



Pharma Domain 101 – The Industry Lingo

- **Drug** - a substance that is used as a medicine
- **Brand Name drug / Branded drug** - a drug that has a trade name and is protected by a patent (can be produced and sold only by the company holding the patent). Originator chemically synthesized drugs and biotechnology-derived drugs are developed as a result of extensive research and development (R&D) and clinical trials in both humans and animals. The originator relies on patents and other forms of intellectual property rights to justify the investment required to bring a product to market.
- **Generic drug** - Generic drugs are duplicative copies of originator chemically-synthesized drugs that contain the same active ingredient, are identical in strength, dosage form, and route of administration. The prices of generic drugs are typically lower than the prices of originator drugs, particularly in the U.S. market where they are typically sold at a substantial discount from originator drug prices.
- **Over-the-counter (OTC) drugs** - are distinguished from originator and generic drugs in that consumers do not need a prescription to purchase the drug. OTC drugs are considered by regulators to be safe for self-diagnosis and self-medication.
- **ANDA (Abbreviated New Drug Application)** - this is a simplified submission of an already approved drug. ANDA's are for products with the same or very closely related active ingredients, dosage, strength etc.
- **Accelerated Approval** - A highly specialized mechanism intended to speed approval of drugs promising significant benefit over existing therapy for serious or life threatening illnesses.
- **Adverse Events** - Unwanted effects that occur and are detected in populations.
- **Clinical Trials** - Human studies designed to distinguish a drug's effect from other influences. Such studies conducted in the U.S. must be under an approved IND and in accord with FDA rules on human studies.
- **FDA** – Food and Drug Administration. Federal agency within the Department of Health that approves and regulates the pharmaceutical industry. The FDA must give approval to market the product in the U.S. The U.S.' rigorous approval process is respected around the world and in many countries approval by the FDA is enough to approve a product in a foreign country.
- **Investigational New Drug (IND)** - An application that a drug sponsor must submit to the FDA before beginning tests of a new drug on humans.
- **NDA** - New Drug Application, An application requesting FDA approval to market a new drug for human use in interstate commerce.
- **NME** - New Molecular Entity, A compound that can be patented, which has not been previously approved.
- **Brand** – Same as branded drug

- **Class (or market)** – Class refers to the brands within the same therapeutic area that together define the market for those brands – i.e. it consists of all those medicines that compete with each other for whole or part of the same market
- **Rx** – Prescription written by a physician
- **Prescription**-An instruction written by a medical practitioner that authorizes a patient to be issued with a medicine or treatment
- **NRx vs TRx** – NRx stands for New Prescription while TRx stands for Total Prescriptions. Total Prescriptions refers to the total prescriptions written by a physician. This is inclusive of refills. As an example, let's say that the patient visits a doctor and the doctor writes him a prescription for a certain line of therapy. Second time that the patient visits the doctor, the doctor asks him to repeat the same medication. In other words, the doctor has written 1NRx and 2TRx.
- **RRx** - Refill Prescription-(TRx-NRx)-additional quantities listed on the Rx for future fulfillment
- **Normalized TRx/Equivalent Units** - One TRx may contain a different amount of pills depending upon the need. To compare apples to apples, the number of pills are counted vs. the number of scripts
- **Call / Detail** – Visit of a rep to a physician in order to promote brands. A sales rep gets anywhere between 2-5 minutes with the physician to promote the brands. In general a rep talks about anywhere between 1-3 brands in a single call.
- **Call Plan** - A set of doctors a territory is to call on in a given period. It can also include the presentation order of products when speaking to a doctor
- **Detailing Doctor** - A sales rep describes the benefits and side effects of each product to a doctor. One product=one detail; multiple details can occur on one call
- **Activity Data** - call and sample activity recorded by each sales rep
- **DEA #** - A DEA number is a number assigned to a doctor by the U.S. Drug Enforcement Administration allowing them to write prescriptions for controlled substances. Legally, the DEA number is solely to be used for tracking controlled substances
- **Sample** - a small dosage of the product reps give to doctors. The doctors then give out to patients for a trial or who can't afford prescription
- **Sample Drop** - when a rep only leaves samples, but does not talk about the products (does not detail)
- **Literature** - information describing the promoted product
- **Voucher** - can be brought to a pharmacy to redeem product for free or lower cost
- **Coupons** - used for patients who don't have insurance and struggle paying for prescriptions
- **Pre-call planning and routing** - reps determine which doctors to call and what route to take during the day from one doctor to the next
- **Key Opinion Leader (KOL)** – doctors who are advocates for the product
- **Speaker** - is a doctor who is an expert on a subject matter/product - speaks for the manufacturer on benefits of product
- **Wholesaler Acquisition Cost (WAC)** - Price a wholesaler purchases product from a manufacturer
- **Average Wholesaler Price (AWP)** - Price a wholesaler sells to a retailer or end-user
- **Point of Care (POC)** - Location where a consumer gets medical attention (FP/GP, Hospital, clinic...)

- **Market** - Group of similar brands that compete for the treatment of a disease state
- **Market Share** - The percent of the market that a particular brand has
- **Primary / Secondary / Tertiary** – Position of the brand during rep's interaction with the physician. Eg, let's say the rep talks to a physician about 3 brands – first brand A, then brand B and finally brand C. Then we say that Brand A has been detailed at primary position or that brand A is a primary detail, Brand B – secondary detail and Brand C – tertiary detail.
- **Primary Detail Equivalent, or PDE** – PDE is a metric used to measure the amount of sales rep promotion. A brand detailed on a primary position is assumed to get 1PDE. On the other hand, brands detailed on secondary and tertiary positions are assumed to get 0.5 and 0.1 PDEs (in other words, a secondary detail is assumed to be only half as effective as primary detail. Similarly a tertiary detail is assumed to be only 10% as effective as a primary detail). If a sales rep made 2 calls – Call 1 : A-B and Call 2: B-C-A, then we say that brand A has received $1 \times 1 + 1 \times 0.1 = 1.1$ pdes, Brand B has received $1 \times 0.5 + 1 \times 1 = 1.5$ pdes, Brand C has received $1 \times 0 + 1 \times 0.5 = 0.5$ pdes.
- **Sales Direction** – Sales direction refers to the order in which brands are promoted. Example: A-B, B-A-C, C are all different sales directions.
- **Target** – A physician is referred to as target if he / she is planned to be called upon. A doctor who has high importance to the market
- **Non-Target** - A doctor who does not have as large impact to the market
- **Universe**- Is the full set of doctors a rep has in their geography. Typically includes both target and non-targets
- **Writer** – A writer for a brand is any physician who has written at least 1 prescription for that brand.
- **Reach** – Reach is defined as percentage of physicians who are planned to be called as a percentage of all the available physicians. So for example, if out of 100 available physicians, pharma company chooses to promote to 60 physicians, then we say that the reach is 60%
- **Frequency** – Frequency is defined as number of calls from a rep to a physician in a given time period.
- **Incentive Compensation (IC)**- sales reps are paid base salary and a bonus. The IC is the bonus. Usually the IC plan contains a sales quota for Rx's
- **Sales Quota** - Goal a rep needs to make for a specific product. Many times, they still get paid below 100% attainment - typically no payment is given below 80% attainment
- **Key Performance Indicator (KPI) / Management By Objectives (MBO)** - some IC plans include "softer" goals called KPIs. Some examples of KPIs are expense management, presentation skills, and compliance
- **Sarbanes–Oxley Act (SOX)** - is a United States federal law that set new or enhanced standards for all U.S. public company boards, management and public accounting firms. The bill was enacted as a reaction to a number of major corporate and accounting scandals including those affecting Enron, Tyco International and WorldCom. These scandals, which cost investors billions of dollars when the share prices of affected companies collapsed, shook public confidence in the nation's securities markets
- **Pharmacy** - Pharmacy is the science and technique of preparing as well as dispensing drugs and medicines. The scope of pharmacy practice includes more traditional roles such as compounding and dispensing medications, and it also includes more modern services related to health care,

including clinical services, reviewing medications for safety and efficacy, and providing drug information. Pharmacists, therefore, are the experts on drug therapy and are the primary health professionals who optimize use of medication for the benefit of the patients. Pharmacies fill out prescriptions at the order of the physician and consult the patient on the usage and potential side effects. Types of Pharmacy:

- **Retail Pharmacy**- Independent pharmacies, chain pharmacies and food store and mass merchandiser pharmacies
- **Mail Service Pharmacy** - The physician faxes the prescription and the drug is shipped to the patient
- **Consultant Pharmacy** - Serve nursing homes, assisted living facilities, psychiatric hospitals, etc.
- **Specialty Pharmacies** – Concentrated in just few therapeutic areas such as HIV, Oncology
- **Managed Care** - describes a variety of techniques intended to reduce the cost of providing health benefits and improve the quality of care. Managed care uses a panel or network of health care providers to provide care to enrollees, including
 - A set of designated doctors and health care facilities, known as a provider network, which furnish an array of health care services to enrollees
 - Explicit standards for selecting providers
 - Formal utilization review and quality improvement programs
 - An emphasis on preventive care
 - Financial incentives to encourage enrollees to use care efficiently
- **Managed Care Organization (MCO)** - Patients pay **lower premiums** but have **fewer choices** in terms of physicians or drugs which are pre-approved by the MCO & Patients have to assume extra costs in case of any deviation from the plan's covered care. **Data for MCOs** comes in the form of **filled prescriptions at the plan level** by prescribing physician. To provide quality care and bring the healthcare costs under control, the MCOs use a variety of tools such as:
 - **Contracting** – *Capitated* contracts that offer the provider a fixed fee per month regardless of the amount of services provided or *Discounted Fee-for-Service* contracts
 - **Tiered co-pays** – Patient contributes increasing amount of money for more expensive drugs. Most common is a 3 tier system in which tier 1 is for generics, tier 2 for preferred drugs and tier 3 for all.
 - **Prior Authorizations** – Way to review appropriateness of more expensive care
 - **Reference Pricing** – Manufacturer has the burden of proving that the drug is more effective than other drugs for the higher price
 - **Disease Management Programs** – For managing high-risk patients in chronic disease areas. Aimed at improving and keeping the overall health of the patient stable to avoid costly hospitalization
 - **Formularies** – To control the use of certain drugs. “Open” formulary reimburses for generic and approved drugs as well as non-listed drugs with some cost implications and “Closed” formulary reimburses only listed drugs.
- **Managed care programs** - There are several types of network-based managed care programs.

- **Health Maintenance Organization (HMO)** - Healthcare has to be received from network providers. Each member is assigned a "gatekeeper", a primary care physician (PCP) who is responsible for the overall care of members assigned to him/her. Specialty services require a specific referral from the PCP to the specialist.
- **Preferred Provider Organizations (PPOs)** - A PPO is a health plan that has contracts with a network of "preferred" providers from which you can choose. You do not need to select a PCP and you do not need referrals to see other providers in the network.
- **Point of Service (POS)** - A POS plan utilizes some of the features of each of the above plans.
- **Provider networks** can be used to reduce costs by negotiating favorable fees from providers, selecting cost effective providers, and creating financial incentives for providers to practice more efficiently
- **Medicaid and Medicare** are two governmental programs that provide medical and health-related services to specific groups of people in the United States.
 - **Medicare** - national social insurance program, administered by the U.S. federal government since 1966, that guarantees access to health insurance for Americans aged 65 and older & those with certain disabilities
 - Part A (Hospital Insurance), helps pay for hospital stays
 - Part B (Medical Insurance), helps pay for medically necessary physician visits, outpatient hospital visits, home health care costs, and other services for the aged and disabled.
 - Part C (Medicare Advantage Plans), allow users to design a custom plan that can be more closely aligned with their medical needs.
 - Part D (Prescription drug plans), administered by private insurance companies offers plans with different costs and lists of drugs that are covered.
 - **Medicaid** - a social health care program for families and individuals with low income and resources.
- **Formulary** – A list of medicines that are approved to be prescribed under a particular insurance policy. In the US, where a system of private healthcare is in place, a formulary is a list of prescription drugs available to enrollees, and a tiered formulary provide financial incentives for patients to select lower-cost drugs. For example, under a 3-tier formulary, the first tier typically includes generic drugs with the lowest cost sharing (e.g., 10% coinsurance), the second includes preferred brand-name drugs with higher cost sharing (e.g., 25%), and the third includes non-preferred brand-name drugs with the highest cost-sharing (e.g., 40%).
- **Pharmacy Benefit Management** - They are primarily responsible for processing and paying prescription drug claims. They also are responsible for developing and maintaining the formulary, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers. PBMs aggregate the buying clout of millions of enrollees through their client health plans, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies.

- PBMs build networks of retail pharmacies, known as preferred pharmacy network, to provide consumers convenient access to prescriptions at discounted rates.
- PBMs provide mail-service pharmacies that supply home-delivered prescriptions without the face-to-face consultation provided by a pharmacist.
- PBMs use panels of independent physicians, pharmacists, and other clinical experts to develop lists of drugs approved for reimbursement in order to encourage clinically appropriate and cost-effective prescribing
- PBMs advise their clients on ways to structure drug benefits to encourage the use of lower cost drug alternatives — such as generics — when appropriate
- PBMs have devised e-prescribing technology, which provides physicians with clinical and cost information on prescription options that allows them to better counsel consumers on which medications—including various lower cost options—will be the safest and most affordable choices.
- PBMs pool purchasing power to negotiate substantial discounts from pharmaceutical manufacturers in order to lower benefit costs for clients and consumers.
- **Decile / Quintile** – is ranking of doctors based on their prescribing behavior. Doctors are divided into 10 buckets based on sales – in other words, decile 10 constitutes the doctors accounting for top 10% of the sales, followed by decile 9 consisting of doctors accounting for next 10% of the sales and so on. Generally doctors contributing most to the sales are placed in decile 10.
- **Co-pay** - Co-payment is a flat dollar amount that the insured is required to pay each time a particular service is received. Co-payment is always the same dollar amount, irrespective of the total cost of the service. Insurance companies use copayments to share health care costs and prevent people from seeking medical care that may not be necessary (e.g.: an infection by the common cold)
 - For example, a co-pay of \$20 will imply that every time an insured visits a physician or avails a service, he or she needs to pay a flat amount of \$20 and the balance is paid by the insurance company.
- **Actual Frequency** – Actual number of calls given by a rep to the physician in the defined time period. So for example, if in a month the rep gives 4 calls to a doctor, then the monthly frequency = 4
- **Planned Frequency** – is defined as the number of calls planned to be given by a rep to the physician in the defined time period.
 - For e.g. as per the call plan a rep is required to make 100 calls in a year, however he only makes 50 calls in that time period. In this case the Planned frequency was 100, however the actual frequency, i.e. the actual calls made, were 50
- **Segmentation** – is the process of dividing the broad target market into subsets of homogeneous customers – customers who have similar needs or common characteristics. Typically three criteria can be used to identify different segments:
 - Homogeneity (common needs/behavior within segment)
 - Distinction (unique from other group)
 - Reaction (similar response)

- **DDD Outlet** – DDD stands for Drug Distribution Data. IMS's DDD outlet data is used to track through which channel the prescription was filled (retail, mass, mail order, hospitals, etc.). Due to confidentiality agreements, the exact location is not supplied.
- **Product Group** - A group of related goods that are manufactured by a single company. Companies benefit from creating product families in that they can leverage the loyalty their existing customers feel toward an existing product to get them to buy additional, related products
- **Typical sales Structure** - Representative ---> District Manager ---> Regional Manager ---> Area Manager ---> National Sales Director (Many times the sales structure will have 3-4 layers of reporting)
- **Zip/Terr** - A file that contains zip codes associated to each territory. File is typically only two fields, zip code and territory and contains all zips in US where zips that don't have a territory will be assigned to "Unassigned Territory"
- **SLN** - State License Number - state specific, doctors need to attain in order to practice in any state
- **ME#** - Medical Education number - doctor receives number upon graduation, based on degree - two doctors with different degree can have same ME#
- **Professional Designation** - Degree doctor receives - can be MD, DO, NP etc.
- **Pharmaceutical** - Any chemical substance intended for use in the medical diagnosis, cure, treatment, or prevention of disease.
- **Biotechnology** - Use of living systems and organisms to develop medicine production
- **Medical Device** - Instrument which is used for medical purposes in patients, in diagnosis, therapy or surgery
- **Wholesaler/Distributor** - There are many small companies that sell pharmaceutical products. It is not cost effective for Pharma companies to sell directly to these small customers. Instead, they use wholesalers to distribute product. They typically have large warehouses to store product and receive a discount from manufacturers due to bulk purchases. Top wholesalers are AmeriSource Bergen, Cardinal Health, McKesson
- **Hospital** - Largest and most complex POC. Can be classified into federal, community, Long Term Care and institutional hospital units. Vast difference between acute hospital care and outpatient care has resulted in a class of drugs that are administered almost exclusively in hospitals. For e.g. very strong antibiotics. Non-hospital drugs are referred to as Retail drugs. For e.g. drugs treating allergy. Hospital data comes in form of inpatient & outpatient pharmacy purchases, outpatient clinic purchases and prescription outflow at the physician or the hospital. Hospitals are highly complex entities with multiple departments, numerous medical staff and various decision makers. Dedicated sales forces are required to promote drugs to hospitals in most situations
- **Clinic** - Patients get diagnosed and treated for cases not requiring hospitalization. Clinics can be single practicing physician's office, multiple physicians of the same specialty or multiple physicians from multiple specialties sharing an office. Clinics make up the majority category of healthcare providers diagnosing and treating patients and this is where drugs are prescribed most often. Patient receives prescriptions that can be filled at a retail pharmacy. Some drugs such as injections require special administration which must be given at the clinic and these drugs maybe stocked at

the clinic or supplied by an outside pharmacy. Data for clinics comes in the form of purchases and dispensed prescriptions by physicians

- **Long Term Care (LTC)** - Includes nursing homes, assisted living facilities, home health care services, hospice sites and associated pharmacies. Consultant pharmacies in most cases determine the list of approved drugs and influence the sale of particular drug
- **AMA Physician Data Restriction Program (PDRP)** - offers physicians the opportunity to restrict their prescribing data from pharmaceutical sales representatives
- **DEA number** is a number assigned to a health care provider (such as a medical practitioner, dentist, or veterinarian) by the U.S. Drug Enforcement Administration allowing them to write prescriptions for controlled substances. to be used for tracking controlled substances
- **National Provider Identifier (NPI)** - is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS). The NPI has replaced the unique provider identification number (UPIN) as the required identifier for Medicare services, and is used by other payers, including commercial healthcare insurers. The transition to the NPI was mandated as part of the Administrative Simplifications portion of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and CMS began issuing NPIs in October 2006
- **US Market Class-of-Trade (COT)** - IMS COT is the recognized US market standard, organized by classification, facility type and specialty
- **Integrated Delivery Network (IDN) or health system** - An organization that has direct responsibility for centralizing the purchasing or contracting of its affiliated hospitals and ancillary-care facilities; it also offers a continuum of care through services at acute and non-acute sites. Must contain at least 1 acute care hospital and 2 or more non-acute facilities. Excludes a shared-service arrangement whereby several hospitals may work cooperatively to provide a service, such as a regional cancer clinic, but contract independently.
- **Corporate Owner (CO)** - An incorporated entity that serves as a corporate parent. It owns leases, manages and/or establishes purchasing affiliations with two or more healthcare delivery sites. A corporate owner does not offer a continuum of healthcare. They can cover a range of healthcare facilities, including medical groups, clinics, nursing homes, outpatient surgery centers, pharmacies, etc. however corporate owners will not include acute care Hospitals
- **Owner Subsidiary (OSUB)** - An incorporated entity that serves as a corporate parent within a larger parent organization, either a corporate owner or an IDN. An owner subsidiary owns, leases, manages and/or establishes purchasing affiliations with two or more healthcare delivery sites.
- **Adequate Provision** - an alternative way for drug companies to provide risk information about a drug in a broadcast ad.
- **Continuing medical education (CME)** - consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.
- **Direct-to-Consumer (DTC)**- Promotion of Rx drugs by pharma companies direct to consumers via broadcast and print media such as television, radio, magazines, billboards, and also the Internet

- **Direct Marketing** - is any direct communication to a consumer or business recipient that is designed to generate a response
- **eDetailing** - is often used as a blanket term for various online physician marketing, promotional and communication activities
- **ePrescribing** - is the ability of a physician to submit a "clean" prescription directly to a pharmacy from the point of care
- **eSampling** - is the ability of pharmaceutical companies to allow physicians to order and manage Rx drug samples online
- **Fair Balance** - In direct-to-consumer advertising, fair balance refers to the presentation of accurate and fair assessment of the risks as well as the benefits of the drug
- **Off-label** - An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA
- **Sampling** - is the process by which pharmaceutical companies distribute free drugs (Drug Samples) to physicians
- **Sales Aid (detail aid or visual aid)** - is a print piece (booklet or brochure) or an electronic document containing product information.
- **FDA Warning Letter** is a correspondence that notifies a pharmaceutical or other FDA-regulated company about violations that FDA has documented during its inspections or investigations
- **Compliance** - Percent of doses of a drug taken as prescribed while patient is actively taking drug
- **Persistence** - Number of days from first dose until patient stops taking drug