INTERNSHIP REPORT

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Internship Report

Title: GLP-1 and SGLT2 Landscape – Approvals, Evidence, and Market Positioning Insights

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Internship Organization: IQVIA
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1. Introduction

The management of Type 2 Diabetes Mellitus (T2DM) has evolved significantly with the introduction of advanced pharmacological classes such as GLP-1 receptor agonists and SGLT2 inhibitors. These therapies go beyond glycemic control, offering cardiovascular and renal benefits, which have become key differentiators in treatment selection.

However, with increasing competition among therapies especially semaglutide and tirzepatide there is growing complexity in understanding their clinical value, cost-effectiveness, and market positioning. Global regulatory bodies such as the FDA and EMA approve these drugs based on safety and efficacy, while Health Technology Assessment (HTA) agencies evaluate their long-term clinical and economic impact.

This internship focused on analyzing the comparative landscape of GLP-1 and SGLT2 therapies, identifying key challenges in market access, and understanding payer perspectives affecting adoption and reimbursement decisions.

2. Objectives of the Internship

- To analyze the treatment landscape of GLP-1 receptor agonists and SGLT2 inhibitors in T2DM.
- To evaluate regulatory approvals, indications, and product evolution across FDA and EMA.
- To study clinical efficacy, economic evidence, and real-world outcomes of competing therapies.
- To understand payer and HTA perspectives influencing reimbursement decisions.

- To identify key challenges and suggest strategies for improving market positioning and acceptance.

3. Organization Profile – IQVIA

IQVIA is a global healthcare analytics and consulting organization specializing in evidence-based insights for pharmaceutical and healthcare stakeholders. The organization supports companies in clinical development, market access, and health economics through data-driven analyses.

In this project context, IQVIA conducted targeted literature reviews (TLR) and healthcare assessments to evaluate competitor claims and payer objections in the T2DM market. These insights support strategic decision-making for pharmaceutical companies, particularly in positioning therapies like empagliflozin (Jardiance).

4. Internship Activities and Key Contributions

4.1 Analysis of Drug Approval Landscape

- Compiled data on GLP-1 and SGLT2 molecules approved by regulatory agencies (FDA and EMA).
- Studied drug characteristics such as formulation, dosage, frequency, and indications.
- Identified trends such as shift from injectable to oral therapies and expansion into obesity and cardiovascular indications.

4.2 Comparative Clinical Evaluation

- Conducted comparative analysis of GLP-1 receptor agonists (semaglutide, liraglutide) and SGLT2 inhibitors (empagliflozin).
- Evaluated clinical endpoints such as HbA1c reduction, weight loss, cardiovascular outcomes, and renal benefits.
- Identified that GLP-1 therapies show stronger glycemic control and weight loss outcomes, whereas SGLT2 inhibitors demonstrate robust long-term cardiovascular and renal benefits.

4.3 Economic Evidence and Cost-Effectiveness Analysis

- Reviewed multiple economic models assessing cost-effectiveness of GLP-1 and SGLT2 therapies.
- Observed that results are highly variable and influenced by modeling assumptions, time horizons, and funding sources.
- Identified that no single therapy class consistently dominates in cost-effectiveness outcomes.

4.4 HTA Assessment and Payer Perspective Analysis

• Studied HTA decisions across multiple countries including the UK, Canada, Germany, France, and Australia.

• Identified common payer concerns:

- reliance on surrogate endpoints (HbA1c, weight)
- lack of long-term outcome data
- uncertainty in economic models

• Observed that GLP-1 and dual agonist therapies often face restricted or negative reimbursement decisions, while SGLT2 inhibitors show relatively stronger acceptance.

4.5 Market Positioning and Competitive Analysis

- Evaluated competitor claims related to semaglutide and tirzepatide (clinical superiority, cost-effectiveness, weight loss).
- Assessed counterevidence supporting empagliflozin, including real-world studies such as EMPRISE.
- Concluded that strong real-world evidence and cardio-renal benefits enhance payer trust and positioning of SGLT2 inhibitors.

5. Key Learnings

- **Therapeutic Understanding:** Developed in-depth knowledge of advanced T2DM therapies and their mechanisms.
- **Market Access Insights:** Learned how payers evaluate drugs based on clinical, economic, and real-world evidence.

- **Analytical Skills:** Gained experience in comparing multiple data sources and interpreting complex healthcare evidence.
- **HTA Awareness:** Understood the importance of regulatory and reimbursement frameworks in drug adoption.
- **Strategic Thinking:** Learned how data-driven insights influence pharmaceutical positioning and decision-making.

6. Challenges Faced

- Limited availability of long-term data for newer therapies like tirzepatide.
- Variability and inconsistency in economic models across studies.
- Complexity in interpreting HTA decisions due to differences in country-specific policies.
- Difficulty in aligning clinical trial outcomes with real-world effectiveness.

7. Recommendations

- Encourage generation of long-term real-world evidence for newer therapies.
- Improve transparency and standardization in economic modeling approaches.
- Focus on clinically meaningful endpoints (mortality, cardiovascular events) rather than surrogate markers.
- Strengthen alignment between clinical evidence and payer expectations.
- Develop integrated strategies combining clinical outcomes, economic value, and patient impact.

8. Conclusion

This internship provided comprehensive exposure to the evolving T2DM treatment landscape and the complexities of pharmaceutical market access. The study highlighted that while GLP-1 receptor agonists and dual agonists offer strong efficacy in glycemic control and weight management, their adoption is limited by uncertainties in long-term outcomes and economic models.

In contrast, SGLT2 inhibitors, particularly empagliflozin, demonstrate consistent clinical and real-world benefits, making them more aligned with payer requirements. The findings emphasize that successful therapy positioning depends not only on clinical efficacy but also on robust evidence, economic validation, and stakeholder acceptance.

This experience significantly enhanced my understanding of pharmaceutical strategy, healthcare policy, and evidence-based decision-making in real-world settings.