INN Working Doc 25.635
October 2025
Distr.: PUBLIC
ENGLISH ONLY

58th MEETING OF THE WHO ADVISORY GROUP FOR DRUG STATISTICS METHODOLOGY

Geneva, Switzerland (virtual meeting)
28-29 October 2025

Executive Summary

International Nonproprietary Names (INN) Programme and Classification of Medical Products
Product Standards, Specifications and Nomenclature Unit (PSN)
Medicines and Health Products Policies and Standards Department (HPS)
Health Systems, Access and Data Division (HSD)
World Health Organization, Geneva

58th MEETING OF THE WHO ADVISORY GROUP FOR DRUG STATISTICS METHODOLOGY

Geneva, 28-29 October 2025 (virtual meeting)

EXECUTIVE SUMMARY

Welcome and opening remarks

The Director of WHO's Medicines and Health Products Policies and Standards Department, Mr Deusdedit Mubangizi, welcomed participants to the 58th Meeting of the WHO Advisory Group for Drug Statistics Methodology. He emphasized that expert groups play a crucial role in providing robust, independent advice to WHO and Member States on norms and standards. This advisory group focuses on the ATC/DDD system, which is essential for guiding policies, research, and drug utilization studies. Standardized methodologies for drug utilization are critical to ensure reliable advice and support equitable access to medicines.

WHO values the committee's independent work, done without remuneration, and acknowledges the high level of expertise contributed. Following WHO's restructuring and the creation of the Chief Scientist's Office in 2019, procedures for advisory groups were updated to strengthen independence and consistency. This advisory group is expected to provide scientific, technical, and strategic evaluations of ATC/DDD systems and recommend priorities for their advancement. WHO relies on the advisors' advice to keep ATC/DDD aligned with evolving science, new therapeutic areas, and complex substances. Integration of ATC/DDD systems into broader health information frameworks, global drug monitoring, and health statistics is a key expectation. The advisors should also ensure alignment between the ATC/DDD system, International Nonproprietary Names (INN), and the Model Essential Medicines List (EML) for optimized drug classification and usage. The Director underlined that the continuous improvement of methodologies and tools is vital to maintain effectiveness and impact in global health programs. He emphasized the importance of efficiency and transparency, supported by digital tools like IDMIS that replace the process of collating comments from the paper and emails. Advisory groups must operate within WHO's rules to guarantee independent and consistent advice, as mandated by Member States and endorsed by the Executive Board.

WHO values the role and contribution of Norway and its WHO Collaborating Center, National Institute of Public Health, in advancing the ATC/DDD system, which has been globally adopted since 1996. Strengthening collaboration is a priority to ensure independent, robust, and science-based advice for Member States. Ongoing discussions with the Norwegian center aim to streamline processes and align with WHO's framework for advisory committees, reinforcing consistency and independence in recommendations. Additional ATC/DDD meeting, scheduled in December 2025 or January 2026 is recommended to address pending agenda items. The Director expressed gratitude to the Secretariat and collaborating institutions for their contributions and officially opened the meeting, encouraging fruitful deliberations.

Election of Chair and Rapporteur

Professor Vera Vlahović-Palčevski was elected as Chair and Dr Nitin Bagul was elected as Rapporteur to draft the Executive Summary of the meeting.

Minutes of the 57th meeting

The minutes of the 57th meeting were adopted without objection.

Points for discussion from the WHO headquarters

Dr Raffaella Balocco welcomed the WHO Advisory Group members along with Dr Christine Berglund, Director, Division of Health Data and Digitalisation, Norwegian Institute of Public Health, and observers from the Spanish Agency, Uppsala Monitoring Centre, EMMA project, IFPMA, and the INN liaison. She thanked the advisory committee experts for their successful adoption of the IDMIS tool, which allows members to enter their expert comments directly into the online system. Dr Balocco emphasized that the IDMIS tool enables effective virtual consultations and is particularly valuable for experts who cannot attend meetings in person, as it allows them to contribute their expertise in advance.

Report from the WHO Collaborating Centre

Dr Mohammad Nouri Sharikabad provided a brief update from the Centre, expressing gratitude to Mr Deusdedit Mubangizi for his kind words and outlining recent team changes, with several members departing and new staff being introduced. He reported that the Centre has processed 96 new fifth-level codes during meetings M56 and M57, and 100 new applications received for M58 will be presented to the Advisory group at the additional meeting either in December 2025 or January 2026. The Centre assigned 14 new DDDs earlier in the year and an additional 15 new DDDs for M58, while also responding to 350 ATC/DDD inquiries. Centre highlighted that the ATC/DDD Index for 2025 was published in both English and Spanish and distributed alongside the Centre's annual extensive training course on ATC/DDD methodology.

Assigning new ATC codes

60 ATC (Anatomical Therapeutic Chemical) classification requests were processed for various medical products. The requests encompassed a wide range of therapeutic areas including analgesics, anticoagulants, ophthalmological preparations, antimicrobials, immunosuppressants, oncology treatments, respiratory medicines, and gene therapies. Notable actions included renaming existing codes (such as changing N02BB02 to "metamizole"), adding guideline annotations for prodrugs, changing subgroup descriptions, and assigning new codes to emerging therapies including multiple CAR-T cell products and gene therapy treatments. Several requests involved reviewing combination products, updating classification levels, and addressing substances that required special notes in the guidelines. Newly created 4th level codes include J06BE for atoltivimab/maftivimab/odesivimab, a fixed-dose combination of monoclonal antibodies for the treatment of Ebola virus. The majority of requests originated from the INN Programme, with additional submissions from pharmaceutical companies and national regulatory agencies including the Spanish Agency of Medicines and Medical Devices.

ATC Objections Requests - Codes discussed

Three ATC (Anatomical Therapeutic Chemical) classification objection requests for medical products were discussed. Request for diazoxide choline from First Databank has been deferred with code V03AH01, pending additional information about the mechanism of action. Request for thymalfasin from Sovle Consulting International was assigned code L03AX25, with the objection not retained. Request for tolebrutinib from Sanofi was assigned code L04AA62, with the objection similarly not retained, though further evaluation with information on similar substances was noted

ATC/DDD and Antimicrobials – The importance of Combinations

Professor Albert Figueras presented to the WHO Advisory Group on the critical importance of addressing gaps in the ATC/DDD classification system, particularly regarding antimicrobial combinations. The ATC/DDD (Anatomical Therapeutic Chemical/Defined Daily Dose) classification system, originally developed in Norway in the 1970s and adopted by WHO in 1981, serves as a crucial tool for drug utilisation research, medicines safety, and healthcare administration globally. The

system faces two major challenges requiring regular updates: expanding its scope to include region-specific medicinal substances to support universal health coverage and public health goals and adapting to modern therapeutics by incorporating complex personalized therapies while leveraging advances in information management such as large-scale pharmacovigilance databases and electronic medical records. Current gaps in the classification include numerous vague "various" or "other" codes and groupings that lack specificity, limiting the system's ability to accurately track individual medicines.

A particularly urgent issue is the inadequate coding of antimicrobial combinations, which undermines efforts to address the antimicrobial resistance crisis. Vague codes such as "combinations of penicillins" (J01CR50), "penicillins, combinations with other antibacterials" (J01RA01), and "amoxicillin and beta-lactamase inhibitor" (J01CR02) prevent accurate tracking of antimicrobial use in many countries, as products without appropriate specific codes risk being overlooked in large-scale data analyses. To maximize the system's global utility and support antimicrobial stewardship policies, the classification must integrate both the curators' perspective on system maintenance and users' needs for precise, actionable data that can effectively monitor the primary driver of antimicrobial resistance: inappropriate antimicrobial use.

Enhancing ATC/DDD for Global Surveillance of Antimicrobial Use (WHO GLASS)

Dr Verica Ivanovska further elaborated on the direct implications of these ATC limitations for the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS-AMU), which relies on the ATC/DDD methodology for standardized global reporting. The lack of unique codes for fixed-dose combinations significantly impairs surveillance efforts and antimicrobial stewardship monitoring, particularly for AWaRe (Access, Watch, Reserve) classification targets. Critical examples include J01CR02, which groups together Access-category amoxicillin/clavulanic acid with Reserve-category amoxicillin/pivsulbactam; J01CR50, which combines multiple non-recommended penicillin combinations; and J01DD52, which conflates Reserve antibiotics like ceftazidime/avibactam with non-recommended combinations like ceftazidime/sulbactam. Dr Ivanovska recommended that the Advisory Group establish a WHO-led working group involving AMR, EML, INN teams, ATC advisors, and WHOCC to align ATC coding detail with surveillance objectives, prioritize fixed-dose combinations relevant to AWaRe and stewardship goals, and integrate continuous AWaRe color-coded labelling within the ATC/DDD index to support global consistency and precise tracking of antimicrobial consumption patterns.

EMMA Project

Dr Giuseppe Roberto introduced the Exposure to Medications Measured using ATC/DDD classification system (EMMA) project that aims to foster comparability and reproducibility of studies that use the ATC/DDD standard. The EMMA project is structured in three task forces:
i) an on-line survey to collect nation-level on the implementation and maintenance of the ATC/DDD system, ii) a scoping review to document how researchers reports on the use of the ATC/DDD system in pharmacoepidemiology and drug utilization studies, iii) recommendations for the creation of an online application for DDD per package calculations.

Based on the results from the task force i) and ii) ATC/DDD-specific reporting recommendations and checklist will be also created.

As for the EMMA survey, the survey activities ended in July 2025 with a total of 100 completed surveys from 52 countries. Validation of survey responses is currently ongoing. To provide a general idea about the final output of the EMMA survey, some preliminary results from non-validated survey responses were presented. Notably, final study results are expected to provide a picture of the countries, among those covered by the EMMA survey, in which the ATC/DDD system is in place together with info on the accessibility of such resources, their governance and the methodology for the implementation and maintenance of the system. Interestingly, the preliminary results showed that some countries have adopted non-standard ATC codes and DDDs for substances that are not currently

addressed by the system, thus representing a potential threat for the nature of the ATC/DDD standard itself if not appropriately managed. The ongoing validation of responses is also highlighting the difficulty of finding and accessing information about the topic of the EMMA survey. Final results from the EMMA survey are expected by the end of February 2025.

Next meeting

The 59th Meeting of the WHO Advisory Group for Drug Statistics Methodology will be held face to face at the WHO headquarters, Geneva, Switzerland on 28 and 29 April 2026.