Assessing Market Access Strategies for Empagliflozin 10/25mg Tablet A Comparative Analysis of Domestic Markets Type 2 DM

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Prem Dilip Agrawal

Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

Associate Professor

School of Pharmaceutical Management

IIHMR University, Jaipur

2023

Appendix C: Title Page

Assessing Market Access Strategies for Empagliflozin 10/25mg Tablet A Comparative Analysis of Domestic and International Markets Type 2 DM

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

In

PharmaceuticalManagement

By

Prem Dilip Agrawal

Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

Associate Professor

School of Pharmaceutical Management

IIHMR UNIVERSITY, JAIPUR

2023

Appendix D: Declaration by Student

DECLARATION BY STUDENT

I hereby declare that this dissertation titled Assessing Market Access Strategies for Empagliflozin 10/25mg Tablet a Comparative Analysis of Domestic and International Markets of Type 2 DM is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student

Date

MSN Laboratories Private Limited
MSN House, Plot No.: C-24,
Sanath Nagar Industrial Estate, Sanath Nagar,
Hyderabad, Telangana, Pincode: 500 018, India.
CIN: U24239TG2003PTC041583
Phone: +91-40-30438600 Fax: +91-40-30438798

June 1, 2023

TO WHOM SO EVER IT MAY CONCERN

This is to certify that, **Prem Agarwal,** pursuing **MBA Pharmaceutical Management** from **IIHMR, Jaipur** has successfully completed the internship in **Domestic Sales & Marketing** department in our organization, during the period **March 6, 2023 till May 31, 2023.**

During this period, we found him to be very hard working and sincere. We would also like to appreciate his enthusiasm and outstanding project report submitted to the organization. We acknowledge his efforts and recognize his work to be excellent.

We wish him all the best in his future endeavor.

for MSN Laboratories Private Limited

V Jerome

Jerome Vincent
DGM -HR

Appendix F: Certificate from Faculty Guide and School Dean

CERTIFICATE

This is to certify that dissertation titled Assessing Market Access Strategies for Empagliflozin 10/25mg Tablet A Comparative Analysis of Domestic and International Markets of Type 2 DM is a record of the research work undertaken by (Prem Dilip Agrawal) in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide	School Dean
IIHMR University, Jaipur	IIHMR University, Jaipur
Date	Date

Abstract

Evaluation of market access strategy for Empagliflozin 10/25mg Tablets) Comparison of local and international market and hospital studies applied to Type 2 DM "Evaluation of economic cost for treatment of Type 2 DM. - Direct and indirect cost of valvular atrial fibrillation length of stay in hospital Research Design that aims to create a comprehensive HF clinics service for heart failure, CKD, HBa1c patients in India, including drug costs (there are available treatment options at the Indian site) and product loss: This study will analyze Empaone's business entry strategy in local and international markets. Qualitative data will be analyzed using content analysis to identify themes and patterns in the data. Data will be compared between national and international markets to identify similarities and differences in marketing strategies. As a result, we captured the market using this method and with the help of our sales team, we increased 1 cr in a year and carried our strategy to success.

ACKNOWLEDGEMENT

As my project report nears completion, I would want to take this time to thank everyone who contributed in a significant way to my research. It gives me great pleasure to take advantage of this once-in-a-lifetime opportunity to thank my esteemed faculty and the Dean and Associate Professor of the School of Pharmaceutical Management at the IIHMR in Jaipur for their unmatched and outstanding support and encouragement as I worked to finish my course and dissertation. Throughout the process, people admired his work ethic, ethics, simplicity, and lack of fear. He deserves a lot of credit for helping me with my project because I couldn't have done it without his help. I often ponder whether or not seeing "GOD" in this world will make them like my parents, who always wish me the best. I would like to express my gratitude from the bottom of my heart. I prostrate myself at the feet of my devoted parents, friends, and family members, whose unwavering moral standards, love, and affection have consistently been unwaveringly bestowed upon me at all stages of life and have given me more than I deserved. Without their support, cooperation, and well wishes, the task would not have been possible. Last but not least, I want to thank "GOD- Almighty," who gave me the confidence and fortitude to realize my ambition and blessed me with blessings.

Date: 25-05-2023 Prem Dilip Agrawal

Place: Jaipur Name & Signature of Student

Table of content

Introduction: -

Aim of doing the market research was to analysis the marketing strategy working for the field force to make the sale of the product which we are selling in the market.
Research customer needs, wants, and expectations.To understand customer satisfaction from the company's products.Determines the necessary changes and improvements in the company's supp ort measures.Investigate current business issues and opportunities for appropriate action.Report on launching new drug, modifying current products and discovering new uses for existing produ cts.Designs and tests the appropriate packaging of the company's products so that the packaging is as good as possible.Examine the current price, distribution and competition business to make n ecessary changes if necessary.Find ways to popularize the company's products and increase sales . It can be because of a decrease in insulin secretion
or resistance, or both. In people with diabetes, hyperglycemia can cause different diseases of the body and, together with other metabolic disorders, life-threatening, and health-
affecting consequences.

Most of these problems are microvascular (retinopathy, nephropathy, and neuropathy) and macr ovascular problems, which increase the risk of heart disease by two to four times. This exercise r eviews the pathophysiology of DM and emphasizes the management of the disease by a collabor ative team. Three types of DM can be roughly divided into three types: type 1 , type 2 , and gestational diabetes (GDM). Monogenic diabetes and secondary diabetes additional less typical kinds of diabetes.

The majority of diabetics (90%) have type 2 diabetes mellitus (T2DM). Reduced insulin resistance in T2DM is referred to as insulin resistance. Due to the ineffectiveness of insulin un this situation, the body begins to create more insulin to regulate blood sugar, but over time, this production declines and T2DM results. Most patients with T2DM are over the age of 45. However, because of obesity, inactivity, and high-calorie diets, it affects kids, teenagers, and adults more frequently.

The global epidemic is diabetes. The prevalence of DiabeticMellitus is increasing worldwide du e to lifestyle changes and increasing obesity. In 2017, 425 million people worldwide had diabete s. According to the International Diabetes Federation (IDF), nearly 10 percent of Americans hav e diabetes in 2015. Seven million of these remain undiagnosed. Age also increases the risk of diabetes. People over the age of 65 make up about 25 percent of people with diabetes.

Brief about molecule

Empagliflozin (sodium glucose cotransporter (SGLT)-2 inhibitor) enhances the excretion of glucose and has an antihyperglycemic effect by blocking the kidney's glucose transporter. An osmotic diuresis, which may also drop blood pressure but more so (SBP) systolic blood pressure than diastolic blood pressure (DBP), is a secondary result of increased glucose in the urine. Loss of calories and a drop in body weight are additional results of the increased excretion of glucose. Combined with metformin and a sulfonylurea, empagliflozin is prescribed orally once a day for persons with type 2 diabetes when food habits, physical work out, and dual therapy (with metformin and a sulfonylurea) are insufficient for glycemic control. Dapagliflozin and are further SGLT-2 inhibitors that are currently authorized in Canada.

Empagliflozin, a selective sodium-glucose cotransporter 2 inhibitor, reduces hyperglycemia in patients with type 2 diabetes by decreasing renal sugarlevel reabsorption and increasing urinary sugar excretion. 11 In patients with type 2 diabetes, including all patient with type 2 or 3 kidney disease, use of empagliflozin was associated with lower HbA1c levels,body weight and b p, but no increase in rate of heart. 12-19 Empagliflozin has shown to reduce intraglomerular pressure. It improves ultrafiltration in patients with type 1 diabetes20,21 and these results have been shown to translate into better kidney function. 22 However, there are concerns that sodium-glucose cotransporter 2 inhibitors may cause kidney damage.

Cardiovascular results are the first endpoint of the current EMPA-REG OUTCOME study23.

Here, we present the end point of second study specifically designed to investigate the effect of empagliflozin on microvascular outcomes, particularly kidney disease.

MOA of Molecule

The sodium-glucose co-transporter-2 (SGLT-2) enzyme is present in the proximal tubules of the kidneys and is how empagliflozin functions. Empagliflozin decreases renal reabsorption of glucose and raises urine excretion of glucose through SGLT2 inhibition.

Toxicity

Employ normal symptomatic and supportive interventions, as well as gastrointestinal cleaning where necessary, as experience with empagliflozin overdose is limited. Hemodialysis has not been researched but is unlikely to be helpful in empagliflozin overdose due to the drug's relatively high protein binding

Organization details

A well-known pharmaceutical firm with a large influence on the world's healthcare sector is MSN Labs. Since its founding in the [insert year], MSN Labs has expanded quickly to establish itself as a leading force in the creation and production of top-notch generic pharmaceuticals.

MSN Labs, an organisation with its headquarters in Hyderabad, India, strives to offer patients all around the world accessible healthcare solutions by operating with a strong dedication to innovation, quality, and affordability. In order to deliver a diverse portfolio of pharmaceutical products to meet the changing needs of patients and healthcare providers, the company has built a strong infrastructure, including cutting-edge manufacturing facilities, cutting-edge research and development centres, and a highly skilled workforce."

The extensive product portfolio of MSN Labs, involves wide range of therapeutic areas, including cardiovascular, central nervous system, respiratory, cancer, and many more, is one of the company's key competitive advantages. Numerous illness categories are covered by the company's vast range of product solutions, which also meet urgent medical demands and enhance patient quality of life globally.

Additionally, a group of seasoned scientists and researchers that work for MSN Labs are credited with the company's significant emphasis on research and development (R&D). The company makes significant investments in R&D efforts with the goal of creating novel formulations, enhancing drug delivery technologies, and improving the efficacy and safety of its products. The launch of several first-to-market generic products and the acquisition of numerous international patents have been made possible by MSN Labs' dedication to innovation.

MSN Labs places quality at the heart of all business operations, and the company follows strict quality control procedures throughout the whole manufacturing process. The US Food and Drug Administration (FDA), the European Medicines Agency (EMA), as well as numerous other international regulatory bodies have granted MSN Labs various certifications and regulatory clearances. The company's constant dedication to upholding the highest standards of quality, safety, and efficacy in its pharmaceutical goods is attested to by these certifications and approvals.

MSN Labs has a significant global presence thanks to its constant dedication to excellence and its keen focus on client satisfaction. The business has established itself as a trustworthy partner for healthcare providers throughout the world by exporting its products to over nations. MSN Labs aims to significantly improve access to cost-effective, high-quality medications and improve patient wellbeing globally by working with international partners.

MSN Labs is a vibrant, forward-thinking pharmaceutical company with a presence all over the world. Its dedication to affordability, innovation, and quality distinguishes it as a reliable player in the international healthcare sector. MSN Labs continues to make important contributions to the pharmaceutical industry and advance the cause of affordable healthcare globally with a broad product portfolio, a strong emphasis on R&D, and a commitment to improve patient outcomes.

Market introduction

The regulatory frameworks regulating the pharmaceutical business in the chosen markets will be thoroughly examined, with a focus on the registration and approval procedures, labelling and packaging specifications, clinical trial laws, and pharmacovigilance systems. Examining cost-effectiveness analyses, appraisals of health technology, reference pricing systems, and price discussions with health insurance providers will all be considered when examining pricing mechanisms and reimbursement regulations.

In order to highlight parallels and variations in market access hurdles, regulatory frameworks, and pricing/reimbursement policies, the comparative analysis will evaluate market access strategies for Empa between domestic and overseas markets. The results will shed light on Empa's commercial potential and viability in each market.

The research findings will be used to inform suggestions for enhancing Empa's market access strategy in both home and foreign markets. In order to highlight parallels and variations in market access hurdles, regulatory frameworks, and pricing/reimbursement policies, the comparative analysis will evaluate market access strategies for Empa between domestic and overseas markets. The results will shed light on Empa's commercial potential and viability in each market.The research findings will be used to inform suggestions for enhancing Empa's market access strategy in both home and foreign markets. These suggestions will include tactics for removing particular obstacles to market entry as well as chances for cooperation with regulatory bodies, health insurance companies, and other stakeholders.

This study seeks to advance our knowledge of pharmaceutical product market access tactics and offer crucial information for the effective introduction and widespread distribution of Empa.

Bothmethodwillbe used to collect and analyze data. (Sales & Marketing). Secondary data such as annual reports, company websites, business reports,and academic publications will be used to ga ther information about Empaone and its business strategies. Important information will be gather ed through research and interviews with stakeholders such as company executives, business exec utives, and business professionals. Quantitative data can be analyzed by descriptive statistics and statistical methods such as regression analysis to find patterns and relationships in the data. Qualitative data will be analyzed using content analysis to identify themes and patterns in the dat a. Data will be compared between national and international markets to identify similarities and differences in marketing strategies. As a result, we captured the market using this method and wi th the help of our sales team, we increased 1 cr in a year and made our strategy a reality.

Literature review

James E Frampton 2018

Empagliflozin, a potent sodium glucose cotransporter-2 inhibitor, has been approved for the treatment of patient with type 2 diabetes in the EU, the USA, and Japan among other nations. It is a successful and generally well-tolerated antihyperglycaemic medication. Empagliflozin is similar to other drugs in its class in that it is independent of insulin and is easy t o take by mouth once daily, due to the risk of hypoglycemia. It can therefore be used to treat T2D patients both alone and in combination therapy with other anti-diabetic drugs that have complementary mechanisms of action. For lowering blood sugar, empagliflozin has favourable result on a variety of non-glycaemic outcomes, including small decreases in body weight, blood pressure. It demonstrated cardioprotective and renoprotective properties in individuals with T2D and existing cardiovascular disease (CVD), generally independent of glycemic control, in a trial for necessary cardiovascular (CV) outcomes (EMPA-REG OUTCOME). Empagliflozin has not been associated with a higher risk of amputation or bone fractures, in contrast to canagliflozin (the only other SGLT2 inhibitor to date to exhibit CV and renal benefits). Whether used as a monotherapy or as a supplement, it is frequently well tolerated. To sum up, empagliflozin is a helpful treatment option for the management of T2D. The medication should be preferred in individuals with high CV risk who need to take a (additional) antidiabetic treatment in order to meet their glycaemic target due to its demonstrable cardioprotective benefits.{2}

Goyal R, Jialal I JAN 2023

A drug called empagliflozin is used to manage and treat type 2 diabetes mellitus. It belongs to the group of diabetic drugs known as SGLT-2 sodium-glucose co-transporters. This activity explains the benefits of empagliflozin as a treatment for type 2 diabetes mellitus, how it works, and when it should not be used. The mechanism of action, dosing, and monitoring essential to members of the interprofessional team in the care of patients with type 2 diabetes will be highlighted in this session. The objectives were to Determine the criteria for starting empagliflozin therapy.

List the conditions that should not be treated with empagliflozin. Describe the side effects of empagliflozin medication that are common and unusual. Examine interprofessional tactics that will enhance results when empagliflozin therapy is prescribed or ordered.

Bernard zinam et al November 2015

It is unclear how treatment and the sodium-
glucose cotransporter 2 inhibitor empagliflozin affect the cardiovascular system and death in pati ents with type 2 diabetes at high risk of heart disease. 7020 people received treatment (after a me dian of 3.1 years). In the empagliflozin group, 490 of 4687 patients (10.5%) experienced a prima ry event, compared with 282 (12.5%) of 2333 patients.1% received placebo (hazard ratio for em pagliflozin group: 0.86; 95.02% confidence interval: 0.74 to 0.99; P = 0.04 means domination). Although there was a significant reduction in cardiovascular events in the empagliflozin group (5.9% versus 3.7% in the placebo group; 38% relative reduction in allcause mortality), the rates o f myocardial infarction and stroke did not differ between the different groups. (5.7% and 8.3%, r espectively; 32% risk reduction) and hospitalization for heart failure (2.7% and 4.1%, respectivel y; 35% relative reduction). The secondary outcome was not significantly different between grou ps (P = 0.08 means domination). An increase in the genital area was seen in patients receiving e mpagliflozin, but no other side effects were observed. After trial, they gave the following results: Outcome of significant cardiovascular and allcause mortality in diabetic patients with type 2 dia betes who, when added to standard therapy, empagliflozin was at higher risk of heart disease tha n in the control group. The number of patients decreased compared to placebo.{3}

Reifsnider O, Kansal A et alDec 2020

Analysis using the QALY US WTP threshold of US$50,000150,000 showed that adding sitaglipt inafter secondline empagliflozin is an excellent option for the treatment of T2D compared with s econd line sitagliptin and empagliflozin. .

CVD was treated with metformin monotherapy. 26 Twoline empagliflozin increases QALYs an d increases life expectancy with a small increase in lifetime costs in the baseline scenario; this is a scenario that changes the population's CV history and calculates that commercial billing and M edicare considerations are separate. Together, these results achieved ICERs below the strict WT P cap of $50,000/QALY. 2nd line empagliflozin outperforms sitagliptin in the short term, such a s 1 to 10 years, and has a WTP of $100,000 in Response US Value – either full or basic. patients (with or without CVD) when / QALY. According to DSA research, ICER is resistant to changin g most of its access parameters. In some simulated situations (eg.That is, in terms of QALY bene fits and cost savings) for the treatment of T2D.{4}

A primary end event occurred over a median of 16 months in 361 of 1863 participants receiving empagliflozin and in 462 of 1867 people receiving a placebo; the hazard ratio for cardiovascular death or heart failure hospitalisation was 0.75 with a 95% confidence interval. No matter if a patient had diabetes or not, empagliflozin had a consistent impact on the primary result. In comparison to the placebo group, there were fewer heart failure hospitalisations overall in the empagliflozin group. Patients using empagliflozin had a decreased risk of significant renal outcomes and the annual rate of decline in the estimated glomerular filtration rate was slower in the empagliflozin group than in the placebo group. With empagliflozin, simple genital tract infections were reported more frequently.{5}

Methodology

Background:

In type-2 diabetic mellitus (T2DM), costs are a significant factor in noncompliance with prescribed treatments. The least expensive EMPA preparation per month is the half-tablet empagliflozin (EMPA)-25 mg; however, there is no information available on the effectiveness of this dosage. In this study, the effects of EMPA at doses of 10, 12, and 25 mg on actual weight reduction and glycaemia outcomes were compared.

Methods:

Retrospective data collection and analysis were done on records of two distinct patients with T2DM who were using EMPA as part of their usual medication for the condition and were over the age of 35. In accordance with the dosage of EMPA, patients were divided into three groups: EMPA 10 mg/day (1 EMPA-10 tablet) was given to Group 1, EMPA 12.5 mg/day (1 EMPA-25 half-tablet), and EMPA 25 mg/day (1 EMPA-25 tablet) was given to Group 2. The main results were weight loss and improved glycemic control.

Results: Data from 599 patients (184, 239, and 176 in Groups 1 through 3 respectively) were reviewed out of the 3601 records from Hyderabad collaborating hospitals that were screened for empagliflozin patients. All three groups were comparable in terms of sex, blood pressure, hemoglobin, renal function, and medication use. Group 3 had the lowest BMI, the greatest HbA1c, and the longest duration of diabetes. They were also significantly older. Glycemic effectiveness was comparable among groups, as seen by HbA1c Groups 1-3, which had values of 0.9 (1.9 - 0.0), 1.0 (1.8 - 0.5), and 1.0 (1.5 - 0.22), respectively; P = 0.363. Patients as well as significantly larger percentage of patients reaching HbA1c 5.7% (12% vs with comparison to EMPA-10, = 0.021.{1}

The most economical way to use EMPA in clinical practice is half EMPA-25.

The daily consumer of sglt-2 in Hyderabad is 900.

Comparative analysis

BRANDS	COMPANY	PROD_LNCH	MAT MAR'20	MAT MAR'21	MAT MAR'22	MAT MAR'23	CAGR%	FEB'22	FEB'23	MAR'21	MAR'22	Jan'23	Feb'23	MAR'23	MAT GR	MTH GR	MS% Mar'23
EMPAGLIFLOZIN			**351.53**	**392.86**	**366.24**	**338.77**	**-68%**					**25.38**	**26.38**	**28.19**	**-7.5**	**6.8**	**100**
JARDIANCE	BOEHRINGER INGELH.	201510	235.31	257.59	233.04	226.05	**-68%**	17.93	18.22	20.81	19.29	16.34	18.22	19.17	-3%	-1%	67%
GIBTULIO	LUPIN LIMITED	201609	116.23	133.01	117.29	96.15	**-72%**	8.46	6.60	10.32	8.95	7.37	6.60	7.34	-18%	-18%	28%
EMPAONE	**MSN LABS**	**202110**	**0.00**	**0.00**	**0.51**	**7.94**	**1451%**	**0.09**	**0.97**	**0.00**	**0.19**	**0.92**	**0.97**	**1.06**	**1451%**	**446%**	**2%**
OBORAVO	CIPLA	202011	0.00	2.26	13.01	6.07		1.25	0.31	0.64	1.18	0.51	0.31	0.35	-53%	-71%	2%
VICRA	DR REDDYS LABS	202110	0.00	0.00	2.39	1.83		0.33	0.03	0.00	0.51	0.06	0.03	0.03	-23%	-94%	1%
COSPIAQ	TORRENT PHARMA*	202212	0.00	0.00	0.00	0.73		0.00	0.25	0.00	0.00	0.19	0.25	0.25	#DIV/0!	#DIV/0!	0%
Grand Total			**351.533**	**392.8616**	**366.2376**	**338.771**		**28.066**	**26.3842**	**31.775**	**30.129**	**25.384**	**26.384**	**28.19**			

Doctors or Healthcare professionals survey

Why they prefer Empagliflozin over Dapa ?

- Better reduction of HbA1C with empa reduces 0.7 in 24 weeks over dapa reduces 0.6 in 52 weeks
- Empa reg outcome reduces all causes death 35%
- Can be given to patient with egfr rate morethan equal to 20 over dapa i.e 30.

Marketing activities

Our company finds out the potential doctors and tries to engage them in activities like hvg in this activity we provide high-value gifts to the doctors such as a trip to Varanasi Puri Tirupati and in return the company expects business from them the expectation of business more than twice of the expenditure. Also, our company provides them Lenin shirts six shirts in a year

We also invite potential doctors for the R&D center visit to show them how we prepare and test our drugs as we launch the bioequivalent innovator brand in the market this can build trust towards doctors and the company, and they will prescribe the medicines.

Our Msn also arranges CMEs for doctors whenever there is a new study of any molecule in the market, and we are about to launch any revised study over a marketed product. We have also arranged a CTB event over 300 doctors attended the event across India in this event a book is launched which contain articles provided by different doctors on type 2 dm and we felicitated them and provided a copy of that book. Along with the event they were provided with a short trip to Hyderabad.

The success of your pharmaceutical business depends on CRM technology. It helps you gather information about your potential customers and act on that information to build a strong and lasting

partnership. CRM software collects and organizes information about communication preferences, social history, Internet behavior, and more. Examples of use of this information include sending email referrals based on website traffic and cross-selling new drugs and treatments based on pre-existing conditions. You can customize each recipient's experience by sending notes about their birthday and other important dates.

- Delivering after-sales assistance
    - sending offers for free samples
    - Provide Free Samples

  In the free test, this is one of the most commercial drug deals and it's a good idea to let your Health Care Worker network allow it. After all, most doctors will prescribe medication if they get free samples. However, you need to be careful and make sure the models are distributed responsibly. Building trust and managing patient needs in your pharmaceutical business is more important than ever, as patients can search for and use information provided to them by Health Professionals on the Internet.. You can more easily target patients by using the same channels and creating marketing campaigns by figuring out where they go online to learn about symptoms, medications, and therapies as well as forums where they discuss their experiences.

  Research methods

  The survey was done on the field I have talked with 50 doctors about the drug and why they prefer to prescribe this product over outer gliptins and gliflozins

  Response from the medical prescriber what that it helps to cure type2dm with renal safety along with decreasing hba1c level more quickly than the other gliflozins

  Some have talked about the studies which we carried out on empagliflozin, and the studies claim that it can be used in general patients with type 2 dm as well as persons having CV disease as well as kidney disorder

  Some have talked about the drug reduces the chances of heart attack and also reduces the hospitalization rate of the patient it reduces causing other cv events

  Nepro doctors have talked about kidney safety like empa can be given to patients with more than eGfr rate 20 which is more kidney damage over dapa also increase the kidney filtration rate by increasing absorption.

This research survey includes 4 specialties of doctors CP, Cardiologist, and Nephrologist, Endocrinologist of Hyderabad some doctors are mentioned here KD Modi (endo), Hemant Harish (cardio), Aman Selvan(cardio) Ramesh Gudupatti (cardio), Nishant Reddy(C.P)

Using gliptins the therapy cost is quite high over gliflozins also the gliptins can cause adverse effects and which can lead to heart disease and which lead to patient compliance

The empagliflozin or our company matches the bioequivalence of the innovator, and the rate is also friendly so they prefer our brand over another competitor brand

We also try to maintain patient compliance for this drug and they can get better availability of the drug in the market.

Conclusion

In conclusion, the evaluation of Empa's (Empagliflozin tablet) market access strategies through a comparative analysis of domestic markets gives insightful information for successful market entry and growth. Understanding the dynamics of markets, including their regulatory frameworks, competitive environments, pricing schemes, distribution systems, and consumer preferences, was the main goal of the study.

Several significant conclusions have been drawn from this investigation. First off, there are encouraging potential for growth in the global market for Empa, driven by ageing populations, rising demand for anticoagulant drugs, and growing knowledge of the drug's efficacy and safety. However, it is critical to take into account regional variations in legal requirements, reimbursement practises, and market entrance hurdles. Successful international market access depends on building solid relationships with regional distributors, adhering to local laws, and completing in-depth market research.

However, the local market offers a comfortable setting for Empa's market access approach. A number of advantages exist, including well-established distribution networks, simplified regulatory procedures, and familiarity with the healthcare system.

Therefore, spending money on market research, carrying out clinical trials, and interacting with patient advocacy organisations is crucial to gather information and adjust plans.

In order to evaluate market entry plans for Empa, both domestic and international markets must be carefully examined, taking into account each one's particular dynamics and difficulties. Pharmaceutical businesses can maximise their efforts for market entry and expansion by utilising opportunities, minimising risks, and tailoring tactics to fit particular markets. The results of this comparative research offer insightful information that can inform choices and help Empa reach its full potential in both home and foreign markets.

References

1.Dutta D, Sharma M, Aggarwal S, Agarwal A, Dhall A. Treatment outcomes of graded dose of empagliflozin in type-2 diabetes: A real world study. Ann Afr Med. 2022 Jan-Mar;21(1):26-33. doi: 10.4103/aam.aam_69_20. PMID: 35313401; PMCID: PMC9020632.

2. Frampton, J.E. Empagliflozin: A Review in Type 2 Diabetes. *Drugs* **78**, 1037–1048 (2018). https://doi.org/10.1007/s40265-018-0937-z

3. Goyal R, Jialal I. Diabetes Mellitus Type 2. [Updated 2022 Jun 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan

4.Reifsnider O, Kansal A, Pimple P, Aponte-Ribero V, Brand S, Shetty S. Cost-effectiveness analysis of empagliflozin versus sitagliptin as second-line therapy for treatment in patients with type 2 diabetes in the United States. Diabetes Obes Metab. 2021 Mar;23(3):791-799. doi: 10.1111/dom.14268. Epub 2020 Dec 15. PMID: 33236481; PMCID: PMC7898389.

5. Giusy Pietrafesa, Roberta De Zio, Simona Ida Scorza, Maria Francesca Armentano, Martino Pepe, Cinzia Forleo, Giuseppe Procino, Andrea Gerbino, Maria Svelto, Monica Carmosino. (2023) Targeting unfolded protein response reverts ER stress and ER Ca2+ homeostasis in cardiomyocytes expressing the pathogenic variant of Lamin A/C R321X. *Journal of Translational Medicine* **21**:1.