

The Uniform System of Classification (USC)

Purpose

The Uniform System of Classification (USC) is a therapeutic classification system created by IQVIA America and the Pharmaceutical Marketing Research Group to resolve a need for therapeutic classification of pharmaceutical products. This system is market-oriented and is unique to North America (the United States and Canada) and is the standard for pharmaceutical product classification. The only pharmaceutical categorization system that rivals the USC is the Anatomical Classification system (ATC), used outside the United States and Canada.

The USC provides logical groupings of pharmaceutical products considered to compete in the same or similar markets; each category provides the manufacturer a solution to determine the market share for their product(s), as well as their competitors. This type of classification creates market shares showing movement and changes in a given area resulting from new product launches and competing products.

Structure

The USC is a five-digit, hierarchical, classification system.

The **USC 2 level**, ranging from 01 to 99, can accommodate ninety-nine unique categories. The subsequent levels accommodate nine unique subcategories.

The **USC 3 level** consists of the detail from level two in addition to any detail associated with level three; the range is limited to nine unique subcategories

The **USC 4 level** consists of the detail from level two, three and four. This level typically will carry the chemical structure, indication, or method of action.

The **USC 5 level** provides the most granular detail. This level consists of the detail strung from levels two, three and four.

Example of USC structure

<u>02000</u>	<u>ANALGESICS</u>	→	USC Level 2
<u>02100</u>	<u>NON-NARCOTIC ANALGESICS</u>	→	USC Level 3
02110	ANTI-MIGRAINE		
02120	ACETAMINOPHEN		
<u>02130</u>	<u>SYNTHETICS, NON-NARCOTIC</u>	→	USC Level 4
02131	INJECTABLE		
02132	NON-INJECTABLE		
02133	FORM UNKNW (C/M)	→	USC Level 5
02140	ASPIRIN & RELATED		
<u>02200</u>	<u>NARCOTICS, ANALGESIC</u>		
<u>02210</u>	<u>SYNTHETICS, NARCOTIC</u>		
2211	INJECTABLE		
02212	PROPOXYPHENES		
02213	FORM UNKNOWN (C/M)		
02214	NON-INJECTABLE		

Process

The USC is a proprietary product, belonging exclusively to IQVIA; although a client may request a new USC class or the reclassification of a product, IQVIA is solely accountable for the appropriate classification of all drugs and for the approval/denial of all drug reclassifications. IQVIA Pharmaceutical Action Committee makes all decisions concerning the structure/function of the USC and decisions on drug classifications.

Elements of Classification

Several attributes are considered when rendering a decision regarding the placement of a product or the creation of a new USC category. These include:

- **Therapeutic Category** – Groupings of similar pharmaceutical products; these are represented in the USC level 2 descriptions.
 - E.g. – Vascular Agents; Antineoplastic Agents.
- **Pharmacology** – The mechanism of action of the product; how it exerts its effect in the body; typically represented in the USC level 3 descriptions.
 - E.g. – Angiotensin Converting Enzyme (ACE) Inhibitors; Alkylating Agents.
- **Chemical Structure** – The chemical classification of the product, including similarities or differences from other, similar products; usually covered in USC level 4 descriptions.
 - E.g. – Nitrogen Mustards (antineoplastic); Polyenes (antifungal).
- **Indication** – The Food and Drug Administration (FDA) approved indications for use of the product; this is especially useful when the product shares attributes

(pharmacology, chemical structure) with other agents, but is indicated for use in a disease state/process that is significantly different.

- E.g. – Treatment of systemic fungal infections; treatment of infections caused by susceptible bacterial organisms.

Classification Process

After a product receives final FDA approval, the information necessary to enter the product into the I database is obtained; this information is generally provided by the product's manufacturer or obtained from the CDER New and Generic Drug Approval internet website. The information is reviewed by the Product Database Management (PDM) Analyst responsible for the manufacturer and the PDM Database Editor.

- If the product's attributes are consistent with an existing USC, the product is assigned the appropriate USC.
- If the product represents a significant departure from any existing USC in the same therapeutic class, the product is assigned a temporary USC. A request is generated for review of the product by the Pharmaceutical Action Committee (PAC); the PAC then determines whether a new USC is required.
- A client may request a product reclassification and/or the addition of a new USC by filing a completed USC Action Request Form.
- A client may request the addition of a new USC for a product that has not been approved by the FDA, if final approval is expected within the next 6 months, by filing a completed USC Action Request Form.

Pharmaceutical Action Committee (PAC)

The PAC is comprised of Business Line Managers, representing IQVIA's major Sales and Prescriptions audits, Data Integrity, Statistics, and Product Data Management.

The Committee Chair, a registered pharmacist, serves as the "point person" for receipt of all materials related to the reclassification of currently assigned products and restructure/re-organization of the body of the USC. Any Committee member may call for a meeting; it is the responsibility of the Chair to organize the regularly scheduled meetings of the Committee. The Committee meets a *minimum* of 4 times a year; additional meetings are scheduled, as required by the emergence of new products or other USC related issues. Decisions will be communicated via the PAC Response Form outlining the date the change will occur, allowing adequate time for communication to all stakeholders.