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INVENTION OF SYSTEM DYNAMICS PRODUCT LIFE CYCLE MODEL FOR THE PHARMACEUTICAL INDUSTRIES

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Abstract

Identifying elements those are affecting on the sales of Pharma product for precise planning and prevention of decline stage of PLM cycle is very needful analysis now days when industries and associated supply chain are fighting with each other. System dynamics model has to be used to study the behavior of supply, demand and competition. Pattern of 650 medicines has been studied and along with that there reference mode also has been studied. Simulated quantitative dynamics model by considering real world data between years 2011 to 2019 from South East Country. Demand and forecasting marketing efforts and R & D Activities revealed that critical elements in the formation of generic PLC model. 50% increase of manufacturers, marketing, R &D activities can enhance 50% sale in declined stage of the product. PLC can give deep insights of the process and factors which causes declining stage arrival of their product earlier. PLC and PLM helps to avoid product to enter in declined stage even if demand for product drops in market with respect to time or as a sudden effect.

Keywords: Pharma, PLM, PLC, Demand, Product, Medicine etc.

INTRODUCTION

PLM is a strategic process which manages organization products effectively from start to the time when product will exit the market either due to its declination with respect to time or sudden vanishes the product demand. PLM allows using product and processing related information to make good business related decisions. PLM concept means creating strategy between industrial products and peoples. Medical sector in recent years sought many medical instruments for improvement of quality, better service, avoid insufficient use etc. Market for product is dynamics due to rapid change in tool and manufacturing technology, research, rules and regulations, protocols which keeps changing consistently. PLM implementation needs, strong evaluation and analysis of the system to accommodate an address change such as market development, regulations and technology etc. Use of PLM in Pharmaceutical industry is very important. It is justifiable too. Organization which as comprehensive strategy for PLM, implemented PLM which avails the service benefits such as increased revenue, clinical benefits, increased growth phase of product life cycle management [1-4].

Drugs development is associated with clinical trials, PLM plays a vital role in the connectivity of two stages and transparency. PLM is helpful in regards such as removal of defective products from market; accelerate development process and reducing of the development cost etc. PLM is responsible for supporting the innovation, open innovation through marketing activities, manufacturing and production, business model etc. PLM innovation management through all stages across life cycle of product by integrating product and information [2, 5].

Coordinating product information across all life cycle stages is a major role played by the PLM. Shifting of resources from one place to another in the case of underutilization or wastages, a PLM is an optimum resources manager from better productivity point of view. 1st stage in the PLM implementation is identifying factors affecting on the performance of the PLM. Less research has been undertaken so far in the PLM domain as per PLC is concern. Pharmaceutical market in last few years has grown suddenly. Specifically market on generic medicine, as generic medicine offers same advantages as that of brand medicine and yet come at an affordable price and despite the growth they facing challenges at domestic and international level product selling. Concentration of government on price setting they have no scope of price competition rather they maximize the profit by reducing the cost. Main objective of the paper is to study system behavior and factors affecting which causes product to meet declined phase. Elements causing declining stage of PLC/Product, which company will avoid pass through proper decision, strategies protocol and able to maintain market share and performance without going below benchmark which would otherwise cause organization to narrow out the competition [1-3,6]

In year 1967, Cox studied PLC for 780 pharmaceuticals;

predict different types of PLC behavior. PLC model is a system which comprise of thousands of products. Its characteristics, behavior, influence has been studied to reveal out the conclusion. Other studies predicted sales pattern for different kinds of medicines. Factors affecting on PLC. In the year 1991, Jernigan-Bell shaped pattern as common for PLC. In year 1990, Henry and Smith has studied increasing price of drugs, increase competition and shortness of particular kind of drugs in the market. In year 1994, Bergsorm, Hoog has studied the switching between prescribed medicines to over the counter one, influence of the PLC pattern and also studied increases in the sales volume and factors associated with that. In year 2000, Bauer and Fisher have studied the new and old drugs in cardiovascular groups, early medicine gain faster and rapid sale than new one [4, 7-9]

In year 2010 Fisher has studied the quality and entry order of pharma products which affects maximum sale and time to reach maximum PLC curve. Studies have also shown that, positive effect of advertisement and publicity on physician and pharmacies and patients on the drugs sales. Studies and R & D Quality effect on the sale of specific kind of drugs. In the year 1969, Bass has studied the peoples buy the medicine or product under influence of factory advertisement or as per the instructions. Bass Model is diffusion theory which tells how innovations speared through user perception and instructions. System Dynamics Model tells/shows relationship between variables which used to model different relationship between variables over the period of time. It analyzes the system behavior, guiding the policy makers, managing the companies and this falls in an applicability of the system model. In year 2011, Kazemi has proposed System Dynamics Model/SDM and suggested several practical factors such as quality price, consumer satisfaction, product attractiveness etc. In year 2012, Safri has studied the loop for PLC and factors involved in it. He has considered factors such as demand, uncertainty, product innovation, R & D undertook by the manufacturer etc [2-5].

In year 2020, Carcos has suggested the System Dynamics Model for supply management system in pharma industry. System behavior is studying by considering government, biological environment, pharmacist, hospitals and patients etc. In year 2019, Moosvand has studied and developed System Dynamics Model for generic supply chain of pharmaceutical industry. He has collaborated PLC with suppliers, new technology and optimization technology etc. In year 2017, Wu and Mao has studied the drugs supply chain actors and System Dynamics Model to evaluate the performance. In the year 2013 Abzollahiajl has developed System Dynamics Model considering elements such as availability, affordability and quality etc. System Dynamics Model combined or integrated with PLC has studied over period of time for different variable relationship and its effect has studied on the sale. Through this paper problem sources are predicted, also planning of specific strategy for satisfying PLC is also discussed in the paper. PLM planning influence on companies open innovation through System Dynamics Model [1-3, 7-9]

2. MATERIAL AND METHODS

System modelling dynamics shapes the System Dynamics Model.

1.1 Problem definition and reference mode: Cause of an existing problem. Identify the key factor behavior. Less important variable will be decreased or eliminated. These variables are kind of affects the system but do not get affected by it. By reducing variables system can be simplified. System affecting variables are considered on priority basis and irrelevant are deleted or eliminated.

2.1 Developing casual loop diagram: This diagram depicts the relationship between different variables in PLC system. Based on system behavior model boundaries are formed.

3.1 Developing stock and flow diagram: Diagram is developed based on nature of variables. Stock variables will be material and money, accumulation of resources etc. Flow variables are stock variables.

4.1 Testing of variables: The test of two types, one is structure test and another is behavior test. In structure test, mechanical calculations compared with relations between elements in real system. In behavior test, it is ensured the model behavior and it will be similar to the real system behavior or not.

3. DATA COLLECTION AND ANALYSIS

It involves following stages,

Problem definition: Identification of factors involved in the formation of PLC and behavior of PLC for generic pharma products by developing comprehensive system dynamics model. 545 generic medicine data of drugs has been collected for analysis and study purpose. The data was between years 2000 to 2020. Software and technology has used in the data collection. Graphs have been plotted. Tables have been written for data articulation. Regression line is set, R2>0.9. The system dynamics model has ran in three subsequent stages such as, considered the dynamics hypothesis, second is casual loop of PLC related relations confirmed through questionnaire to identify cause of reference and last is run quantitative dynamics model based on real world data and experts definitions.

3.1 Details of the medicine used and their suppliers: Name of the drugs is Valsartan 80mg, Soframycine 150mg, used as pattern has a greatest R2 value i.e. greater than 0.9. The data is of generic drugs available between 2000 to 2020.

3.2 Identification of reference mode: Approximately 25% pharma product of domestic manufacturer does overshoot and collapse. The overshoot and collapse, upward and downward trend is due to unable to explain and understand the change of the patter i.e. demand and supply matrix. Different pattern of product life cycle depicted through matrix below,

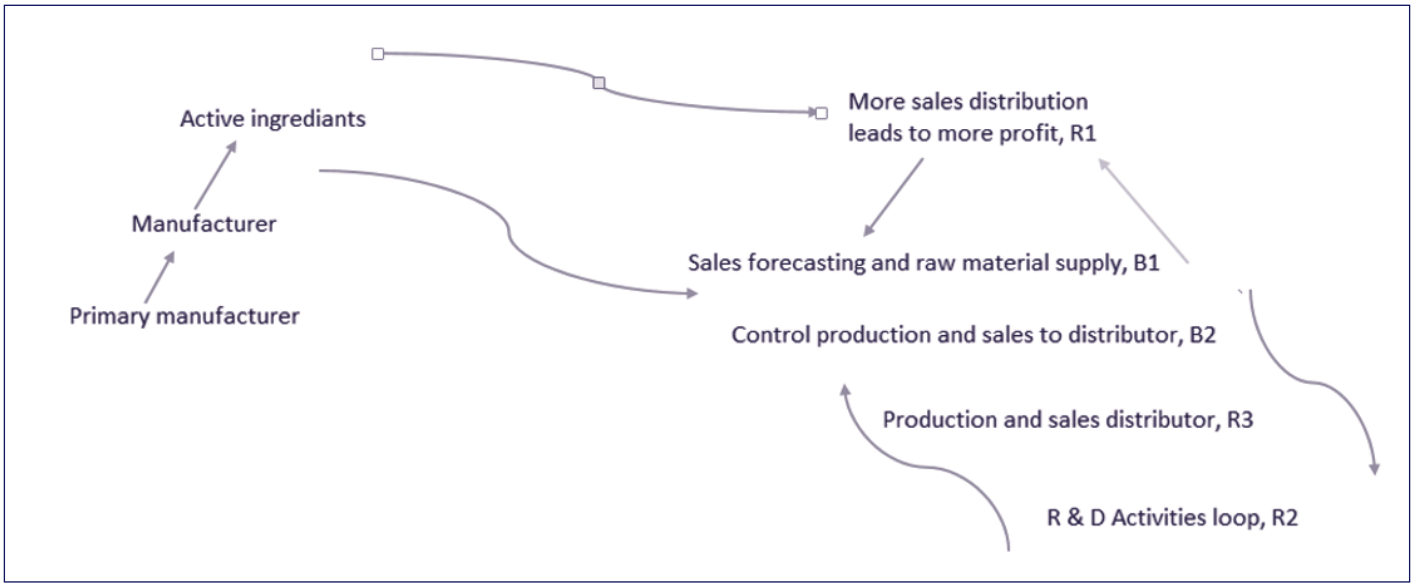
[Structure: PLC type & %, Linear upward and downward trends, 11.40%, Bi-Nominal upward and downward trend, 10.38%, Outshoot and compose, 20.95%, Oscillating, 50.80%, No line fitted, 6.27%]

3.3 System dynamics casual loop for PLC: It comprise of supplier sub system, demand sub-system and competition sub-system.

Sub system of supply side: Qualitative system dynamics model of pharmaceutical product life cycle is explained below.

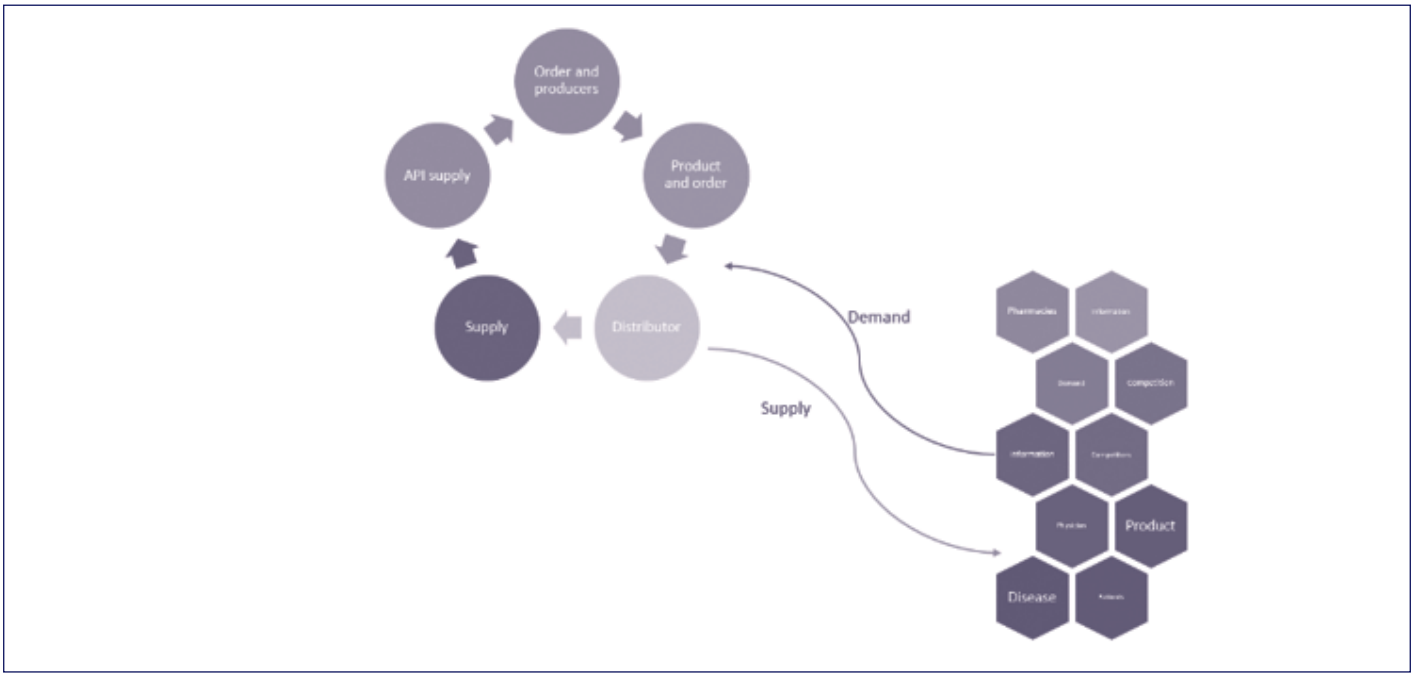
Primary manufacturer manufacture the ingredients and secondary manufacturer receives the active ingredients. The Positive feedback loop represents the more sales to distribution can represent the more profit. Balancing loops adjusted with feedback loops. Effect of sales forecasting and supply raw material, the loop B1 controls while loop B2 controls production and sales to distributors. Loop R3 presents the primary variables, production and sales to distributor. Primary variables received to manufacturer, marketing, feedback loop, R & D activities loop, also affects the sales to distributor and drugs quality.

Fig (1): Qualitative system dynamics model for pharmaceutical product life cycle management



3.3 Variable analysis: Mostly referred as a set of variables is chosen from literature and technical reports, thesis etc. Most common and useful from study point of view chosen to proceed for further analysis after talking with an experts. Relation between variables of PLC entered into system. Casual loops diagrams and qualitative models have been developed. Casual loop diagrams have been further used to develop stock and flow model inculcating material variables. Then System Development Analysis is performed for the period of 2000 to 2020. Results were obtained for the PLC sub-system of generic pharmaceutical products. PLC has a three sub-systems viz. supplier system centric to producer and distributor. Demand sub-system includes variables such as disease, patient and physician etc. and last is competition system.

Fig (2): Supply and demand relationship represented through concept model of PLC



3.4 Subsystem of demand side: Patient and diseases, physician and pharmacies, variable and relationship explained below,

Patient and disease: Number of patients depends on disease incidence which affected by population.

Physician and pharmacies: Physician is mediator between patient and pharmacies. Loyalty to manufacturer important to increase market share. Manufacturer loyalty can affect by increasing physicians.

Increase in patients: Product unavailability, product satisfaction and consumption etc.

Pharmaceutical intermediate consumers they chose manufacturer of prescription based on inventory and quality of the product. Number of pharmacies can enhanced or pharmacy availability by increasing medicine stock.

3.5 Competition sub-system: Components of competition are as, price, availability, domestic competitors, volume of imported medicine, number of local producers and importers etc. Basic of system domain method, elimination of external variables that are not effected from within system. Environmental factors are excluded.

3.5.1 Model simulation, PLC system behavior: subsystem of supply side are conclusions, flow of raw material, production arte in first six years, upward, along with population growth and number of patients, decline in 2018, due to reduced demand of the drugs. Increased again in year 2019 onwards due to increase in demand of the drugs. Product satisfaction was a general increase due to growth in R & D activities. Quality rise noted between 2012 to 2019. Loyalty decreases due to decrease in manufacturing availability, in year 2018. In year 2019, drop in production results in drop in sale, total demand has increased across country.

Fig (3): Various behaviors of the system

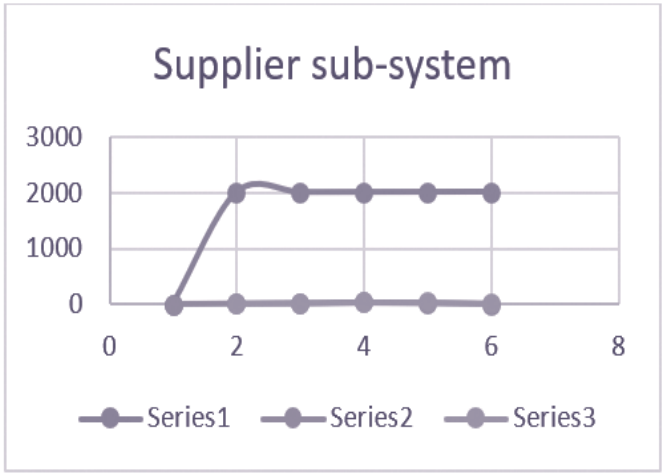
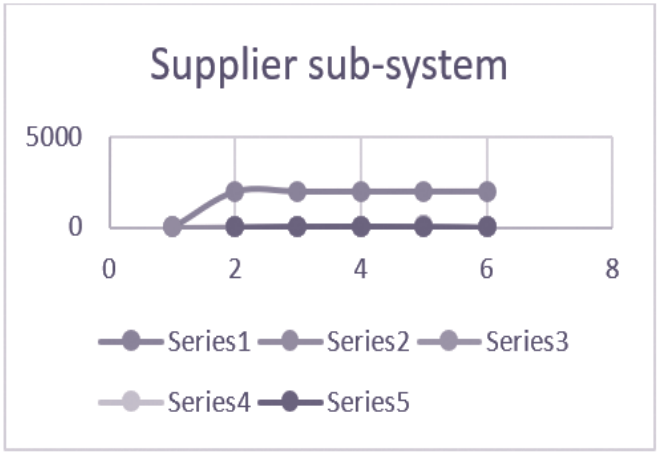


Fig (a): Supplier sub-system



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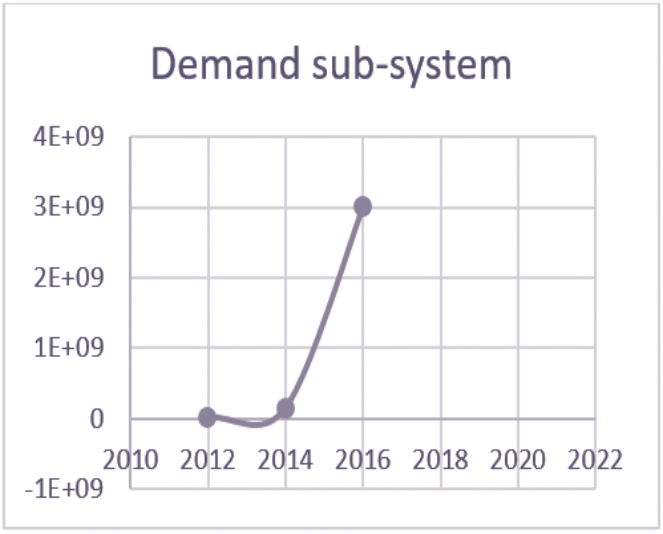


Fig (c): Demand sub-system

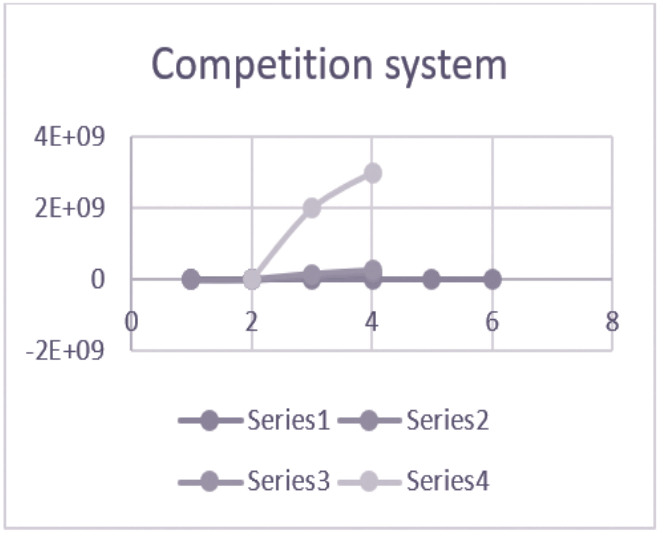


Fig (d): Competition sub-system

Sub-system of demand side: Due to increase in population of hypertensive disease incidence (15 to 20%), number of users of sophramycene and Valsartan has estimated 10.25 million in 2022 and increased up to 10.77 million in year 2019. Consumption of another medicine decreased by 32% in year 2018 compared to year 2017 due to Chinese raw material causing recycling of drugs and reducing demands. Demand has grew in year 2019, contamination of raw material fixed and production resumption takes place.

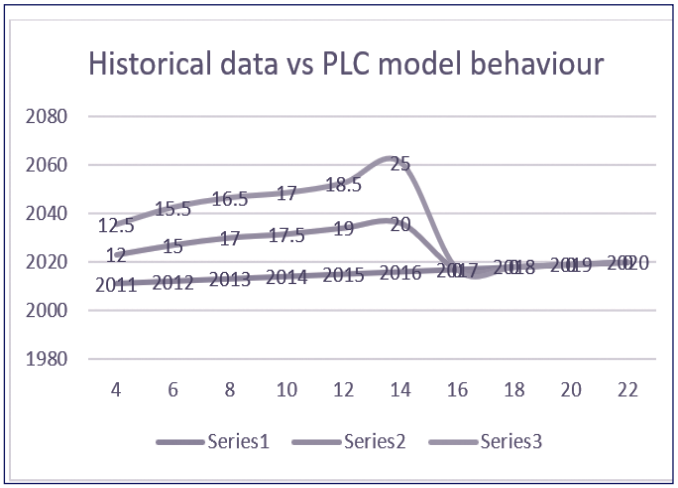
Competition sub-system: Domestic competitors have increased in between the years 2012 to 2020. Total consumption decreased in year 2018 due to some serious contamination and impurity reported by Indian food and drugs administrations. Brand medicine trend starts declining from year 2013. After year 2014 trend was constant. Domestic production raises from year 2012 to year 2019.

PLC simulation results are as follows,

- Demand of medicine raised during study period.
- In year 2018 due to contamination demand has decreased and thus production has also decreased.
- Import volume noted constant during same era and thus domestic companies has started dominating the market. The market share of company could not be maintained due to unstable production, R & D and advertising etc. Company drugs reached to decline stage in PLC cycle.

3.6 Model validation: Model boundary adequacy test is conducted by two methods i.e. by interview and by standardize questionnaire. The sensitivity analysis of model shown impact of company policies on PLC. Elements considered R & D, advertisement; distribution points which mainly responsible in royalty and market shares. The graph below shows advertisement activities and impact on sales in between year 2018 and 2019.

Fig (4): Comparison of historical data vs real data with model behavior included



In above graph, system developed model and PLC model shows close approximation in the behavior.

- Discussion on the graph, Graph (a)
- All graphs present the basic model.
- Change in the sale with no decrease in advertisement activities.
- Change in sale with 20% increase in advertisement activities.
- 50% increase in advertisement between year 2018 and 2019 financial year.
- Increase in sale by 28 to 60% compared to basic model in last two years.
- Demand of drugs has inclined in year 2017.
- Further increase in advertisement do not effect on sale increase any further.

Graph (b),

- Increase in R & D activities and its impact on sale for year 2017 to 2019.
- 20% Increase in R & D activities.
- 50% Increase in R & D activities in year 2017 to 2019.
- R & D Activities in between 2017 and 2019 raised the sale in year 2018, In year 2019 due to delayed effect of R & D activities on loyalty.
- Advertisement activity is more important than R & D.
- R & D is recommended when sale is poor and it is applicable when specific kind of drugs is dropping in demand from market suddenly.

Graph (c),

- Compares number of distributors and their impact on sale for year 2018 to 2019.
- Decrease in number of distributor.
- 50% increase of distributors in year 2018 to 2019.
- Increase in distributor did not effect on the sale.

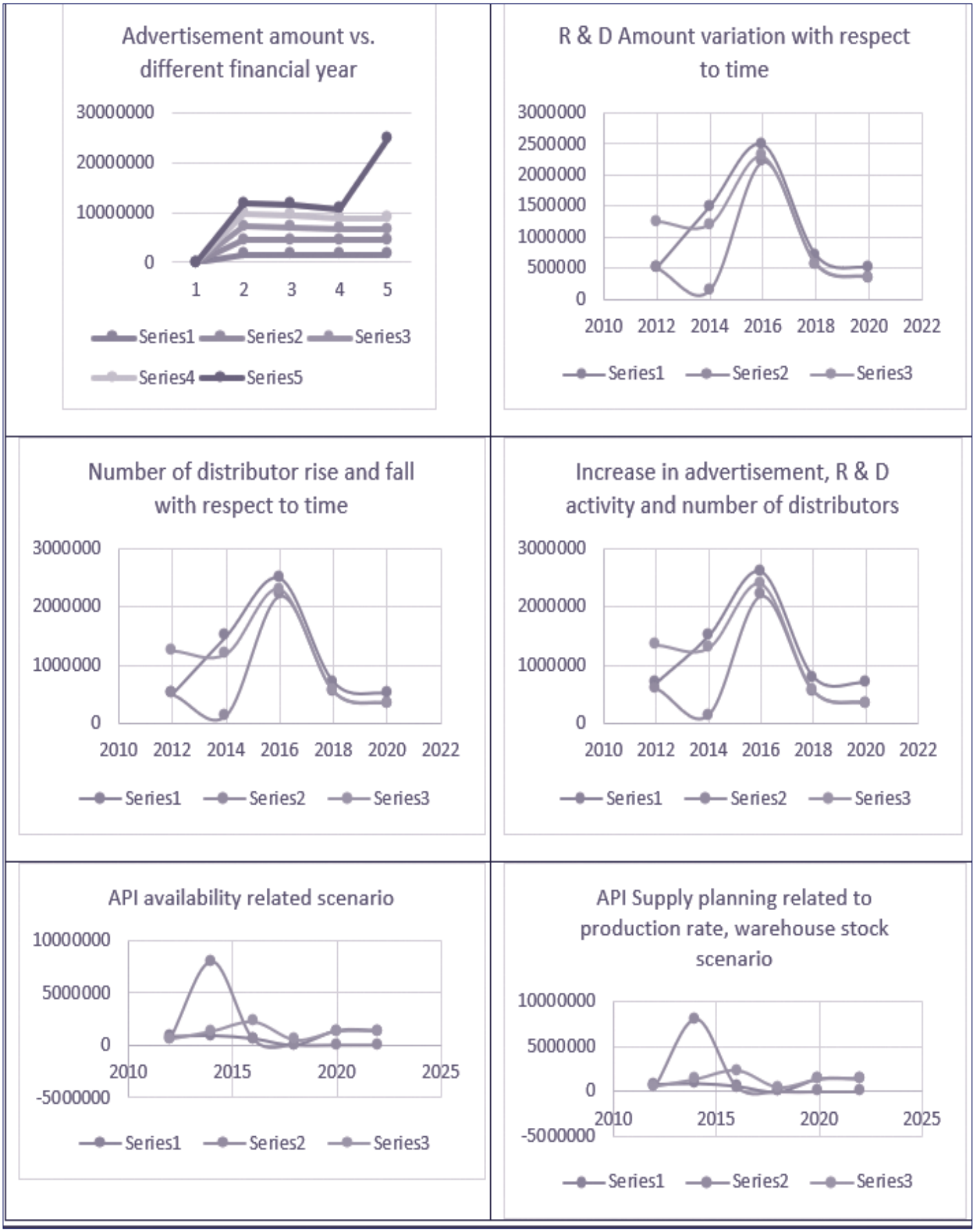
Graph, (d),

- Considered mixed impact of all variables from category of graph plotted named as a,b and c.
- The maximum value of each variable is considered.
- Also represents, increase in production based on approximate estimation made for the demand.
- Increasing 50% of advertisement, R & D activities, distribution points, raises sale up to 51 to 79%.
- Production rate based on demand estimation in year 2018 and that raises sale by 100% in year 2019 and prevent an occurrence of decline stage at PLC.

Through few graphs drawn above the discussion can be taken place as,

Analysis changes in API and warehouse associated variables effect on sale as they effect on production rate also. API impacts on sales between years 2012 to 2020. 20% decrease in API availability in country. 50% decrease in API availability in country from 2002 to 2019. Decrease in API decays sale in between 2015 to 2017. 2018, decrease in API stock now effect on the sales despite of the low production rate. API supply and impact on sales in between 2012 to 2019.

Fig (5): Numerical sale in different scenario of API, warehouse planning in between 2012 to 2019.



Two months' supply delay time. Two month's supply decreases and delay time, 20% increase of API. API decreases of supply in between year 2015-17. No impact as demand for drugs decreases and available stock was enough to fulfill market demand. In year 2019, decreased production, API stock was enough to address the production. Increasing API order between 2015-2017, compared to year 2018, total demand noted decrease in the year 2019.

DISCUSSION

Safety focuses on PLC for generic pharma in India. Collapse and shoot are considered as a reference mode. Overshoot and collapse pattern are formed by considering behavior of supply demand, competition sub-systems as a component of the pharma, PLC model. Considered polices of manufacturer to prevent reduction of product sales to avoid an occurrence of product declined stage. More than 2/3rd medicine in Scotland, Egypt and Turkey faces one declined phase in an entire life cycle. This is due to lack of the plan to monitor sales trend of generic drugs, forecasting system based on which production planning is done, less scope to R & D activities and improper marketing management. The main intention of study to demonstrate how pharma industries can avoid occurrence of declined stage through PLC by adoption of optimistic integral managerial strategies.

4.1 Elements of PLC generic medicine: The elements can be discussed as below,

a. Sales forecasting and production planning: Basic behind PLC formation is demand of product and forecast based on specific trend. Parodic data monitoring is crucial but required in the view to form PLC model. Self-forecasting includes allocation of production budget, planning for employee inventory determination for factory. Sales forecasting is important when market demand would be rises further. Sales forecasting can be done accurately by establishing close relationship with customer. Keep in close, physician, and pharmacist increases accuracy of forecasting. Sales history is another part to increase accuracy of forecasting. Sales forecasting of competitors is another way of obtaining accuracy in forecasting. At maturity of PLC production rate is below the demand rate. In declined stage company should make efforts to sell the drugs by push mechanism. Market share depends on availability, marketing & R & D activities of the manufacturer. Based on these three elements, modifying production rate, company can prevent declined stage of PLC.

b. Research and development activities: During declined stage, R & D activities can significantly increase the sell. R & D can return product sale during product drop or declined stage. Planning of R & D activities through cost effectiveness, merging with marketing sectors leads companies to earn the profit.

c. Marketing: There has a significant role of marketing on the sale. Advertisement, awareness creation, repetition known among pharmacist and sales division. Recommendation by pharmacist to use specific types of drugs increases the sale. Patients and physician are the two elements of advertising. Customer satisfaction can be achieved through product quality and marketing activities. Product sale can be undertaken through effective marketing. Product performance can achieved through integration of R & D activities and effective marketing. Through this integration the cost reduction and optimum resources allocation and use, risk sharing, new technologies access can be addressed.

d. Availability: 27% Increase in distribution points across world impacts a very little on the sale. As a reason same product will be appeared in a distribution portfolio. Distribution centers at optimum locations and ensures case at accessibility of drugs, and thus provides or establishes the coordination between manufacturer and distributor. Reducing number of distributors helps to achieve a better control on sales network and enhancing efficiency of supply chain. According to product portfolio for selling in hand, distributors should stay optimize to reduce cost and ensure an availability of product. The number of distributors should be finalized based on above decisions.

4.2 System dynamics model for open innovation: To boost the production capabilities, industries are shifting, simulation of multi factor modelling and smart decision making systems are undertook for help and further installations and upgradations of system to said bench marks. PLM is capable to reduce product development cycles, cost, quality issues etc. Business strategies paving ways on open innovation and enhance competitiveness, performance etc. System dynamics model of PLC includes multi sales, strategic planning, feedback, capacity of showing different relationship. PLM allows integrative business process, information product portfolio at managerial and technical level PLM allows firm to administer wide range of product information through various life cycles of product. Information managing through PLM requires product design details, service details, customer requirement, market information, requirement of all stake holders being part of the supply chain model. Outside in information flow is required for an open innovation. System Development Product Life Cycle Management helps innovation process in following ways,

- Efficiency enhancement through raw material planning, accurate sales forecasting.
- Importance of information sharing is, monitor customer needs and competitors. Share of information between marketing and R & D through integration, keeping in view customer need and requirement.
- Producer's loyalty is directly proportional to customer's satisfaction.
- Open innovation is information sharing from customer part of product development for more customer loyalty.
- Involvement of all stake holders, from all fields and sectors, coordination and integration, information sharing, open innovation addresses effectively. It leads to improve product quality and customer needs will be served in desired possible way.
- In real world, collection of data is not possible and thus sample data is collected, and virtue of these results would vary from actual requirement and thus this gap is tried to minimize in this paper.

5. CONCLUSION

The conclusion for paper can be written as follows,

- Study in between 2000 to 2019, to simulate and run, dynamics model of generic drugs products, of pharmaceutical industry.
- The System Development, system dynamics model of PLM has been studied.
- Most important elements of PLC are, accurate forecasting, marketing and R & D activities.
- Relationship between these components leads to understand customer requirement and the way they could be satisfied, loyalty, quality and everything can be achieved very smoothly.
- Pharma industries, implements the proposed dynamics model with little alterations made according to requirement would get benefited from the said/mentioned model.

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