

MARKET INVESTIGATION OF SULFONYLUREAS AND NEW CHEMICAL ENTITIES IN MAJOR URBAN CITIES OF INDIA

Dissertation Submitted to



The IIHMR University, Jaipur

for the partial fulfillment of the award of the
degree of Master of Business Administration
(MBA)

in

Hospital and Health Management/Pharmaceutical
Management/Rural Management

by

Pruthvi Manish Bhanabhagawanwala

Under the Supervision and Guidance of

Dr. Saurabh Kumar Banerjee

2022

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Market Investigation of Sulfonylureas and New Chemical Entities in Major Urban Cities of India** 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.



Pruthvi Manish Bhanabhagawanwala

Date: 1st July 2022

CERTIFICATE



Date: 21st Jun 2022

Whom So Ever It May Concern

This is to certify that **Mr. Pruthvi Bhanabhagawanwala** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed his internship at **Healthark Insights Wellness Solutions LLP** during **March 22, 2022 to June 19, 2022**.

A handwritten signature in black ink, appearing to read "Amol Pandya", with a horizontal line underneath.

Sincerely,
Amol Pandya
HR Manager
Healthark Insights

Place: **Ahmedabad**

Date: **21st June 2022**

Preceptor/ Head of the Organization:

Dr. Purav Gandhi

Name of the Organization:

Healthark Insights Wellness Solutions LLP

CERTIFICATE

This is to certify that dissertation titled **Market Investigation of Sulfonylureas and New Chemical Entities in Major Urban Cities of India** is a record of the research work undertaken by (Name of Student) in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management)/MBA (Pharmaceutical Management)/MBA (Rural 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.

Dr. Saurabh Banerjee
IIHMR University, Jaipur

Date: **1st July 2022**

Dr. Saurabh Banerjee
IIHMR University, Jaipur

Date: **1st July 2022**

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Thank You.

Pruthvi Bhanabahagwanwala

MBA PM12

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Abbreviations

MODY	Maturity-onset Diabetes of the young
DPP4	Di-peptidyl peptidase 4
SGLT2	Sodium-Glucose co-transporter 2
GLP1	Glucagon-like peptide
K-ATP	Potassium Adenosine Tri-phosphate
T2DM	Type 2 Diabetes Mellitus
NCEs	New Chemical Entities
OHA	Oral Hypoglycemic Agents
DPCO	Drug Price Control Order

Abstract

Diabetes is one of the major chronic diseases in the world. Around 500 million people in the world are suffering from diabetes & with the ~75 Mn population, India is 2nd largest country with the diabetic population. There is wide variety of treatment options available for T2DM and New Chemical Entities are evolving for better treatment options. From which, sulfonylureas are the widely prescribed drug. There is change in the paradigm of prescription practices for sulfonylureas. The research was aimed to determine market conditions of sulfonylureas as well as to understand NCEs which can change the future of diabetic therapy. By this study, market volume and market value of different sulfonylureas, its product and brands as well as prescription trends after the COVID was studied. For that, both primary and secondary research were used to collect the information. The primary research was conducted in two major cities of Gujarat i.e., Surat & Ahmedabad with the questionnaire and target population consisted of Dispensing Pharmacists at retail pharmacy store. For survey, non-probability convenience sampling used with the sample size of 100 with confidence interval of 95%. The collected data was analyzed in excel. The market value of sulfonylureas was estimated of 323.3 Mn with the market volume of 7.36 Mn. Sulfonylureas was comprised of Glimepiride (13.9%), Glipizide (4.8%), Gliclazide (4.8%), Glibenclamide (8.3%), Metformin + Glimepiride (15.3%), Metformin + Pioglitazone+ Glimepiride (20%), Metformin + Glimepiride + Viglibose (22.4%). Due to NCEs, there might be the shift on the traditional therapy of diabetes. For sales of the sulfonylureas, sales force is playing major role for market expansion.

Keywords: *Anti-diabetic Market, Sulfonylureas, Market value, Market share, potential, NCEs, Clinical Trials*

1. Introduction

Diabetes is one of the highest prevalent diseases in the world and India leading to morbidity and many other diseases such as cardiovascular complications. ⁱDiabetes Mellitus is a disease where the body can't control blood glucose levels. Majorly, it is classified as:

- Type 1 diabetes: Autoimmune disorder where the immune system destroys β -cells of the pancreas, may be caused by genes and environmental factors
- Type 2 diabetes: There may be various factors to cause type 2 diabetes such as ethnic groups, and obesity in which the major cause is insulin resistance

Both subtypes have different physiology, evaluation, and management but lead to the same outcome, i.e., hyperglycemia. Other than that, it is classified based on maturity-onset diabetes of the young (MODY) by:

- Gestational,
- Neonatal
- Steroid-induced diabetes

Diabetes 1 & 2 mainly results from insulin secretion (type 1) and/or insulin action (type 2). Mainly type 1 diabetes occurs in children and adolescents and type 2 diabetes is highly prevalent in middle-aged and older people generally affected by prolonged hyperglycemia due to sedentary lifestyles and dietary choices. Now, Due to the destruction of β -cells of the pancreas, insulin secretion is low or absent in type 1 diabetes, but type 2 diabetes involves variation in insulin levels and sensitivity causing deficiency in insulin secretion in the body resulting in type 2 diabetes, but type 2 diabetes occurs due to many other factors such as obesity. Type 2 diabetes has genetic factors also. The pathophysiology of diabetes is unclear as there are many factors associated with it but a blood glucose level greater than 180 mg/ dL is considered hyperglycemic.

Generally, type 2 diabetes is treated with lifestyle and diet modification (type 1 diabetes occurs due to insulin resistance and no lifestyle change can overcome that) but for severe cases, medications are preferred. ⁱⁱNow, for type 1 diabetes, insulin is the only treatment option. All the patients with type 1 diabetes have to take insulin every day. For type 2 diabetes there are treatment options such as:

- Insulin: Some the patients have to take insulin in severe cases of type 2 diabetes
- Oral Medications: It is used as a single dose or combinational therapy i.e.,
 - Metformin

- Thiazolidinediones
- Sulfonylureas
- Meglitinide
- DPP-4 Inhibitors
- SGLT2 Inhibitors
- Alpha-glucosidase inhibitors
- GLP-1 receptor agonists
- Diet & Exercise: This will help you to maintain your blood sugar level in both type 1 and type 2 diabetes

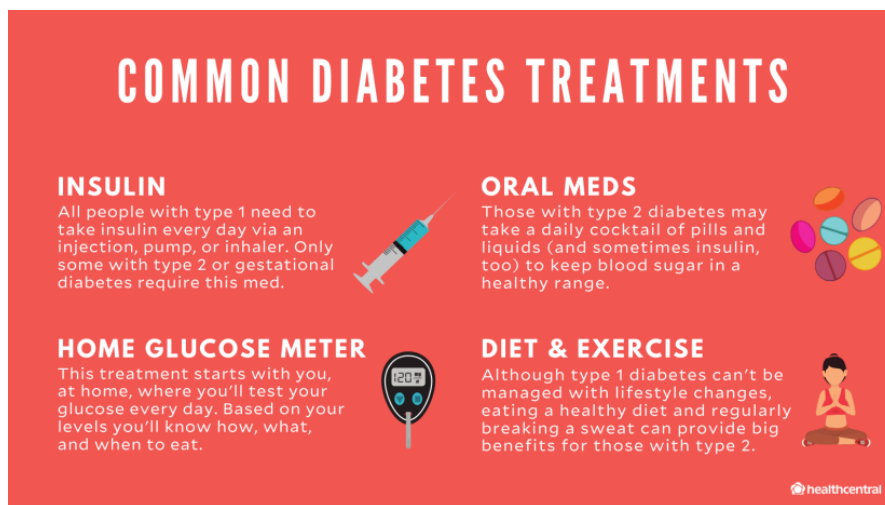


Figure 1: Common Diabetes Treatment

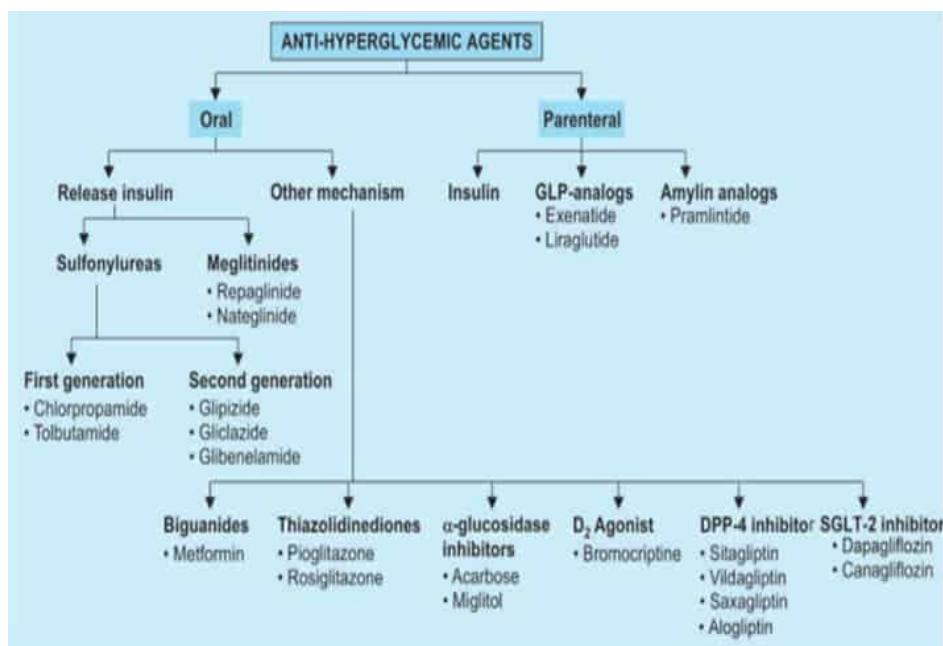


Figure 2: List of Oral Hypoglycemic agents

1.1 Statistics about diabetes:

ⁱⁱⁱGlobally, around 0.5 Bn people are suffering from diabetes. Middle-income country shows the highest prevalence of diabetes with Asia as an epicenter of it. India is the diabetic capital in the world. ^{iv}With a diabetic population of 74.2 Mn India is 2nd largest country after China. ^vIt is expected to increase by over 134 Mn cases by 2045, from which 57% will remain undiagnosed.

^{vi} Parameters	Statistics (2021)
People with diabetes (new cases)	74195
Prevalence of diabetes (%)	9.6
Undiagnosed people	39400
Undiagnosed people (%)	53
Probability of death due to diabetes	647,831
Diabetes-related death (under 60y) (%)	2.8

Table 1: Diabetes Statistics in India

1.2 Sulfonylureas and as a diabetes treatment

A wide variety of oral medications are used to maintain blood sugar levels. Majorly insulin and metformin are used as primary treatment options but sulfonylureas are another treatment option that is preferred for diabetes management. ^{vii}Sulfonylureas are the earliest and most widely used oral hypoglycemic agents to treat diabetes mellitus. It promotes the secretion of insulin from pancreatic cells and maintains blood sugar levels.

Mechanism of Action of Sulfonylureas:

^{viii}The Sulfonylureas receptor is the K-ATP channel in pancreatic cells which regulates the release of insulin. Now, sulfonylureas bind with the K-ATP channel and inhibit these channels. This alters resting potential and Ca^{+2} influx is increased. This stimulates the secretion of Insulin from the β -cells of the pancreas. Sulfonylureas exhibit effects on other cells than the pancreas, but the clinical importance of that effect is not much. Sulfonylureas are not effective for treating type-1 diabetes as it is insulin-dependent & sulfonylureas act by increasing insulin secretion

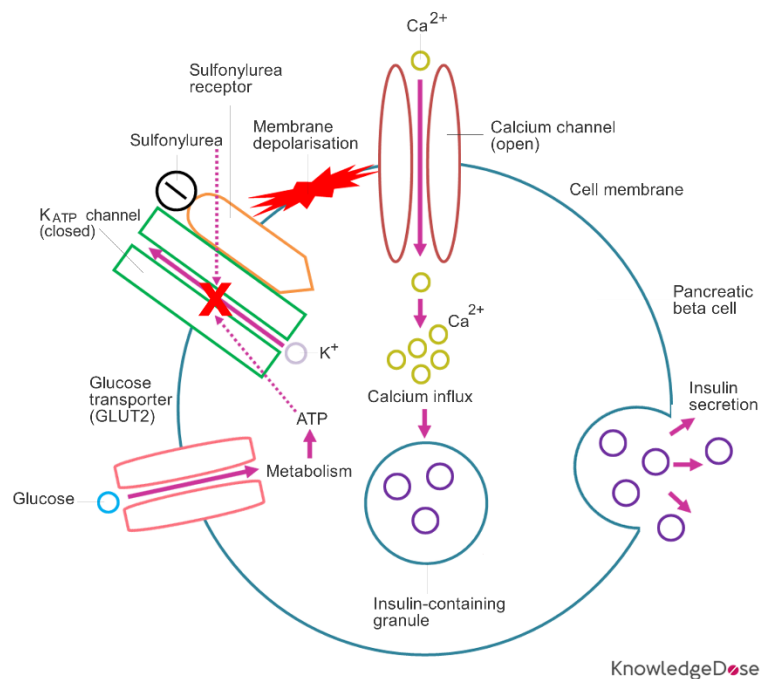


Figure 3: MOA of sulfonylureas on β -cells of the pancreas

Route of administration of Sulfonylureas:

^{ix}Oral administration of sulfonylureas as normal and long-acting (extended release) pills of various dosage forms i.e., 0.5, 1, 1.5 & 2 mg taken once daily with breakfast or lunch. It is taken in addition to the diet for sugar control of patients with T2DM. Combinational drug therapy of sulfonylureas is generally preferred for high effectiveness & better onset of action.

Side effects of Sulfonylureas:

Some common side effects of sulfonylureas:		
Diarrhea	Abdominal pain	Muscle pain
Vomiting & Nausea	Weakness	Sore throat
Upset Stomach	Loss of Appetite	

Rare side effects:		
Respiratory tract infection	Fever	Anemia (low RBC)
Weight Gain	Leukopenia (Low WBC)	
Hypoglycemia ○ Sudden Perspiration ○ Tachycardia ○ Blurred vision	Kidney Problems ○ Swelling of limbs ○ Dark Urine ○ Change in amount of urine	

Table 2: Side Effects of Sulfonylureas

1.3 NCEs for T2DM

As per US-FDA, NCE is a drug that contains no active molecule that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug & Cosmetic Act. It is developed by the company in the primary stage which can be a potential treatment for the disease after the clinical trials.

^xFor the treatment of diabetes, there are nearly 100 anti-hyperglycemic agents are being evaluated for clinical trials. Due to the high prevalence of diabetes across the world and new advancements like precision medicine, more personalized and accessible treatments are identified for better onset. For example, recently FDA approves Tirzepatide i.e., a new drug entity for type 2 diabetes, which is a once-a-week injection that manages blood sugar content and decreases food intake.

2. Research Problem & Objectives

2.1 Research Problem

Sulfonylureas are commonly prescribed medicine for the treatment of T2DM for a longer period. Either single dose or multi-dose therapy, it is the most common and frequently prescribed drug for middle-income countries. For the treatment of diabetes, there are a wide variety and class of drugs available in the market and sulfonylureas is reaching market saturation as well as there are thousands of brands available to treat diabetes. So, due to high competition in the diabetes market and for better treatment options, market assessment is necessary. Also, drug markets are constantly evolving and there is continuous research and development for better & effective disease therapy. New Chemical Entities are constantly launched into the market for better diabetes control. So, the purpose of the study is to understand the existing market condition of sulfonylureas and determine the potential for sulfonylureas as well as NCEs.

2.2 Research Objectives

The objectives of the research are:

- To estimate market value and market volume of Sulfonylureas and NCE evolving
- To determine market of drug products and brands of Sulfonylureas
- To determine the market drivers and challenges for Sulfonylureas
- To understand future of evolving NCEs and its possible impact on traditional therapy

3. Literature Review

¹Traditional diabetes medications are causing unwanted adverse effects leading to incompliance and a decline in treatment rate. To increase the compliance of diabetes, many therapies and NCEs are evolving such as β -cell generators and gene therapy along with oral hypoglycemic agents to better control this disease. Currently, with the evolution of nanoparticles, new methods of glucose monitoring and insulin supplements are holding the potential to improve the life of the diabetic patient, but any of these new agents or NCEs are effective alone for better disease control. So, the combination of these new emerging agents with traditional oral anti-diabetic agents is required which will effectively improve the propensity to manage the criticality of the disease. (Vijay Mishra, 2021)

²Due to the early discovery of insulin and other oral hypoglycemic agents, the saturation of the market is near and to overcome that many therapeutic alternatives are being launched into the market and FDA approved more than 60 drugs and around 100 drugs are in the process of clinical trials. Now, due to the unpredictability of T2DM, more precision medicines are in the evaluation process intending to achieve precision treatment shortly. For that, personalized diabetes management i.e., patient's attitude, medical condition and history, social support for maintaining blood sugar levels, patient compliance, and patient satisfaction are being incorporated and getting successful results. Along with this, the combination of traditional hypoglycemic agents with new entities has the potential to counter side effects as well as more precise treatment. Now, due to the shift in T2DM treatment and the incline of diabetology, innovative therapeutic approaches are launched and developed. For example, the Oral insulin capsule ORMD-801 had auspicious results in phase II clinical trials and is now being evaluated in phase III trials. (Dahlén, 2022)

¹ Mishra V, Nayak P, Sharma M, Albutti A, Alwashmi A, Aljasir M et al. Emerging Treatment Strategies for Diabetes Mellitus and Associated Complications: An Update. *Pharmaceutics* [Internet]. 2021;13(10):1568. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8538773/>

² Dahlén A, Dashi G, Maslov I, Attwood M, Jonsson J, Trukhan V et al. Trends in Antidiabetic Drug Discovery: FDA Approved Drugs, New Drugs in Clinical Trials and Global Sales. *Frontiers in Pharmacology* [Internet]. 2022;12. Available from: <https://www.frontiersin.org/articles/10.3389/fphar.2021.807548/full>

³Due to artificial treatment options, there are high chances of atrocious consequences. Plant-derived peptides and proteins from plant-based derivation are emerging as a new way of treating diabetes. Enzymatic breakdown of specific proteins yields peptides that can be used for treating the disease. These peptides can give cost-effective therapy options. Studies are showing that bioactive peptides are disrupting enzymes & transporter systems that cause diabetes. Many peptides and short RNAs are controlling cellular communication by changing the molecular structure and show effects on diabetic patients. (Mahankali, 2021)

⁴Many natural products which can suppress α -glucosidase & α -amylase are potential for treatment for T2DM with lowering adverse effects for restraining hyperglycemia. Natural products such as polyphenols are being evaluated for α -glucosidase & α -amylase inhibition. Here, Drug Repositioning can decrease time and money as drugs are already used for other indications. In silico approaches are complementing and integrating into drug repositing will form future drugs. Although drug design and development for T2DM is in the early stages, it can be linked to the mechanism of T2DM treatment. In silico approaches have the advantages of low cost and fast speed, which is a major factor for the high adoption of this technique worldwide. Currently, in silico approaches are accelerating discoveries from natural compounds and reaching pre-clinical levels which include mainly *Garcinia linii* extracts. With this New Chemical Entity design, new leads are being identified for therapeutic effects in anti-hyperglycemic effects and Management of diabetes in human clinical trials. (Riyaphan, 2021)

³Mahankali S. A Treatment to Cure Diabetes Using Plant-Based Drug Discovery. Hindawi [Internet]. 2022 [cited 16 June 2022];. Available from: <https://www.hindawi.com/journals/ecam/2022/8621665/>

⁴Riyaphan J, Pham D, Leong M, Weng C. In Silico Approaches to Identify Polyphenol Compounds as α -Glucosidase and α -Amylase Inhibitors against Type-II Diabetes. *Biomolecules* [Internet]. 2021;11(12):1877. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8699780/>

⁵Over the past two decades, significant development is created to understand the risk factors of T2DM and its metabolic pathways of disease progression as well as prevention parameters, but despite these advances, the incidence and prevalence of T2DM are increasing constantly. So, new metabolic pathways and NCEs are being targeted for novel pharmacotherapy to target the disease and produce a favorable outcome. Most of the identified novel compounds have potent effects as anti-hyperglycemic agents but safety and tolerance are still being identified in clinical trials. There are around 129 active studies of T2DM in phase I to phase IV across the world. Along with that, advances in monoclonal antibodies and gene therapy may eliminate dysglycaemia and maintain glucose homeostasis for curing diabetes.

⁵Shah N, Abdalla M, Deshmukh H, Sathyapalan T. Therapeutics for type-2 diabetes mellitus: a glance at the recent inclusions and novel agents under development for use in clinical practice. *Therapeutic Advances in Endocrinology and Metabolism* [Internet]. 2021;12:204201882110421. Available from: <https://journals.sagepub.com/doi/10.1177/20420188211042145?cid=int.sj-full-text.similar-articles.3>

4. Study Design & Methodology

4.1 Study Design:

Study Type: Descriptive Study

Data Source: Primary & Secondary Research

Data Collection Technique/ Tools:

Primary Research: Semi-structured Questionnaire

Secondary Research: Data of market conditions

Data Analysis tool: Research Data analysis using excel

4.2 Sample Design:

Target Population: Dispensing Pharmacist

Sampling Method: Non-probability Convenience Sampling

Sample size: 100 Dispensing Pharmacist (95% Confidence Interval)

Study Location: Ahmedabad & Surat

4.3 Ethical Consideration:

The research was done with appropriate research guidelines and respondents were provided sufficient amount of time for responses. Before research, consent and permission was taken. Identity of the respondents was not disclosed. Secondary research was done with reliable and appropriate references

5. Results

5.1 Market volume and value of sulfonylureas:

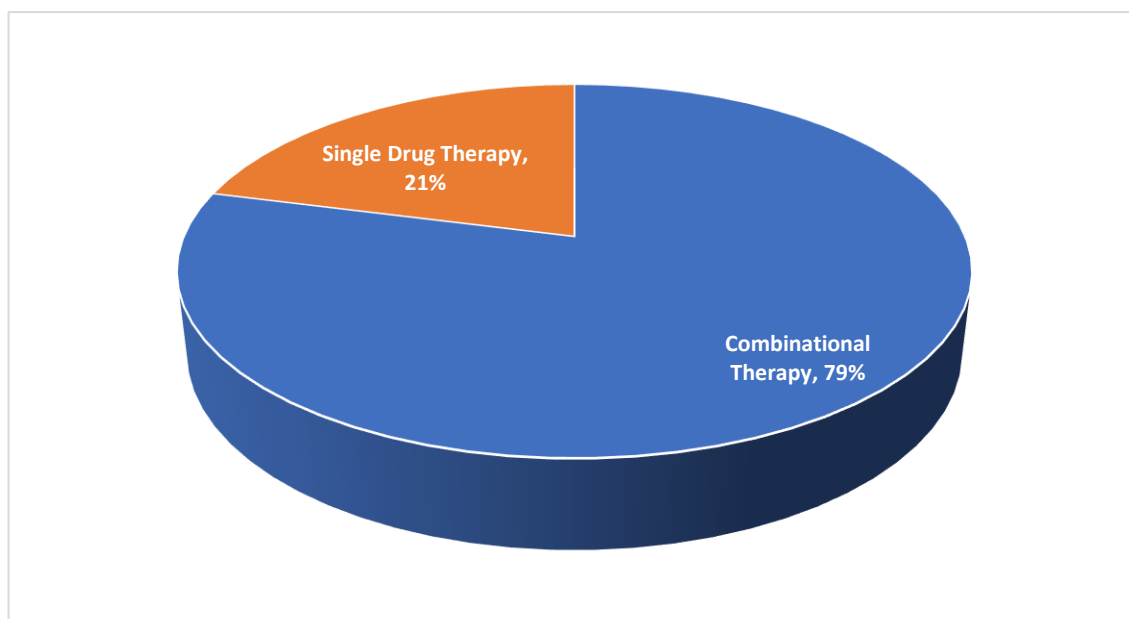
^{xi}As per the report, it is found that the prevalence of diabetes in urban cities of India was at ~14% with a higher prevalence in women (~10%) compared to men (~9%), with the diagnosis rate of only 47%. Due to this burden of diabetes in India is high.

^{xii}The treatment rate of diabetes was found to be around 36%. The study was conducted in major cities of Gujarat (Ahmedabad & Surat). As per data, the market share of sulfonylureas was found to be 27% in Oral hypoglycemic agents. The average dose/ day of any OHA is 2. By this information, the total market volume was calculated. The average selling price of sulfonylureas was found to be 4.2 as per the DPCOs pricing list. So, the depicted results are:

Population		1,57,43,226
Prevalence Rate (%)	14%	22,04,051.64
Diagnosis Rate (%)	47%	10,35,904.27
Treatment Rate (%)	36%	3,72,925.54
Share of Sulfonylureas	27.05%	1,00,876.36
Average Dose/ Day		2
Total Market Volume		73,639,741.26
Avg. selling price (INR)		4.39
Total Market Value (INR)		32,32,78,464 ₹

Table 3: Market volume and total market value of sulfonylureas

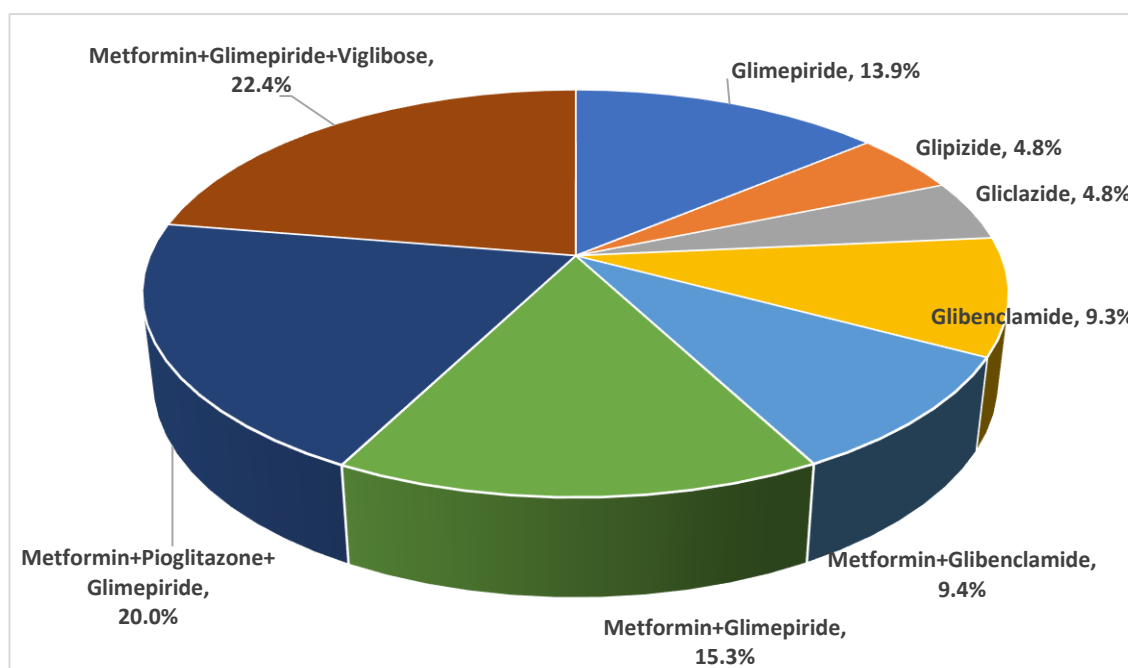
5.2 Preferred Therapy of Sulfonylureas:



Graph 1: Distribution of Single Dose and Combinational therapy

From the primary research, it is found that more than 1/3rd of prescriptions of sulfonylureas therapy were for combinational therapy. Only 21% of total prescriptions were single drug therapy including Glimepiride, Glipizide, Gliclazide, and Glibenclamide. It is also found that for combinational therapy, Glimepiride was the preferred molecule for the prescription.

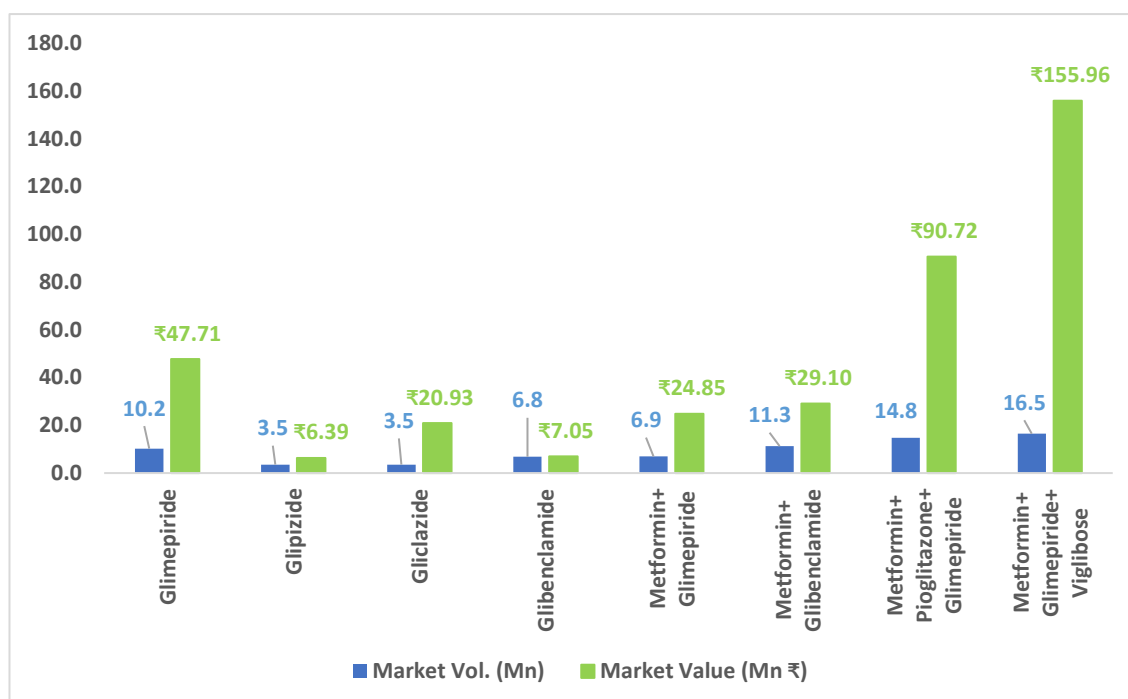
5.3 Top prescribed molecules and their share:



Graph 2: Top Prescribed Molecules of Sulfonylureas (Single Dose and Combinational therapy)

From the study, it is found that the top prescribed molecule of sulfonylureas are Glimepiride, Glipizide, Gliclazide, and Glibenclamide (Single dose therapy) & Metformin + Glimepiride, Metformin + Pioglitazone + Glimepiride & Metformin + Glimepiride + Viglibose (Combinational therapy) from which, combinational therapy i.e., ^{xiii}Metformin + Glimepiride + Viglibose has the highest prescription rate (22.4%) across all combinations of sulfonylureas with Metformin + Pioglitazone + Glimepiride, second (20%). Metformin + Glibenclamide has a prescription rate of 15% for two-drug combinational therapy. Single dose therapy of sulfonylureas including Glimepiride (13.9%), Glibenclamide (9.3%), Glipizide (4.8%), and Gliclazide (4.8%) generally prescribed by the physicians but the trend shows that combinational therapy is preferred by the doctors rather than the single dose therapy due to its effectiveness and the better onset of action.

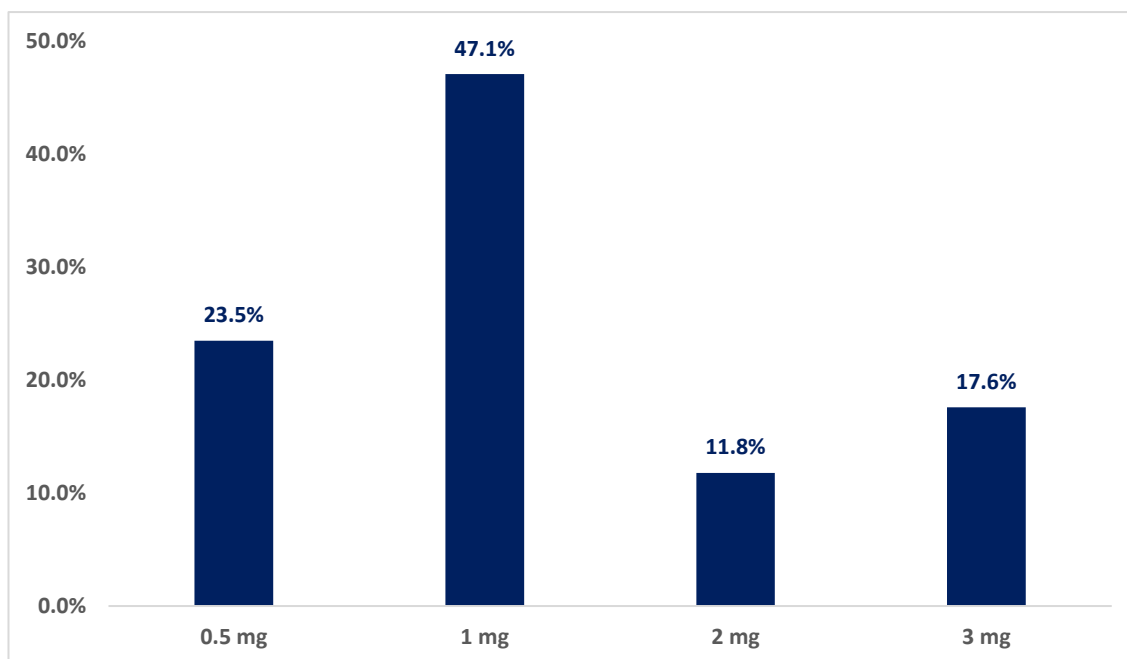
5.4 Market volume and Market value of the top prescribed molecule



Graph 3: Market Volume & Market Value of Top Prescribed Molecules of Sulfonylureas (Single Dose and Combinational therapy)

Market value & market volume of sulfonylureas was calculated based on the data in table 3 and the average selling price was taken from DPCO. Based on that, the market value of an individual molecule is calculated. It is found that combinational therapy of Metformin + Glimepiride + Viglibose has the highest market value and market volume among all the prescriptions with Metformin + Pioglitazone + Glimepiride next. Single dose therapy of Glimepiride has the highest share among Glipizide, Gliclazide, and Glibenclamide.

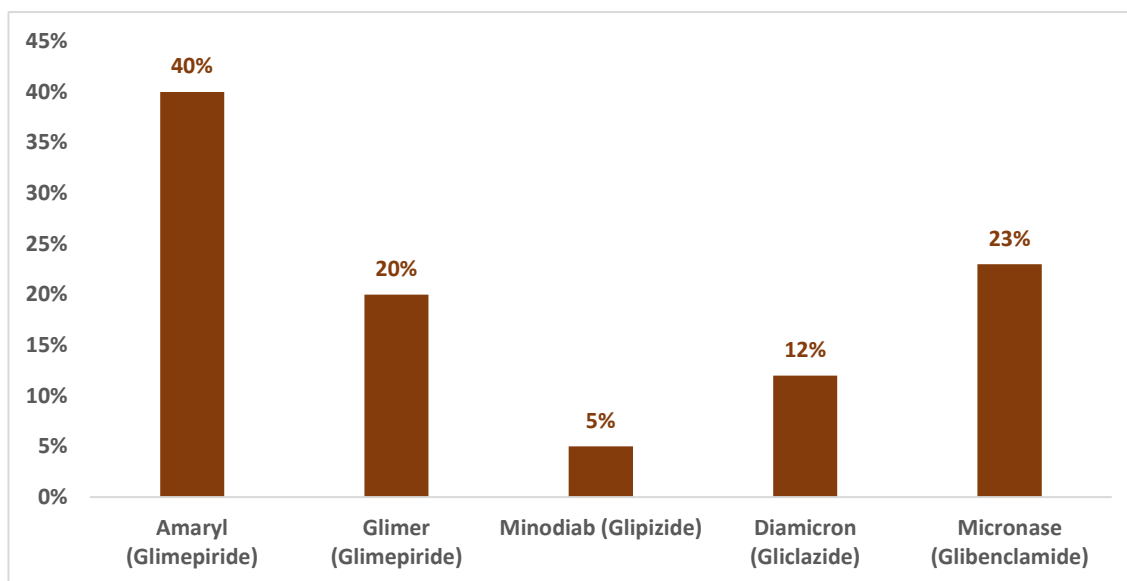
5.5 Dosage Distribution of Sulfonylureas



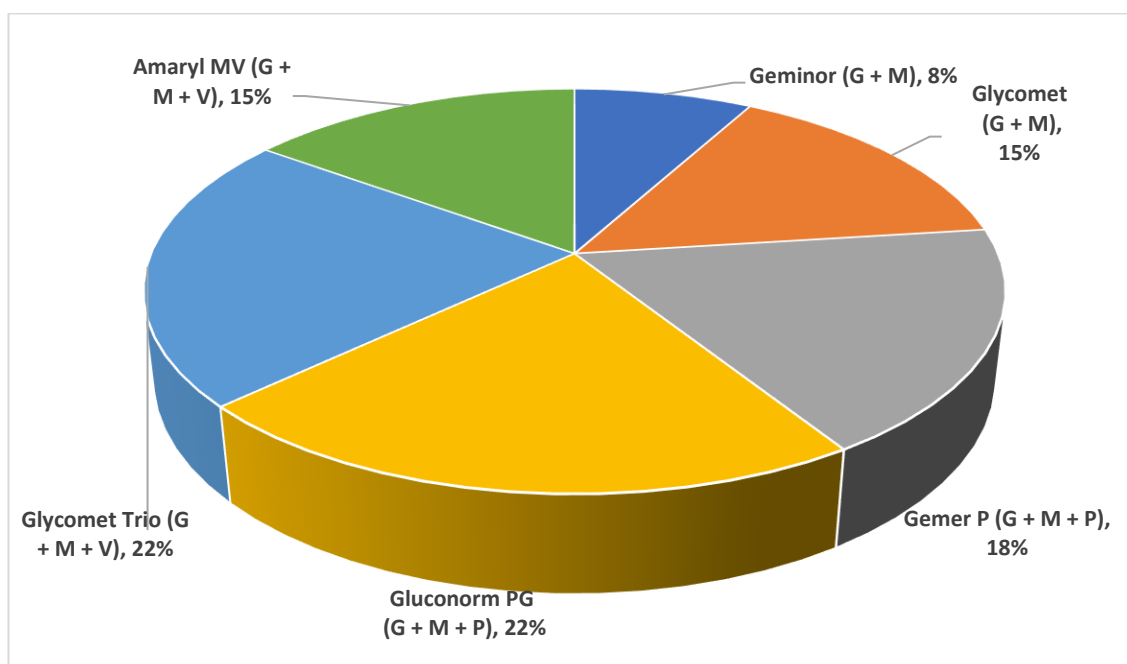
Graph 4: Market Volume & Market Value of Top Prescribed Molecules of Sulfonylureas (Single Dose and Combinational therapy)

Dosage distribution was found from the survey and as per the survey, it is found that the 1 mg dose of any sulfonylureas was prescribed the most as majorly the prescriptions were combinational therapy. For the severe cases in which blood sugar level was not controllable, a high dose is prescribed as the daily limit of sulfonylureas was a maximum of 6 mg for severe cases. It is found that a 0.5 mg dose of sulfonylureas was prescribed for maintenance therapy. Other than that, the dose of the drug is primarily depended upon the severity of the disease.

5.6 Brands and its share



Graph 5: Top Brands and its prescription share (Single Dose Therapy)



Graph 6: Top Brands and its prescription share (Combinational Therapy)

For Single Dose therapy:

As per the survey, it is found that Amaryl i.e., Glimepiride of Sanofi Pharmaceuticals has the highest generation of prescriptions (40%). It has 4 SKUs. Glibenclamide single dose therapy of Pfizer pharmaceuticals named Micronase has a prescription generation of 23% i.e., second highest prescribed brand. Another Glimepiride brand named Glimer of Abbott Pharmaceutical has a prescription share of 20%.

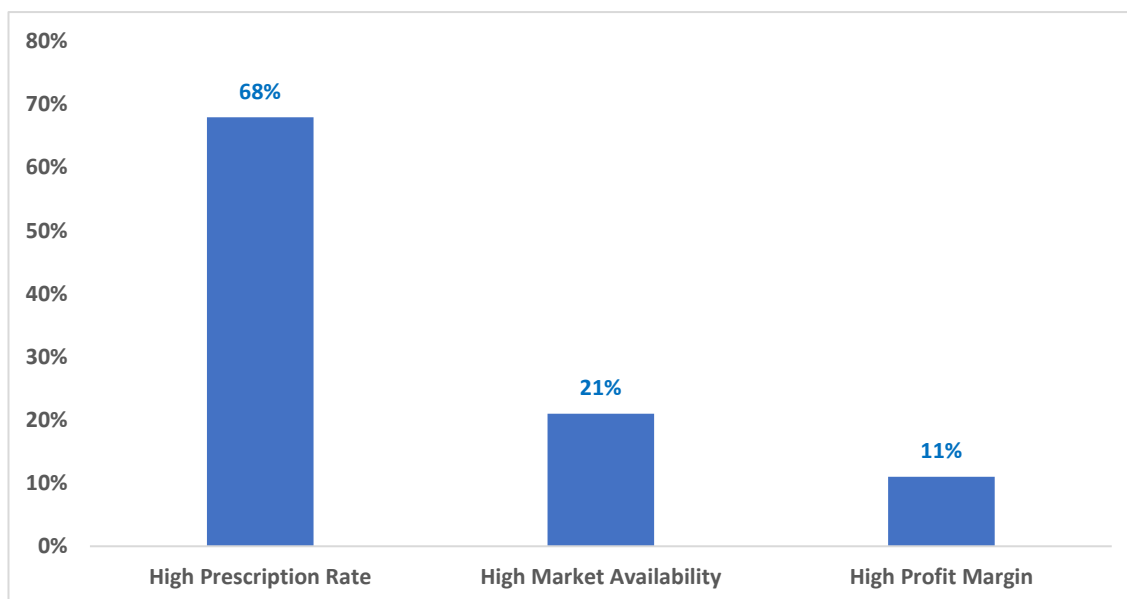
For Combinational Therapy:

As per the survey, it is found that Glycomet from USV limited a has 15% prescription share e for the Metformin + Glimepiride combination. Among all the brands, Glycomet Trio of USV Limited is a combination of Metformin + Glimepiride +Viglibose and Gluconorm PG of Lupin Limited the highest prescription share in combination therapy i.e., 22%.

As per data, it is found that the top market players for sulfonylureas are:

- USV Pharmaceuticals Limited
- Sanofi India Limited
- Lupin Limited
- Pfizer India
- Abbott

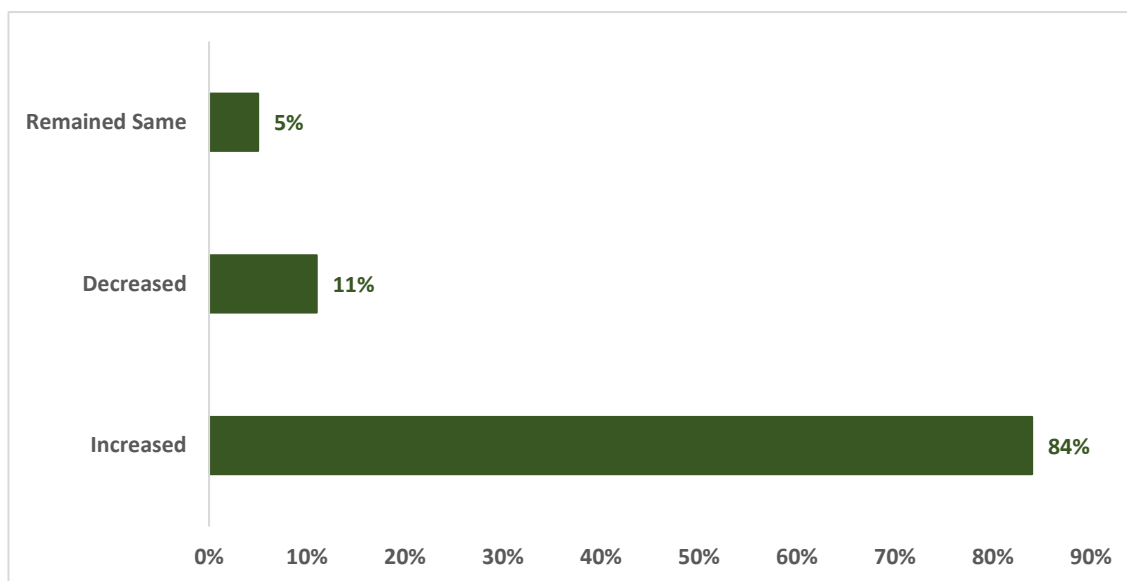
5.7 Reasons for Availability of brands present in the market



Graph 7: Reasons for availability of Brands

The reason for the availability of sulfonylureas was identified by the primary survey and it was found that the high prescription rate was the major reason for sulfonylureas' presence in the Market (68%). As per 21% of respondents, High market availability is the second most reason. 11% get a high-profit margin on sulfonylureas prescription.

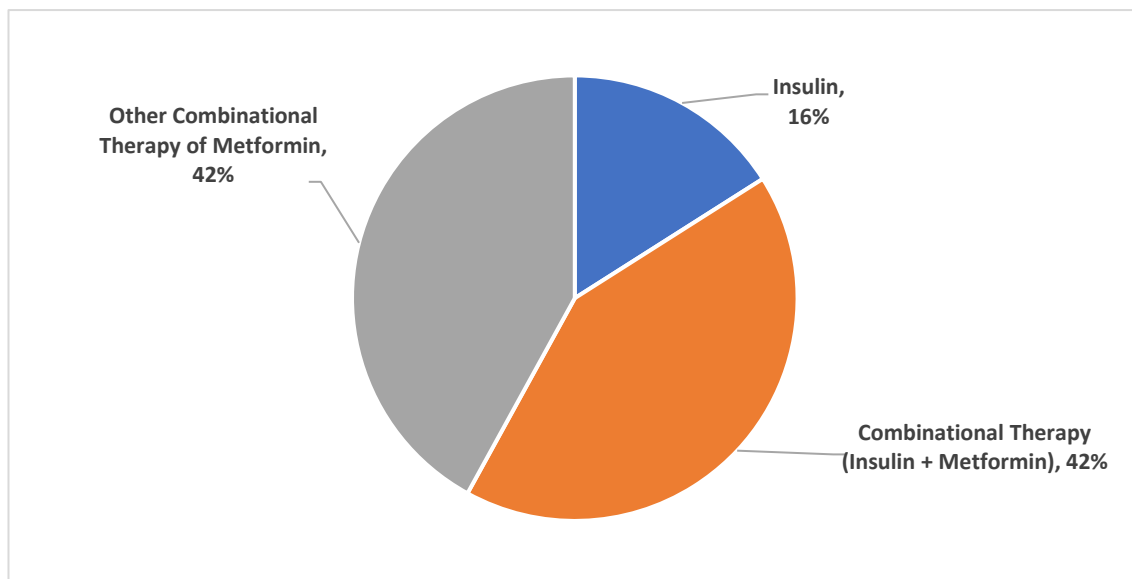
5.8 Prescription and Selling price trends:



Graph 8: Prescription and selling trends

COVID-19 has a major impact on the prescription generation and prices of drugs. As per 84% of respondents, prescription and selling prices were increased after the COVID-19 and as per 11%, it was decreased.

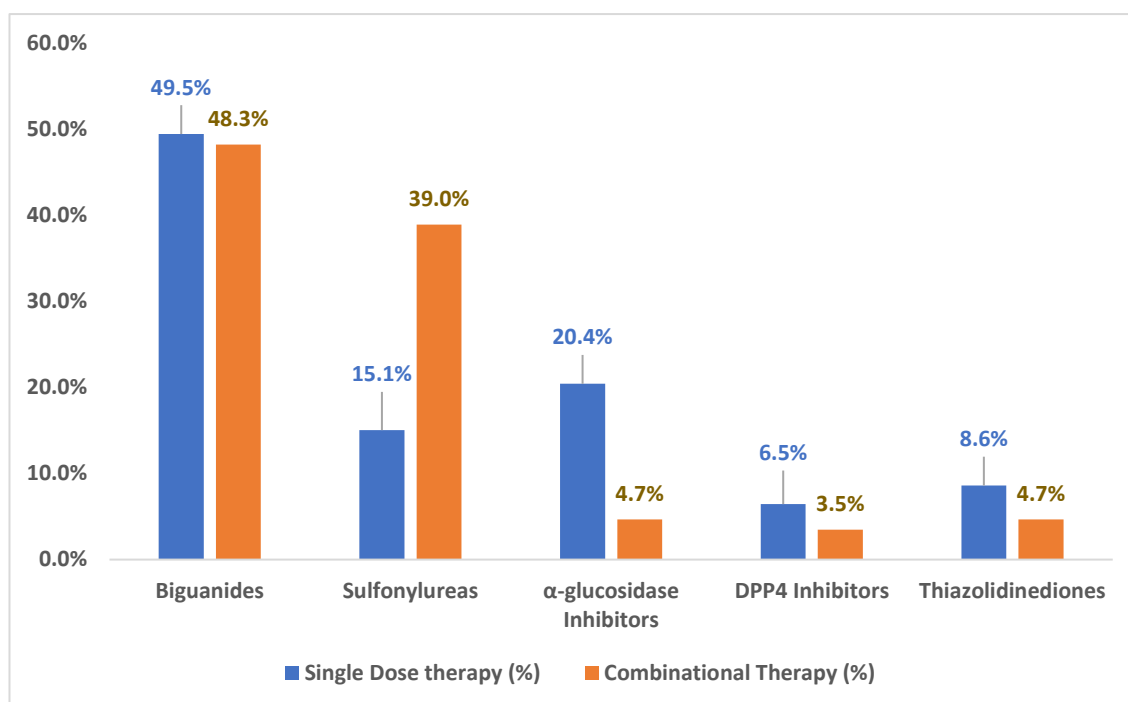
5.9 Other substitute therapy than sulfonylureas



Graph 9: Substitute therapy of Sulfonylureas

There are 3 major substitute therapies for sulfonylureas i.e., Insulin (single dose), Combinational therapy of Metformin and Insulin, and Combinational therapy of Metformin other than with sulfonylureas. As per 16% of respondents, Insulin was a substitute therapy for sulfonylureas. For 42% of respondents, other combinational therapies of Metformin substitutes for Sulfonylureas.

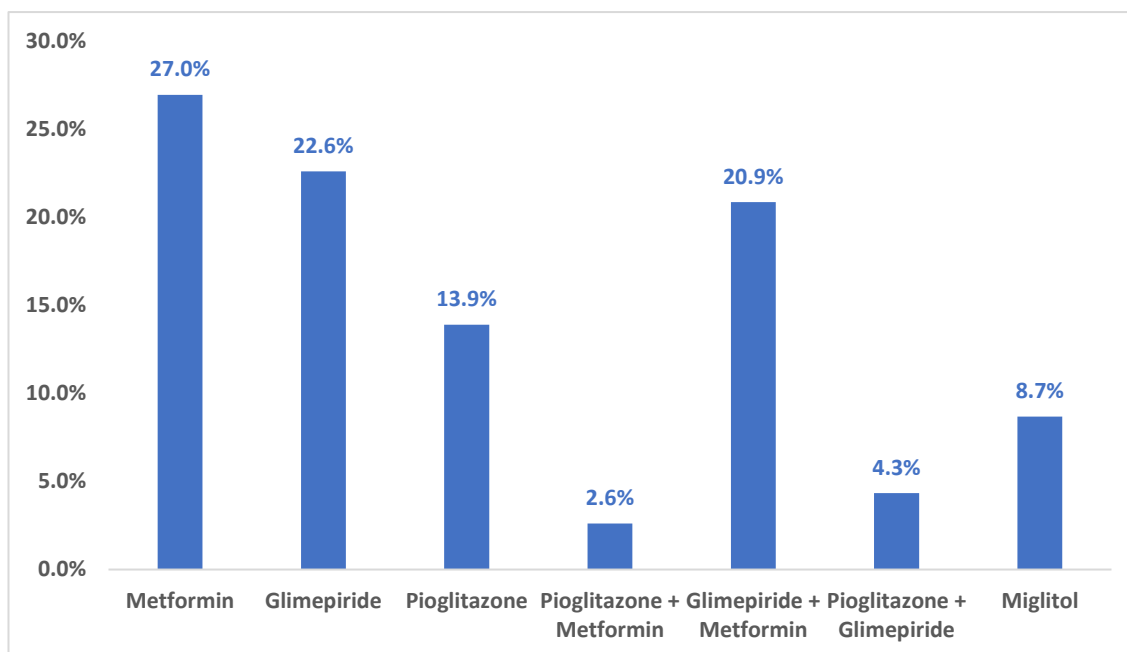
5.10 Share of OHAs in India:



Graph 10: Share of Oral-Hypoglycemic Agents (Single Dose vs Combinational Therapy)

As per secondary research for Oral Anti-diabetic therapy, it is found that Biguanides i.e., Metformin has the highest share in the Indian market in both single doses as well as combinational therapy (around 50% for both). Sulfonylureas i.e., Glimepiride, Glipizide, Chlorpropamide, etc. are the second most preferred treatment for diabetes but majorly combinational therapy of sulfonylureas is preferred more rather than the single dose (15% of a single dose, ~40% combinational therapy) (Glimepiride + Metformin, Glimepiride + Metformin + Pioglitazone). Share of other class of drugs i.e., α-glucosidase inhibitors, DPP4 inhibitors, and Thiazolidinediones has less prescription rate than Biguanides and Sulfonylureas, as it is less preferred as Oral Hypoglycemic agents in India

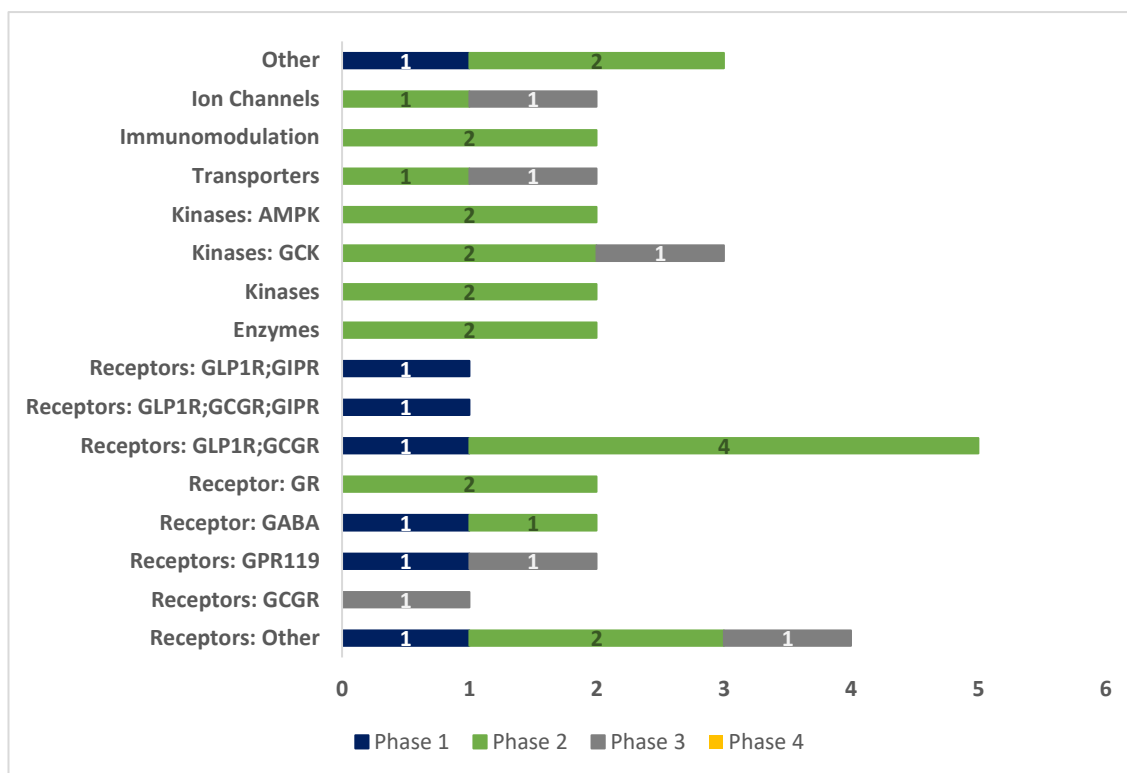
5.11 Share of drug prescribed



Graph 11: Share of drug prescribed

For the research, it is found that Metformin (27%) has the highest prescription rate along with Glimepiride (23%) at second. As per data, it is depicted that combinational therapy of sulfonylureas i.e., Glimepiride + Metformin (21%) has the highest prescription share among the combinational therapy and it is widely preferred by the doctors. Other combinational therapies of sulfonylureas i.e., Pioglitazone + Glimepiride (4.3%) are not prescribed frequently in these areas.

5.12 NCEs under Clinical Trials



Graph 12: Distribution of New Chemical Entities in phase of Clinical Trials

According to the FDA data, it is found that there are around 36 NCEs under clinical trials. In which, entities are targeting various receptors, Enzymes, Kinases, Transporters, Immune systems, Ion Channels, and Others.

	Phase 1	Phase 2	Phase 3	Phase 4
Receptors	6	9	3	
Enzymes		2		
Kinases		6	1	
Transporters		1	1	
Immune System		2		
Ion Channels		1	1	
Others	1	2		

Table 4: Ongoing clinical trials of NCEs

6. Conclusion

The sulfonylureas occupy 22% of the total OHA market in Ahmedabad and Gujarat but this market is highly influenced by the other OHA therapies. In recent years, many new chemical entities will be launched, which may have higher potency and a better onset of action. For oral hypoglycemic therapy, other than metformin single dose therapy, doctors prescribed combinational drug therapy. But there is high competition and due to that market is quite fragmented. For new entrance, it is quite difficult to enter the market because of customer loyalty to older brands. There are high chances after the approval of new chemical entities and advanced therapy options for T2DM, the market scenario will change. Better market penetration could be implemented to maximize market share as well as salesforce participation can play a major role in prescription generation in these competitive markets.

7. Limitation

The sample size was less. The study was conducted only in Surat and Ahmedabad. It only depicts current data and not forecast.

8. Appendix

Questionnaire

1.	What is the dosage distribution of sulfonylureas?	a. 0.5 mg b. 1 mg c. 2 mg d. 3 mg
2.	What is most preferred by the doctors? Single or combinational therapy?	a. Single Drug therapy b. Combinational Therapy
3.	What are the top prescribed brands of sulfonylureas? (Single Drug Therapy)	a. Amaryl (Glimepiride) b. Glimer (Glimepiride) c. Minodiab (Glipizide) d. Diamicron (Gliclazide) e. Micronase (Glibenclamide)
4.	What are the top prescribed brands of sulfonylureas? (Combinational Therapy)	a. Geminor (G + M) b. Glycomet (G + M) c. Gemer (G + M + P) d. Gluconorm PG (G + M + P) e. Glycomet Trio (G + M + V) f. Amaryl MV (G + M + V)
5.	Reason for selling of sulfonylureas?	a. High Prescription Rate b. High Market Availability c. High Profit Margin
6.	What is the frequency of prescription and selling price trends after pandemic?	a. Increased b. Decreased c. Remained Same
7.	What is other substitute therapy highly used for Diabetes other than Sulfonylureas?	

9. References

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