



Batch PM- 14

Year 2022-24

MBA- Pharmaceutical management

Name: Himanshu Deepak Sane

Roll No. 0389

Organization for Dissertation: Rusan Pharma

Mentor : Dr Sudhinder Singh Chowhan



# Global Market Analysis and Expansion Strategies for Buprenorphine Products

This study provides a comprehensive analysis of the global market for buprenorphine products, focusing on their current status and future expansion potential. Buprenorphine, a partial opioid agonist, has gained significant attention in recent years due to its effectiveness in treating opioid use disorder and managing chronic pain, with fewer risks compared to full opioid agonists.

# Overview of Buprenorphine and its Applications

1

## Historical Development

Buprenorphine was synthesized in the 1960s and early clinical studies in the 1970s and 1980s explored its potential for pain relief and treating opioid dependence. Its unique pharmacological properties made it attractive for opioid dependence treatment due to lower respiratory depression risk compared to full agonists.

2

## Regulatory Approvals

Buprenorphine (Temgesic) was first approved in the UK for pain management in 1981, followed by approval in the USA (Buprenex) in 1985. The sublingual buprenorphine/naloxone combination (Suboxone) gained FDA approval for opioid dependence treatment in 2002, a significant milestone.

3

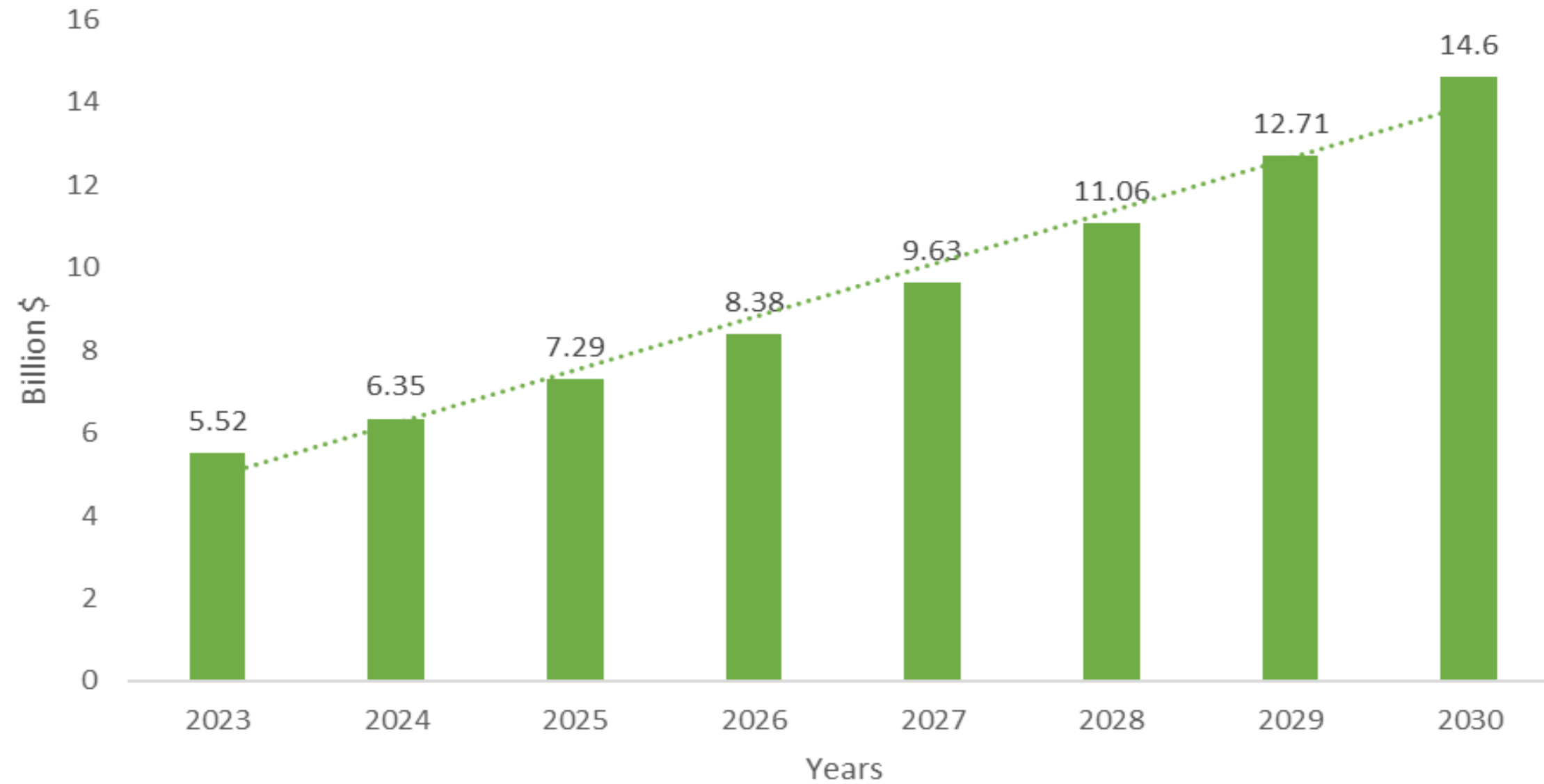
## Clinical Applications

Buprenorphine is used for both opioid dependence treatment and pain management. It acts as a partial agonist at mu-opioid receptors, providing effective relief with a lower risk of overdose and respiratory depression compared to full opioid agonists.



## Global Buprenorphine Market Size

CAGR rate 14.9%



# The Global Burden of Opioid Use Disorder and Chronic Pain

## Socioeconomic Impact

Opioid use disorder (OUD) affects millions globally, contributing to over 120,000 deaths annually. It has significant socioeconomic consequences, including healthcare costs, lost productivity, and social marginalization.

## Challenges in Access

Effective treatments for OUD and chronic pain can be inaccessible due to factors like high costs, limited healthcare infrastructure, geographical barriers, and socioeconomic disparities. Addressing these challenges is crucial for improving patient outcomes.

## Demographic Trends

OUD affects more men than women, with the highest rates of opioid-related deaths among individuals aged 40-50. Heroin overdoses are most prevalent in younger age groups.

# Market Landscape for Buprenorphine Products

## 1 Key Formulations

Buprenorphine is available in various forms, including transdermal patches, sublingual tablets, buccal films, implants, and injectable formulations. These different delivery methods cater to diverse patient needs and preferences.

## 2 Dosing and Administration

Buprenorphine dosing and administration vary based on the specific formulation and indication. Sublingual tablets are commonly used for opioid use disorder treatment, while transdermal patches and buccal films are more prevalent for chronic pain management.

## 3 Combination Products

Buprenorphine is often combined with naloxone, an opioid antagonist, to deter misuse and abuse. These combination products, such as Suboxone, are widely used for opioid dependence treatment.

# Key Players in the Buprenorphine Market



## Siegfried

A Swiss CDMO specializing in APIs, including controlled substances, and finished dosage forms.



## Sanofi

A global pharmaceutical major with a diverse portfolio, including key products like Lantus and Dupixent.



## Johnson Matthey

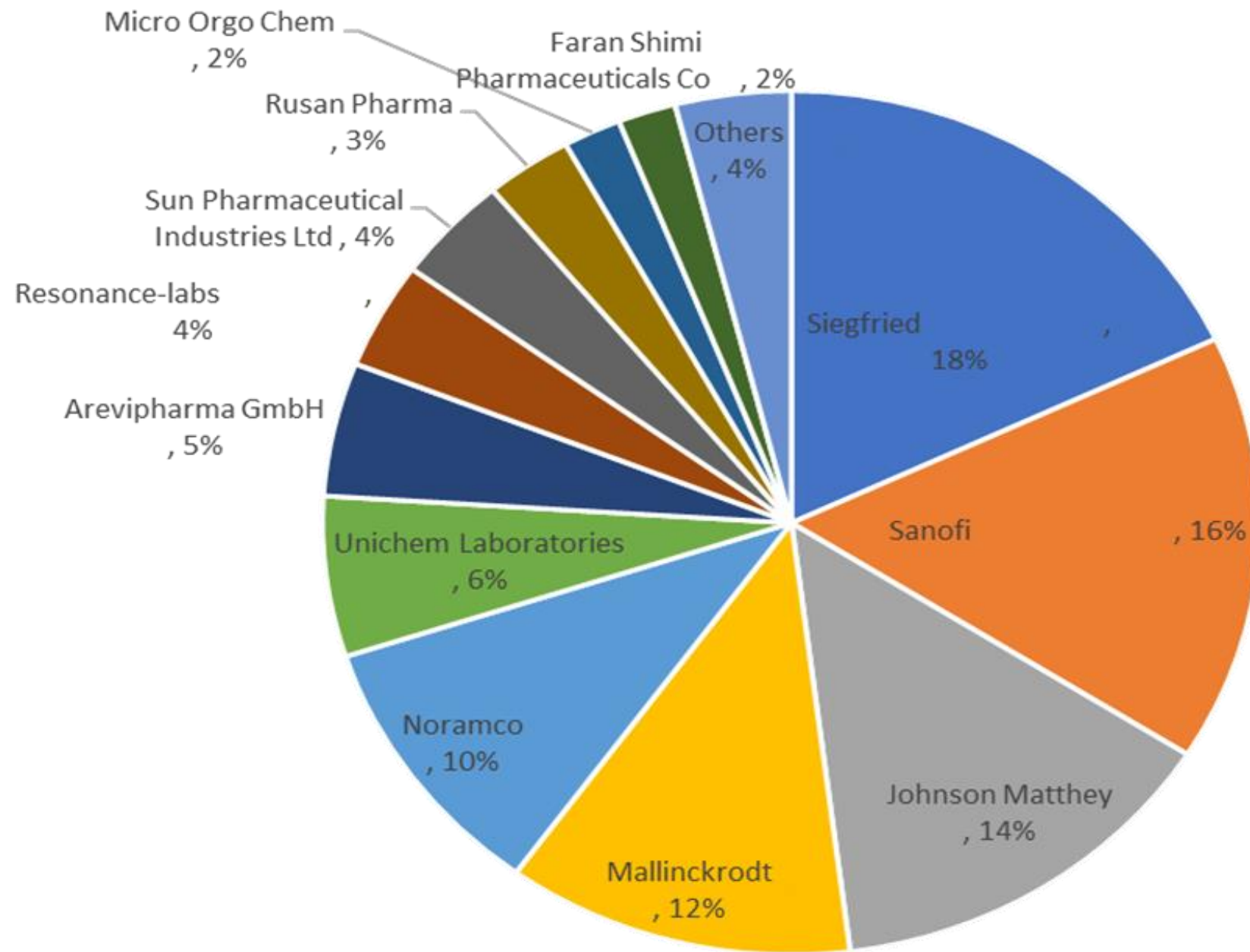
A UK chemicals company with a pharmaceutical division focused on controlled substance APIs.



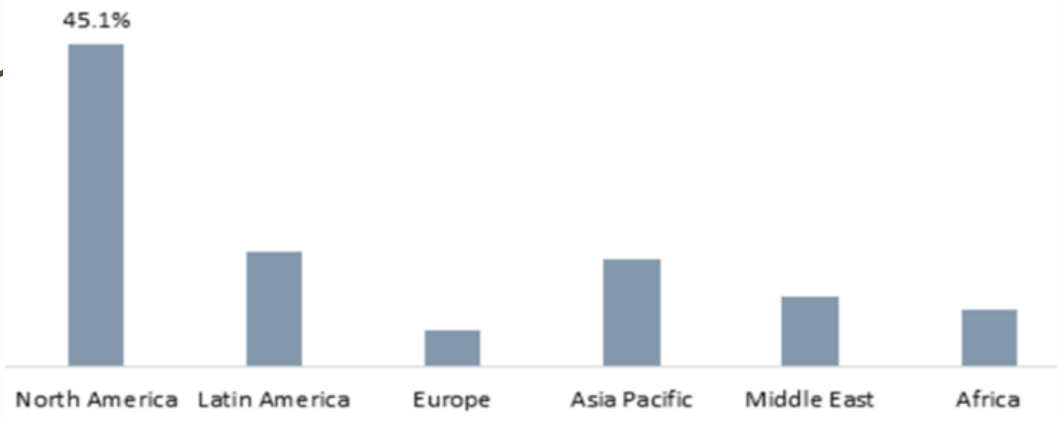
## Mallinckrodt

A US specialty pharmaceutical company producing APIs and finished drug products, including controlled substances.

## Market Share of Companies For Buprenorphine



# Regulatory and Policy Landscapes



| Region        | Regulatory Framework                                                    | Reimbursement Policies                                                      |
|---------------|-------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| North America | FDA approval required, stringent clinical trial requirements            | Medicaid and private insurers increasingly covering buprenorphine treatment |
| Europe        | EMA approval required, diverse regulatory requirements across countries | Reimbursement mechanisms vary across European countries                     |
| Asia-Pacific  | Regulatory requirements range from stringent to moderate                | Access and reimbursement challenges in some countries                       |

**The Markets size for Buprenorphine by regions and forecasting from 2023 to 2030 (in \$ Billion)**

| Region        | Percentage value (in \$ Billion) | 2023 value (in \$ Billion)         | Market Forecasting for 2030 Value ( in \$ Billion) |
|---------------|----------------------------------|------------------------------------|----------------------------------------------------|
| North America | <div><div></div></div> 45.10%    | <div><div></div></div> 2.484       | <div><div></div></div> 6.517                       |
| Latin America | <div><div></div></div> 21.50%    | <div><div></div></div> 1.185       | <div><div></div></div> 3.109                       |
| Europe        | <div><div></div></div> 13.80%    | <div><div></div></div> 0.76        | <div><div></div></div> 1.994                       |
| Asia Pacific  | <div><div></div></div> 12.70%    | <div><div></div></div> 0.7         | <div><div></div></div> 1.837                       |
| Middle East   | <div><div></div></div> 4.60%     | <div><div></div></div> 0.253       | <div><div></div></div> 0.665                       |
| Africa        | <div><div></div></div> 2.30%     | <div><div></div></div> 0.127       | <div><div></div></div> 0.333                       |
|               |                                  | Tota Value 2023 = \$ 5.509 Billion | Tota Value 2030 = \$ 14.455 Billion                |

# Barriers to Access and Adoption

## Stigma and Misconceptions

Stigma surrounding opioid dependence and misconceptions about buprenorphine can discourage individuals from seeking treatment and make them feel ashamed.

## Healthcare Challenges

Shortages of healthcare providers trained to prescribe buprenorphine and limited availability of treatment facilities can hinder access to this effective medication.

## Supply Chain Issues

Logistical challenges in the supply chain and distribution of buprenorphine can create delays and frustrations for patients seeking treatment.



# Expansion Strategies and Best Practices

1

## Geographic Expansion

Targeting underserved regions with high opioid dependence rates and limited access to buprenorphine, while partnering with local organizations to overcome barriers.

2

## Product Innovation

Developing new buprenorphine formulations and delivery systems to cater to diverse patient needs and improve treatment adherence.

3

## Marketing and Awareness

Implementing targeted campaigns to educate the public and healthcare providers, combat stigma, and build trust in buprenorphine treatment.



*Thank You*