Regulatory Focus™
A RAPS Publication

The WHO anatomical therapeutic chemical/defined daily dose toolkit

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This article provides a high-level overview of the anatomical therapeutic chemical/defined daily dose (ATC/DDD) toolkit developed by the World Health Organization (WHO) for drug utilization studies. This kit facilitates comparison of drugs at the national, international, and regional levels, monitoring of trends in drug product use, and assessment of drug safety. The article provides a description of the process to request ATC/DDD codes and the way the request is reviewed by the WHO International Working Group for Drug Statistics Methodology.

Keywords – ATC, DDD, drug utilization, WHO

Introduction

Drug utilization research, which is defined by WHO as the research related to marketing, distribution, prescription, and use of drugs in society, is meant to assess whether a specific drug therapy is rational or not.[1,2] Drug utilization studies rely on two elements that are endorsed by WHO and are considered the gold standard in facilitating presentation and comparison of the national-, international-, and regional-level statistics of drug marketing, distribution, prescription, and/or use.[3] The first element is the anatomical therapeutic chemical (ATC) classification. This is a system for grouping drug substances and drug products into classes according to the human body organ or system upon which the drug acts as well as the therapeutic, pharmacologic, and chemical properties of the drug. The second element is known as the defined daily dose (DDD). This is considered the unit of measurement for use in drug utilization studies.[4] In most cases, the DDD is the assumed average maintenance dose of the drug for an adult per day. This article highlights the different areas where the ATC/DDD system can be beneficial, describes the structure of the system, and explains the requirements and procedures to follow for requesting an ATC classification for a drug.

Uses of the ATC/DDD system

The main purpose of the ATC/DDD system is to serve as a tool to help in the statistical analysis and presentation of drug utilization data, such as drug sales, dispensing, and consumption data.[3,5] Evaluation of trends in this data is valuable for various users, such as healthcare professionals in settings like pharmacies, payers, and clinics, as well as government agencies (such as regulatory authorities) for improving drug use at the national and/or international level (**Table 1,** p. 3). For example, using the ATC/DDD system allows for drug safety assessment in a selected population through examining and comparing frequency of adverse reaction reports against trends in drug utilization in that population. This information can be helpful to health authorities such as the US Food and Drug Administration (FDA) in postapproval drug product surveillance.

In addition, the ATC/DDD system is instrumental in monitoring and comparing trends in cost. For example, ATC classification can be useful in determining the extent of any trend present between the increase in cost and use of drugs for a therapeutic group, which makes it helpful for health plan providers and payers. However, the ATC/DDD system should not be used for specific pricing decisions of individual drug products, comparison of pricing among ATC groups, or to indicate reference pricing for therapeutic groups. This is because the ATC/DDD system is designed mainly to allow for comparison of trends in drug utilization within and across the different therapeutic groups. It is also important to note that the ATC/DDD system does not provide any implications about relative efficacy of drugs. Therefore, drugs assigned to the same ATC group are not necessarily therapeutically equivalent. Similarly, having drugs assigned to different ATC groups does not indicate that they have different therapeutic effectiveness.

Principles of ATC

The ATC system is a five-level hierarchy. The first level is divided into 14 anatomical (or pharmacological) groups:[13]

- **Group A –** Alimentary tract and metabolism
- **Group B –** Blood and blood-forming organs
- **Group C –** Cardiovascular system
- **Group D –** Dermatological
- **Group G –** Genitourinary system and sex hormones
- **Group H –** Systemic hormonal preparations, excluding sex hormones and insulin
- **Group J –** Anti-infective for systemic use
- **Group L –** Antineoplastic and immunomodulating agents
- **Group M –** Musculoskeletal system
- **Group N –** Nervous system

Table 1. Main users, use, and benefits of drug utilization statistics relying on ATC/DDD system data[6]

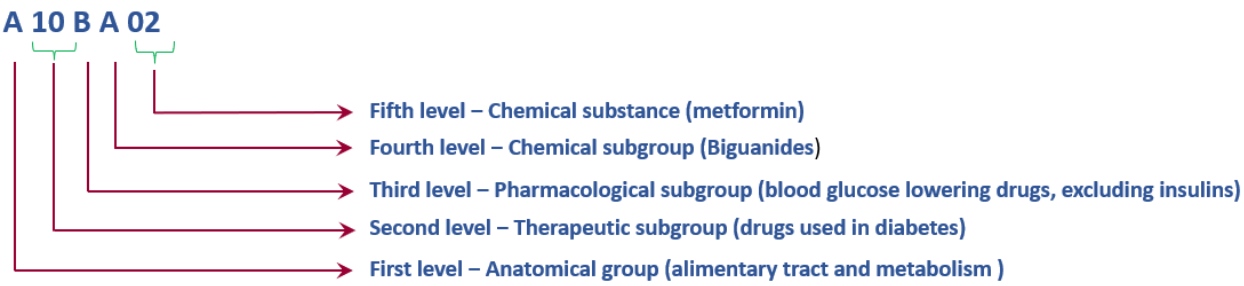
Main users	Uses	Benefits
Manufacturers, applicants, wholesale distributors	Compare drug sales at the national, regional, or international level.	Help better understand the drivers for drug product sales and the reason for higher sales in one local region or part of the world over the other.
Healthcare providers	In pharmacovigilance – Link ADR to drug classes.	Assist in drug safety assessment in certain populations.
	In pharmacoepidemiology – Link drug consumption trends to frequency of ADR reported in certain population.[7]	Improve prescription drug selection.
	Monitor and evaluate the prescribing, dispensing, and use of drug products	Determine, at the institutional, national, or regional level, trends of use, misuse or abuse of certain drugs (such as antibiotics and opioids).[5,8,9]
	Determine DDDs per bed days in hospital.[10]	Gauge the in-hospital use of drugs.
Regulatory authorities	Retrieve information about medicine use. Determine at the regional or national level trends of misuse or abuse of drugs.	Set effective policies and regulatory actions based on current knowledge and understanding of the use of drugs. Can be used for educational intervention, including scientific articles and letters to clinicians. Allow assessment of impact of regulatory intervention.
Pharmacoeconomic professionals	Monitor and compare trends in costs and utilization.[11,12]	Conduct research studies to understand the impact of trends in cost increases with consumption of drugs for a therapeutic group.
Health plan providers and payers	Monitor and compare costs of classes of drugs and individual drugs in a class. Assist in surveillance for potential drug shortage.[11,12]	Have a better view of drugs' availability.
Pharmacies	Compare drug use between regions (for chain pharmacies with multiple locations) and examine trends in drug use over time.[11,12]	Have knowledge of the sales, dispensing, and use of drugs in their areas for better dispensing of drugs.

ADR, adverse drug reactions; **ATC,** anatomical therapeutic chemical; **DDD,** defined daily dose.

- **Group P –** Antiparasitic products, insecticides, and repellents
- **Group R –** Respiratory system
- **Group S –** Sensory organs
- **Group V –** Various

Figure 1 (p. 4) provides an example, metformin, of the different levels of an ATC code. Each of the other four levels contains multiple subgroups.[14] The code starts with a letter referring to the main group followed by two digits for the

Figure 1. ATC code for metformin[14]



second-level subgroup, two letters for the third and fourth levels subgroup, respectively, and two digits at the end specific to the drug substance. The second level is therapeutic or pharmacological group classification. In the metformin example below, drugs used to treat diabetes (the second level) is a subgroup of alimentary tract and metabolism drugs (the first level). The third and fourth levels are either therapeutic, pharmacological, or chemical group classification. The fifth level in the hierarchy is specific to the drug substance. Overall, each drug in the ATC system is described by a seven-part alphanumeric code.

The final decision on the ATC classification of a drug substance is made by the Working Group for Drug Statistics Methodology ("working group" in subsequent mentions). In selection of the drug name to be used in the ATC system, the international nonproprietary name (INN) is usually the preferred name. The use of other names, such as the US adopted name or British-approved name, is considered secondary and can be used if an INN hasn't been assigned. For a drug substance to be included in the ATC system, it has to be either:

- A new chemical entity (NCE) or biological substance for which an application for marketing authorization is ready for submission or has already been approved, or
- An herbal medicinal product assessed and approved by regulatory authority based on submitted data for safety, efficacy, and quality.

The main principle in the ATC system is that drug products are classified based on the main therapeutic use of the active ingredient. Different routes of administration and/or strengths for the same main therapeutic use of the active ingredient would have the same ATC code (e.g., diclofenac for rheumatoid arthritis has the same ATC code, M01AB05, for oral, parenteral, and rectal routes of administration). However, when the main therapeutic use of the same active ingredient varies with the route of administration or strength, a different ATC code is given for each therapeutic use. For example, timolol, a beta-blocker, has an ATC code when used orally and parenterally, as a cardiovascular drug (C07AA06) different from that of timolol when it is used as an eye drop for

treatment of glaucoma (S01ED01; **Table 2**). Also, finasteride tablets, which are available in two different strengths, have two different ATC codes. The low-strength finasteride tablet is used mainly for treatment of male pattern baldness (ATC code D11AX10), whereas the high-strength main indication is treatment of benign prostatic hypertrophy (ATC code G04CB01).

When the main therapeutic use for the same drug product is different for different countries, only one ATC code is given according to the most common therapeutic indication from a global standpoint based on available literature. This determination is made by the WHO Collaborating Centre for Drug Statistics Methodology (CCDSM) with advice from the working group. A prodrug with a different nonproprietary name and/or dosage from its parent active drug is usually assigned a different ATC code. Because ATC codes can be assigned pharmacologically at the second, third, and fourth levels according to mechanism of action rather than therapeutic effect, drugs with similar therapeutic effects may be assigned to different groups. For example, drugs used to treat hypertension do not all fall under the secondary-level therapeutic classification of C02 – antihypertensives. Instead, they also fall under three other secondary-level pharmacological classifications, namely C03 – diuretics, C07 – beta blocker, and C08 – calcium channel blocker (Table 2). Therefore, drugs sharing the same ATC classification up to the fourth level should not always be considered pharmacotherapeutic equivalent. The number of groups at each of the four levels varies and depends on the number of therapeutic, pharmacological, or chemical groups that can describe all classes of drugs falling under this level.

Table 2. General principles of ATC code assignment of drug products[13,15]

Drug	ATC code	Second-level classification	Indication	ROA
Diclofenac	M01AB05	M01 – Anti-inflammatory, antirheumatic	Rheumatoid arthritis	Parenteral, oral, rectal
Timolol	C07AA06 S01ED01	C07 – Beta blocker S01 – Ophthalmologic	Hypertension Glaucoma	Oral, parenteral Eye
Finasteride tablet 1 mg 5 mg	D11AX10 G04CB01	D11 – Other dermatological preparations G04 – Urological	Male pattern baldness Benign prostatic hypertrophy	Oral Oral
Prazosin	C02CA01	C02 – Antihypertensive	Hypertension	Oral
Hydrochlorothiazide	C03AA03	C03 – Diuretic	Hypertension	Oral
Amlodipine	C08CA01	C08 – Calcium channel blocker	Hypertension	Oral

ATC, anatomical therapeutic chemical; **ROA,** route of administration.

Combination products – of two or more active ingredients – are assigned distinct ATC codes versus their individual active ingredients. However, classification of combination products and assignment of their codes is sometimes challenging. Combination products classification usually follows that of the main therapeutic active ingredient. For example, a combination product of naproxen and esomeprazole is used mainly for the anti-inflammatory and analgesic effects of naproxen. Esomeprazole, a proton pump inhibitor, is added to overcome the increased risk of peptic ulcer associated with the use of naproxen. In this case, the first four levels of the ATC classification for the combination product follows that of the main therapeutic ingredient, naproxen (M01AE), and the last two digits for the fifth level follows a 50-series digit code (i.e., 50 to 59 code). Therefore, the ATC code of a naproxen/esomeprazole combination product is M01AE52 (**Table 3**). Similarly, ATC classification of a naproxen/misoprostol combination product follows the same rule, but its ATC code (M01AE56) is different (at the fifth level, from the 50 series) from the aforementioned naproxen/esomeprazole combination product code (Table 3). However, this is not always the case, as many combination products that have the same main therapeutic ingredient are grouped to share the same ATC code (e.g., all available diclofenac combination products are ATC code M01AB55).

Sometimes, when the active ingredients are of the same fourth-level classification, their combined product will have a fifth-level digital code that follows either a 20 or 30 series. For example, the ATC code of a combination product of lidocaine (ATC code N01BB02) and prilocaine (ATC code N01BB04) is N01BB20 (Table 3).

Combination products containing psycholeptic drugs that do not belong at its second level of classification to psycholeptics (N05) or psychoanaleptics (N06) are classified using a 70 series at the fifth level. At the first four levels, the combination will have the ATC classification of the main therapeutic ingredient. For example, the combination of acetylsalicylic acid with the psycholeptic drug (not belonging to N05 or N06 classification), which is used mainly for the therapeutic analgesic indication (N02) of acetylsalicylic acid, is given an ATC

Table 3. General principles of ATC code assignment for combination products[13,15]

Drug 1		Drug 2		Main therapeutic ingredient	Combination
Name	Code	Name	Code		
Naproxen	M01AE02	Esomeprazole	A02BC05	Naproxen	M01AE52
Naproxen	M01AE02	Misoprostol	A02BB01	Naproxen	M01AE56
Diclofenac	M01AB05	Esomeprazole	A02BC05	Diclofenac	M01AB55
Diclofenac	M01AB05	Misoprostol	A02BB01	Diclofenac	M01AB55
Lidocaine	N01BB02	Prilocaine	N01BB04	—	N01BB20

code of N02BA71. It is noteworthy to mention though that most of the 70 series codes are old and the products assigned to them are now obsolete.

Principles of DDD

The DDD should not be confused with the prescribed daily dose. The former is an average maintenance dose per day for the main indication of the drug in adults, whereas the latter is an average dose prescribed according to a representative sample of prescriptions.[11] The DDD is useful in expressing the drug use for the general population (e.g., 10 DDD/1,000 inhabitants per day may reflect 1% of the population taking the DDD per day or 2% of the population taking 0.5 of the DDD per day).

Defined daily dose is assigned only to drug products with ATC codes that have been approved and marketed in at least one country. Within an ATC code only one DDD is assigned per route of administration. The long-term maintenance dose is preferred over the initial dose when assigning the DDD. For drug products where dose titration is possible, the DDD is assigned based on the titration recommendation. For example, with a drug whose dosage recommendation states, "Titrate up to a high dose if it is tolerated," the high dose would often be the DDD selected. In contrast, when the recommendation is to "consider increasing the dose only if efficacy is not satisfactory with the initial dose," the initial dose would normally be the preferred DDD. For drug products having a therapeutic dose and a prophylactic dose, the DDD is commonly the therapeutic dose unless prophylaxis is the main indication of the drug product. When the recommended dose of a drug product is based on body weight, the DDD is assigned according to an assumed adult body weight of 70 kg. In cases where the same drug product has a different dose in different countries for the same indication, the DDD is usually an average of those doses and does not refer to a specific country's prescribed dose. Various dosage forms for the same drug are normally assigned the same DDD except in certain cases, such as those where the indication varies with the dosage form and where the dosage forms would have distinct ATC codes as well (see the timolol example in Table 2). A different DDD may also be assigned for different dosage forms of the drug if substantial difference in bioavailability exists (e.g., oral and parenteral morphine).

Different stereoisomeric forms of a drug are usually assigned different ATC codes (e.g., ketamine [ATC code N01AX03], a racemic mixture of both R and S entantiomers, and esketamine [ATC code N01AX14], the S enantiomer only). However, polymorphic forms of the same drug are assigned the same ATC code and DDD, irrespective of any difference in bioavailability between the polymorphic forms. In general, DDDs are given in the amount of active ingredient present in the drug product in units of grams (g), milligrams (mg), micrograms (mcg), millimole (mmol), unit (U), thousand units (TU), or million units (MU). For combination products of more than one active ingredient, the

main principle for assignment of the DDD would be based on the daily unit dose (UD) of the product regardless of the number of active ingredients present. For example, the DDD for a tablet dosage form taken once daily and containing multiple active ingredients is one tablet (UD).

Certain classes of drugs do not have DDDs because dosing is variable or hard to measure. These include topical products, vaccines, antineoplastic agents, and contrast agents.

Once assigned, changes in assigned DDDs are usually kept to a minimum, as they can complicate drug utilization research. Only large changes in the prescribed daily dose (in the order of 50% or more) or change in the main indication would prompt a change in the DDD.[16] However, this rule of limiting changes to the DDD does not apply in the first three years of an ATC code and DDD assignment for a new drug, as review and minor alterations may be necessary. End users can propose DDD changes to the WHO CCDSM but only after the first three years of revision of the DDD.

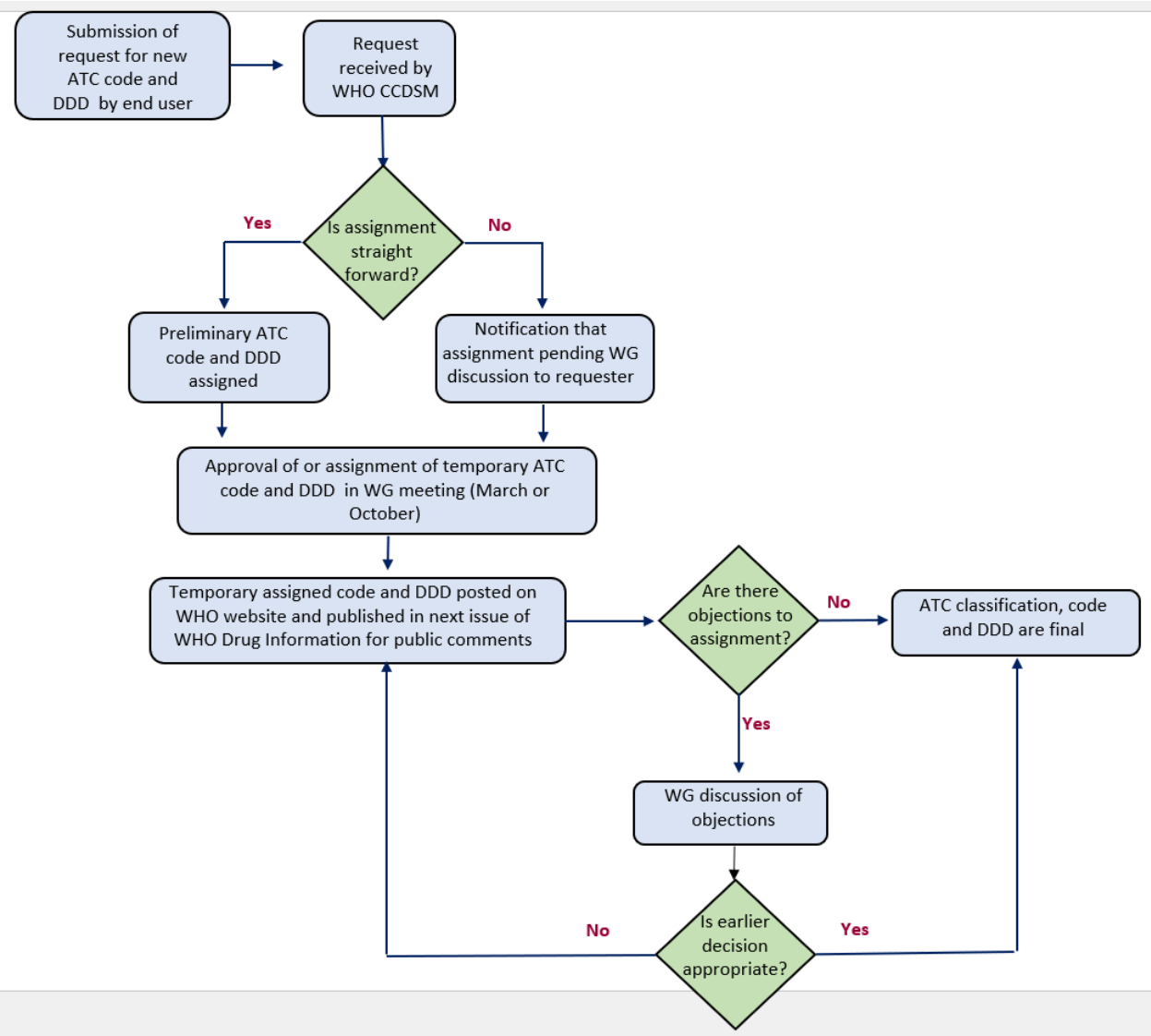
Procedure and requirements for requesting ATC classification

The WHO CCDSM, based in Oslo, Norway, is responsible for classifying drugs and assigning codes according to the ATC system and establishing DDDs for drugs. It is also responsible for performing any necessary review or revision of the ATC classification system as a whole, such as forming new classes for newly discovered drugs that do not fit in any of the existing classes of the ATC system.

The process of assigning an ATC code and DDD for a new drug substance is described in **Figure 2** (p. 9). Basically, the process for entering a new drug substance in the ATC classification is initiated with a request that should be submitted in English using the formal application form available at the WHO website.[17] The request should be submitted by one of the users of the system (e.g., manufacturer, regulatory body, or researcher) to the CCDSM. However, some of the information needed to complete the application may only be available to the manufacturer or marketing drug applicant and not available to the general public. In such cases, other users, if interested in requesting an ATC code, can work with the manufacturer to fill in this information and submit the request. Manufacturers are often cooperative, as they typically have an interest in pursuing drug product classification in the ATC/DDD system, especially for new drugs.

Within six to eight weeks of receipt of the request, the CCDSM replies to the applicant with either a preliminary ATC code, if the assignment is straightforward, or notification that ATC code assignment is pending and under further review. The latter case usually happens when the drug substance is difficult to fit in any of the existing classifications or can potentially fit into more than one classification. In either case, the ATC code is considered formal only

Figure 2. Process of assigning an ATC code and DDD for a new drug substance[17]



ATC, anatomical therapeutic chemical; **CCDSM,** Collaborating Centre for Drug Statistics Methodology; **DDD,** defined daily dose; **WG,** working group; **WHO,** World Health Organization.

after approval of the working group meeting minutes. The working group meets twice a year, in March and October. The new ATC codes are posted on the WHO website and published in WHO Drug Information after the March and October meetings.

Interested parties may provide comments on and/or objections to the posted classification by February 1 or September 1 – a month before the meetings – for discussion during the meetings. If, after the discussions, the working group

deems its earlier meeting decision appropriate, then the classification is considered final. However, if the group determines the objection justifiable and a new classification decision is needed, a new temporary ATC code will be assigned and posted on the WHO site and published in the next issue of WHO Drug Information for further public comments.

The submission package for requesting an ATC code should include the following information:[17]

- Chemical structure of the substance for which an ATC code is requested and its relationship to similar drugs;
- Pharmacology and mechanism of action and relationships to similar drugs;
- Main indication as shown in the product information in the country where it is licensed or submitted for licensing;
- Other licensed indications or those for which licensing is or will be proposed;
- Proposed ATC classification with justification based on the evidence submitted;
- Status concerning marketing authorization; and
- Information about therapeutic use, if available.

Coordination of MAA submission and ATC classification request

An NCE is usually not included in the ATC classification system until a market authorization application (MAA) has been submitted in at least one country. However, it is not necessary to get an MAA approval before submitting the request for the ATC code for the chemical entity. In some complex cases – for example, where the fifth-level of the ATC code is difficult to assign – the ATC code is assigned only after a drug product is approved in at least one country.

It may be prudent to plan to submit the ATC code request ahead of time because the working group meets, as mentioned earlier, only twice a year. They have a standard and firm due date set for submitting the requests for discussion in each meeting. For the March working group meeting, requests should be submitted before January 15; for the October meeting, the timeline for submission is before August 15.[18] Therefore, if you are planning to submit an MAA for an NCE sometime at the beginning of the first quarter of 2024 and interested in getting an ATC classification, you may want to submit the request for the ATC code assignment before 15 January 2024 to meet the timeline for the March working group meeting. However, it is important to note that review and approval of an MAA by regulatory authorities is an independent process and is not affected by ATC/DDD classification procedure.

Conclusion

The ATC/DDD system is the gold standard for drug utilization studies, including those evaluating drug sales, use, and safety assessment. Therefore, it is a useful tool of great interest to government agencies, drug distributing and pharmacy dispensing end users, and drug product manufacturers and sponsors. Because of limited meeting times per year (two times) for the working group to discuss or decide on any ATC/DDD classification request, submission of ATC/DDD classification requests should be planned ahead of time. In fact, it may be beneficial for marketing authorization applicants to consider planning ATC/DDD classification strategy for their new drug products during development of the drug products and their marketing strategy.

Abbreviations

ATC, anatomical therapeutic chemical; **CCDSM,** Collaborating Centre for Drug Statistics Methodology; **DDD,** defined daily dose; **FDA,** [US] Food and Drug Administration; **INN,** international nonproprietary name; **NCE,** new chemical entity; **UD,** unit dose; **WHO,** World Health Organization.

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Citation Ghorab M, Brorson K. Overview of the WHO anatomical therapeutic chemical/defined daily dose toolkit. REGULATORY FOCUS. Published online 26 September 2023. https://www.raps.org/News-and-Articles/News-Articles/2023/9/The-WHO-anatomical-therapeutic-chemical-defined-da

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