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**49th MEETING OF THE WHO INTERNATIONAL WORKING GROUP FOR DRUG STATISTICS METHODOLOGY**

**Geneva, 23 March 2021 (virtual meeting)**

# *Executive Summary*

***INN Programme and Classification of Medical Products Unit***
**Health Products Policy and Standards Department (HPS)**
***Access to Medicines and Health Products Division (MHP)***
***World Health Organization, Geneva***

# 49th MEETING OF THE WHO INTERNATIONAL WORKING GROUP FOR DRUG STATISTICS METHODOLOGY

## Geneva, 23 March 2021

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## EXECUTIVE SUMMARY

### Opening of meeting

The meeting was opened by *Dr Clive Ondari*, Director, Health Products Policy and Standards Department. Dr Ondari welcomed the working group experts and acknowledged the contribution of the secretariat from the WHO Collaborating Centre for Drug Statistics Methodology at the Norwegian Institute of Public Health (*the 'Centre'*) in preparing the advice for the working group and organising the virtual meeting.

*Dr Ondari* noted the efforts of WHO to align work being undertaken by the International Nonpropriatery Names (INN) Programme in establishing standards for the consistent naming of drug substances with the classification of drugs. Dr Ondari commented that achieving consistent worldwide naming conventions would facilitate drug classification and promote the safer use of pharmaceutical products.

### Introductory remarks

*Dr Raffaella Balocco*, Head, INN Programme and Classification of Medical Products Unit welcomed participants and ran through procedural aspects of the meeting. For the benefit of new members, there were introductions from all members to the working group.

Roles and obligations of WHO Experts were highlighted. In particular, the World Health Organization (WHO) International Working Group for Drug Statistics Methodology was formed to develop the Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) system as an international standard to assess drug utilization and promote its appropriate use and practical application through the development of methods and guidelines. The responsibility of Working Group for Drug Statistics Methodology falls under the INN Unit.

Further information about the working group is available on the WHO INN website https://www.who.int/teams/health-product-and-policy-standards/inn/atc-ddd and the Collaborating Centre for Drug Statistics Methodology website at: https://www.whocc.no/atc_ddd_methodology/who_international_working_group/. Kindly note that the working Group members and related short CV are disclosed on the WHO INN website page the month before the meeting.

### Election of Chair, Vice-Chair and Rapporteur

*Professor Morten Andersen* was elected as Chair of the meeting and *Professor Ilse Truter* as Vice-Chair. *Dr Kerry Atkins* was elected rapporteur.

**ATC classification items**

All new temporary ATC codes and alterations are published at the ATC/DDD Centre's website and in *WHO Drug Information* (https://www.who.int/our-work/access-to-medicines-and-health-products/who-drug-information) with deadline for objections 1 September 2021.

***finerenone***

An application for an ATC code for *finerenone (108) (70)* was considered. *finerenone* was indicated to delay the progression of kidney disease and to reduce the risk of cardiovascular mortality and morbidity in adults with chronic kidney disease (stage 3 and 4 with albuminuria) and type 2 diabetes.

Members recommended that *finerenone* should be classified in ATC code C03DA in accordance with its pharmacological mechanism. Members advised that a comment should be included in the Guidelines.

***Monoclonal antibodies for the treatment of infections***

Members considered a request to classify the combination of *tixagevimab (124) (85)* and *cilgavimab (124) (85)* in J05AX *Other antivirals*. Members noted that another monoclonal antibody, *ibalizumab (97) (59)*, indicated for the treatment of HIV, was classified in J05AX. Members further discussed that the ATC groups J06BB *Specific immunoglobulins* and J06BC *Other immunoglobulins* also included human monoclonal antibodies.

Members recommended to establish two new ATC 4th levels for monoclonal antibodies in J06B, one for viral infections and one for bacterial infections, and assign an ATC code for *tixagevimab* and *cilgavimab* in the 4th level for viral infections. Members considered that given the importance of being able to examine the utilisation of HIV treatment, *ibalizumab* should continue to be classified within J05A.

***Bacterial lysates***

The members considered a request to establish general principles to classify preparations containing bacterial lysates. Members noted that these products were generally classified according to the indication of the relevant ATC 4th levels.

Members recommended that it would be pragmatic to continue with the current practice of classifying bacterial lysates, noting that this would allow the discretion to classify these products according to their indication of use in different regions. Members considered that advice should be included in future 'Guidelines for ATC classification and DDD assignment' on the convention to classify bacterial lysates.

***aducanumab***

At the 48th meeting, the Working Group recommended a temporary classification of *aducanumab (110) (72)* in N06DX03 *Other anti-dementia drugs*.

Members noted that *aducanumab* cannot be considered as a psychoanaleptic (ATC 2nd level N06 *Psychoanaleptics)*. However Members did not take the objection to the temporary

classification into account but reaffirmed the previous decision to include *aducanumab* in N06DX03, considering that it was preferable to classify this substance in the therapeutic ATC 4th level N06DX rather than create a new ATC code without specifying the indication of use.

***L01XC monoclonal antibodies***

Members recalled the decision from the 48th meeting requesting a revision of L01XC monoclonal antibodies due to the rapid increase in the number of substances that were being classified in this ATC code. Members advised to create a temporary reclassification with the creation of specific 4th levels for substances that have the same molecular target. Members considered that the principle for ATC classification should be followed where a 4th level should only be established if there are least two substances with the same molecular target on the market.

Members recommended that an external hearing should be performed before the re-classification of L01XC is finally decided, and that the temporary codes should be made available on the ATC/DDD Centre's website.

***Fibroblast growth factor receptor tyrosine kinase inhibitors***

Members considered applications to classify two fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitors, *infigratinib (112) (74)* and *futibatinib (119) (81)*. Members noted that L01EX included two existing FGFR listings, *erdafitinib (113) (75)* and *pemigatinib (118) (80)* and considered that a new ATC 4th level should be established for these substances. Members recommended the ATC 4th level L01EN *Fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitors* was established and to include *erdafitinib, pemigatinib, infigratinib* and *futibatinib* in this new ATC group.

***semaglutide* and *liraglutide***

Additional ATC codes for *semaglutide (101) (63)* and *liraglutide (87) (49)* were sought for the use as anti-obesity drugs. Members noted that the substances had existing classification in A10 *Drug used in diabetes*. As the strengths and pharmaceutical form of the new products overlapped with the presentations for *semaglutide* and *liraglutide* as antidiabetic drugs, to be consistent with the principles used for ATC classification, members advised that the new presentations for *semaglutide* and *liraglutide* as anti-obesity drugs should be classified in the existing ATC codes,A10BJ06 and A10BJ02, respectively.

***lenacapavir***

Members recommended that *lenacapavir (121) (83)* for the treatment of HIV-1 infection should be classified in J05AX *Other antivirals*, noting that other substances with its mechanism of action had not applied for an ATC classification.

***Dengue virus vaccines***

Members considered classification requests for two dengue virus vaccines, QDENGA™ and DENGVAXIA™. Members recommended the creation of a new 5th level in J07BX *Other viral vaccines* for these products. Members noted that a separate ATC 4th level for dengue virus vaccines could be considered when more vaccines are marketed.

### *Colchicine*

An additional ATC code for colchicine was sought for its use in the reduction of atherothrombotic events in patients with existing coronary artery disease. Members advised to maintain the classification of colchicine in M04AC because of other existing colchicine products with the same strength.

### *Defined Daily Dose Items*

Members accepted several new defined daily doses (DDD) proposed by the Centre. All new temporary DDDs and alterations are published at the ATC/DDD Centre's website and in WHO Drug Information with deadline for objections 1 September 2021 (www.whocc.no).

Members noted a three-year review of DDDs assigned from January 2019. No DDDs were changed. The revision of the DDD for *baricitinib (107) (69)* was however postponed to the next meeting (October 2021) due to new dose recommendations in some countries.