

2

Market Overview

RESEARCH SCOPE AND METHODOLOGY

Scope and Segmentation

This research service provides a strategic analysis of the U.S. injectable drug pipeline with 2009 as the base year. Included are pipeline analysis for injectable drugs broken down by clinical trial phase. All of the new compounds in Phase III, II/III, II, I/II, and I compounds are listed. In addition, market challenges, drivers and restraints are identified and assessed. Also included is a discussion on hot trends and topics in this market.

The market is segmented into the following sections by drug delivery route:

- Intramuscular Injectable Drugs
- Subcutaneous Injectable Drugs
- Intravenous Injectable Drugs
- Other Injectable Drugs

For each of the segments of the market a brief background is included. The other injectable drugs segment includes injectables that are delivered in drug delivery routes that are different from the other segments. These drug delivery routes include the following:

- Intracoronary Injectables
- Intradermal Injectables
- Intralesional Injectables
- Intratumoral Injectables
- Intravitreal Injectables
- Site-Directed Injectables

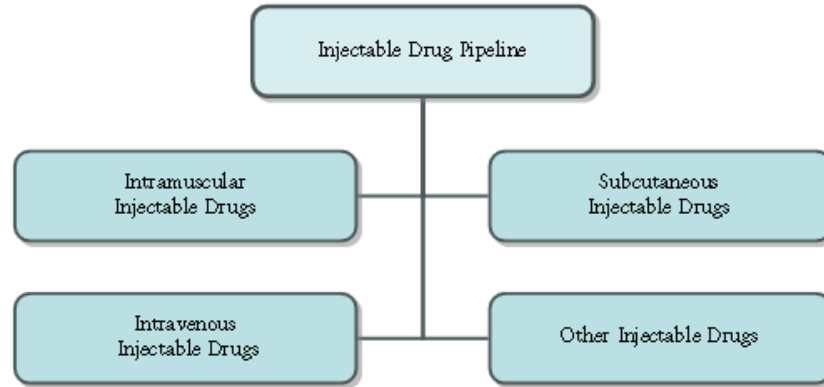
This research service does not cover the use of drugs that are administered through an intravenous infusion but do include those that are administered through an intravenous push or a bolus injection. It does not include injectables used for imaging or for diagnostic purposes. Some medications are administered through multiple delivery routes and are listed under both categories. In addition some compounds are in multiple phases of clinical trials are being developed for more than one disease. As such, these medications are listed in all applicable areas.

Some companies have been acquired and merged during the writing of this piece. In these cases, the products were listed under the company that originally developed the product and not the acquiring company, as these processes as well as divestitures or other portfolio decisions are ongoing as of Q2 2009. Examples of these M&A cases are Pfizer/Wyeth and Merck & Co./Schering-Plough.

Chart 2.1 shows the market segmentation for the U.S. injectables drug pipeline in 2009.

CHART 2.1

Injectable Drug Pipeline: Market Segmentation (U.S.), 2009



Source: Frost & Sullivan

Research Methodology

The information in this research service was obtained using an assortment of primary and secondary information sources.

Primary interviews were conducted with industry participants in senior management positions such as Chief Executive Officer, President, Chairman, Vice President of Sales and Marketing, Vice President of Corporate Communications, Director of Investor Relations, and Manager of Business Development. These interviews were done to provide information and insight into general trends in the market, company specific information about their own respective products, and other information about the U.S. injectable drug pipeline.

ClinicalTrials.gov was used as an initial raw data source for injectable drug clinical trials that were being conducted. Other secondary research included data from various sources to gain insight into treatment options, statistics, and other associated medical factors. Some of these sources are as follows:

- Agency for Healthcare Research and Quality
- American Academy of Allergy, Asthma, and Immunology
- American Cancer Society (ACS)
- American College of Rheumatology (ACR)
- American Heart Association
- American Lung Association (ALA)
- American Macular Degeneration Foundation (AMDF)
- American Medical Association
- American Thoracic Society
- Aplastic Anemia & Myelodysplastic Syndromes International Foundation (AA & MDSIF)
- Arthritis Foundation
- Centers for Disease Control and Prevention (CDC)
- ClinicalTrials.gov
- Crohn's & Colitis Foundation of America (CCFA)
- Lupus Foundation of America, Inc.
- National Asthma Education and Prevention Program
- National Cancer Institute

- National Center for Health Statistics
- National Health Interview Survey (NHIS)
- National Heart, Lung, and Blood Institute
- National Institute of Arthritis and Musculoskeletal and Skin Diseases
- National Institutes of Health (NIH)
- National Multiple Sclerosis Society
- National Organization for Rare Disorders, Inc. (NORD)
- National Psoriasis Foundation
- Specialty and scientific journals
- Public Filings (Securities and Exchange Commission) and press releases
- Internet resources (e.g., company websites, disease websites)

MARKET INTRODUCTION

Introduction

According to the FDA, there are 111 recognized routes of administration for drugs. Of these the most commonly used are topical, oral, ocular, nasal, pulmonary, and injectable. Although there are more oral products in development and on the market in the U.S., injectable medications are still significant. Injectable medications bypass the digestive system and can deliver therapies to a localized area or systemically. They are used to treat a large variety of diseases from diabetes, cancer, and autoimmune disorders. For biopharmaceuticals, injection is by far the most common drug delivery route because they tend to have poor bioavailability when taken through other drug administration routes. Currently injectable drugs come primarily in the following forms:

- Prefilled Syringes
- Self-Injection Systems
- Vials
- Ampoules

PREFILLED SYRINGES

A prefilled syringe contains a single-dose of medication and a fixed needle. They can be made from glass or plastic and are typically reserved for medications that are administered either by subcutaneous or intramuscular injection. Compared to using the traditional vials as a primary container, prefilled syringes are easier and more convenient for patients, caregivers, and medical staff to use. For instance they eliminate several steps in the injection process such as the need to remove the drug from the vial and the reconstitution of lyophilized medications. In addition, use of prefilled syringes helps ensure safety by eliminating dosing errors and minimize the risk of needle sticks. They also help eliminate waste by decreasing the number of containers and packaging required to perform an injection. In addition, use of prefilled syringes reduces medication waste because vials are intentionally overfilled by 20 to 30 percent to account for potential drawing errors.

SELF-INJECTION SYSTEMS

Self-injection systems contain multiple doses of medication in a cartridge and are used several times. These devices are typically reserved for medications that are taken daily or multiple times per day such as insulin, human growth hormone, and fertility treatments. Self-injection systems can be either reusable or disposable. The first and most commonly used self-injection system is the pen injector.

Another self-injection system is the automatic injector which automatically inserts the needle into the injection site and performs the injection. Historically automatic injectors were reserved for emergency situations like the administration of epinephrine. Examples of automatic injectors include Rebiject and SureClick.

VIALS

One of the oldest primary containers for injectable drugs are vials. These containers are usually made from glass and have a stopper over the neck from which the medication can be drawn with the use of a hypodermic needle. To help ensure sterility and safety from contamination or tampering, injectable drug vials have secondary seals made from aluminum shells and an attached plastic button.

AMPOULES

Ampoules are the first containers just for injectable medications. They are essentially glass vials that are hermetically sealed to protect the medication from the air. The ampoule is opened by breaking open the top and removing the medication with a hypodermic needle. Only a few medications, like local anesthetics, still come in ampoules.

DRUG DELIVERY OPTIONS

Injectable medications can be delivered through several different methods including the following:

- Intramuscular Injectables
- Subcutaneous Injectables
- Intravenous Injectables
- Other Injectables

Hot Topics and Trends

SELF-INJECTION ON THE RISE

With increases in the number of Americans suffering from diseases like diabetes and cancer that require the use of injectable medications, the amount of patients who self administer their medication via this route is escalating. Further propelling this trend is the increasing amount of medications that are available in easier to use platforms such as self-injection systems and prefilled syringes. Other trends that are contributing to the growth of self-injection are the development of novel injectables and biopharmaceuticals for chronic diseases that were previously untreatable such as genetic disorders like hemophilia and Gaucher's disease. Another important factor is increased use of home health care. Historically, home health care was reserved for the elderly or terminally ill. As insurance companies and agencies are trying to find ways to cut health care costs more and more, the range of treatments done on an outpatient basis was expanded. Also, home treatment, especially for injectable drugs is seen as an area of opportunity for many pharmaceutical and biotechnology companies.

Chart 2.2 presents the willingness of cancer patients to use prefilled syringes and autoinjectors in the U.S. in 2009.