Social Management in Pharmaceutical Healthcare Sector

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Authors’ contributions

This work was carried out in collaboration among all authors. Author TYV designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors KT and TBY managed the analyses of the study and managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aims: There is an increase in demand for the social environment regulations in the pharmaceutical companies, which is a crucial strategy issue in long-term planning due to the incidence of social influence. The influence of society over resource allocation and its control over innovation is all the perceptions of today’s needs. This research aims to highlight the managerial issues faced by the pharmaceutical healthcare sector of Ukraine. Our study is unique as we have analyzed the whole pharmaceutical sector of Ukraine in terms of management issues. There is no such research done yet. In addition, we have also researched the official databases and laid down the models for management practices.

Methodology: The research was done to analyze the major issues in the social management of the pharmaceutical healthcare system. In addition, the related studies based on managerial issues were studied. The following databases were used to study the guidelines: World Health

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Organisation, Food and Drug Administration, International Council for Harmonization, and European Union.

**Results:** The results were found to be when comparing behavioural studies with non-behavioural; non-behavioural was found to be 64%, whereas behavioural was 34%. To have an in-depth knowledge of the managerial issues, we have provided an inverted tree diagram representing the significant issues in pricing and medical expenditures. These contributed 21.7% of non-behavioural studies, and in behavioural studies, it was found to be consumer or physician-level behaviour 23.4% contributing the central part of the issue.

**Conclusion:** Here we conclude that the pharmaceutical healthcare sector plays a crucial role in the global healthcare of the general public-facing management issues; hence should be analyzed and follow the guidelines to analyze the issues within the company and set goals. Therefore, improving the management of the pharma sector will, in turn, improve public health in Ukraine.

**Keywords:** Social management; pharmaceutical industry; managerial issues; management practices.

## 1. INTRODUCTION

The impact of social management is very crucial in any organization; when it comes to the healthcare system, it becomes more crucial to research and improve it. The practical and productive influence of all the social processes of the organization comes under social management. The involvement of an individual, group, team in the social processes governs the efficiency of the social management of an organization. According to the ongoing social trends, long-term essential strategic planning and short-term efficient tactical planning significantly affect companies' survival [1]. There is an increase in demand for the social environment regulations in the pharmaceutical companies, which is a crucial strategy issue in long-term planning due to the incidence of social influence. The influence of society over resource allocation and its control over innovation is all the perceptions of today's needs. The initial essential processes are the drugs, their distribution, and their marketing and available funds by controlling prices and profits. Recent studies indicate that the future of multinational pharmaceutical companies has recorded a low level in social management. By effective forecasting social techniques, the future can be successfully evaluated. It is often forecasted that socially and economically valuable industries usually are less likely to meet the future demands of the industry for the well-being of the society. Social management for a pharmaceutical industry comprises the quality controls, safety, and efficacy of the medicines at the national and international levels. Digitalization also improves social and technological processes along with economy [2]. The drug industry is a socially accountable sector producing medicines, facing challenges to follow the growing standards. All drugs manufactured should have GMP and GDP certificate for their distribution [3]. The study's primary purposes of implementing the measures of the management systems. This paper explains the development of pharma organization standardized models to aim for quality management, health and safety. This paper targets the fundamental issues in management in an organization producing medicines in the broader domain manner. The implementation of management models has become a necessity for modern business [4]. While choosing the models for increasing efficiency and productivity, the organization needs to set basic requirements. These will help plan the framework and fulfill demands for end consumer needs. The pharmaceutical industry of Ukraine produces about 3000 drugs sold in the market. All types of dosage forms are produced solid, liquid, powder, etc. All the main categories of drugs are produced here in the Ukraine pharmaceutical industry, such as cardiovascular drugs, vitamins, analgesics, GI tract, antibiotics, etc. [5]. The leading national companies in Ukraine are JSC-Joint Stock Company Damitsa, corporation arterial (LLC- Kyivmedpreparat and JSC Galichfarm), LLC FC health, JSC Borschagovsky, JSC Farmak. This big pharmaceutical industry produces more than 5.1 million UAH comprising 10% of the national market medicines [6]. Researchers are more focusing on management issues; several studies are defining a single problem. Here we have a broad spectrum of the research. We have analyzed all major management issues, and also we have described various guidelines and models to be adopted for decreasing the defects. The models should be implemented as a preventive measure for pharmaceutical
companies. Some major companies in Ukraine executing are cost-effective and more productive. The advertising strategies is influenced by many stochastic internal and external factors [7]. Our study is unique as we have analyzed the whole pharmaceutical sector of Ukraine in terms of management issues. There is no such research done yet. In addition, we have also researched the official databases and laid down the models for management practices.

2. METHODOLOGY

The research was done to analyze the major issues in the social management of the pharmaceutical healthcare system. In addition, the related studies based on managerial issues were studied. The following databases were used to study the guidelines: World Health Oranization, Food and Drug Administration, International Council for Harmonization, and European Union. For specifically searching the pharma sector of Ukraine, we have done an exploratory search for all the pharma companies in the Ukraine market (Table 1).

2.1 Major Issues Studied

The significant issues studied in the pharmaceutical healthcare sector are structured in the inverted tree diagram (Fig. 1).

The peak studies year 2020 are related to research journals in the pharmaceutical industry and economics and management research. While searching, there is increasing interest in the academic perspectives in the pharmaceutical healthcare sector, which is playing an essential role in global healthcare. Some of the significant issues identified are as follows: the financial expenses of pricing and medical of the industry; the marketing studies: STP(targeting and positioning strategies), PR(promotion), CB (consumer behaviours) [8]. R & D (research and development) is very crucial in every step of the drug process and well being of the public health; For single organizational level: M & SOM (Manufacturing and service operations management); for studies between healthcare industries and pharmaceutical: SCM (supply chain management); OB-organizational behaviours describe how individuals behave in the competitive environment with regulatory pressures; CGS- corporate growth strategies; it studies the increasing probability of mergers and acquisitions in the pharma industry; other issues such as environmental management.

Below is the inverted tree diagram figure depicting the issues with various sub-issues and exciting insights. The studies depicted in Fig. 1 show that approx 64% of the literature focuses on non-behavioural studies. Significant

| Pharma company       | Location in Ukraine | National(N)/Multinational(Mn) |
|----------------------|---------------------|-------------------------------|
| Amaxa Ukraine        | Kyiv                | N                             |
| Agio Pharmaceuticals | Kyiv                | N                             |
| Takeda Ukraine       | Kyiv                | N                             |
| Tov Takeda Ukraine   | Vinnytsia           | N                             |
| Pfizer               | Kyiv                | MN                            |
| Roche                | Kyiv                | MN                            |
| Zdorov’ya            | Kharkiv             | N                             |
| Valartin             | Kyiv                | N                             |
| Farmasoft Tov        | Kyiv                | N                             |
| Mntek Ooo            | Kyiv                | N                             |
| S Pharma Llc         | Shchaslyve          | N                             |
| Kcr Ukraine Llc      | Kyiv                | N                             |
| Lyum’yer             | Kyiv                | N                             |
| Psi Cro Kiev          | Kyiv                | N                             |
| Indar Prat           | Kyiv                | N                             |
| Sperco Ukraine       | Vinnytsia           | N                             |
| J & J                | Kyiv                | MN                            |
| Atis                 | Kyiv                | N                             |
| Joint Stock Company  | Kharkiv             | N                             |
| Global Clinical Trials| Kyiv                | MN                            |
contribution in this perspective is given by R&D, SCM, and pricing studies. The pricing and expenditure studies, including PR and STP, are non-behavioural studies in nature. The pricing and advertising behavioural aspects depicted in Fig. 1 are classified under CB. The organizational behaviours and its other aspects are also presented of SCM, R&D, corporate growth strategies issues. These searches focus on the relations, interactions within the industry. The ongoing increased competition in the pharmacy industrial market requires optimizing the materialistic or technological, or financial issues [9]. Behavioural studies have now become vital to understand as well as non-behavioural practical issues. Significant issues related to physician and consumer pricing issues are also studied. Searching the sub-issues under these major issues has led to in-depth knowledge of these issues. The spurt in the studies of pricing-related issues suggests increasing concerns with the pricing of medicinal products and their ease of access to the public healthcare system. The increased number of consumer-level studies relates directly to the importance of physicians and pharmacists playing an end consumer. The figure depicts that over the last years, interest has been increased in SCM, R&D, and manufacturing management. This allows focusing service management in the pharmaceutical industry. These efforts suggest that there has been a shift towards efficiency-based systems. Other issues denote upcoming issues of strategies. Promotion and advertising studies open a new pace for management research.

2.2 Recently Applied Management Practices in the Pharmaceutical Healthcare Sector Ukraine

2.2.1 QRM-quality risk management

All processes or products, or programs have a chance of developing "risk"[10]. Risk means evaluating the probability of risk with severity and potential loss in the complete process. For effectively applying for quality risk management programs in the organization, risk – should be clearly defined as the emerging increase in the stakeholders with a conflicting interest in the pharmaceutical industry. RMP-risk management programs are now reorganized; FDA has implemented changes within the agency and industry it regulates. Positioning papers have been started to be published with guidelines by FDA for a risk management. QRM is a method used to assess, communicate, control, and review the risk associated with the drugs throughout the product life cycle [11]. The decisions are required to be taken at any time in the complete process. For medical device use safety guidelines, human factors are incorporated for risk management. It classifies the device development hazards as a part of this risk management program.

2.2.2 QD- Quality by design

The product does not solely test quality, but it has to be built in by design. ICH Q8 concerns pharmaceutical development to target quality design into the manufacturing process, formulation and ingredients [12]. Design space is subjected to regulatory approval. These situations create more opportunities for more flexible regulatory approaches. The design of pharmaceutical research should be related to its purpose.

2.2.3 Preventive and corrective management

The deficiencies in the management systems should be analyzed for the detection of trends. These trends will allow the prevention of upcoming problems. Prevention is better than cure, and also, it is a cheaper way than to fulfil the expenses of the problem fixing. Problems are opportunities for betterment. Generally, CAPA experts do root cause analysis by four-step management [13]: identification: problem identification ; evaluation: assessing the risk ; investigation: assigning the responsibility ; analyze and documentation: the root cause ; JSC Ukraine pharma has a new tracking system for corrective actions, which results in faster time enclosure of any corrective action. As a result, access and speed are easy and fast. As a result, professionals are now focusing on more issues.

2.2.4 The process capability analysis

It is the analysis between the voice of the customer with the process commonly termed as VOC vs VOP. VOC directly relates to the customer requirement, which is defined by the process specifications. VOP directly relates to controlling limits; it's the performance data that varies with time. The capability index is used as a management tool for the comparison of the performance of the process.
2.2.5 Six sigma

This is a basis for the management of the organization. It is defined as a business process that helps increase the companies’ profits by improving the quality and eliminating the defects that often occur in all companies. So it’s a management plan that helps to improve the...
Six Sigma follows the DMAIC model: Define, Measure, Analyze, Improve, and Control. Each element of the model defines a crucial aspect of the improvement in the management of the organization.

Six Sigma has been adopted by the JSC pharmaceutical firm, where staff is trained to apply the DMAIC methodology. CI- continuous improvement teams are involved. The team identified wasteful processes and efficiently added 20 million more units of capacity per year.

2.2.6 The Process Analytical Technologies (PAT)

The main aim of PAT is to enable control of the manufacturing process by applying chemical, physical, microbiological, and risk analysis methodologies. As a result, it yields cost savings and efficiencies in manufacturing. Therefore, it has a lot of benefits in the management of the organization.

2.2.7 The Total Quality Management (TQM)

It is a critical concept, not a technique. It involves every element of the company from an integrated, systematic, and consistent perspective. It is the part of management philosophy directly relates to customer satisfaction and improvement of the organization. It is a continuous improvement process. It improves profit, competition, productivity, and market share of the company [15].

2.2.8 The Hazard Analysis and Critical Control Point (HACCP)

It is a part of a safety management system. The primary purpose is to reduce the risk and hazards. It is a methodology comprising the complete process of assessment, identification, and control of safety hazards. For example, antibiotics, cytotoxic substances, and hormones require hazard assessment and control [16]. There are seven principles as set by WHO: 1. Hazard analysis; 2. Control point determination; 3. The setting of critical limits; 4. Monitoring CCPs; 5. Establishment of corrective actions; 6. Verification of HACCP; 7. Documentation.

3. RESULTS

We have conducted an exploratory search on management issues and guidelines followed by the pharmaceutical industry. By thorough search of online databases of UKRAINE and WHO, FDA, EU, we have set out the guidelines that are structured for the management system improvement in the pharmaceutical healthcare sector. To have an in-depth knowledge of the managerial issues, we have provided an inverted tree diagram representing the significant issues in which pricing and medical expenditures contributed 21.7% of non-behavioural studies. In behavioural studies, it was found to be consumer or physician-level behaviour 23.4% contributing to issues. When comparing behavioural studies with non-behavioural, non-behavioural was 64%, whereas behavioural was 34%. Services management issues contributed 8.9% in non-behavioural and organizational behaviours made 8.6% issues in the pharmaceutical healthcare sector of Ukraine. While searching more than 150 published papers and official databases for guidelines, it is highlighted that it is the need of the hour to search by case studies for pharmaceutical factories to improve management issues by applying the guidelines and general practices implementation.

4. DISCUSSION

The pharmaceutical healthcare sector of Ukraine has been subjected to varying needs of the consumers, with infrastructural and funding constraints. Successful management in this sector must deliver good quality medicines and industry development depending on organizational management [17]. Here we have searched the management issues faced by the pharmaceutical sector of Ukraine; these issues are of vital interest for researchers and practitioners. Considering the need to access the management issues, we have searched official pharmaceutical websites and accredited journal publications to access the main issues faced by this sector. Hence, identifying the issues is the first step towards improving the management. We have identified the major and minor issues faced by Ukraine pharmaceutical healthcare sector. It has been noticed that interest is increasing over the past few decades to analyze the industry's defects. But there is a knowledge gap found in finding the managerial issues in this sector, so this study is the basis for finding the
issues [18]. Then there are different models to apply corrective measures. We have used official databases to discuss the problem-solving guidelines of utmost importance to deal with the issues. Some examples have been mentioned that follow the guidelines by an integrated system and are time-saving and cost-saving. The primary issues have been divided into behavioural and non-behavioural. Significant issues have been searched in these two categories, and to have in-depth knowledge, sub-issues have also been discussed. The inverted tree diagram representation has been used to overview the pharmaceutical healthcare sector of Ukraine. These are based on the aspects of knowledge, assets, and information. Consumers and physicians play a crucial role, focus on the pricing and medical expenditures, which are the basis of the needs for generating policies and decisions. These research structures have clarified different issues and guidelines to solve the problem accordingly, especially in the European region. Application-oriented perspectives are used for dealing with research and development, including manufacturing processes. Emerging demand on the behavioural and non-behavioural aspects of the management in this health sector has created interest in the field studies. This study is unique as it focuses on efficiency management by assessing the end consumer demands of physicians and pharmacists. There is a scope of exploring current best practices of management of the organization.

5. CONCLUSION

Strategic planning in the organizational culture is most important in management systems. The studies noticed that interest in strategic management planning is enhancing in the pharmaceutical healthcare sector. Therefore, companies should utilize their assets to implement and solve managerial issues. The pharmaceutical healthcare sector of Ukraine is under fire due to the sudden increase in production demands. This article explores the role of management issues and problem-solving strategies. Applying management principles and practices in the organization can highlight the more patient-oriented opportunities as the pharmaceutical department is of significant social importance and is directly aiming at global health in independent Ukrainian state development. The management system is aimed at human health preservation and promotion. All these analyses help in the identification of the guidelines to be followed to improve the issues critically. The guidelines and models help in the cost-effective programs. This study concludes that the critical factors involved in managing the pharmaceutical healthcare sector analyzed by each firm and implemented by an integrated guidelines system to grow the competition and ultimately reduce cost utilization.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our
area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

**COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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