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51st MEETING OF THE WHO INTERNATIONAL WORKING GROUP FOR DRUG STATISTICS METHODOLOGY

Geneva, 24-25 March 2022 (virtual meeting)

Executive Summary

International Nonproprietary Names (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

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EXECUTIVE SUMMARY

Opening of the meeting

Opening remarks were offered by *Dr Clive Ondari*, Director, Health Products Policy and Standards Department (HPS).

Dr Raffaella Balocco Mattavelli welcomed the participants of the meeting. One new member was welcomed to the Working Group: *Dr Ryosuke Nakamura*, National Institute of Health Science, Division of Medicinal Safety Science, Japan.

Election of Chair and Rapporteur

Dr Morten Andersen was elected as Chair of the meeting. *Dr Kerry Atkins* was elected rapporteur.

Report from the WHO Collaborating Centre for Drug Statistics Methodology

Mr Christian Lie Berg gave a short briefing regarding the work previously done at the WHO Collaborating Centre for Drug Statistics Methodology ("the Centre"). A more extensive presentation will be given during the autumn meeting.

ATC classification items

All new temporary ATC codes and alterations are published at the Centre's website and in WHO Drug Information (https://www.who.int/our-work/access-to-medicines-and-health-products/who-drug-information) with the deadline for objections 1st September 2022.

Malaria vaccines

At its 38th meeting, the Working Group discussed the classification of the malaria vaccine Mosquirix™ for active immunisation against P. falciparum malaria and hepatitis B, where it was decided to postpone the classification until the vaccine is approved by a regulatory authority. Members noted that Mosquirix™ was primarily used as a malaria vaccine. The Working Group decided to classify the malaria vaccine in J07X *Other vaccines* with a new ATC 4th level J07XA *Parasitic vaccines* and 5th level J07XA01 *Malaria vaccines*.

Nirsevimab

At its 50th meeting, the Working Group recommended that nirsevimab be classified at the ATC 5th level as J06BD *Antiviral monoclonal antibodies*. An application to reclassify nirsevimab as a vaccine, or alternatively, as a prophylactic monoclonal antibody in a new 4th ATC level was considered. The Working Group decided to maintain the classification of nirsevimab in J06BD *Antiviral monoclonal antibodies*. The Working Group advised to implement a comment in the *Guidelines* regarding nirsevimab's indication and use as a prophylactic antiviral monoclonal antibody.

L04AA Selective immunosuppressants

At its 50th meeting, the Working Group considered possible options to reclassify substances in L04AA *Selective immunosuppressants* through establishing new ATC groups in L04A by mechanism of action, including sphingosine 1-phosphate (S1P) receptor modulators, anti-CD20 monoclonal antibodies, selective mammalian target of rapamycin (mTOR) inhibitors and Janus Kinase (JAK) inhibitors.

Members further discussed decisions from M50 on the revision of L04A and options for classification developed by the WHO Collaborating Centre. The Working Group requested an external open hearing process on two alternatives for classification prior to the next meeting (M52): assign five new ATC 4th levels in L04A based on the pharmacological mechanism of action; or a hybrid classification approach with pharmacological subgroups and two new ATC 3rd levels for organ transplant and for multiple sclerosis. The public consultation has been published at the WHO Collaborating Centre's website.

Gabapentin, pregabalin, and mirogabalin

A revision of the classification of the gabapentinoids was discussed at the 46th meeting of the Working Group. Members noted that gabapentin and pregabalin were classified in N03AX *Other antiepileptics*, whereas mirogabalin was classified in N02BG *Other analgesics and antipyretics* according to the indication neuropathic pain. Members considered that in recent years the main therapeutic use of gabapentin and pregabalin was in the treatment of neuropathic pain. During the 51st meeting, the Working Group decided to establish a new ATC 4th level, N02BF *Gabapentinoids* and alter the classification of gabapentin, pregabalin and mirogabalin. The Working Group advised that a comment could be included in the Guidelines in N03AX *Other antiepileptics* that gabapentin and pregabalin are classified in N02BF.

Midazolam

An application to reclassify the oromucosal formulation of midazolam to N03A *Antiepileptics*, N03AE *Benzodiazepine derivatives* was considered. The Working Group decided it was appropriate to maintain the classification of the oromucosal formulation of midazolam in N05C *Hypnotics and sedatives*, N05CD *Benzodiazepine derivatives*, N05CD08 midazolam with the other pharmaceutical formulations of midazolam.

Cell and gene therapy products

The Working Group recalled its decision from M50 to consider establishing an ATC 4th level for gene-cell therapies in L01X. It was decided to establish L01XL *Antineoplastic cell and gene therapy*. It was further decided to standardise the procedures for ATC applications for cell and gene therapy products in line with other products and remove the sentence in the Guidelines regarding "a positive opinion (EU) or marketing authorization" for cell and gene therapy products.

New ATC codes

Members approved a total of 43 new ATC codes proposed by the Centre in the period October 2021 - February 2022.

Defined Daily Dose Items

Members accepted the new defined daily doses (DDD) proposed by the Centre. All new temporary DDDs and alterations are published at the WHO Collaborating Centre's website and in WHO Drug Information with deadline for objections 1st September 2022.

Members considered a three-year review of DDDs assigned from January 2020. No DDDs were changed.