Daman Drug Formulary (DDF) Monitoring Report

CHI'S PHARMACEUTICAL DICTIONARY:
Market Monitoring and Data Harmonization

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Executive Summary

Context and Challenges

The Council of Health Insurance (CHI) in Saudi Arabia oversees the private health insurance sector and manages the Daman Drug Formulary (DDF). Discrepancies in pharmaceutical classification systems across SFDA list, DDF, NPHIES platforms have led to complaints, and data inconsistencies, hindering seamless integration and compliance.

Objectives

The objective of this report is to maps the drug classification systems used by SFDA, and CHI, highlighting discrepancies, while describing the methodology for harmonizing classifications using SFDA as a benchmark, and providing a reference drug list to support alignment and data analysis

Key Outputs and Pilot Implementation

The Harmonized CHI List and the BUPA List will serve as core outputs. The pilot will be implemented via NPHIES Intelligence reports, enabling direct integration into the CHI dashboard.

Work - Approach

Mapping Drug Classification Systems

Drug classification and coding structures used by SFDA and CHI's (DDF/NPHIES) **were mapped and presented**

Comparing Drug Classification Systems

Drug classification and coding structures **were compared to identify inconsistencies** or overlaps between SFDA List, DDF, and NPHIES platforms.

Using Data Linkage to Harmonize drug Classification

Multi-steps to harmonize Drug classifications and address discrepancies across SFDA List, DDF, and NPHIES platforms **were adopted.**

Mapping and Matching:
Drugs were matched between NPHIES and SFDA using GTIN or trade names.

2 **Drug Type Standardization:**
Rule-based approach was applied to classify drugs into unified types

3 **Route of Administration Grouping:**
Synonymous & clinically equivalent administration routes were grouped.

4 **Strength & Strength Unit Harmonization:**
Drugs were grouped by scientific name, strength and unit consistency were evaluated.

5 **CHI Harmonized Drug List**
A preliminary drug list was generated benchmarking SFDA to support data analytics.

Quality Check (QC)
QC was performed to ensure accurate standardization and grouping.

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Recommendations

- Implement the Use of SFDA Codes: Enforce the adoption of SFDA registration numbers and GTINs across all healthcare entities.
- Training Programs: Educate stakeholders (prescribers, pharmacists, claims staff) on standardized drug terminology and substitution rules.
- Joint Governance Committee: Establish a cross-agency committee to ensure alignment and consistency in drug classifications.
- Automate the added fields through integration in NPHIES: Integrate the added data fields for seamless workflow alignment.
- Periodic Monitoring: Regularly review and update drug classifications to address non-standard terms and ensure clarity

This List is only used for data analysis purpose and not for substitution purposes

Outline

01 Background and Objectives

02 Mapping Pharmaceutical Classification Systems

03 Comparing Pharmaceutical Classification Systems

04 Using Data Linkage to Harmonize Pharmaceutical Classification

01 Background and Objectives

- *Context and Challenges*
- *Key Stakeholders*

CHI'S PHARMACEUTICAL DICTIONARY: Market Monitoring and Data Harmonization

Context and Objective

Context and Background

The Council of Health Insurance (CHI), as the national authority overseeing the private health insurance sector in Saudi Arabia, conducts routine monitoring and compliance assessments through the NPHIES platform. Recently, CHI has observed a growing number of complaints and clarification requests, primarily from insurer, related to discrepancies between CHI's findings and data reported by market stakeholders. These issues largely stem from variations in pharmaceutical categorization, coding systems, analytical methodologies, and other inconsistencies that hinder seamless data Linkage, particularly among SFDA, NPHIES, and the DDF.

Objectives

This report aims to:

- Map the various pharmaceutical classification systems currently used in SFDA, NPHIES and DDF, with real-world examples illustrating common discrepancies.
- Describe CHI's methodology for addressing inconsistencies and harmonizing pharmaceutical classifications within the NPHIES platform for compliance and monitoring purposes, taking SFDA as a benchmark.
- Provide access to a reference drug list to support alignment and compliance efforts across private sector stakeholders.

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Main Stakeholders in the Health Insurance and Drug Regulation Ecosystem in Saudi Arabia

Insurance/PBM/Providers

Third-party administrators (TPAs), Insurers and Providers in the private sector in Saudi Arabia, serve as key users of platforms such as NPHIES and DDF.

Saudi Food and Drug Authority (SFDA)

The Saudi Food and Drug Authority (SFDA) is the national regulatory body responsible for the approval, registration, and oversight of all pharmaceutical products in Saudi Arabia. It maintains a centralized database, the Human Drug List, which includes approved drugs along with key identifiers

Council of Health Incurance (CHI)

The Council of Health Insurance (CHI) is responsible for maintaining and monitoring the Daman Drug Formulary (DDF), as part of its role in overseeing the private health insurance sector in Saudi Arabia. The National Platform for Health and Insurance Exchange Services (NPHIES) is the national unified digital health platform developed by the Saudi Health Council (SHC) in collaboration with CHI and operated by Sehati.

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02

Mapping Pharmaceutical Classification Systems

- *SFDA Drug Classification and Codes*
- *DDF Drug Classification and Codes*
- *NPHIES Drug Classification and Codes*

Mapping Pharmaceutical Classification Systems

As part of this, a review of the drug classification definitions and coding systems report used by the SFDA, CHI's Daman Drug Formulary (DDF), and the NPHIES platform.

Define and Document

Map and define the drug classification and structures used by the SFDA, CHI's Daman Drug Formulary (DDF), and the NPHIES platform, focusing on drug type, subtype, and coding identifiers.

Review Regulatory and Technical References

Review official databases, regulatory guidelines, and technical documents to understand the rationale behind classification logic and definitions.

Provide Drug Examples

Illustrate differences across systems using a real-world drug example, highlighting how the same product may showcase discrepancies in the different systems (SFDA, DDF, and NPHIES), reinforcing the need for harmonization.

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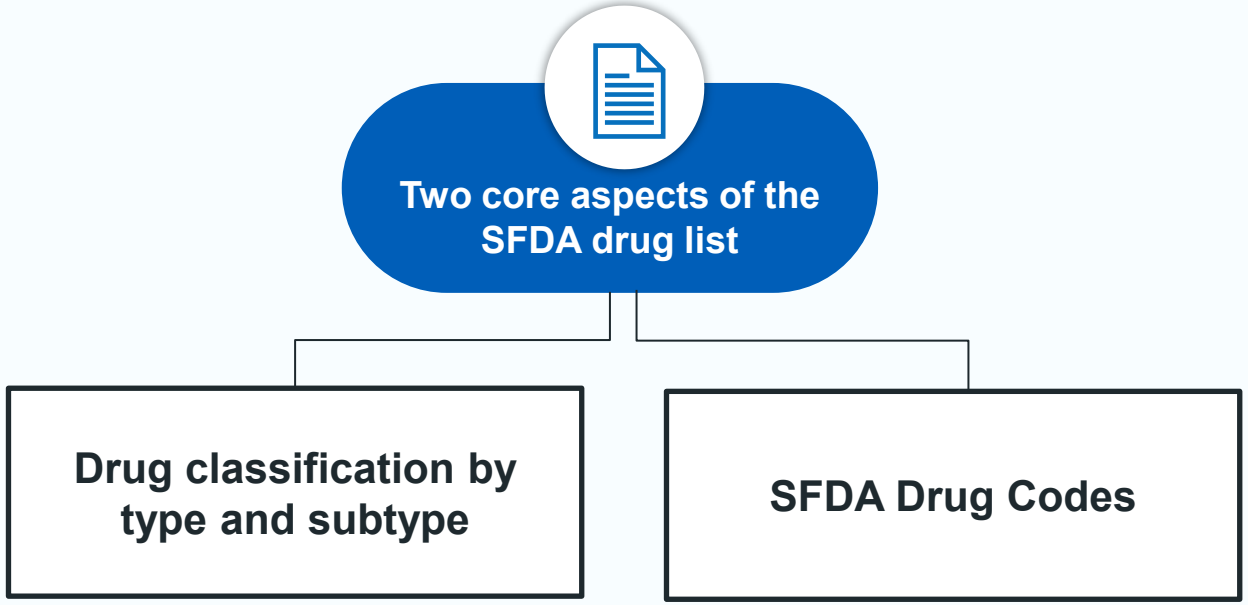
1- SFDA Drug Classification and Codes



Drug Classification

SFDA classifies drug products during registration into Types and Sub-types based on their origin and nature including brand (NCE), Generic, Biological, Biosimilar

SFDA Drug Codes

SFDA uses several coding systems to categorize and identify drugs including GTIN, ATC code, Description Code, Registration number

Other data fields from the SFDA list are outside the scope of this report. Further details can be found in Appendix 1.

1- SFDA Drug Classification and Codes – Cont.

Drug Classification

Drug Type/Sub-Type	Definition
Brand (Innovator) Product (NCE)	The first form of a drug (with a specific API and dosage form) approved by regulatory authorities, usually supported by comprehensive preclinical and clinical data.
Generic Product	A product that contains the same API(s), in the same strength and dosage form, as the brand (innovator) product and is considered therapeutically equivalent.
Biological Product	A product derived from living organisms, such as vaccines, monoclonal antibodies, recombinant proteins, or gene therapies.
Biosimilar	A highly similar version of an already-approved biological product, demonstrating no clinically meaningful differences in terms of safety, purity, and potency.

The SFDA drug list also includes various other drug types that lack clear definitions, such as **Allergen Products** (e.g., allergen extracts), **Biotechnology Products** (e.g., epoetin beta**), Blood Products** (e.g., albumin and coagulation factors), **Vaccines, IV Solutions** (e.g., lidocaine and levofloxacin solutions), and **Known Active Substances**, which encompass a wide range of molecules such as sildenafil and cefixime.

Saudi FDA. *Saudi FDA Products Classification Guidance Operations Sector*. 20 Sept. 2024.

1- SFDA Drug Classification and Codes – Cont.

SFDA Drug Codes

01 SFDA Registration Number

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

02 Global Trade Item Number (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.

03 Therapeutic Classification (ATC)

SFDA aligns with international classification for therapeutic categories. The Anatomical Therapeutic Chemical (ATC) code is often used to classify drugs by their pharmacological class.

04 Description Code

The Description Code is typically used to capture or summarize key identifying information about a product—such as the drug's Scientific name, strength, and dosage form—in a standardized alphanumeric format.

05 Scientific Code Root

The Scientific Code Root Number refers to a code that SFDA assigns to represent the active pharmaceutical ingredient(s) (API) or the scientific name of the drug

06 Pharmacological Form Code Root

A code that classifies the dosage form or pharmaceutical form (e.g., tablet, capsule, injection, cream, etc.)

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Saudi FDA. *Saudi FDA Products Classification Guidance Operations Sector*. 20 Sept. 2024.

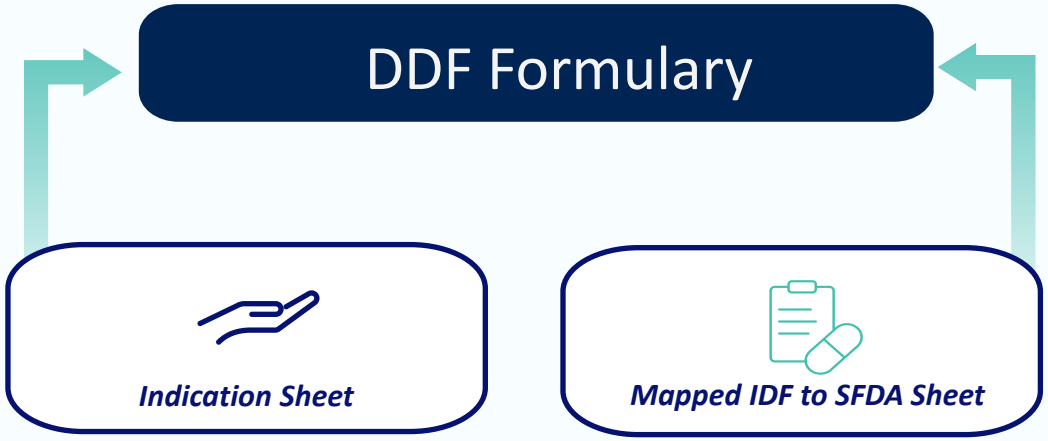
1- SFDA Drug Classification and Codes – Cont.

SFDA Registered Drug Examples

	Crestor 20 mg film coated tablets	Stelara 90mg/1ml solution for injection
SFDA Registration Number	1506233820	1511222905
Scientific Name	Rosuvastatin	Ustekinumab
Scientific Description Code Root	7000001121	7000001301
Trade Name	Crestor 20 mg film coated tablets	Stelara 90mg/1ml solution for injection
Drug Type	NCE	Biological
Drug Subtype	-	Other
Pharmaceutical Form	Film-coated tablet	Solution for injection in pre-filled syringe
Pharmaceutical Form Code Root	100000073665	200000016496
Administration Route	Oral Use	Subcutaneous use
ATC Code	C10AA07	L04AC05
Description Code	7000001121-20-100000073665	7000001301-90-200000016496
GTIN	5000456011013	05413868100990

2- DDF Drug Classification and Codes

The Council of Health Insurance (CHI) is an independent governmental entity established to oversee the implementation of the Cooperative Health Insurance System. Its mission is to support the quality and efficiency of the health insurance sector in alignment with the Kingdom's vision for an integrated and sustainable healthcare system



Key goals of the DDF include

- Standardizing medication coverage and prescribing practices across private insurers
- Enhancing equitable access to essential therapies
- Promoting cost-effective treatment, with a particular emphasis on the use of generic medications to support financial sustainability

2- DDF Drug Classification and Codes

What Information Does the Indication Sheet Provide?

The Indication sheet includes the list of approved indications mapped with the corresponding scientific molecules and relative prescribing information.

Field	Definition
Indication	The medical condition for which a drug, test, or procedure is recommended, and which determines coverage eligibility.
ICD 10 AM Code	The standardized coding system for diseases and health conditions, used for classifying and reporting clinical indications.
Drug pharmacological Class	A group of active substances that share similar pharmacological properties, defined by their mechanism of action, physiological effect
Drug pharmacological Subclass	A more specific category within a pharmacological class, providing detailed classification of the drug's behavior or structure.
Scientific Name	The active ingredient of the product that is responsible for the beneficial health effects experienced by consumers.
Scientific Description Code Root	This a code generated by the SFDA and is unique per scientific name (active ingredient).
Substitutable	Indicates whether the drug may be substituted with an equivalent alternative, based on SFDA guidance.
ATC Code	The ATC Classification is an internationally accepted classification system for medicines that is maintained by the WHO. The WHO assigns ATC codes to all active substances contained in medicines based on the therapeutic indication for the medicine.
Pharmaceutical Form	It 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.

Field	Definition
Pharmaceutical Form Code Root	This Unique numerical SFDA code is generated for each Dosage form (Pharmaceutical form) e.g., Tablet:100000073664
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.
Administration Route	Refers to the method in which a medication is introduced to the body e.g., Oral, Intravenous, Intramuscular, rectal.
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.
Prescribing edits	Coverage rules or conditions that must be met before a drug is approved, such as prior authorization or step therapy.
Quantity Limit Adults/Pediatrics	The maximum daily dose is allowed for adult or pediatric patients, based on clinical justification. If not applicable, the field is marked as 'NA' or left blank.
Notes	Additional prescribing information, including restrictions, warnings, or administrative notes relevant to the product.
Patient Type	Specifies the care setting in which the drug is covered, such as inpatient use only.
SFDA Registration Status	Indicates whether the drug is officially registered with the SFDA, marked as 'Yes' or 'No'.

2- DDF Drug Classification and Codes

What Information Does the Mapped DDF To SFDA Sheet Provide?

The “Mapped DDF to SFDA” includes the list of scientific molecules included in the “Indication Sheet” regularly mapped with SFDA medication list. This mapping, based on the SFDA description prices code, is used to identify corresponding trade names and associated.

Scientific Name	Scientific Description Code Root	ATC Code	Pharmaceutical Form and Code	Description Code	Administration Rout	Strength and Strength unit	Trade Name
Registration Number (new and old)	GTIN	Last Update Date	RegisterYear	Product Type	Drug Type and Sub-Type	ATC Code 2	Size and Size Unit
Package Types and Size	Legal Status	Product Control	Distribute area	Public Price	Shelf Life	Storage conditions	Marketing Company and Country

Manufacture Name, DMS ID and country	Secondary Package Manufacture	Agent (main, 2nd and 3rd)	Marketing Status	Authorization Status

These fields are like those of the SFDA, please refer to Appendix 1

2- DDF Drug Classification and Codes

Examples from the “Indication Sheet”

	Crestor 20 mg film coated tablets	Stelara 90mg/1ml solution for injection
Indication	Dyslipidemia	Psoriasis
ICD 10 AM Code	E78	L40
Drug pharmacological Class	Lipid modifying agents, plain	Immunosuppressants
Drug pharmacological Subclass	HMG-Coa reductase inhibitors	Interleukin inhibitors
Description Code	7000001121-20-100000073665	7000001301-90-200000016496
Scientific Name	Rosuvastatin	Ustekinumab
Scientific Description Code Root	7000001121	7000001301
ATC Code	C10AA07	L04AC05
Pharmaceutical Form	Film-coated tablet	Solution for injection in pre-filled syringe
Pharmaceutical Form Code Root	100000073665	200000016496
Administration Route	Oral use	Subcutaneous use
Strength	20	90
Strength Unit	Mg	Mg/ml
Substitutable	-	-
Prescribing Edit	CU	PA, MD, QL
MDD Adults	NA	300 mg subcutaneous at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks
MDD Pediatric	NA	NA
Notes		
Appendix	Appendix 54	Appendix
Patient Type		-
SFDA Registration Status	Yes	Yes

3- NPHIES Drug Classification and Codes

Overview of NPHIES

The National Platform for Health and Insurance Exchange Services (nphies) is a joint initiative led by the Council of Health Insurance (CHI) in collaboration with the National Health Information Center and the Ministry of Health in Saudi Arabia. Launched as part of the Kingdom's Vision 2030 goals to enhance the healthcare sector, nphies aims to establish a unified digital infrastructure for exchanging patient health information across stakeholders, including healthcare providers, insurance companies, third-party administrators, and system suppliers.

NPHIES Features

nphies provides a unified digital platform designed to streamline healthcare operations and improve data integrity across Saudi Arabia's health ecosystem. Its core features include a unified health record, standardized medical codes, and reliable, interoperable data exchange. The platform supports digitization of services, governance and regulatory oversight, and facilitated access to care. By minimizing administrative burdens and reducing operational costs, nphies enables greater efficiency for providers, payers, and third-party administrators. Ultimately, it aims to enhance beneficiary health outcomes and align healthcare delivery.

NPHIES Metadata

The extracted core metadata fields outlined in slides 17 and 18 from the NPHIES platform are essential for drug-level claims analysis. They support standardized data structuring, enable precise mapping to regulatory sources, and facilitate analyses of utilization trends, substitution behavior, and reimbursement compliance.

The full NPHIES metadata contains many additional fields, only those directly applicable to drug-related claims have been included in this report

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"Nphies Activation." *Chi.gov.sa*, 11 Mar. 2021, www.chi.gov.sa/en/MediaCenter/News/Pages/News-11-3-2021.aspx.
NPHIES منصة نفيس | التبادل الصحي والتأميني الرقمي. "نفيس." *Nphies.sa*, 2025, nphies.sa/about.

3- NPHIES Drug Classification and Codes

Drug Examples

Variables		Crestor 20 mg film coated tablets	Stelara 90mg/1ml solution for injection
Item Code	Product_or _Service _Code	5000456011013	05413868100990
Item Description	Display	Crestor 20 mg film coated tablets	Stelara 90mg/1ml solution for injection
Type	Activity_Type	Medication	Medication

03

Comparing Pharmaceutical Classification Systems

- *SFDA VS CHI Formulary “Daman Drug Formulary”*
- *Consistency of Drug Classification with SFDA Specifications*

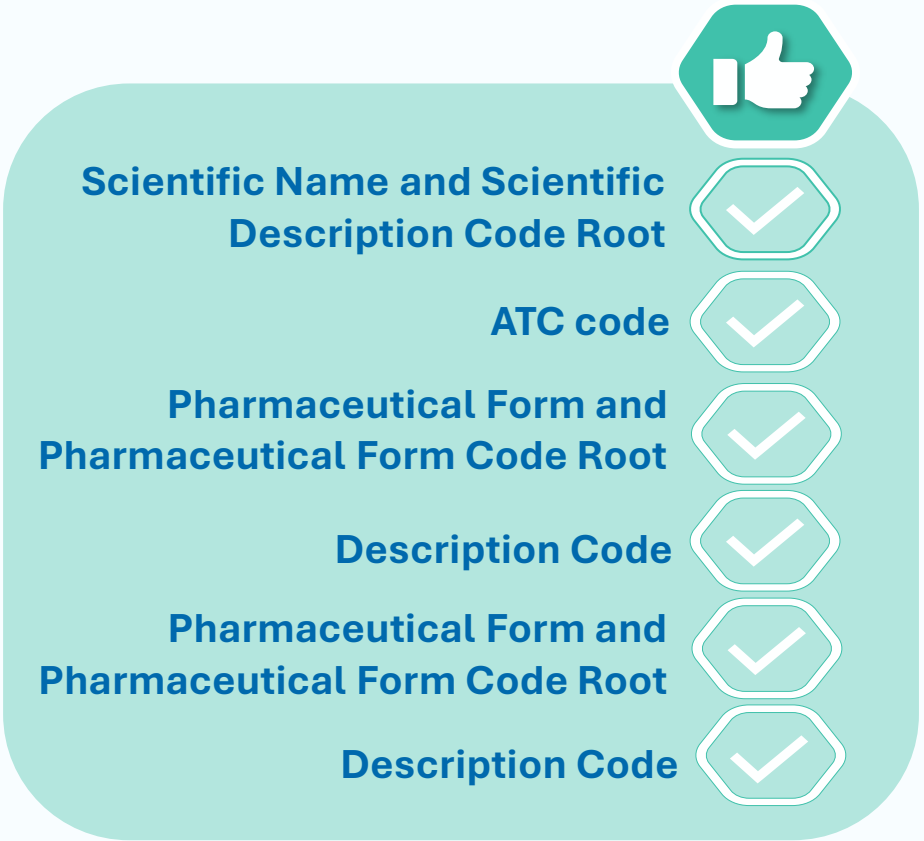
Comparing Pharmaceutical Classification Systems

This section presents a comparative mapping of drug classifications across SFDA, DDF, and NPHIES. The exercise aims to uncover areas of consistency and discrepancy, highlighting overlapping definitions and terminologies.

SFDA VS CHI Formulary “Daman Drug Formulary”

SFDA vs Indication Sheet

The CHI Indication Sheet shares core data fields with the SFDA database, allowing for alignment and traceability between formulary entries and registered products. It also includes additional fields specific to insurance coverage and utilization management, which are beyond the scope of the SFDA dataset.



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SFDA VS CHI Formulary “Daman Drug Formulary”

SFDA vs Mapped DDF to SFDA Sheet

The "Mapped DDF to SFDA" sheet links CHI’s formulary with SFDA’s drug database. It lists scientific molecules mapped to SFDA trade names and public prices, using the same layout and fields as the SFDA list. This ensures easy cross-referencing and keeps CHI’s formulary aligned with SFDA updates.

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SFDA VS CHI Formulary “Daman Drug Formulary”

SFDA vs NPHIES

Two key fields serve as common linkage points between the systems:

SFDA and NPHIES operate in distinct yet interconnected domains

The shared identifiers between SFDA and NPHIES enable seamless integration, while ensuring alignment with SFDA’s standardized drug codes and classifications for consistent drug identification and regulatory compliance.

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Consistency of Drug Classification with SFDA Specifications

Crestor 20 Mg Film Coated Tablets

	Register Number	Register Year	Old register Number	Product type	Drug Type	Sub-Type	Scientific Name	Scientific Description Code Root	Trade Name	Strength / unit
SFDA	1506233820	2004	54-7-04	Human	NCE	(Blank)	Rosuvastatin	7000001121	Crestor 20 mg film coated tablets	20 mg
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

	Pharma Form	Pharma form Code Root	Administration Route	AtcCode1	AtcCode2	Size	Size Unit	Package Types	Package Size	Legal Status
SFDA	Film-coated tablet	100000073665	Oral use	C10AA07	(Blank)	(Blank)	(Blank)	Blister	28	Prescription
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

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Consistent ● Not Consistent ●

Consistency of Drug Classification with SFDA Specifications

Crestor 20 Mg Film Coated Tablets

	Product Control	Distribute area	Public price	shelfLife	Storage conditions	Marketing Company	Marketing Country	Manufacture Name	Manufacture Country	2nd Manufacture Name
SFDA	Uncontrolled	Pharmacy	130.65	36	store below 30°c	AstraZeneca	United Kingdom	LPR pharmaceuticals	United States	(Blank)
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

	2nd Manufacture Country	Secondary package manufacture	Main Agent	Second Agent	Third Agent	Marketing Status	Authorization Status	Description Code	GTIN	Last Update
SFDA	(Blank)	Tabuk pharma	Al Naghi Company	(Blank)	(Blank)	Marketed	Valid	7000001121-20-100000073665	5000456011013	10/1/2023
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

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● Consistent ● Not Consistent

Consistency of Drug Classification with SFDA Specifications

Stelara 90mg/ml solution for injection

	Register Number	Register Year	Old register Number	Product type	Drug Type	Sub-Type	Scientific Name	Scientific Description Code Root	Trade Name	Strength / unit
SFDA	1511222905	2013	20-626-21	Human	Biological	Other	Ustekinumab	7000001301	Stelara 90mg/1ml	90 mg/ml
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

	Pharma Form	Pharma form Code Root	Administration Route	AtcCode1	AtcCode2	Size	Size Unit	Package Types	Package Size	Legal Status
SFDA	Solution for injection in pre-filled syringe	200000016496	Subcutaneous use	L04AC05	(Blank)	1	ml	Pre-filled syringe	1	Prescription
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

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● Consistent ● Not Consistent

Consistency of Drug Classification with SFDA Specifications

Stelara 90mg/ml solution for injection

	Product Control	Distribute area	Public price	shelfLife	Storage conditions	Marketing Company	Marketing Country	Manufacture Name	Manufacture Country	2nd Manufacture Name
SFDA	Uncontrolled	Hospital	11103.25	36	store in a refrigerator	Janssen-Cilag International NV	Belgium	Baxter pharmaceuticals	United States	(Blank)
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

	2nd Manufacture Country	Secondary package manufacture	Main Agent	Second Agent	Third Agent	Marketing Status	Authorization Status	Description Code	GTIN	Last Update
SFDA	(Blank)	(Blank)	Cigalah Group	(Blank)	(Blank)	Marketed	Valid	7000001301-90-200000016496	5413868100990	30/28/2023
DDF Indication Sheet	●	●	●	●	●	●	●	●	●	●
DDF Mapped Sheet	●	●	●	●	●	●	●	●	●	●
NPHIEs	●	●	●	●	●	●	●	●	●	●

Consistent ● Not Consistent ●

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04

Using Data Linkage to Harmonize Pharmaceutical Classification

- *NPHIEs to SFDA Matching*
- *Drug Type Standardization*
- *Route of Administration Grouping*
- *Strength and Strength Units Harmonization*
- *CHI Harmonized Drug List Proposed Preliminary List*
- *Final Quality Check and Cleaning*

Using Data Linkage to Harmonize Pharmaceutical Classification

Objectives

For analysis of generic and biosimilar penetration, cost savings, and other data, **a matching process** between NPHIES and SFDA datasets, combined with **standardization steps**, followed by a cleaning process was performed to accurately classify drugs, enabling reliable analysis and promoting alignment across the system.

As part of CHI's ongoing monitoring efforts within the NPHIES platform, analyzing pharmaceutical data requires robust data linkage to harmonize drug classification. This alignment will enhance CHI's capacity to effectively assess generic and biosimilar uptake, enabling more accurate monitoring and identification of cost-saving opportunities

Steps Towards a Harmonized Drug List

Step 1:
NPHIES and SFDA Matching

NPHIES data is matched with SFDA to retrieve drug attributes including type, route of administration, package size, and strength.

Step 2:
Drug Type Standardization

A rule-based approach was applied to standardize drug type classification by referencing SFDA's classification. This involved mapping diverse entries based on shared attributes like scientific name.

Step 3:
Route of Administration Grouping

Routes of administration were harmonized using SFDA's official list by grouping synonymous or equivalent terms under a unified standard.

Step 4:
Strenght and Strength Unit Harmonization

Strength values were standardized to a common unit within each scientific name to maintain consistency across different products.

Step 1: Matching NPHIEs to SFDA

Exact Matching

- Identify exact matches between NPHIES and SFDA drugs by product codes (GTIN and Product_or_Service_Code) or drug names (Trade Name and Display).
- Matched drugs automatically receive SFDA attributes.

Approximate Matching

- For unmatched drugs, compare drug names based on:
  - Drug base Name (first word): Similarity at ≥95% accuracy.
  - Drug Numbers: Numeric parts of the drug name must match exactly.
- If the drug base name matches, SFDA attributes that describe the general identity of the drug are added (Scientific Name, Drug Type, …)
- If numeric parts also match exactly, additional SFDA attributes that are sensitive to precise dosage and packaging details are added (Description Code, Strength, …).

Remaining Unmatched Drugs

- Drugs without a successful match after the above steps remain unmatched and don't receive additional attributes from SFDA.

Disclaimer: Unmatched Drugs

Delisted: Include the unmatched drugs, despite matching with GTIN and Descriptions.

Unlisted: Include unlisted drugs from SFDA, having GTIN codes like 9999999999999,999999990,9999999999996, etc.

A qualitative assessment to explore the breakdown of the Unmatched Drugs will be detailed in another report.

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Step 2: Drug Type Standardization

Rules Based Approach to Drug Type Classification

1 Reading the primary drug type (e.g., NCE, Biologic, Generic).

2 Interpreting the subtype field, if available (e.g., Biosimilar, blood product).

3 Applying rules to assign a clear, unified category for consistent classification.

SFDA DRUG TYPE		SFDA DRUG SUB-TYPE		STANDARDIZED AS
Radiopharmaceuticals or Blank or NCE (New Chemical Entities)	+	-	=	Brand (NCE)
Biological		Biological , Allergen Products, Biotech Products, Blood Products, Vaccines, Other, or Blank		Originator
Biological		Biosimilar		Biosimilar
Generics		Blood products		Originator
Generics		NCE		Brand (NCE)
Generics		IV Solution, Known Active Substance, Other, or Blanks		Generic

Please refer to **Appendix 8** for the rationale behind SFDA Drug Type standardization was suggested.

Step 2: Drug Type Standardization

Manual Corrections

Following the Rules-Based Approach to Drug Type Classification, certain inconsistencies were identified that required manual correction to ensure accurate and unified classification.

Errors Necessitating Manual Correction

Each drug is grouped at the molecule level, based on its scientific name (active substance). If any product associated with a molecule shows inconsistent or conflicting drug type classification (e.g., mixture of brand, generic, originator, or biosimilar labels within the same molecule group), the entire group is flagged for review.

Manual Label Adjustments within Flagged Groups

Once a group is flagged, the following manual corrections were applied to standardize classification:

- **Products labeled as "Generic" within a flagged molecule group** are reclassified as **"Biosimilar"** if the molecule is a biologic, reflecting the correct regulatory category.
- **Products labeled as "Brand (NCE)" within a flagged molecule group** are reclassified as **"Originator"** if they represent the original branded product for that molecule.
- **All other product labels** (e.g., already correctly classified as Originator, Biosimilar, Brand (NCE), or Generic) **remain unchanged**.

Examples

Trade Name	Standardized Drug Type	Manually Amended Drug Type
HERCEPTIN 150MG VIAL	Generic	Originator
SANDOSTATIN LAR 20MG VIAL	Originator	Brand (NCE)
SANDOSTATIN LAR 30MG VIAL	Originator	Brand (NCE)
SANDOSTATIN 0.1MG-ML AMP	Originator	Brand (NCE)

Please refer to **Appendix 2** for the comprehensive list of manual corrections applied during the Drug Type Standardization process.

Step 3: Route of Administration Grouping

Why Grouping Was Needed

Similar or synonymous routes (e.g., IV, Injection, Parenteral) are often labeled differently. This variability hinders accurate classification, comparability, and data analysis

For meaningful and standardized data analysis, route of administration grouping was performed (e.g., IV, SC, and IM grouped as Parenteral)

Trade Name	Scientific Name	Administration Route	strength
MIACIN 500MG-2ML AMP	Amikacin	Parenteral use	500 mg
AMCOCID 500MG-2 ML AMP	Amikacin	Parenteral use	500 mg
AMKANT	Amikacin	Intramuscular and intravenous use	500 mg

Trade Name	Scientific Name	Administration Route	strength
UNASYN 1000:500MG VIAL	Ampicillin, Sulbactam	Intramuscular and intravenous use	1500 mg
AMPIPLUS 1.5GM POWDER FOR INGECTION	Ampicillin, Sulbactam	Parenteral use	1500 mg

Step 3: Route of Administration Grouping Cont'd

1. Synonymous and clinically equivalent administration route terms were grouped into standardized categories (see appendix 3 for examples)
2. A rule-based mapping approach was applied, followed by manual review and expert validation to ensure accuracy.
3. The process was implemented for applicable administration routes; others remained unchanged (see appendix 4 for the unchanged list).

Manual Corrections

LUCENTIS 10 Mg-mL Intravitreal Injection	Intravenous use → Intravitreal use
DEVARIN 10 Mg Orodispersible Tablet	Ocular use → Oral Use

Grouped Categories

Parenteral use

- Intravenous
- Intravenous use
- Parenteral use
- Intramuscular use
- Subcutaneous use
- Intramuscular, subcutaneous
- Intravenous, Intravesical
- Intramuscular and intravenous use
- Intrathecal, Intravenous, Intramuscular
- Intravenous, Subcutaneous
- Intravenous, Intramuscular, Subcutaneous
- Intravenous bolus use

Oral use

- Oral use
- Oromucosal use
- Sublingual use

Topical use

- Topical
- Cutaneous use
- Epilesional use

Nasal use

- Nasal use
- nasal use

Ocular use

- Ophthalmic use
- Ocular use

The finalized standardized routes were then integrated into the dataset for consistent reporting and analysis.

Step 4: Strength and Strength Units Harmonization

Grouping by Scientific Name

- Products were first grouped based on their scientific (generic) name.
- This grouping allowed for evaluating consistency in strength and strength unit across all product variations under the same molecule.

Retaining Original Strengths When Units Were Uniform

- If all products within a scientific name group used the same strength unit (e.g., mg or IU), the original strength values were retained.
- No conversion was needed, as the data was already consistent and directly comparable.

Converting to a Dominant Strength Unit When Units Varied

- When products under the same scientific name had varying strength units, all values were converted to the most common (dominant). For example:
  - Products listed in mcg were converted to mg.
  - Products in mg/mL were converted to mg by multiplying by the package size

Scientific Name	AdministrationRoute	Strength	Strength Unit	Size	Size Unit	New Strength	New Strength Unit
Risperidone	oral use	1	mg			1	mg
Risperidone	oral use	2	mg			2	mg
Risperidone	oral use	3	mg			3	mg
Risperidone	oral use	4	mg			4	mg
Risperidone	oral use	1	mg/ml	100	ml	100	mg

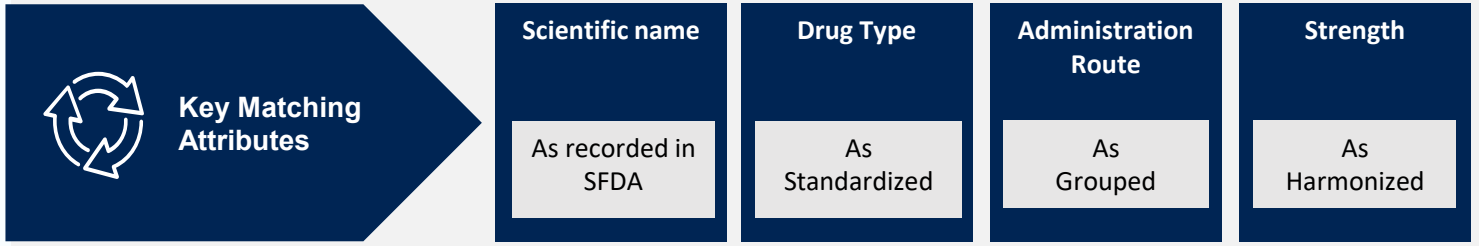
Step 5: CHI Harmonized Drug List

Proposed Preliminary List

Matching Methodology

- To support analyses related to generic utilization and cost savings, a standardized classification approach was developed to determine whether a drug has an available alternative.
- A drug is classified as with alternative if another product with the same scientific name and matching attributes (such as route of administration and strength) is available but categorized under a different drug type* (such as a Brand with a Generic alternative, or an Originator with a Biosimilar alternative).

The methodology relies on a combination of product-specific attributes retrieved through matching NPHIES and SFDA datasets. (refer to appendix 5 for example)

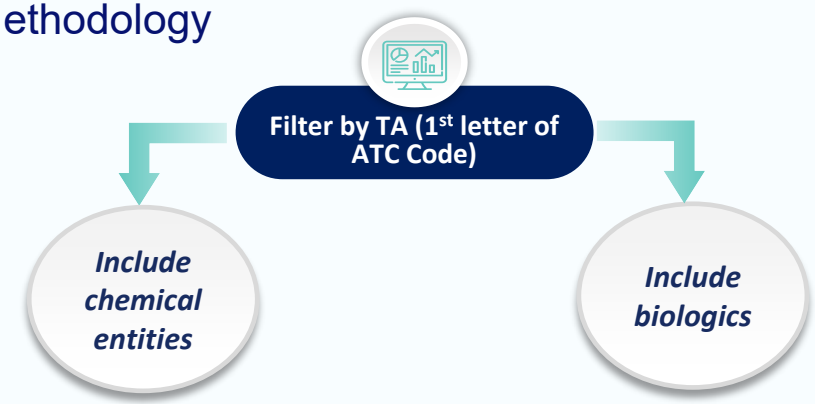


This List is only used for data analysis purpose and not for substitution purposes .

First Layer of Quality Check

To pilot the harmonization approach, a representative sample of products across various therapeutic areas and molecule types was selected. This is a manual check related to the findings, for cleaning purposes.

Methodology



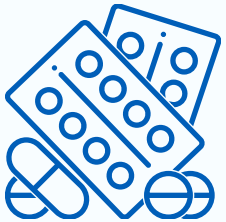
Scientific Names

61

Biologic Products

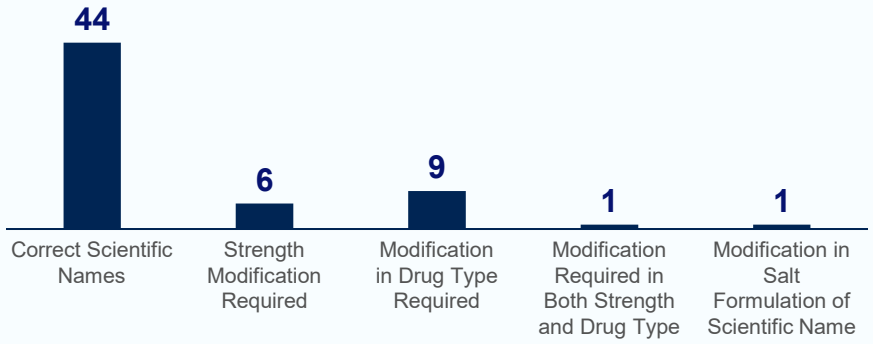
21

Chemical Products



40

Results of Quality Check: 72% Success



Rounding Errors in Strength Standardization

Budesonide 0.125 mg/mL and 0.25 mg/mL were both rounded to 0 mg. They were wrongly reported as alternatives.

Scientific Name Order Mismatch

Scientific names reported in reverse order were not captured as alternatives to each other:

- Metformin HCL, Pioglitazone vs
- Pioglitazone, Metformin HCL

Missing Salt Forms

Salt forms missing in records led to mapping errors (e.g., Atovaquone/ Proguanil vs Atovaquone/ Proguanil Hydrochloride).

Blank Strength Records

Blank strength records, such as Haluran Inhalation Solution (Sevoflurane), required manual correction (e.g., assign 250 mL strength to match similar products).

Second Layer of Quality Check: Coding and Systematic Validation

To further strengthen drug type standardization, a second quality check was performed, involving coding techniques to capture and map trade names systematically. This step aimed to identify and standardize trade names that were still reported with inconsistent drug type classifications.

Coding and Mapping of Trade Names

A search strategy was applied to automatically capture trade names with unique first word and their reported drug types. This enabled efficient detection of inconsistencies for targeted manual review.

For example, for Valium, all instances of “VALIUM” and similar trade name variants were retrieved along with their assigned drug type.

Manual Review Criteria

The manual verification process after coding relied on:

- Grouping by scientific name, trade name, year of registration in SFDA, and product strength.
- Identifying the first registered product for a molecule (typically classified as Brand (NCE) or Originator, with unique strength), while noting that If a new product introduced a new dosing strength, it was also classified as Brand or Originator.
- Where multiple products were labeled as Brand, year of SFDA registration and globally acknowledged trade names were used to confirm correct Brand/Originator status.

Resolution of Discrepancies

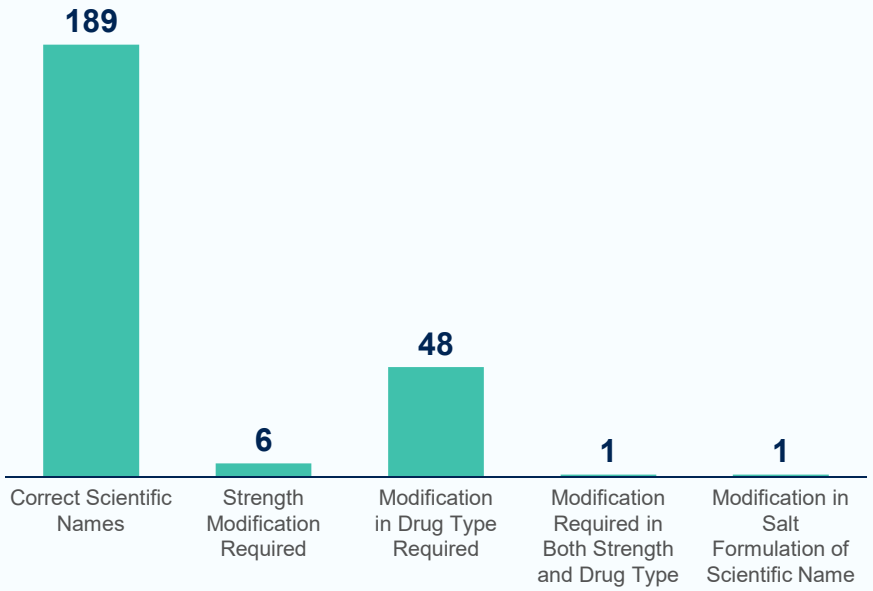
All inconsistencies were reviewed and corrected to align with regulatory definitions and market realities.

116	UNIQUE **FIRST-WORD TRADE NAMES** IDENTIFIED
31	UNIQUE **FIRST-WORD TRADE NAMES** FLAGGED FOR REVIEW
53	TOTAL NUMBER OF **SFDA PRODUCTS** WITH MANUAL CORRECTIONS

Please refer to **Appendix 6** for the comprehensive list of manual corrections applied during the Final Layer of Quality Check.

Results of Both Quality Checks

Results of Piloting: **77.14% Success**



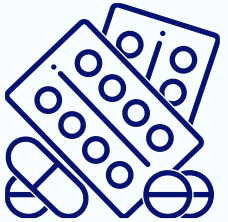
Scientific Names

245

Biologic Products

27

Chemical Products



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مجلس الضمان الصحي
Council of Health Insurance

05 Key Outputs & Pilot Implementation

Key Output and Pilot Implementation

Please refer to the CHI Harmonized Drug List (December).
Periodically Updated & Published Every 3 Months.

CHI Harmonized Drug List

To provide a standardized and classified dataset by adding four fields, standardized drug type, strength, route of administration, and therapeutic alternatives status, to the existing SFDA list

The pilot will be implemented via NPHIES Intelligence reports, enabling direct integration into the CHI dashboard for automated extraction and streamlined analysis.

This List is only used for data analysis purpose and not for substitution purposes.

Appendix

Abbreviations

AMCP	Academy of Managed Care Pharmacy
API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical
CHI	Council of Health Insurance
DDF	Daman Drug Formulary
GTIN	Global Trade Item Number
NCE	New Chemical Entity
NPHIES	National Platform for Health and Insurance Exchange Services
NHIC	National Health Information Center
SFDA	Saudi Food and Drug Authority
SHC	Saudi Health Council
TPAs	Third-party Administrators
WHO	World Health Organization

Terminologies

- **DDF 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.
- **DDF Mapped IDF 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.**SFDA:** The Saudi Food and Drug Authority (SFDA) is the national regulatory body responsible for the approval, registration, and oversight of all pharmaceutical products in Saudi Arabia.
- **CHI:** The Council of Health Insurance (CHI) is responsible for the National Unified Drug Formulary (DDF), also known as the Insurance or Daman Drug Formulary, as part of its regulatory role in the private health insurance sector in Saudi Arabia.
- **NPHIES:** National Platform for Health and Insurance Exchange Services (NPHIES) is the national unified digital health platform developed by the Saudi Health Council (SHC) in collaboration with CHI and operated by Sehati.
- **Drug Type:** Refers to the classification of a drug based on its type: originator, generic, brand, or biosimilar.
- **Brand:** A brand drug is a medication approved through a full application that includes all required data on safety, effectiveness, and manufacturing. It is typically protected by patents and is the reference standard for generic versions. It is sold under a proprietary (trademarked) name chosen by the manufacturer.
- **Generic:** A generic drug is a medication that is the same as its brand-name counterpart in active ingredient, dosage form, strength, route of administration, safety, effectiveness, and intended use. It demonstrates bioequivalence and meets the same quality standards but may differ in inactive ingredients or appearance. Generics are approved through an abbreviated pathway, allowing faster and more affordable access to treatments.
- **Biologics**: Biologics are medical products such as vaccines, blood components, gene therapies, and therapeutic proteins. They are derived from natural sources (human, animal, or microorganism) and are often produced using biotechnology.
- **Reference Product (herein referred to as Originator):** A reference product is an FDA-approved biological product that was approved through a stand-alone application containing full data on its safety and effectiveness for each of the indications being sought. It serves as the standard against which a proposed biosimilar is evaluated.
- **Biosimilar:** A biosimilar is a biologic that is highly similar to its reference product (originator), with no clinically meaningful differences in safety, purity, or potency. It is approved through an abbreviated pathway focused on demonstrating similarity rather than independently proving safety and effectiveness.

CHI Drug Formulary Master Excel Sheet User Guide. 2023.
FDA. “Generic Drugs: Questions & Answers.” FDA, 16 Mar. 2021, www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.
Wagener, Dan. “What’s the Difference between a Brand-Name Drug and a Generic Name Drug?” *GoodRx*, GoodRx, 16 Aug. 2019, www.goodrx.com/drugs/medication-basics/brand-vs-generic-drugs.
Center for Biologics Evaluation and Research. “What Are “Biologics” Questions and Answers.” FDA, 6 Feb. 2018, www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.
FDA. “Review and Approval.” FDA, 13 Dec. 2022, www.fda.gov/drugs/biosimilars/review-and-approval.

Appendix 1 – SFDA Fields and Definitions

Field Name	Definition
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 ….
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
Product Type	Human Drug
Drug Type	It is an abbreviation used by the SFDA to describe the product marketing status: Radiopharmaceuticals, NCEs (New Chemical Entities, Biological or Generics
Sub-type	It is an abbreviation used by the SFDA to sub categorize the product marketing status: Biological, Allergen Products, Biotech Products, Blood products, Vaccines, Biosimilar, IV solution, Known Active Substance, Other
Scientific Name	It 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	It is a code generated by the SFDA and is unique per scientific name (active ingredient)
Trade Name	it is the trademark name given to a specific medication and can be either brand or generic
Strength	It is the amount of drug in each dosage form, for example, 500 mg/tablet.
Strength Unit	It is the unit of measurement used by the SFDA to describe the product strength e.g., mg, G, mmol.
Pharmaceutical Form	It 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	It is Unique numerical SFDA generated code for each Dosage form (Pharmaceutical form) e.g., Tablet:100000073664
Administration Route	Refers to the method in which a medication is introduced to the body e.g., Oral, Intravenous, Intramuscular, rectal.
ATC Code	It 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.
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
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

Appendix 1 – SFDA Fields and Definitions Cont’

Field Name	Definition
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	Refers to Saudi Arabia (local) or any other manufacturing country (imported).
Second Manufacturer Name	
Second Manufacturer Country	
Secondary Package Manufacture	مصنع التغليف الثانوي
Main Agent	الوكيل الأول
Second Agent	الوكيل الثاني
Third Agent	الوكيل الثالث
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
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.
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.

Appendix 2 – List of Manual Corrections on Drug Type Standardization

Trade Name	Standardized Drug Type	Manually Amended Drug Type
VICTOZA 6MG/ML SOLUTION FOR INJECTION	Brand (NCE)	Originator
STALORAL POLLENS MAINTENANCE	Brand (NCE)	Originator
ACTEMRA 20 MG/ML SOLUTION FOR INJECTION/INFUSION	Brand (NCE)	Originator
ACTEMRA 20 MG/ML SOLUTION FOR INJECTION/INFUSION	Brand (NCE)	Originator
ACTEMRA 20 MG/ML SOLUTION FOR INJECTION/INFUSION	Brand (NCE)	Originator
AVASTIN 400 SOLUTION FOR INFUSION	Brand (NCE)	Originator
AVASTIN 100 SOLUTION FOR INFUSION	Brand (NCE)	Originator
FOSTIMON HP 75 IU VIAL (IM) USE	Generic	Biosimilar
FOSTIMON HP 150 IU VIAL IM(WOMEN URIN)	Generic	Biosimilar
HERCEPTIN 150MG VIAL	Generic	Originator
TYSABRI 300 MG/15ML	Brand (NCE)	Originator
SAXENDA 6 MG/ML SLOUTION FOR INJECTION IN PRE-FILLED PEN	Brand (NCE)	Originator
HUMIRA 40MG/0.4ML PRE- FILLED SYRINGE	Brand (NCE)	Originator
MENOPUR MULTIDOSE	Brand (NCE)	Originator
MENOPUR MULTIDOSE	Brand (NCE)	Originator
MENOPUR 75 IU POWDER FOR SOLUTION FOR INJECTION	Brand (NCE)	Originator
COSENTYX 150 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN	Brand (NCE)	Originator
ACTEMRA 162 MG/0.9 ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	Brand (NCE)	Originator
NEULASTIM 6MG-0.6ML PRE-FILLED SYRINGE	Brand (NCE)	Originator
HEPARINOL 5000 IU/ML INJECTION	Generic	Biosimilar
HEPARINOL 1000 IU/ML INJECTION	Generic	Biosimilar
MENOPUR 75 IU POWDER FOR SOLUTION FOR INJECTION	Brand (NCE)	Originator

Trade Name	Standardized Drug Type	Manually Amended Drug Type
%ALBUNORM 20	Generic	Biosimilar
VAXCEL HEPARIN SODIUM INJECTION	Generic	Biosimilar
ZELYSSA 18 MG PER 3 ML	Generic	Biosimilar
EVONANZ 18 MG PER 3 ML	Generic	Biosimilar
VALIUM TAB 2 MG	Generic	Brand (NCE)
VALIUM TAB 5 MG	Generic	Brand (NCE)
VALIUM AMP 10 MG-2 ML	Generic	Brand (NCE)
GLUCOPHAGE 850MG TABLET	Generic	Brand (NCE)
GLUCOPHAGE 500MG TABLET	Generic	Brand (NCE)
GLUCOPHAGE	Generic	Brand (NCE)
TIOMIST	Brand (NCE)	Generic
ACICLOVIR 250 MG/10ML	Brand (NCE)	Generic
ACICLOVIR 500 MG/20ML	Brand (NCE)	Generic
SANDOSTATIN LAR 20MG VIAL	Originator	Brand (NCE)
SANDOSTATIN LAR 30MG VIAL	Originator	Brand (NCE)
SANDOSTATIN 0.1MG-ML AMP	Originator	Brand (NCE)
OCRAN	Biosimilar	Generic
SYNGRO	Biosimilar	Generic
BASAGLAR TEMPO PEN	Originator	Biosimilar
BASALOG ONE	Originator	Biosimilar
VIVARO	Originator	Biosimilar
TRESIBA FLEXTOUCH 100 U/ML SOLUTION FOR INJECTION	Brand (NCE)	Originator
RYZODEG FLEXTOUCH 100 U/ML	Brand (NCE)	Originator
GLIPTAMET	Brand (NCE)	Generic
OZEMPIC	Originator	Brand (NCE)
RYBELSUS	Originator	Brand (NCE)

Appendix 3 – Examples for Route of Administration Grouping

Trade Name	Scientific Name	Administration Route	grouped Administration Route
Epinephrine Inj	Adrenaline	Intravenous use	Parenteral use
Dilute Adrenaline (Epinephrine) 1:10000 Solution For Injection	Adrenaline	Parenteral use	
Adrenaline 0.1mg/Ml Injection	Adrenaline	Intrathecal, Intravenous, Intramuscular	
Adrenaline 1:1000 Inj	Adrenaline	Intravenous use	
Adrenaline/Epinephrine Inj 1:1000 Injection	Adrenaline	Intramuscular use	
Adijet	Adrenaline	Intramuscular and intravenous use	
Aronep	Adrenaline	Intramuscular use	
VIAGRA 50 MG ORODISPERSIBLE TABLET	Sildenafil	oral use	Oral use
TURBO	Sildenafil	oromucosal use	

Appendix 4 – List of Unchanged Route of Administration

Dental use
Rectal use
Intravenous and Inhalation Use
Intravenous, Oral
Irrigation Use Only
Transdermal use
Auricular use
Intradermal use
Hemodialysis
Intraperitoneal
Intraarticular use
Intratracheal use
Oral use, Vaginal use
Oral, Rectal
Vaginal use
Inhalation use
Intrathecal use
Subretinal use
Intravitreal use
Intraabdominal use

Appendix 5 – CHI Harmonized Drug List Example

*The following tables present the classification of products as **With Alternative** or **Without Alternative**, based on the standardized drug type, strength, and route of administration. This classification reflects products that share the same scientific name but differ in drug type category (e.g., Brand vs. Generic, Originator vs. Biosimilar) following the standardization process.*

Drug Type	Sub-Type	New Drug Type	Trade Name	Scientific Name	Scientific Description Code Root	Pharmaceutical Form	AdministrationRoute	Strength	Strength Unit	Size	Size Unit	New Strength	New Strength Unit	Package Types	Package Size	Standardized Route	Alternative Status
Biological	Biological	Originator	CLEXANE 20MG\0.2ML PREFILLED SYRINGE	Enoxaparin Sodium	7000000453	Solution for injection	intravenous use	20	mg	0.2	ml	20	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biological	Originator	CLEXANE 40MG\0.4ML PREFILLED SYRINGE	Enoxaparin Sodium	7000000453	Solution for injection	intravenous use	40	mg	0.4	ml	40	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biological	Originator	CLEXANE 60MG\0.6ML PREFILLED SYRINGE	Enoxaparin Sodium	7000000453	Solution for injection	intravenous use	60	mg	0.6	ml	60	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biological	Originator	CLEXANE 80MG\0.8ML PREFILLED SYRINGE	Enoxaparin Sodium	7000000453	Solution for injection	intravenous use	80	mg	0.8	ml	80	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	17000000453	Solution for injection	intravenous, subcutaneous	150	mg	1	ml	150	mg	Pre-filled syringe	2	Parenteral Use	Without Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	17000000453	Solution for injection	intravenous, subcutaneous	120	mg	0.8	ml	120	mg	Pre-filled syringe	2	Parenteral Use	Without Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	7000000453	Solution for injection	intravenous, subcutaneous	100	mg	1	ml	100	mg	Pre-filled syringe	2	Parenteral Use	Without Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	17000000453	Solution for injection	intravenous, subcutaneous	80	mg	0.8	ml	80	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	17000000453	Solution for injection	intravenous, subcutaneous	60	mg	0.6	ml	60	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	17000000453	Solution for injection	intravenous, subcutaneous	40	mg	0.4	ml	40	mg	Pre-filled syringe	2	Parenteral Use	With Alternative
Biological	Biosimilar	Biosimilar	INHIXA	Enoxaparin Sodium	7000000453	Solution for injection	intravenous, subcutaneous	20	mg	0	ml	20	mg	Pre-filled syringe	2	Parenteral Use	With Alternative

Drug Type	Sub-Type	New Drug Type	Trade Name	Scientific Name	Scientific Description Code Root	Pharmaceutical Form	AdministrationRoute	Strength	Strength Unit	Size	Size Unit	New Strength	New Strength Unit	Package Types	Package Size	Standardized Route	Alternative Status
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	8	mg	0.16	ml	8	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	16	mg	0.32	ml	16	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	24	mg	0.48	ml	24	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	32	mg	0.64	ml	32	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	64	mg	0.18	ml	64	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	96	mg	0.27	ml	96	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative
NCE	Known Active Substance	Brand (NCE)	BUVIDAL	Buprenorphine	7000000180	Solution for injection	subcutaneous use	128	mg	0.36	ml	128	mg	Pre-filled syringe	1	Parenteral Use	Without Alternative

Appendix 6 – Additional Manual Corrections on Drug Type Standardization after the second quality check

Trade Name	Standardized Drug Type	Manually Amended Drug Type
ISOPTIN S.R 240MG F.COATED TAB	Generic	Brand (NCE)
ONE-ALPHA CAPS 0.25 MICROGM	Generic	Brand (NCE)
STALORAL POLLENS INITIAL	Brand (NCE)	Originator
STALORAL ANIMAL ORIGIN INITIAL	Brand (NCE)	Originator
STALORAL MITES INITIAL	Brand (NCE)	Originator
STALORAL MITES MAINTENANCE	Brand (NCE)	Originator
STALORAL ANIMAL ORIGIN MAINTENANCE	Brand (NCE)	Originator
STALORAL MOULDS INITIAL	Brand (NCE)	Originator
STALORAL MOULDS MAINTENANCE	Brand (NCE)	Originator
MUCOSOLVAN 30MG-5ML ORAL LIQUID	Generic	Brand (NCE)
MUCOSOLVAN 15MG-5ML ORAL LIQUID	Generic	Brand (NCE)
MUCOSOLVAN 30MG-5ML ORAL LIQUID	Generic	Brand (NCE)
MUCOSOLVAN LA 75MG CAPS	Generic	Brand (NCE)
ZITHROMAX 200MG-5ML SUSP.AFTER RECONSTIT	Generic	Brand (NCE)
UNITUM 5% GEL	Generic	Brand (NCE)
UNITUM VERDE 7.5 MG/5ML MOUTHWASH AND GARGLE	Generic	Brand (NCE)
BETNOVATE CREAM 0.1%	Generic	Brand (NCE)
BETNOVATE OINTMENT 0.1%	Generic	Brand (NCE)
GAVISCON DOUBLE ACTION ORAL SUSPENSION	Generic	Brand (NCE)
GAVISCON ADVANCE PEPPERMINT FLAVOR ORAL SUSPENSION	Generic	Brand (NCE)
GAVISCON ADVANCE PEPPERMINT LIQUID SACHET	Generic	Brand (NCE)
GAVISCON ADVANCE PEPPERMINT LIQUID SACHET	Generic	Brand (NCE)
GAVISCON COOL CHEWABLE TABLETS	Generic	Brand (NCE)
GAVISCON DOUBLE ACTION ORAL SUSPENSION	Generic	Brand (NCE)
GAVISCON ORIGINAL ANISEED ORAL SUSP	Generic	Brand (NCE)
GAVISCON PEPPERMINT CHEWABLE TABLETS	Generic	Brand (NCE)
GAVISCON PEPPERMINT LIQUID	Generic	Brand (NCE)

Trade Name	Standardized Drug Type	Manually Amended Drug Type
CENTRUM TABLET (ADVANCED FORMULA)	Generic	Brand (NCE)
DEPAKINE CHRONO 500MG TABS	Generic	Brand (NCE)
SUPRAX D 400MG TABLET	Generic	Brand (NCE)
LANOXIN 0.25MG/ML INJ	Generic	Brand (NCE)
HALDOL 5MG TABLET	Generic	Brand (NCE)
ELDOQUIN CREAM 2%	Generic	Brand (NCE)
LEVONIC	Brand (NCE)	Generic
IMODIUM 2MG CAPSULE	Generic	Brand (NCE)
VERMOX 100MG TABLET	Generic	Brand (NCE)
STALEVO 200-50-200MG FILM COATED TAB.	Generic	Brand (NCE)
DALACIN C 300MG CAPS	Generic	Brand (NCE)
ZAVEDOS 1MG/ML VIAL	Generic	Brand (NCE)
SILDENAFIL OHRE PHARMA	Brand (NCE)	Generic
FOSTER PRESSURISED SOLUTION FOR INHALATION	Generic	Brand (NCE)
REBIF 22 MCG/0.5 ML SOLUTION FOR INJECTION IN CARTRIDGE	Biosimilar	Originator
REBIF 44 MCG/0.5 ML SOLUTION FOR INJECTION IN CARTRIDGE	Biosimilar	Originator
EUVAX B 10MCG VIAL	Biosimilar	Originator
AMYDRAMINE PAEDIATRIC SYRUP	Generic	Brand (NCE)
CELEZON	Brand (NCE)	Generic
COZAAR 100 MG FILM-COATED TABLET	Generic	Brand (NCE)
DICYNONE 2ML-AMP 250MG	Originator	Brand (NCE)
DICYNONE 500 MG TABLETS	Originator	Brand (NCE)
NEUROVIT AMPOULES	Brand (NCE)	Generic
JALRA 50 MG TABLET	Brand (NCE)	Generic
JALRA 50 MG TABLET	Brand (NCE)	Generic
KLACID XL 500MG TAB	Generic	Brand (NCE)

Appendix 8 – SFDA Drug Type Examples

DrugType	Sub-Type	Scientific Name	ScientificDescriptionCodeF	Trade Name	Strength	StrengthUnit	PharmaceuticalFo
Biological	Biosimilar	Trastuzumab	7000001268	CANHERA 150MG VIAL	150	mg	Infusion
Biological	Biosimilar	Trastuzumab	7000001268	OGIVRI	420	mg	Lyophilisate for solution f
Biological	Biosimilar	Trastuzumab	7000001268	CANHERA	440	mg	Powder and solvent for soluti
Biological	Biosimilar	Trastuzumab	7000001268	HERZUMA 150MG VIAL	150	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	7000001268	Kanjinti	150	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	27000001268	Kanjinti	420	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	7000001268	Trazimera	150	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	17000001268	HERZUMA	440	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	7000001268	Trazimera	440	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	7000001268	Ontruzant	150	mg	Powder for concentrate for solu
Biological	Biosimilar	Trastuzumab	7000001268	Ontruzant	420	mg	Powder for concentrate for solu

Drug Type Standardized to Biosimilar

DrugType	Sub-Type	Scientific Name	ScientificDescriptionCodeF	Trade Name	Strength	StrengthUnit	PharmaceuticalForm
Generic	ew Chemical Enti	DIACEREIN	7000001802	Cartimov	50	mg	Capsule, hard
Generic	ew Chemical Enti	LOTEPREDNOL ETABONATE	7000002226	Lotrell	0.5	%	Eye drops, suspension
Generic	ew Chemical Enti	RASAGILINE	7000001744	Ragilin	1	mg	Tablet

Drug Type Standardized to Generics

DrugType	Sub-Type	Scientific Name	ScientificDescriptionCodeF	Trade Name	Strength	StrengthUnit	PharmaceuticalForm
Radiopharmaceutical		GADOTERIC ACID	7000000565	DOTAREM 0.5MOL-L GLASS BOTTLE W-STOPPER	27.932	g	Solution for injection
Radiopharmaceutical		GADOTERIC ACID,GADOLINIUM OXIDE,DOTA	21000005388	DOTAREM 0.5MOL-L GLASS BOTTLE W-STOPPER	27.932,9.062,20.246	g,g,g	Solution for injection
Radiopharmaceutical		GADOTERIC ACID,GADOLINIUM OXIDE,DOTA	21000005388	DOTAREM 0.5MOL-L GLASS BOTTLE W-STOPPER	27.932,9.062,20.246	g,g,g	Solution for injection
Radiopharmaceutical		RADIUM RA-223 DICHLORIDE	7000001083	XOFIGO 1100 kBq/ml Solution for Injection	1100	kBq/ml	Solution for injection
Radiopharmaceutical		LUTETIUM 177LU VIPIVOTIDE TETRAXETAN	7000002742	PLUVICTO	1000	MBq/ml	Solution for injection/infusion
Radiopharmaceutical		GADOTERIC ACID	7000000565	DOTAREM 376MG-ML PREFILLED SYRINGE	376	mmol/ml	Suspension for injection in pre-filled
Radiopharmaceutical		GADOTERIC ACID	7000000565	DOTAREM 376MG-ML PREFILLED SYRINGE	376	mmol/ml	Suspension for injection in pre-filled

Drug Type Standardized to Brand (NCE)

DrugType	Sub-Type	Scientific Name	ScientificDescriptionCodeF	Trade Name	Strength	StrengthUnit	PharmaceuticalForm
Generic	Blood product	NORMAL HUMAN IMMUNOGLOBULIN	27000000906	KIOVIG 100MG/ML SOLUTION FOR INFUSION	100	mg/ml	Solution for infusion
Generic	Blood product	NORMAL HUMAN IMMUNOGLOBULIN	27000000906	KIOVIG 100MG/ML SOLUTION FOR INFUSION	100	mg/ml	Solution for infusion
Generic	Blood product	NORMAL HUMAN IMMUNOGLOBULIN	27000000906	KIOVIG 100MG/ML SOLUTION FOR INFUSION	100	mg/ml	Solution for infusion

Drug Type Standardized to Originator