Study on Forecast of the Revenue and Market Share of a Newly Launched Product Over a Period

By

Ishita Joshi

Dissertation submitted in partial fulfillment of the requirements of the degree

MBA Hospital and Health Management

Academic year, 2017-2019

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IIHMR UNIVERSITY

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Dr. Ishita Joshi student of MBA Hospital and Health Management from The IIHMR University, Jaipur has undergone internship training at PharmACE Analytics Pvt. Ltd. from 04th Feb 2019 to 3rd May 2019.

The candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.
The internship is in fulfilment of the course requirements.

I wish her success in all her future endeavours.

Dr: Ashok Kaushik
Dean, Academics and Student Affairs
The IIHMR University, Jaipur
14 May 19

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The IIHMR University
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PharmaACE

The certificate is awarded to

Ms. Ishita Joshi

In recognition of having successfully completed her internship in the department of

Forecasting

And has successfully completed her project on

"Forecast of the revenue and market share of a newly launched product over a period"

3rd May 2019

She comes across as a committed, sincere and diligent person who has a strong drive and zeal for learning.

We wish her all the best for her future endeavors!

For PharmaACE Innovations LLP

Rashi Chawla

Manager-HR & Admin

Blueridge Qubix, SEZ, IT-5, Ground Floor, Phase 1, Hinjewadi, Pune - 411057

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **A Study on Forecast of the Revenue and Market Share of a Newly Launched Product over a Period** submitted by Ishita Joshi, MBA HM- 22, 0578 under the supervision of Dr.Ashok Kaushik for award of MBA in Hospital and Health Management of the University carried out during the period from 4 February 2019 to 3 May 2019 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

Ishita Joshi

Table of Contents

Abstract

Title

Forecast of the Revenue and Market Share of a Newly Launched Product over a Period

Name of Author

Ishita Joshi

Forecasting is the process of estimating a product's revenue and patient numbers. This helps the pharmaceutical companies to develop strategies to maximize their revenue and market share by considering the factors (launch of competitors' product, discount schemes etc.) that may lead to loss in revenue. The major challenges associated with forecasting are inaccuracy, bias, too detailed or too general forecast. The forecasting process influences various functional areas within an organization i.e. manufacturing, finance, sales and marketing. These functional areas interact with the forecast and exert pressure on the model construct, the inputs and the outputs of the forecast. The objectives of the study are to forecast the market share, volume and revenue of Product C for the client X

The study was conducted at PharmaACE Analytics Private Limited, Pune, Maharashtra for China market with lung cancer as the disease of interest. It is an analytical study conducted for the lung cancer patients who are the potential consumers of Product C of the client using forecasting model. The market share, volume and revenue of the product were forecasted for non-small cell lung cancer (NSCLC).The study was carried out for 3 months from 4 February 2019 to 3 May 2019.

There were a total of 3 scenarios that were used to obtain outputs for patient numbers, units of product sold and revenue (month-wise).

There were a total of 3 scenarios that were used to obtain outputs for patient numbers, units of product sold and revenue (month-wise).In each scenario the average duration of therapy was taken as 4.3 months, the total dose of product per month as 180 mgs where 1 vial of 40 mg and 1.4 vials of 100 mg were used.

The results of the study indicated the impact of assumptions like price cut, affordability and launch of competitors on the client's product. Other factors that can have an influence on the revenue of a pharmaceutical product are the time of implementation of NRDL, average duration of therapy and discount schemes. The revenue of client's product was estimated to be $33.5 million in 2018, followed by $169 million and $197 million in 2019 and 2020 respectively.

The study shows that implementation of NRDL and the resultant increase in affordability contribute towards increase in revenue even after price cut introduced by the client. The reason behind this increase in revenue is that as price cut is implemented, a greater number of patients begin to take treatment with the client's product and hence increase in the market share of the product.

Acknowledgements

The study on "Forecast of the revenue and market share of a newly launched product over a period" was successfully completed due to the efforts and involvement of two organizations and various individuals at different stages.

Firstly, I am grateful to the IIHMR University for giving me an opportunity to pursue my dissertation at PharmaACE Analytics Private Limited, Pune.

Col. (Dr.) Ashok Kaushik (Proctor and Dean, Academics, IIHMR) deserves my sincere thanks for his overall guidance and support throughout the project as my guide.

I would also like to extend my deepest gratitude to Mr. Paritosh Agrawal (Engagement Manager, PharmaACE) for designating me to work on this project. The successful completion of my dissertation would not have been possible without his encouragement and unparalleled support throughout the internship.

I gratefully acknowledge Mr. Vikash Das (Associate Consultant, PharmaACE), who took an active interest in the project and provided his timely guidance whenever needed. His constructive advice played an instrumental role in developing the approach needed to take the project forward.

Special thanks to Mr. Santosh Tolani (Analyst, PharmaACE) for his insightful suggestions. His patience throughout the duration of this project and ingenious suggestions helped me in various phases of the completion of this project.

Last but not the least; I would like to express my heartfelt gratitude to Dr. Nutan P Jain (Professor, IIHMR), my first academic mentor, whose guidance and feedback allowed me to perform to my fullest potential and Dr. Neetu Purohit, for helping me develop a scientific approach and her profound belief in my abilities.

Ishita Joshi
II-year, MBA Hospital and Health Management

BACKGROUND

About the organization

PharmaACE Analytics Pvt. Ltd. is life sciences focused company. Headquartered in USA, the company is dedicated to providing analytic solutions for efficient commercialization of pharmaceutical products.

The company works through teams such as Competitive Intelligence Chart Audit and Forecasting to provide pharmaceutical companies with business-critical research and insights that helps them to make informed decisions. The decisions enable the clients to develop strategies for sales and marketing of newly launched products, develop a perspective of the existing players- their strengths and weaknesses, opportunities for a particular product in the market, analyzing the threats and finding out ways to overcome it.

The Competitive Intelligence team is involved in conducting secondary search to answer various business questions for clients such as opportunities for a product in a particular market through pipeline assessment, data analysis (sales and volume data – top companies' analysis, CAGR), collecting relevant information and validating it. This helps the client to generate insights and answers their business needs.

The Chart Audit team deals with the claims data and is involved in providing the client with epidemiology of the disease of interest. This helps to arrive at number of patients of a disease and the revenue generation from a product for that disease.

The team that is involved in estimating a product's market share and revenue is the Forecasting team.

Apart from these teams, the IT team is responsible for providing the support in terms of creating models so that the forecasting team is able to derive revenues by applying all the factors responsible for increase in revenue or decline.

The company stands out in the field of business consulting because of the differentiators like:

- Simplified value-driven solutions
- Tailored approach
- First-time-right attitude
- Leveraging best practices
- Pharma-Tech amalgamation

CHAPTER 1

INTRODUCTION

Forecasting is the process of estimating a product's revenue and patient numbers. This helps the pharmaceutical companies to develop strategies to maximize their revenue and market share by considering the factors (launch of competitors' product, discount schemes etc.) that may lead to loss in revenue.

The time horizon of forecast ranges from: monthly (12-36 months), annual (1-3 years), short-term (3-5 years) and long-term (5—15 years).

The major challenges associated with forecasting are inaccuracy, bias, too detailed or too general forecast.

The key assumptions used in forecasting decide the accuracy of forecast and thus uncertainties around these assumptions lead to inaccurate forecast. Bias in forecast is unavoidable but hidden bias results in sub-optimal decision making. The balance between a very general or detailed forecast is difficult to strike. An example of a general forecast is when the patient numbers are simply multiplied by market share of the product and then by price of the therapy to obtain revenue. This approach is valid but when questions like whether patient segmentation exists, compliance and testing rate are answered then the forecast loses its validity.

There are examples of drugs in Table 1 that were forecasted as blockbusters, but which actually failed miserably and others that were not recognized to do well in the market but surprisingly became blockbusters.

Company	**Drug Name**	**Peak sales ($millions)**	
		Estimated	***Actual***
Eli Lilly	Effient	300-1600	27
Eli Lilly	Xigris	2000	282
Marion	Cardizem	50	180
Syntax	Naprosyn	40-50	420

Table 1.1 Blockbuster drugs that went bust and others that performed beyond expectation

The forecasting process influences various functional areas within an organization i.e. manufacturing, finance, sales and marketing. These functional areas interact with the forecast and exert pressure on the model construct, the inputs and the outputs of the forecast.

1.1 Operational Definitions

• **Incidence**: The number of new patients of a disease over a fixed period (usually one year)

• **Prevalence**: All surviving patients who have a disease over a fixed period (usually one year). This is the commercially relevant population with active disease.

• **Line of Treatment**: The treatment choices available for the patients. E.g. first line is usually the best available treatment for a disease.

• **Overall Survival**: The time from randomization until death from any cause and is measured in the intent-to-treat population.

• **Progression free survival**: It is defined as the time from randomization until objective tumor progression or death.

• **Biomarker**: A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease.

• **Treatable patients**: The number of patients with a disease of interest who are eligible for taking treatment.

• **Treated patients**: The patients who are receiving treatment out of the total treatable pool.

• **Biomarker testing rate**: The percentage of patients who are tested for a biomarker. Treatment therapy is based on the outcome of the biomarker test.

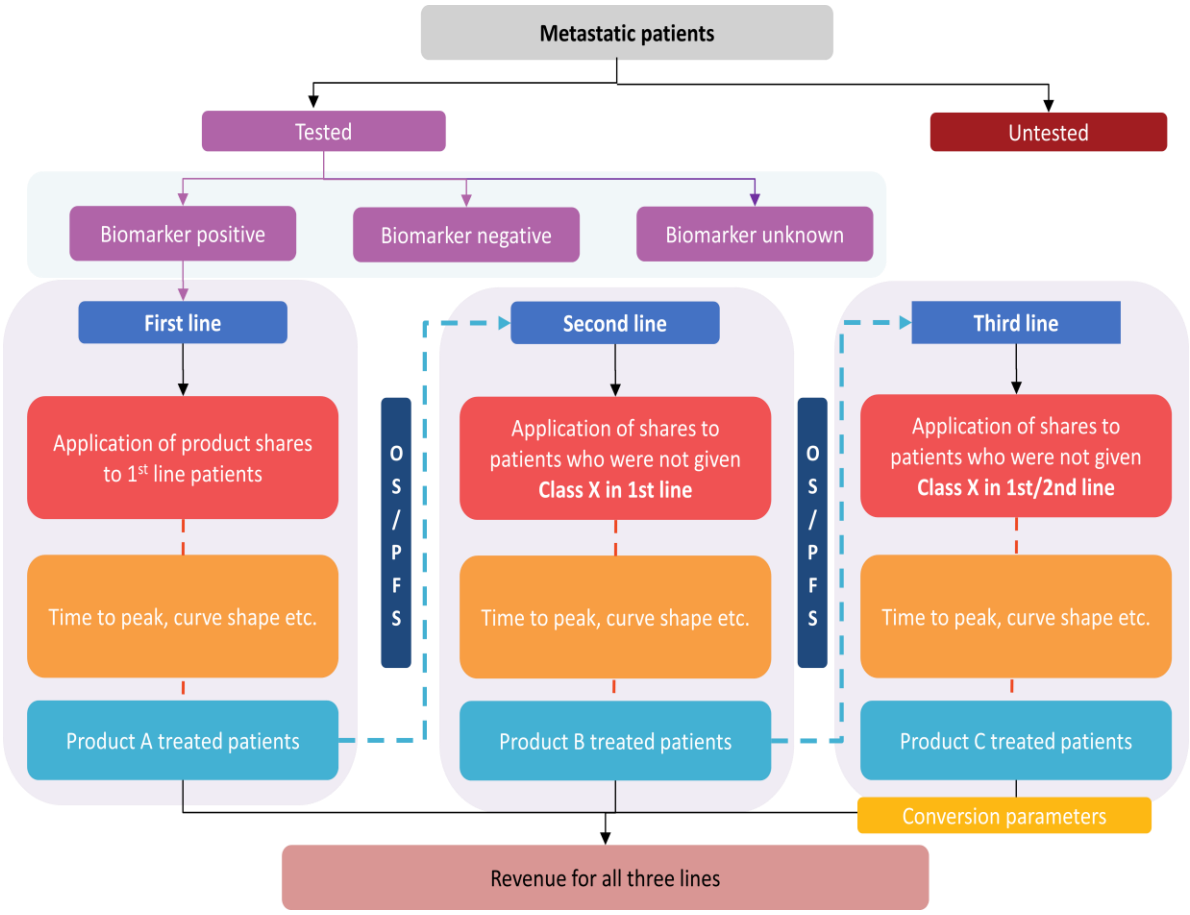
• **Eligible patient share**: The percentage of patients who are eligible to take a particular class of drugs.

• **Effective share**: The percentage of patients who are actually taking the therapy of interest.

• **Shadowing**: The patients who are taking the therapy of interest in a certain line of treatment will not be eligible for the same therapy in the subsequent line and thus have to be excluded from the next line treatable pool.

• **Duration of therapy**: The period for which a percentage of patients will be taking a particular therapy. E.g. 100% patients will take the therapy for the first month and then reduces over the months.

Model flow



1.2 Research Question

- What is the revenue and market share forecast for the client's product due to change in assumptions like implementation of NRDL, affordability, price of the product and discount schemes?
- What will be the impact of launch of competitors on the client's product performance in the market?

1.3 Aim

The aim of the study is to determine the revenue of a pharmaceutical product and the impact of launch of competitors on the performance of client's product in terms of share in the market, change in volume sales and revenue.

1.4 Objectives

- To forecast the volume and revenue of Product C for the client X
- To forecast the market share of Product C for the client X

CHAPTER 2

REVIEW OF LITERATURE

2.1 Immuno-Oncology: Emerging Targets and Combination Therapies

The conventional treatment regimens for cancer (chemotherapy, radiation therapy and biological therapy) have not yielded completely satisfactory results. These treatment modalities have resulted in severe side effects, low target selection ability and low effectiveness to treat metastatic tumors. Advances in immuno-oncology have brought in a revolutionary change in the treatment options available to the cancer patients. Immuno therapies have transformed the treatment paradigm for cancer especially advanced, refractory and relapsed tumors.

These have proved to be effective where the tumor didn't respond to standard of care cancer treatment and thus have received widespread acceptance by physicians for their results(1). Current immunotherapy modalities include monoclonal antibodies targeting T-cell checkpoints of PD-1 and CTLA-4. These therapies work by provoking the host immunity to induce a systemic response against the tumor cells. Usually, the tumor cells are recognized by the immune system; namely the Natural Killer cells and T cells and then destroyed(2). But cancer cells evolve to acquire genetic instabilities and thus evade the immune system and grow abnormally. Therefore, immunotherapies have demonstrated satisfactory results as a single agent and as combined therapy.

The various immuno-therapies available are PD-1 and CTLA-4 inhibitors that are commonly called as checkpoint inhibitors. PD-1 is expressed as a receptor protein on the surface of T cells and works by down regulating the immune system. These monoclonal antibodies block the interaction between PD-1 and its ligands (responsible for immunosuppression) and thus are responsible for boosting the immune system resulting into anti-tumor activity. A combination of anti-PD-1 (nivolumab) and anti-CTLA-4 (ipilimumab) in a phase I trial on patients of metastatic melanoma demonstrated an unprecedented Objective Response Rate (ORR) of 53%, leading to 2-year Overall Survival in 79% of cases. A phase III trial showed that anti-PD-1 alone and a combination of anti-PD-1 and anti-CTLA-4 were more effective and less toxic as compared to anti-CTLA-4 alone. The coupling of checkpoint inhibitors with radiation therapy elevated the Objective Response Rate in prostate cancer, NSCLC and glioblastoma. A phase Ib trial showed that atorolimumab followed by carboplatin in patients of advanced/metastatic NSCLC induced a response rate of 75%.

Although evidence supporting potential of immunotherapies in clinical oncology is immense, but work is still required to improve patient benefit like tumor resistance to immunotherapies needs an in-depth understanding, undesirable side effects arising out of mono or combination immunotherapies needs to be addressed.

2.2 Forecasting new product revenues

LEK Consulting's revenue-forecasting model involves a deceptively simple formula: Customer base* total penetration* product's share of base penetration* price per unit* units per year

The customer base refers to the number of potential customers of a product. This can be achieved through determining whether incidence or prevalence number is relevant. If a disease is chronic in nature or requires life-long therapy, total number of patients of that disease at a particular point of time are needed i.e. prevalence. If a product serves a onetime acute event, then incidence number is useful i.e. number of new patients in a year.

The percentage of customer base that is being served by all the available products is defined as total penetration. Penetration is particularly important if the target audience is being underserved by current products.

Product's share refers to the percentage of market share that your product will capture. This is decided when comparisons are drawn between your product and its competitors based on parameters such as features, benefits, marketing strategies and efforts.

Estimation of your product's peak share and long-term share decline are essential. The factors that have a negative impact on share growth are new entrants and loss of patent protection.

Price per unit of a product is also critical to accurate revenue forecast a it can have a huge impact on volume forecasts. The products that are in early stage should be priced based on price of comparable products. The discount and premium that a new product deserves should also be considered. The key driving force of price is the value to customers. The role of various decision makers in pharmaceutical industry makes product pricing a particularly complex process. The drug is prescribed by the physician, taken by the patients and the bills are reimbursed by the insurer. Therefore, pricing decisions require careful cost benefit analysis and appropriate reimbursement strategies

Compliance by end user is also an important factor to be considered as the units consumed by end-users depends on the extent to which physician's advice is followed by patients. Pricing, convenience of replacement and ease of use are some points that directly affect compliance.

Thus, generating revenue forecasts for a new product is a complex process with involvement of critical strategies, operational and financial decisions that lead to accurate or inaccurate forecasts.

2.3 Revenue forecasting techniques for new pharmaceutical drugs

The three approaches of estimating market share of a pharmaceutical product and in turn its revenue includes bottom-up approach, analyst insights and analogue market (similar products).

The revenue estimation of a new pharmaceutical product involves assessing the market size i.e. incidence and prevalence of the disease of interest and estimation of the market size that can be addressed i.e. the percentage of patients diagnosed and the percentage of patients treated for the disease of interest.

Competitive analysis, pricing study, compliance rate and reimbursement analysis are other factors that need to be considered while forecasting the revenue of a product.

For a pharmaceutical product to take up greater market share, it should have attributes like higher efficacy than the treatment options currently available, better outcomes and improved marketing than other products.

Patients are divided into segments as all patients are not alike. For example, high expressers (PD-1) and low expressers for a disease of interest. This helps to refine the share forecast.

This segmentation and customer base i.e. incidence and prevalence keep changing over time and thus growth driver analysis is done to provide insights on the changing market scenario.

The main driver of revenue forecast is penetration. Peak penetration is estimated by drawing comparisons with similar products, efficacy and safety of currently available products, interviewing physicians to understand the acceptance level, analysis of reimbursement scenarios and comparing the product with other products in pipeline.

2.4 Epidemiology of lung cancer in China

Lung cancer is considered as the leading cause of cancer death in China. The incidence and mortality rate of lung cancer is showing an increasing trend in the recent years with differences in geography and gender due to change in lifestyle of individuals. This necessitates the determination of epidemiological distribution of lung cancer to target the patients in terms of treatment and for further prevention.

The data from approximately 340 cancer registries indicates that the age-standardized incidence rate of lung cancer was 36.7 per 100000 in 2014.

“According to Chen *et al*., the age-standardized mortality rate (ASMR) for lung cancer over all cancer registries was 28.49 per 100 000 with ASMR in men almost double that in women(3)” The survival rates of all cancers have improved but the survival rate of lung cancer remains relatively low.

CHAPTER 3

MATERIALS AND METHODS

3.1 Study Area

The study was conducted at PharmaACE Analytics Private Limited, Pune, Maharashtra for China market with lung cancer as the disease of interest.

3.2 Study Design

It is an analytical study conducted for the lung cancer patients of China who are the potential consumers of Product C of the client using forecasting model. The market share, volume and revenue of the product were forecasted for non-small cell lung cancer (NSCLC).

3.3 Study Duration

The study was carried for 3 months from 4 February 2019 to 3 May 2019.

3.4 Sample Size

The entire lung cancer patients (NSCLC) of China were considered for estimation of volume and revenue of Product C. However, various eligibility cuts like treatment rate and testing rate were applied to arrive at actual patient numbers who would be taking the treatment.

3.5 Study Population

Non-small cell lung cancer patients who would actually be taking treatment with the client's product i.e. Product C. These will be the consumers for the client and will contribute towards revenue generation in future.

3.6 Inclusion Criteria

i. All non-small cell lung cancer (NSCLC) patients of China
ii. NSCLC patients above 18 years of age
iii. All provinces where client's product was being marketed i.e. coverage and 10% of non-covered market

3.7 Exclusion Criteria

i. Small cell lung cancer (SCLC) patients
ii. Patients below the age of 18 years
iii. Non-covered provinces/market

3.8 Sampling Technique

All the NSCLC patients were included in the study.

3.9 Data Collection Method

The epidemiological data for China was provided by the client through cancer registries for NSCLC.

Chart Audit team of the client was involved in collection of the prevalence data eligibility cuts and preference shares.

3.10 Data Type

The research study was carried out on secondary data.

3.11 Data Analysis

The tool used for data analysis is MS Excel based model for forecasting. The process involves estimating the size of target patient pool followed by applying treatment rate to exclude the untreated patients (who are unable to take the treatment for any reason) and finally estimating the market share for each of the drugs available in the market for the forecast indication i.e. NSCLC. The market share of a company's product is affected by the launch of other products for the same therapy, their discount schemes and the response of physicians towards that product. So, all these factors are incorporated in the forecast to avoid overestimation/underestimation of revenues.

CHAPTER 4

RESULTS AND INTERPRETATION

There was a total of 3 scenarios that were used to obtain outputs for patient numbers, units of product sold and revenue (month-wise).

In each scenario the average duration of therapy was taken as 4.3 months, the total dose of product per month as 180 mgs where 1 vial of 40 mg and 1.4 vials of 100 mg were used.

4.1 Scenario I - Assumptions

The launch of Product C for the indication of NSCLC is in June 2018 with an eligible share of 70%. The launch of competitors i.e. Product A is in September 2018, followed by Product B and D in April 2019 and September 2019 respectively.

The eligible share of Product A at its launch was 15% as it is a product from the same class as Product C. Product B's eligible share was 20% at the launch i.e. in April 2019. The higher share was the result of Product B being a local innovation of Product C and thus highly affordable for the population. Product D grabbed an eligible share of 5% at launch as it is similar to Product C but with lower efficacy results in clinical trials.

NRDL implementation of Product C was assumed in May 2019 i.e. 1 year after the product's launch. The percentage of patients who would be reimbursed is decided on the basis of reimbursement uptake curve. The assumption for reimbursement uptake curve was of 6 months and by the sixth month 100% patients would be reimbursed for the therapy (Product C).

At the time of launch, all the patients would fall in the category of self-pay and the product would be less affordable. As the NRDL implementation would take place for Product C, a percentage of patients would fall in the category of reimbursed section and would receive the benefits of NRDL. This would lead to increase in affordability of the product and thus increase in the number of patients who take Product C for NSCLC (Table 4.1).

Affordability	**2018**	**2019**	**2020**
Reimbursed patients	-	80%	84%
Self-pay patients	20%	40%	50%

Table 4.1 Percentage of patients who are able to afford the treatment with Product C

The full price of Product C before NRDL implementation is as given in Table 4.2.

Vial (volume)	Price per vial
40 mg	$ 734
100 mg	$ 1465

Table 4.2 Price per vial of 40 mg and 100 mg

The price cut on NRDL implementation is assumed to be 50% i.e. in May 2019 there would be a 50% reduction in price of Product C (Table 4.3) for the reimbursed section of patients.

Vial (volume)	Price per vial (May 2019)	Price per vial (May 2020)
40 mg	$ 367	$ 312
100 mg	$ 733	$ 623

Table 4.3 Price of 40 mg and 100 mg vial on NRDL implementation for reimbursed section

The self-pay patients would receive just a price benefit i.e. the provinces where NRDL has been implemented would have self-pay patients and other provinces where NRDL has not been implemented would require the patients to pay the full price of the therapy (Table 4.4).Therefore, their price would follow the reimbursement uptake curve.

Vial (volume)	May'19	Jun'19	Jul'19	Aug'19	Sep'19	Oct'19
40 mg	$ 661	$ 613	$ 551	$ 488	$ 430	$ 367
100 mg	$ 1319	$ 1224	$ 1099	$ 975	$ 857	$ 733

Table 4.4 Price of 40 mg and 100 mg vial on NRDL implementation for self-pay section

The above inputs of eligible share, testing rate and affordability are applied to derive the effective share (month-wise).

Effective share = (Eligible share * Segment 1% * Testing Rate + Eligible share * Segment 2% * Testing Rate) * Affordability

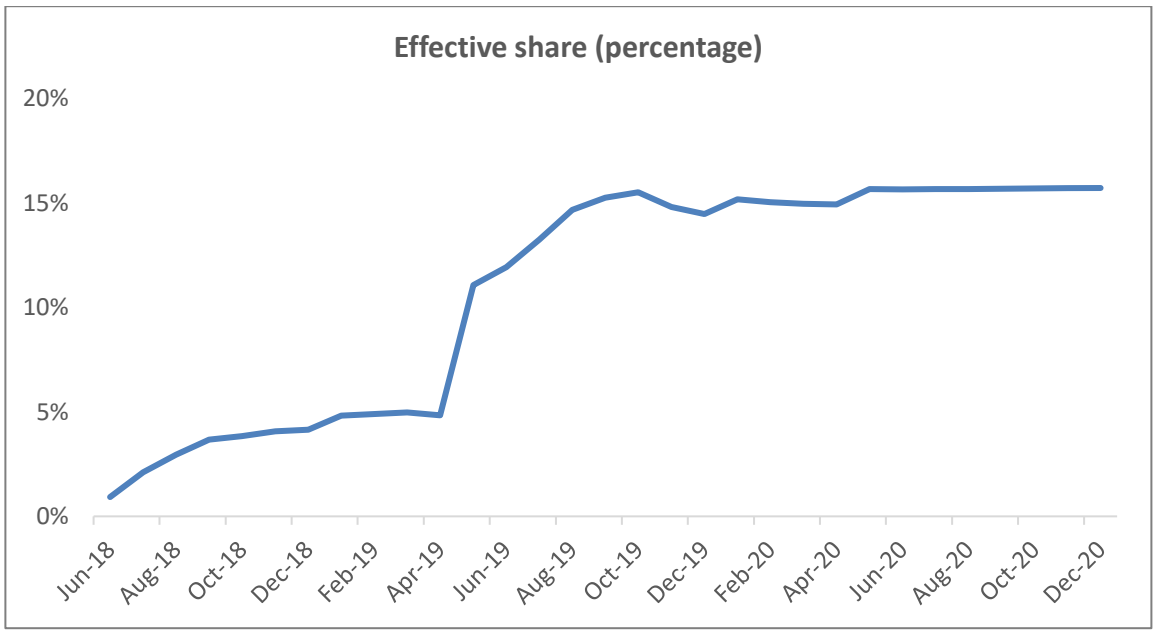


Fig. 4.1 Forecasted Effective Share of the product from launch in June'18 till Dec'20

The effective share was 1% at launch in June 2018 and then increases to 5% by April 2019. In May 2019, NRDL would be implemented for NSCLC and thus there is a sharp rise in effective share which depicts that Product C's share in market will increase due to price cut and subsequent increase in affordability. (Fig 4.1)

This leads to increase in revenue from May 2019 due to 50% cut in the price of the dose and resultant increase in affordability.

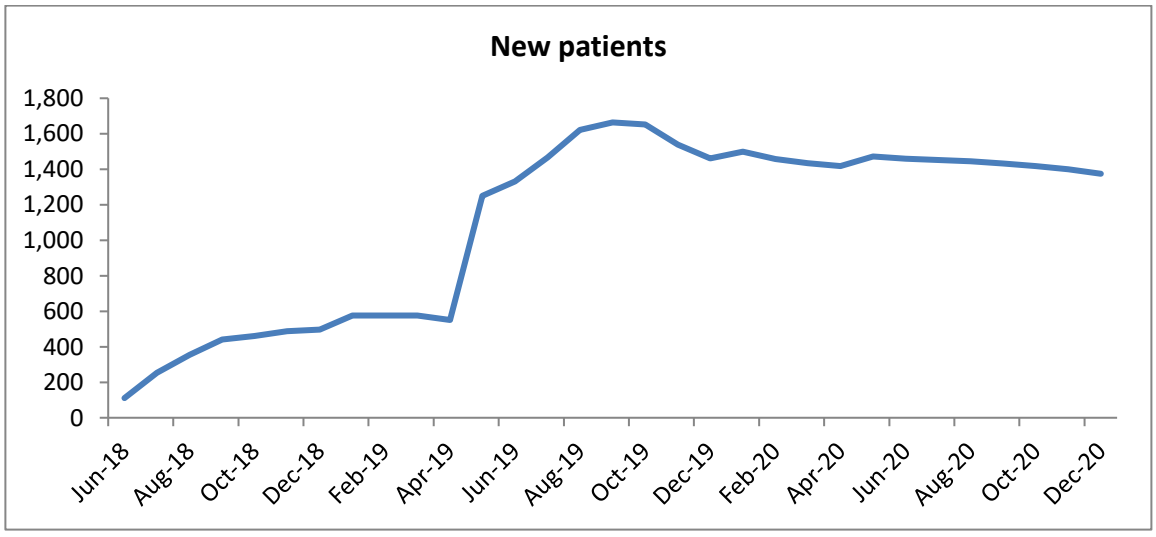


Fig. 4.2 Forecast of number of new patients taking therapy with Product C (month wise)

The number of new patients taking the therapy with Product C gradually increases from the launch but shows a sudden increase in May 2019 due to NRDL implementation showing a

similar pattern as effective share curve. However, in September 2019 due to launch of competitor, there is a gradual decline in the revenue due to share theft from Product C.

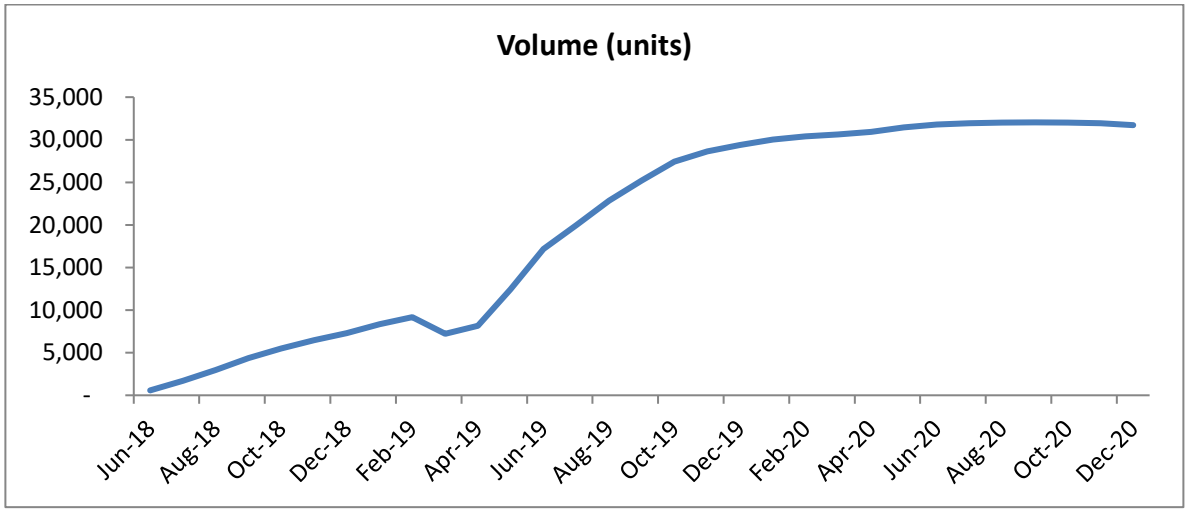


Fig. 4.3 Units of Product C sold monthly

The units of Product C sold show a gradual increase from June 2018 to April 2019 and then sharply increases at the implementation of NRDL in May 2019 (Fig. 4.3).

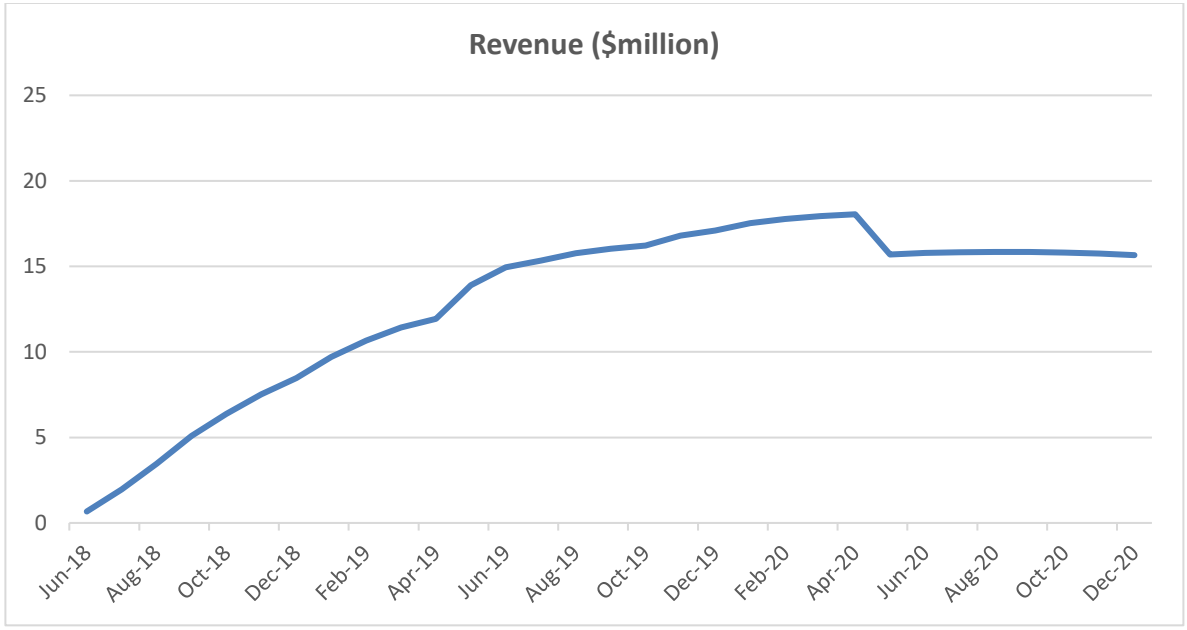


Fig. 4.4 Forecasted monthly revenue of Product C

The revenue of Product C was $0.6 million at launch, $13 million at implementation of NRDL and $15 million by the end of 2020 (Fig. 4.4).

Scenario II - Assumptions

The launch of Product C for the indication of NSCLC is in June 2018 with an eligible share of 70%. The launch of competitors Product A is assumed to be in Nov'18, Product B in May'19 and Product D in Oct'19. The launch of competitors will affect Product C's market share and thus its revenues.

The eligible share of Product A at its launch was 15% as it is a product from the same class as Product C. Product B's eligible share was 20% at the launch i.e. in April 2019. The higher share was the result of Product B being a local innovation of Product C and thus highly affordable for the population. Product D grabbed an eligible share of 5% at launch as it is similar to Product C but with lower efficacy results in clinical trials.

NRDL implementation of Product C was assumed in May 2019 i.e. 1 year after the product's launch. The percentage of patients who would be reimbursed is decided on the basis of reimbursement uptake curve. The assumption for reimbursement uptake curve was of 6 months and by the sixth month 100% patients would be reimbursed for the therapy (Product C).

At the time of launch, all the patients would fall in the category of self-pay and the product would be less affordable. As the NRDL implementation would take place for Product C, a percentage of patients would fall in the category of reimbursed section and would receive the benefits of NRDL. This would lead to increase in affordability of the product and thus increase in the number of patients who take Product C for NSCLC (Table 4.5).

Affordability	2018	2019	2020
Reimbursed patients	-	80%	84%
Self-pay patients	20%	40%	50%

Table 4.5 Percentage of patients who are able to afford the treatment with Product C

The full price of Product C before NRDL implementation is as given in Table 4.6.

Vial (volume)	Price per vial
40 mg	$ 734
100 mg	$ 1465

Table 4.6 Price per vial of 40 mg and 100 mg

The price cut on NRDL implementation is assumed to be 50% i.e. in May 2019 there would be a 50% reduction in price of Product C (Table 4.7) for the reimbursed section of patients.

Vial (volume)	Price per vial (May 2019)	Price per vial (May 2020)
40 mg	$ 367	$ 312
100 mg	$ 733	$ 623

Table 4.7 Price per vial of 40 mg and 100 mg on NRDL implementation for reimbursed section

The self-pay patients would receive just a price benefit i.e. the provinces where NRDL has been implemented would have self-pay patients and other provinces where NRDL has not been implemented would require the patients to pay the full price of the therapy (Table 4.8).Therefore, their price would follow the reimbursement uptake curve.

Vial (volume)	May'19	Jun'19	Jul'19	Aug'19	Sep'19	Oct'19
40 mg	$ 661	$ 613	$ 551	$ 488	$ 430	$ 367
100 mg	$ 1319	$ 1224	$ 1099	$ 975	$ 857	$ 733

Table 4.8 Price per vial of 40 mg and 100 mg on NRDL implementation for self-pay patients

The above inputs of eligible share, testing rate and affordability are applied to derive the effective share (month-wise).

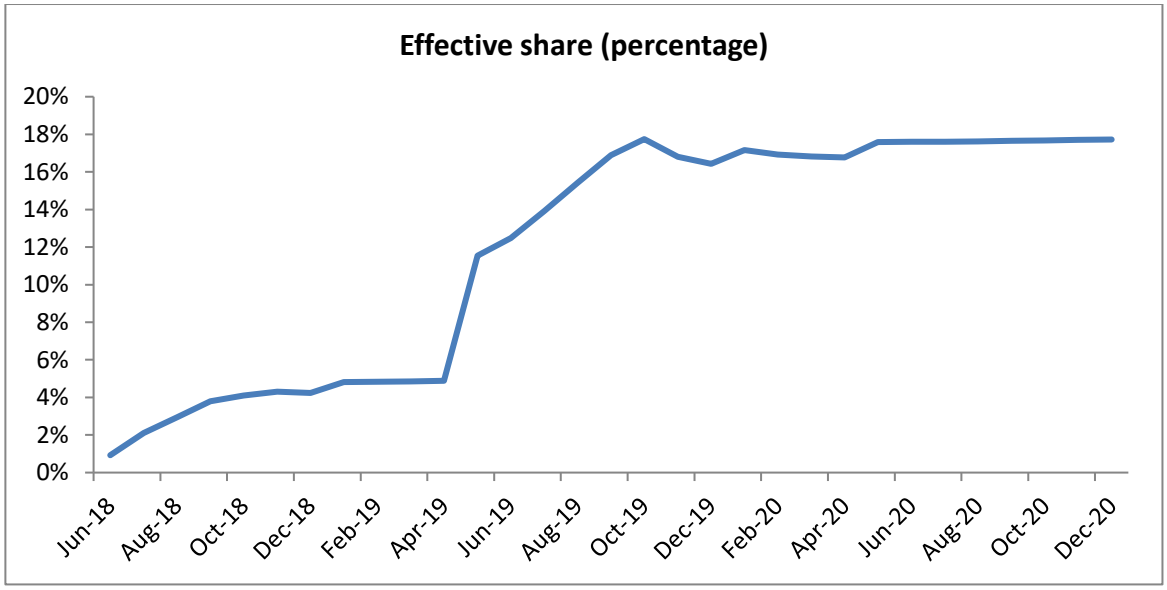


Fig. 4.5 Forecasted Effective Share of the product from launch in June'18 till Dec'20

The effective share was 1% at launch in June 2018 and then increases to 5% by April 2019. In May 2019, NRDL would be implemented for NSCLC and the competitor launch is also

delayed for all the competitors. This leads to late decline in share of Product C and by the end of 2020 the effective share reaches 18% as compared to 16% in case of Scenario I where the competitor launch is earlier (Fig. 4.5).

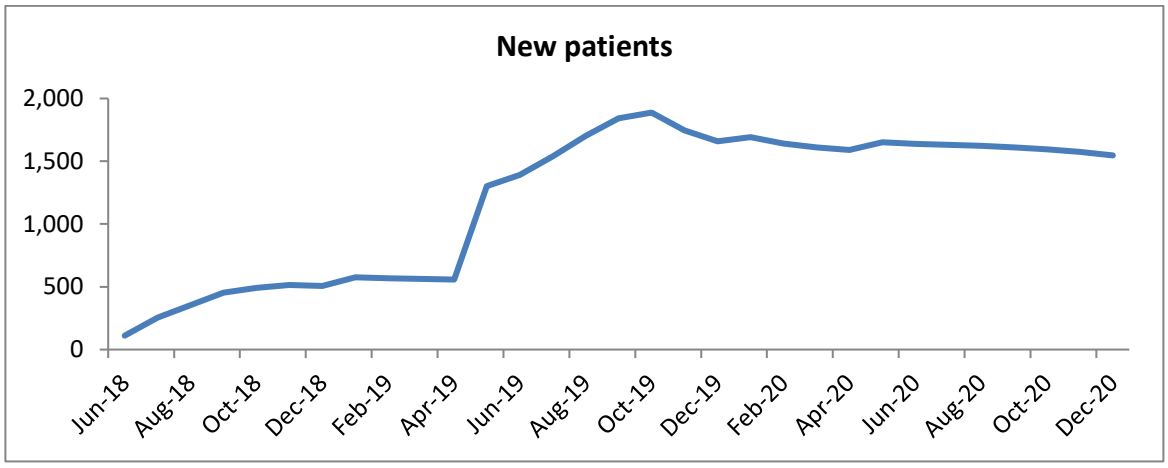


Fig. 4.6 Forecast of number of new patients taking therapy with Product C (month wise)

The number of new patients taking the therapy with Product C gradually increases from the launch but shows a sudden increase in May 2019 due to NRDL implementation showing a similar pattern as effective share curve. However, in September 2019 due to launch of competitor, there is a gradual decline in the revenue due to share theft from Product C.

The new patient numbers in September 2018 is 454 and by the end of December 2020 is 1548 (Fig. 4.6) whereas in case of Scenario I the new patient number was 440 in September 2018 and 1374 by the end of 2020.This reflects an increase in the number of new patients in Scenario II due to late launch of competitors.

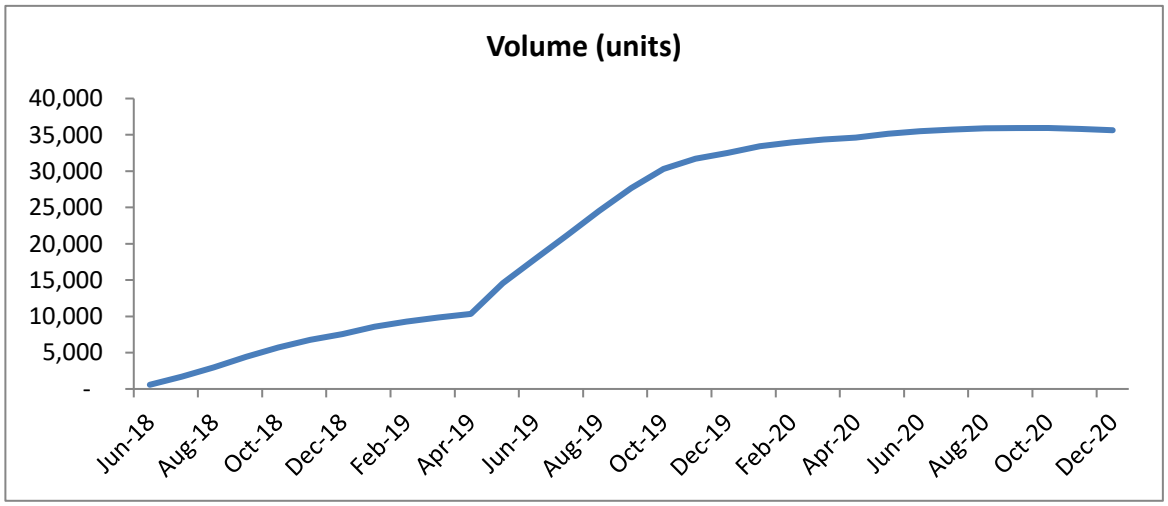


Fig. 4.7 Units of Product C sold monthly

The units of Product C sold show a gradual increase from June 2018 to April 2019 and then sharply increases at the implementation of NRDL in May 2019. In this scenario the units sold in September 2018 was 4443 (Fig. 4.7) whereas in Scenario I it was 4374. By the end of 2020, the units sold are 35,627 whereas in Scenario I it was 31,723.

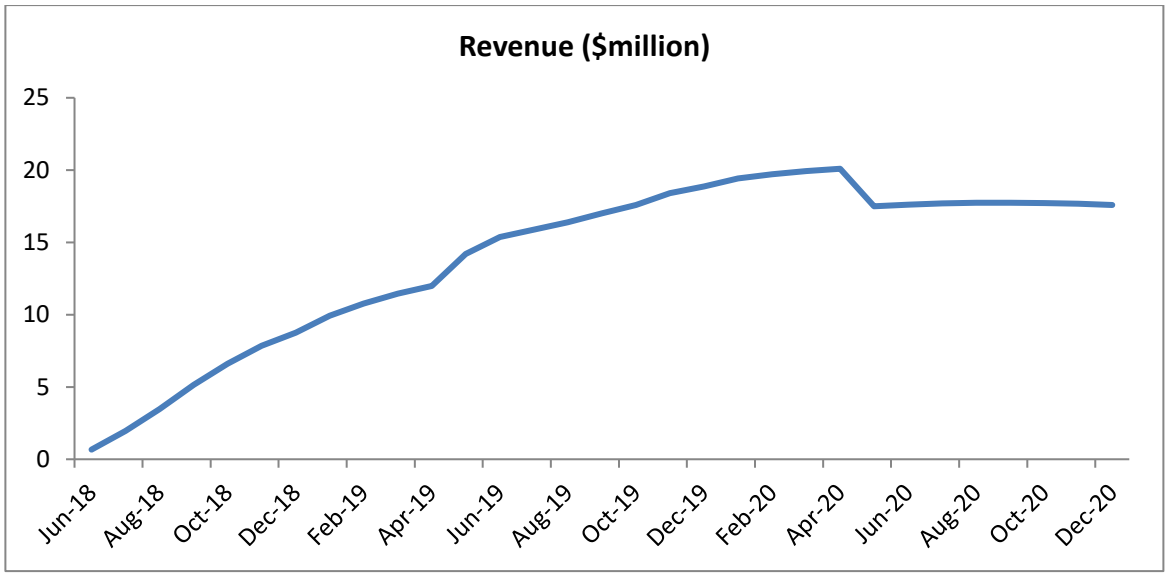


Fig. 4.8 Forecasted monthly revenue of Product C

The revenue of Product C was $0.6 million at launch which is the same as Scenario I as there is no difference in any of the assumptions at launch, $14 million at implementation of NRDL and $17.5 million by the end of 2020 (Fig. 4.8). This increase in revenue is attributed to late launch of competitors that has led to delayed share theft and therefore the volumes of Product C.

Scenario III – Assumptions

The launch of Product C for the indication of NSCLC is in June 2018 with an eligible share of 70%. The launch of competitors i.e. Product A is in September 2018, followed by Product B and D in April 2019 and September 2019 respectively.

The eligible share of Product A at its launch was 15% as it is a product from the same class as Product C. Product B's eligible share was 20% at the launch i.e. in April 2019. The higher share was the result of Product B being a local innovation of Product C and thus highly affordable for the population. Product D grabbed an eligible share of 5% at launch as it is similar to Product C but with lower efficacy results in clinical trials.

NRDL implementation of Product C was assumed in May 2019 i.e. 1 year after the product's launch. The percentage of patients who would be reimbursed is decided on the basis of reimbursement uptake curve. The assumption for reimbursement uptake curve was

of 6 months and by the sixth month 100% patients would be reimbursed for the therapy (Product C).

The full price of Product C before NRDL implementation is as given in Table 4.9.

Vial (volume)	Price per vial
40 mg	$ 734
100 mg	$ 1465

Table 4.9 Price per vial of Product C

The price cut on NRDL implementation is assumed to be 50% i.e. in May 2019 there would be a 60% reduction in price of Product C (Table 4) for the reimbursed section of patients.

Vial (volume)	Price per vial (May 2019)	Price per vial (May 2020)
40 mg	$ 367	$ 294
100 mg	$ 733	$ 586

Table 4.10 Price per vial of 40 mg and 100 mg vial on NRDL implementation for reimbursed section

The self-pay patients would receive just a price benefit i.e. the provinces where NRDL has been implemented would have self-pay patients and other provinces where NRDL has not been implemented would require the patients to pay the full price of the therapy (Table 5).Therefore, their price would follow the reimbursement uptake curve.

Vial (volume)	May'19	Jun'19	Jul'19	Aug'19	Sep'19	Oct'19
40 mg	$ 646	$ 589	$ 514	$ 439	$ 369	$ 294
100 mg	$ 1290	$ 1176	$ 1026	$ 877	$ 736	$ 586

Table 4.11 Price per vial of 40 mg and 100 mg vial on NRDL implementation for self-pay section

At the time of launch, all the patients would fall in the category of self-pay and the product would be less affordable. As the NRDL implementation would take place for Product C, a percentage of patients would fall in the category of reimbursed section and would receive the benefits of NRDL. This would lead to increase in affordability of the product and thus increase in the number of patients who take Product C for NSCLC (Table 4.12).

Affordability	2018	2019	2020
Reimbursed patients	-	83%	87%
Self-pay patients	20%	43%	53%

Table 4.12 Percentage of patients who are able to afford the treatment with Product C

The above inputs of eligible share, testing rate and affordability are applied to derive the effective share (month-wise).

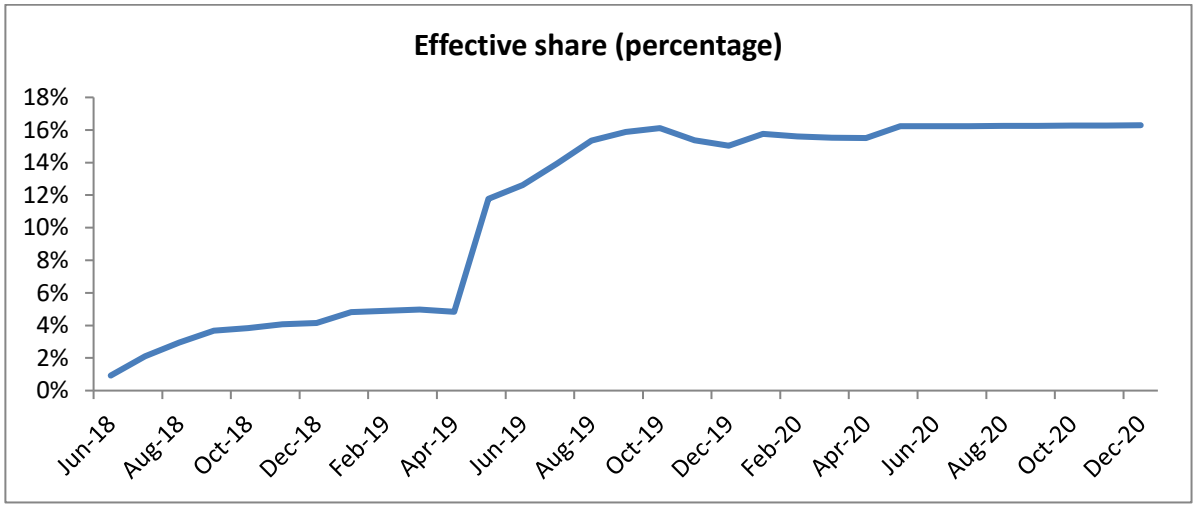


Fig. 4.9 Forecasted Effective Share of the product from launch in June'18 till Dec'20

The effective share was 1% at launch in June 2018 and then increases to 5% by April 2019. In May 2019, NRDL would be implemented for NSCLC and thus there is a sharp rise in effective share i.e. it reaches 11.7% which depicts that Product C's share in market will increase due to price cut and subsequent increase in affordability. The effective share in this scenario is higher than Scenario I where it reached 11% by May 2019. This is attributable to the increase in affordability by 3%.

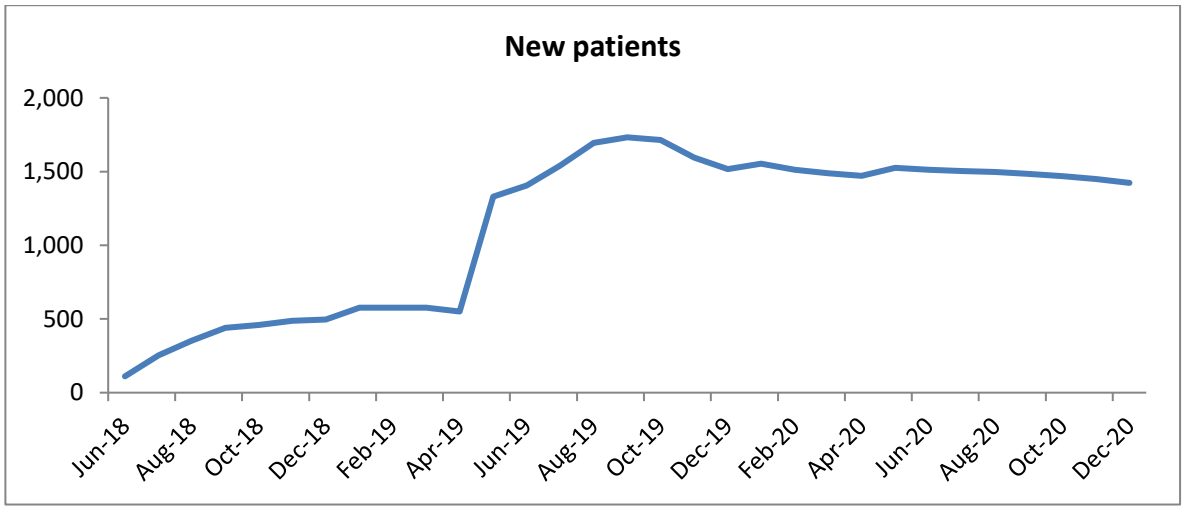


Fig. 4.10 Forecast of number of new patients taking therapy with Product C (month wise)

The number of new patients taking the therapy with Product C gradually increases from the launch but shows a sudden increase in May 2019 due to NRDL implementation showing a similar pattern as effective share curve. However, in September 2019 due to launch of competitor, there is a gradual decline in the revenue due to share theft from Product C.

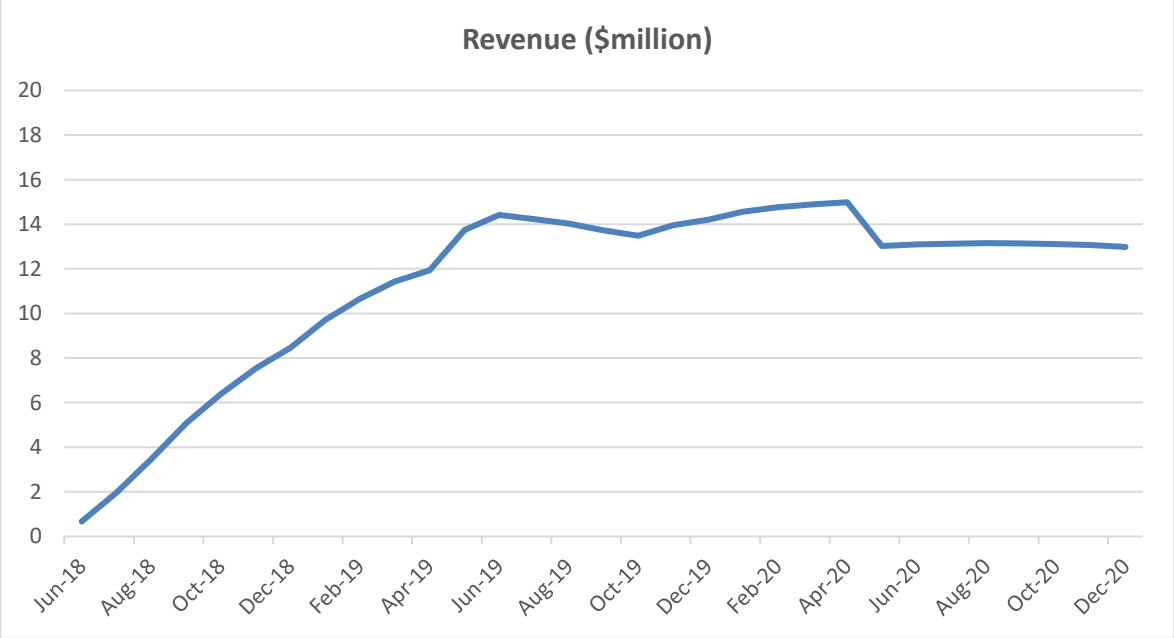


Fig. 4.11 Forecasted monthly revenue of Product C

The revenue of Product C was $0.6 million at launch, $13.7 million at implementation of NRDL and $12.9 million by the end of 2020. The increase in price cut leads to increase in affordability but the revenues decline as the rise in affordability is not significant enough to offset the reduction in price and thus pushes the revenue down.

CHAPTER 5

DISCUSSION, LIMITATION, CONCLUSION AND SUGGESTIONS

This chapter provides a brief explanation of the study including conclusion drawn from the observations in each of the scenarios. These observations have helped in recommending steps to improve the revenue and market share of the client's product and thus their performance in the market.

5.1 Discussion

The research study was conducted on NSCLC patients in all the provinces of China. The main aim of the study was to determine the revenue of a pharmaceutical product and the impact of launch of competitors on the performance of client's product in terms of share in the market, change in volume sales and revenue. The target of all pharmaceutical companies is to capture major market share at the launch of their product and thus maximize revenues.

The results of the study indicated the impact of assumptions like price cut, affordability and launch of competitors on the client's product. Other factors that can have an influence on the revenue of a pharmaceutical product are the time of implementation of NRDL, average duration of therapy and discount schemes. The revenue of client's product was estimated to be $33.5 million in 2018, followed by $169 million and $197 million in 2019 and 2020 respectively. The factors contributing to this revenue were launch of the product in June 2018 and implementation of NRDL in May 2019 with a 50% price cut.

When all other factors were kept constant and the price cut at NRDL implementation was changed from 50% to 60%, it led to increase in affordability by 3% for both reimbursed and self-pay patients. Although the revenue was expected to increase in this scenario due to increase in affordability and thus more patients switching to the product, but the forecasted revenues declined as the increase in affordability could not offset the reduction in price.

5.2 Limitation of the study

This study involves dependency on cancer registries for collection of epidemiological numbers of NSCLC. Thus, determining exact number of NSCLC patients remains a challenge.

In non-covered provinces i.e. where the product is not marketed, an average of 10% is considered as the percentage of patients taking therapy with Product C. This helps to take consider the patients who are taking the therapy in non-covered provinces but is a generalized percentage and therefore the actual percentage may vary.

There may be hidden bias in the model which may lead to sub-optimal decision making.

5.3 Conclusion

The study shows that implementation of NRDL and the resultant increase in affordability contribute towards increase in revenue even after price cut introduced by the client. The reason behind this increase in revenue is that as price cut is implemented, a greater number of patients begins to take treatment with the client's product and hence increase in the market share of the product. Also, the launch of competitors affects the client's revenue negatively.

An early launch of competitors' products leads to early share theft that reduces the patients taking therapy with client's product and hence reduction in the units of the product sold.

5.4 Suggestions

Based on the study results, the following suggestions were proposed to the client to increase the revenue from the product:

- An early implementation of NRDL will help to increase the market share of client's product and lead to an increase in the number of patients taking the therapy. Therefore, a positive effect on revenue will be reflected.
- A 50% price cut on implementation of NRDL is ideal for higher revenue when compared to a 60% price cut. If price cut is increased, it will definitely lead to an increase in affordability but the subsequent increase in revenue is not seen. This is because the patient pool of NSCLC is limited and only a small percentage of patients increase on increase in affordability.
- Enhancing the coverage of client's product to as many healthcare providers as possible will lead to an increase in acceptance of the product and thus help in gaining market share. This will be possible through highlighting the safety and efficacy results shown in the clinical trials.
- Discount schemes like Patient Assistance Programme will help to gain market share till the implementation of NRDL. This will increase the ability of patients to afford the drug. Under this scheme the product is purchased by the patient at full price for a few months and then provided for free by the company for other months. E.g. 2+2 scheme; where the patients pay for the drug for 2 months and then the company provides the drug for free for next two months.
- The provision of returning/reimbursing one month's price of the product if the patient's disease progresses i.e. progression of lung cancer will increase the trust and confidence of the patients towards the client's product.

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