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CHI Drug Formulary Master Excel Sheet User Guide

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Welcome to the official User Guide of the CHI- Unified Drug Formulary (UDF). This meticulously crafted guide is intended to provide comprehensive support in navigating the UDF Master Excel Sheet. Its purpose is to equip healthcare professionals, providers, institutions, researchers, and individuals seeking pharmaceutical information with the necessary guidance and resources.

The User Guide encompasses crucial components that enhance understanding and utilization of the CHI Drug Formulary. It begins with an Introduction to the formulary, offering an insightful overview of the formulary's objectives and purpose. This contextual understanding lays the foundation for interpreting and effectively utilizing the information contained within the formulary.

The formulary development process section outlines the meticulous procedures employed to curate and maintain the CHI Drug Formulary. It elucidates the methodologies, guidelines, and expert consultations involved in its comprehensive content creation and updates. Familiarizing oneself with this process instills confidence in the formulary's accuracy, reliability, and relevance.

Successful navigation of the Master Excel Sheet Drug Formulary requires a clear comprehension of the various sheets it encompasses. The User Guide provides detailed explanations for each sheet, including their specific purposes and the information they offer. This section empowers users to efficiently locate and extract the precise data required, streamlining research and practice endeavors.

In addition, a comprehensive understanding of the field definitions utilized within the CHI Drug Formulary is vital for accurate interpretation of the data. The User Guide meticulously defines each field, elucidating their meanings, units of measurement, and any pertinent notes or considerations. This knowledge enables users to confidently interpret the data and make informed decisions based on it.

We trust that this User Guide will prove indispensable as you explore the CHI Drug Formulary. Whether you seek drug information for patient care, academic research, coverage information or any other purpose, this guide will facilitate your navigation and comprehension of the formulary's contents.

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LIST OF ABBREVIATEION

AHCPR: Agency for Healthcare Research and Quality
CHI: council of Health Insurance
FGC: CHI Formulary Governance Committee
GTIN: Global Trade Item Number
HCP: Health Care Provides
UDF: Unified Drug Formulary
KSA: Kingdom of Saudi Arabia
MDD: Maximum Daily Dose
NCE: New Chemical Entity
OTC: Over the Counter
PE: Prescribing Edits
PTC: Pharmacy and Therapeutic committee
SFDA: Saudi Food and Drug Administration
ST: Step Therapy

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INTRODUCTION TO FORMULARY

WHAT IS A DRUG FORMULARY?

A Drug formulary is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of diseases and promotion of health.

WHAT IS CHI DRUG FORMULARY (UDF)?

CHI Formulary is an evidence-based disease focused open Formulary which provides an essential drug list, either prescription or over the counter (OTC), that is necessary to treat a certain disease. CHI Formulary Governance Committee (FGC) with the Pharmacy and Therapeutic committee (PTC) govern, maintain and continually update the Formulary to make sure that all SFDA drugs are available based on the most recent clinical national and international guidelines to ensure drug safety, efficacy and efficiency for the community of Saudi Arabia.

WHAT IS THE OBJECTIVE OF CHI FORMULARY?

The Objective of this Formulary is to provide impartial and objective information to insurance companies in the Kingdom of Saudi Arabia, as well as to service providers and patients to promote safe, effective and rational use of medicines, which is based on evidence and global best practices. Other objectives include:

- Rationalize use of medicine (therapeutically accurate and cost-effective) Promote the use of generics
- Provide a comprehensive resource to insurance companies and Health Care Professionals (HCPs).
- Standardize the prescribing practices in Kingdom of Saudi Arabia (KSA)by using the best selected evidence-based guidelines.
- Promote affordable and equitable access to healthcare.
- Improve governance in the private health care insurance sector.
- Decrease healthcare expenditure using therapeutically equivalent but more affordable treatment options.”

DEVELOPMENT OF THE FORMULARY

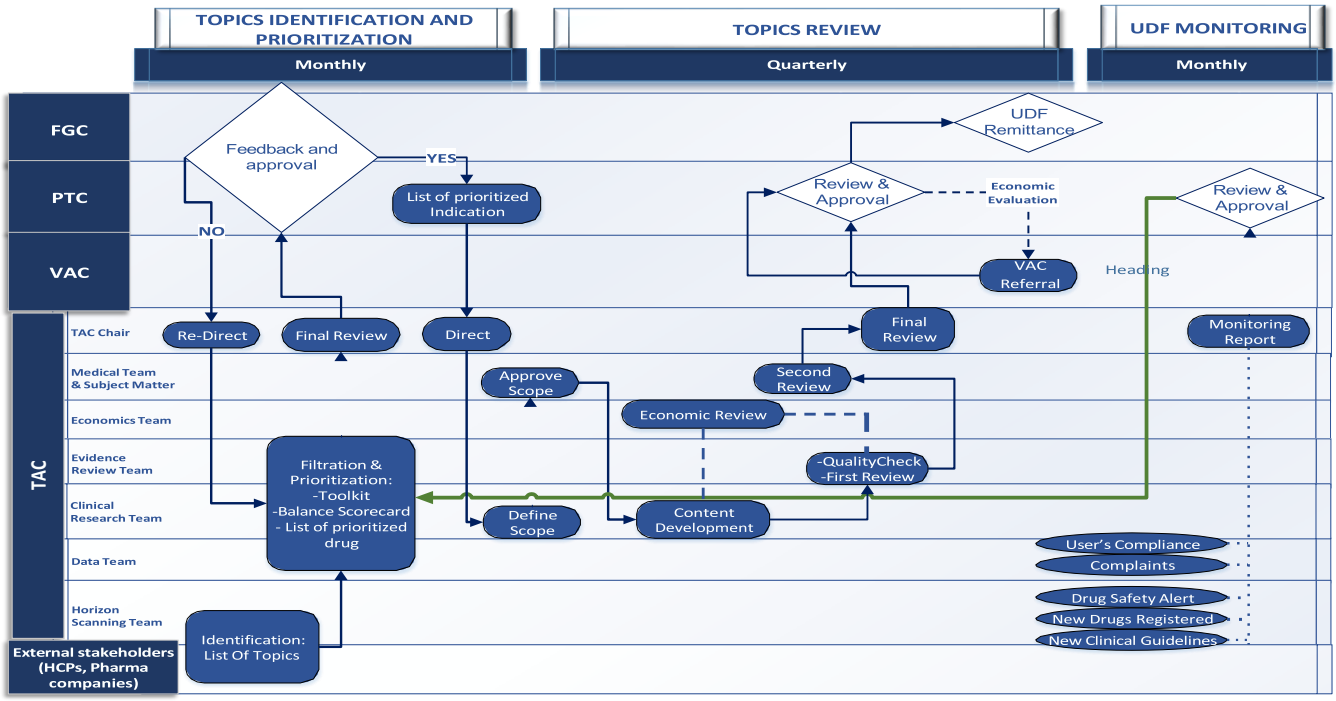

Figure 1 UDF Maintenance & Monitoring Process Flowchart

For additional details refer to the UDF MAINTENANCE & MONITORING PROCESS (IDF-FR-Pr-01-01) retrieved through CHI website https://chi.gov.sa/en/pages/default.aspx

HOW TO USE THE FORMULARY

UDF WORKSHEET DEFINITIONS AND USE

Indication Sheet: this sheet includes the list of approved indications mapped with the corresponding scientific molecules and relative scientific description code root number. The main end users are healthcare providers who can use it to identify the approved indications with their respective ICD 10 codes, in addition to the corresponding approved scientific molecule, dosage form, strength, and prescribing edits.

Mapped UDF to SFDA Sheet: this sheet includes the list of scientific molecules regularly mapped with SFDA medication list to identify trade names and related prices. The main end users are insurance companies, hospitals, pharmacies and others.

Appendix Sheet: Appendices describing protocols and step therapies that users should refer to whenever mentioned in the notes provided within the Indication Sheet as PE for protocol edit and ST for step therapy.

What Information Does the Indication Sheet Provide?

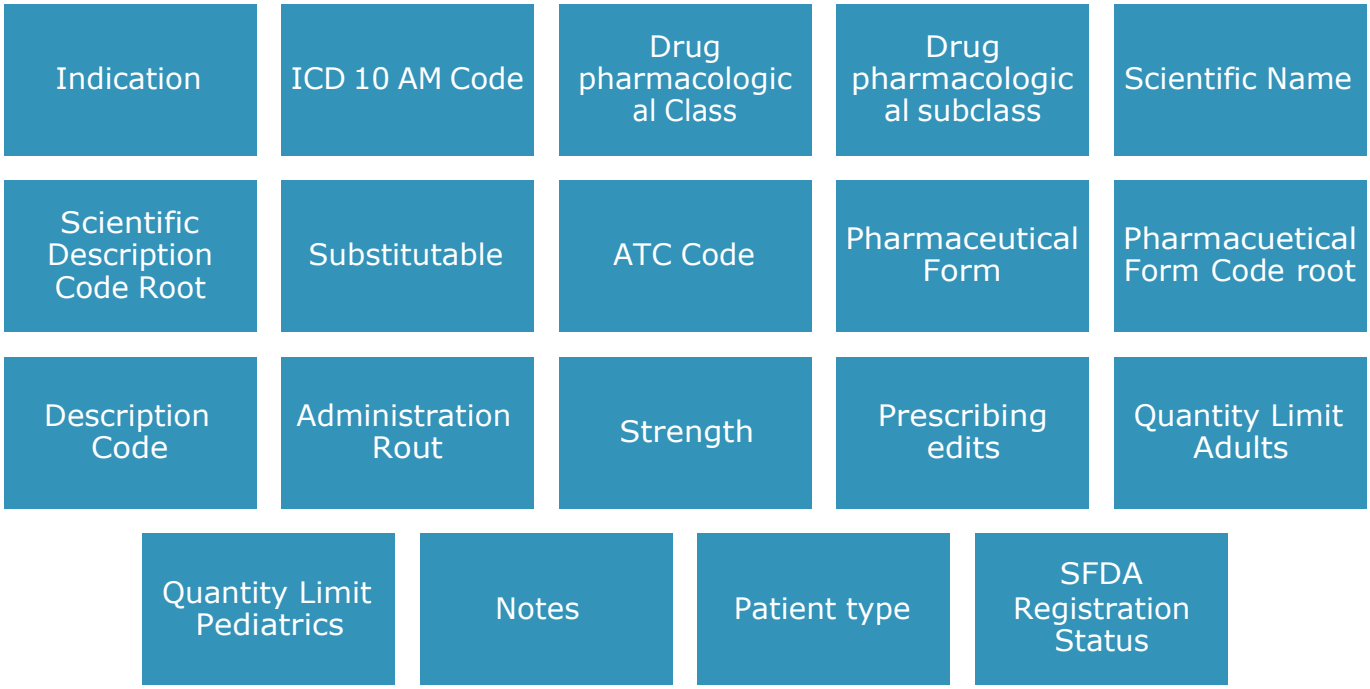

Figure 3 Indication Sheet Fields List

What Information Does the Mapped UDF To SFDA Sheet Provide?

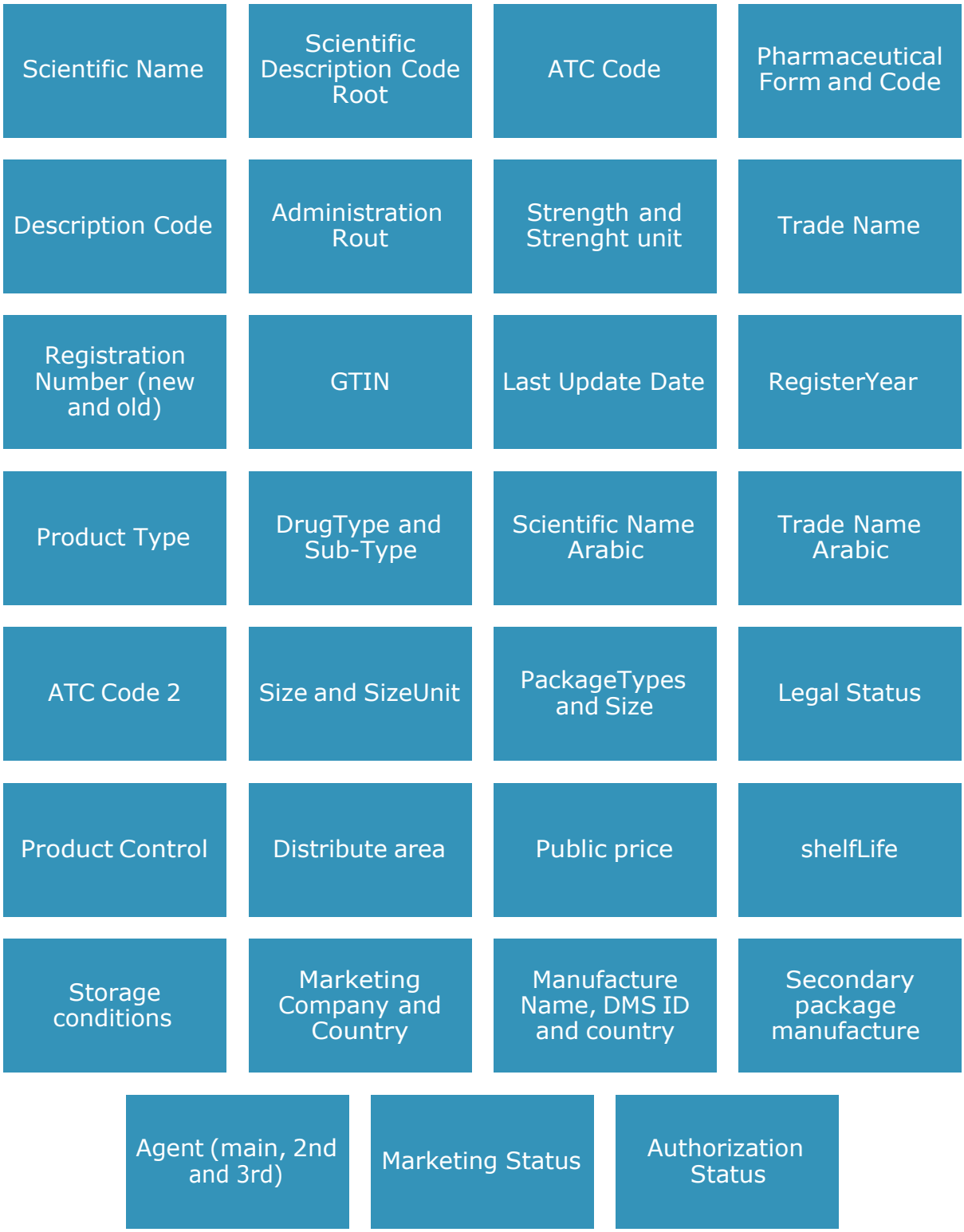

Figure 4 Mapped UDF to SFDA Sheet Fields List

UDF NAVIGATION

The CHI Formulary is provided on an excel sheet platform that users can filter by Indication, ICD 10 AM code, Drug Pharmacological classes, Scientific name Scientific description code root, pharmaceutical form, pharmaceutical form code root, description code and, ATC code.

Formulary provides Appendices with various tables and protocols that users should refer to whenever mentioned in the notes. Hyperlinked Appendices are provided on a separate column for each disease or indication.

EVIDENCE LEVEL USED

Categories of evidence (adapted from AHCPR):

- Ia: evidence from meta-analysis of randomized controlled trials
- Ib: evidence from at least one randomized controlled trial
- IIa: evidence from at least one controlled study without randomization
- IIb: evidence from at least one other type of quasi-experimental study
- III: evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
- IV: evidence from expert committee reports or opinions and/or clinical experience of respected authorities

UDF COVERAGE ESSENTIALS

Medication Prescribing must

1. Medications should be covered if it is mentioned as part of the Indication "ICD-10 AM" coverage.
2. Prescribing must be done based on the Scientific Name, and automatic substation will be done except for generics not therapeutically equivalents as per SFDA list, Prescriber Place do not substitute note "Insurance coverage deductible will be based on the EBP criteria" https://www.sfda.gov.sa/sites/default/files/2023-02/SFDADDD.pdf
3. For Further details on the Insurance Drug formulary related regulations can be found through of the Updated Essential Benefit package through the below link: https://www.CHI.gov.sa/Rules/Pages/document1-7.aspx

UDF PRESCRIBING EDITS TOOLS

Table 1 Prescribing Edits Tools List

Prescribing edits Tools	Description
AGE (Age Edit)	Coverage may depend on patient age
CU (Concurrent Use Edit)	Coverage may depend upon concurrent use of another drug
G (Gender Edit)	Coverage may depend on patient gender
MD (Physician Specialty Edit)	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization)	Requires specific physician request process
QL (Quantity Limit)	Coverage may be limited to specific quantities per prescription and/or time period
ST (Step Therapy)	Coverage may depend on previous use of another Drug
EU (Emergency use only)	This drug status on Formulary is only for Emergency use.
PE (Protocol edit)	Use of drug is dependent on protocol combination, doses and sequence of therapy

Prescribing Edits Examples:

Age edits: Desmopressin in Nocturnal Enuresis should not be prescribed for children < 5 years.
Concurrent Use Edit: Flavoxate in Nocturnal Enuresis should be used as add on to desmopressin after desmopressin failure and cannot be used alone.
Gender Edit: Exemestane in Endometriosis should be used only by Females.
Physician Specialty Edit: Fentanyl in Endometriosis should be prescribed by a gynecologist or pain management specialist.
Prior Authorization: Desmopressin in Nocturnal Enuresis: The prescriber must check the following before prescribing:

- Failure of combination of behavioral and alarm therapy.
- Serum Na at the start of therapy, every 3-7 days and if stable every month then every 3 months thereafter.

Quantity Limit: Idarubicin in Acute Leukemia: Cumulative dose should not exceed 150 mg/m2. Please note that this Quantity Limit is different than the one based on maximum daily dose as this is not necessary based on Maximum Daily Dose.
Step Therapy: Aripiprazole in Social Anxiety: should be used as third line after:

- First-line: Escitalopram, fluvoxamine, fluvoxamine CR, paroxetine, paroxetine CR, pregabalin, sertraline, venlafaxine XR
- Second line: Alprazolam, bromazepam, citalopram, clonazepam, gabapentin

Emergency use only: Furosemide IV form in Hypertension is used only in emergency setting.
Protocol edits: Bendamustine Hydrochloride, Cyclophosphamide, Ifosfamide, Dacarbazine should be used in Lymphoma as per a specific protocol.

Figure 5 Prescribing Edits Examples

Indication Worksheet Fields Definitions

The indication is the medical condition that leads to the recommendation of a treatment, test, or procedure and it's associated with the below fields.

1

ICDE 10 AM Code

International Classification of Diseases (ICD) code, based on WHO definition, is "the international standard for defining and reporting diseases and health conditions. It allows the world to compare and share health information using a common language. The ICD defines the universe of diseases, disorders, injuries, and other related health conditions. These entities are listed in a comprehensive way as a list of codes with their corresponding descriptions.

2

Drug Pharmacological Class and Sub-Class

"Pharmacologic class" the group of active moieties that share scientifically documented properties and is defined based on any combination of three attributes of the active moiety: Mechanism of Action (MOA), histologic Effect (PE), Chemical Structure (CS). Drug "Pharmacological Sub Class" is a sub class of "Pharmacologic class".

3

Scientific Name and Scientific Description Code Root

"Scientific name" is the active ingredient of the product that is responsible for the beneficial health effects experienced by consumers e.g., Acetaminophen.
"Scientific Description Code Root" is a code generated by the SFDA and is unique per scientific name (active ingredient)

4

Substitutable

Non substitutable drugs as defined per the SFDA will be specified within the UDF as

5

ATC Code

The Anatomical Therapeutic Chemical (ATC) Classification is an internationally accepted classification system for medicines that is maintained by the World Health Organization (WHO). The WHO assigns ATC codes to all active substances contained in medicines based on the therapeutic indication for the medicine.

6 Pharmaceutical Form and Pharmaceutical Form Code Root

"Pharmaceutical Form" is the Dosage Form (DF) which is defined as the physical form of a dose of a chemical compound used as a drug or medication intended for administration or consumption. Common dosage forms include pill, tablet, syrup, aerosol, liquid injection.
"Pharmaceutical Form code Root" is Unique numerical SFDA generated code for each Dosage form (Pharmaceutical form) e.g., Tablet:100000073664

7

Description Code

Unique numerical SFDA generated code for each registered scientific name that is composed of 3 main blocks representing (Active ingredient code- strength -dosage form) name including its strength, route of administration and dosage form, maintained on the list to guide users when updating the mapping of the product.

8

Administration Route

Refers to the method in which a medication is introduced to the body e.g., Oral, Intravenous, Intramuscular, rectal.

9

Strength and Strength Unit

"Strength" is the amount of drug in each dosage form, for example, 500 mg/tablet.
"Strength unit" is the unit of measurement used by the SFDA to describe the product strength e.g., mg, G, mmol.

10

Prescribing Edits

Some covered drugs may have additional requirements, rules, or limits on coverage. These requirements and limits are detailed in section "UDF PRESCRIBING EDITS TOOLS"

11

MDD Adult and Pediatric

This is either the adult or pediatric maximum amount of a drug that can be administered per day based on a maximum daily dose. If there is no clinical evidence supporting the quantity limit for that relevant indication, this column will be left as Blank.
NA will be added when its MDD is not available

12

Notes

"Notes" section provides details of the prescribing edits, extra important drug information and special warnings and precautions.

13

Patient type

Specify the inpatient setting (IN)- Coverage is restricted to hospital use.

14

SFDA Registration Status

Define if the scientific name is registered within the SFDA or not (Yes/No)

Mapped UDF to SFDA Worksheet

Table 2 Mapped UDF to SFDA Fields Definitions

Field Name	Definition
Drug Type	it is an abbreviation used by the SFDA to describe the product marketing status for brand (new chemical entity (NCE), biological) generic, Radiopharmaceutical. Drug type: NCE (New Chemical Entity) = Brand Drug type: Biological, Sub-Type: Biosimilar = Generic Drug type: Biological, Sub-Type: Biological = Brand
Sub-Type	it is an abbreviation used by the SFDA to sub categorize the product marketing status biosimilar (= Generic biological), allergen product, IV solution, biotechnology product, blood product
Trade Name	it is the trademark name given to a specific medication and can be either brand or generic
Trade Name Arabic	the Arabic discerption of the product trade name
Registration Number old	initial replaced code generated by the SFDA for each registered drug product specific to the drug trade name including its strength, route of administration and dosage form, maintained on the list to guide users when updating the mapping of the product
Last update Date	The date of the last update done for the medication
Registration number new	Updated code that is unique numerical SFDA generated code for each registered drug product specific to the drug trade name including its strength, route of administration and dosage form, maintained on the list to guide users when updating the mapping of the product
Register Year	Year of registration of the product by the SFDA: 2020, 2021 ….
GTIN	Global Trade Item Number (GTIN) is an identification key that uniquely identifies products worldwide. It can be encoded in various types of data carriers, including Data Matrix.

Scientific Name Arabic	the Arabic discerption of the Active ingredient (scientific name)
AtcCode2	it is the additional ATC code given to a product
Size	amount available in a product
Size Unit	the unit of measurement used for describing the size
Package Types	describe the method that the medication is packet for utilization e.g., Bottles, Blister packs, Sachets, Syringes, Ampoules, Vials
Package Size	the amount of unites available in each package
Legal Status	describe the method that this medication can be dispensed by the pharmacist either requiring a prescription or over the counter (OTC) not requiring a prescription
Marketing Status	describe the SFDA assigned marketing status for the product as marketed, or non-marketed
Authorization Status	describe the SFDA assigned authorization of the product in local market as Valid, Invalid, suspended, withdrawn by MAH, withdrawn by regulatory authority
Product Control	describe the status of the pharmaceutical product monitoring and prescription either uncontrolled substance or controlled substance following the SFDA regulation for narcotic and controlled substance related to prescribing, storage, distribution, and dispensing
Distribute area	describes the area authorized by the SFDA to stock and utilize the medication either as hospital item or pharmacy "retail"
Public price	the maximum price set by the SFDA that a pharmacy can sell the product to consumers.
shelf Life	The true but unknown limit on the period of storage time during which the pharmaceutical or drug product is considered fit for use and effective.
Storage conditions	Describes a climatic condition or a general storage condition under which a substance or product is stored
Marketing Company	the company name of the company authorized by the SFDA to market and disrepute the product in KSA.
Marketing Country	دولة الشركة المسوقة
Manufacture Name	المصنع المعتمد
Manufacture Country	دولة المصنع
Manufacturer DMS Id	رقم الشركة الصانعه في النظام الداخلي لدى الهيئة نظام إدارة االدوية
Secondary package manufacture	مصنع التغليف الثانوي
Main Agent	الوكيل ألول
Second Agent	الوكيل الثاني
Third agent	الوكيل الثالث

USEFUL LINKS

1. SFDA Drug Shortage list [https://www.sfda.gov.sa/en/currentlyInShortageList]
2. SFDA Vigilance (نبيه) [https://ade.sfda.gov.sa/]
3. SFDA Risk minimization measure list [https://www.sfda.gov.sa/en/RMM]
4. SFDA Drug news [https://www.sfda.gov.sa/en/news?keys=&date%5Bmin%5D=&date%5Bmax%5D=&tags=2]
5. SFDA safety alerts [https://www.sfda.gov.sa/en/safety_alert]
6. SFDA drug warning [https://www.sfda.gov.sa/en/warnings?keys=&date%5Bmin%5D=&date%5Bmax%5D=&tags=2&field_warning_number=]
7. SFDA drug list [https://www.sfda.gov.sa/en/drugs-list]
8. CHI Essential benefits package [https://www.chi.gov.sa/en/Rules/Documents/Updated%20Essential%20Benefit%20Package%20%20%28%20effective%201%20October%202022%29.pdf]
9. UDF first-year implementation guide [https://shorturl.at/ajs06]