initiation of Community procedures as a result of identified public health concerns where supply is affected.

In member countries of European Union, the wholesale distribution of medicinal products is an important activity in integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players⁽²¹⁾. These guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products.

Scenario in India

The Indian Government has issued a consolidated paper through Central Drugs Standards Control Organization (CDSCO) on good distribution practices (GDP) for pharmaceutical products to ensure the quality and identity of pharmaceutical products during all aspects of the distribution process like procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices. This is considered as a historical step towards strengthening GDP during various operations of supply chain management. Although this invokes guidelines during transit and storage but it is not considered adequate to maintaining quality of products. Similar to pharmacy practice followed in USA, the role of pharmacist in preventing distribution of substandard medicines are yet to be implemented in India.

CONCLUSION

There is a need for effective supply chain management and planning to achieve the goal of ensuring availability in medical retail stores without increasing the quantity of wasted products in different supply chain phases. The cGMP is a dynamic form of guideline, which gives latest information on "Dos and Don't Do". But nowhere the concept of current practices in Good Distribution Practices GDP has been emphasized. Therefore, the pharmaceutical supply chain management must attempt to continually upgrade the distribution practices with a structured system.

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