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)
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Opening of the meeting

*Dr Raffaella Balocco Mattavelli* welcomed the participants of the meeting. The agenda for M53 was approved without comments. *Prof Morten Andersen* was elected as chair of the meeting. *Dr Kerry Atkins* was elected as rapporteur for the executive summary to be published on the WHO webpage.

Report from the WHO Collaborating Centre for Drug Statistics Methodology

*Dr Mohammad Nouri Sharikabad* gave a briefing regarding the work done at the WHO Collaborating Centre for Drug Statistics Methodology (the ‘Centre’). It was noted that the Centre would hold an Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) course in Portugal in April 2023 and the annual ATC/DDD course in Oslo on 8-9 June 2023.

ATC classification items

In total, 54 new ATC 5th level codes were established in addition to three ATC 4th level codes, and three ATC code objections were discussed.

The Working Group decisions included the following:

- To maintain the classification of bispecific antibodies in L01FX *Other monoclonal antibodies and antibody drug conjugates* and to assign new ATC 5th level codes for epcoritamab, glofitamab and talquetamab in L01FX. It was considered that establishing a new ATC 4th level would not be beneficial for pharmacoepidemiologic research at this time as all current bispecific antibodies could be appropriately classified within L01FX. The possibility to reclassify bispecific antibodies would be further considered when more products were available in the market.
- To establish a new ATC 5th level for vamorolone in H02AB *Glucocorticoids* and to include a comment in the guidelines regarding the differences of vamorolone to other glucocorticoids.
- To establish a new ATC 4th level for combinations of monoclonal antibodies with antineoplastic indications in L01F, with the classification as L01FY *Combinations of monoclonal antibodies and antibody drug conjugates*. It was recommended to include a comment in the Guidelines in L01 and L01XY that combinations of monoclonal antibodies are classified in L01FY.
- To classify clazosentan in a new code, C04AX *Other peripheral vasodilators* noting that the substance exerts its major effects in the cerebrovascular system.
- To maintain the classification of deucravacitinib in L04AF *Janus-associated kinase (JAK) inhibitors* and to include a note in the Guidelines stating TYK2 inhibitors are classified in this group.
- To maintain the classification of leriglitazone in A16AX *Various alimentary tract and metabolism products* as this substance is used to treat patients with a metabolic disorder, adrenoleukodystrophy (ALD).
• To maintain the classification of amyloid and tau radiopharmaceuticals in V09AX Other central nervous system diagnostic radiopharmaceuticals. It was noted that in addition to PET radiotracers, other biomarkers were used for Alzheimer disease diagnostics. Establishing a new ATC 4th level for PET radiotracers was not considered appropriate at this time as the future use of the PET radiotracers was uncertain and other biomarkers may also be established.

In relation to new codes proposed by the Centre since the latest meeting, the Working Group decided the following:
• To establish a new ATC 4th level in A10X: A10XX Other drugs used in diabetes and to classify teplizumab in the new 4th level.
• To establish a new ATC 5th level for apadamtase alfa and cinaxadamtase alfa in B01AD Enzymes and to include a comment in the Guidelines that the level includes enzymes, proenzymes and enzyme replacement therapies.
• To classify efanesoctocog alfa in an existing code (B02BD02) and etranacogene dezaparvovec in a new ATC 5th level code in B02BD Blood coagulation factors.
• To establish a new ATC 4th level in C02K: C02KN Other antihypertensives and classify aprocitentan in the new 4th level.
• To classify the combination of ramipril and indapamide in C09BA05 in C09BA ACE inhibitors and diuretics.
• To classify tacrolimus in D11AH01 in D11AH Agents for dermatitis, excluding corticosteroids and to revise the Guidelines to note this group is mainly used for atopic dermatitis or eczema.
• To establish a new ATC 5th level code for capivasertib in L01EX Other protein kinase inhibitors.
• To establish a new ATC 5th level code for delandistrogene moxeparvovec in M09AX Other drugs for disorders of the Musculo-skeletal system.
• To establish a new ATC 5th level code for donanemab in N06DX Other anti-dementia drugs.
• To classify sodium thiosulfate in V03AB06 in V03AB Antidotes and to include a comment in the Guidelines in V03AF that thiosulfate is classified in V03AB.

**Defined Daily Dose Items**

The Working Group approved the dose protocol presented by the Centre with one exception to assign a DDD of 3 UD (=3 vials) for N02BE51 paracetamol, combinations excl. psycholeptics.

DDDs for 20 new single substances were assigned in addition to 10 DDDs for combination products, and two DDD alteration requests were discussed. In relation to the alteration request for C03DA01 spironolactone, the Working Group postponed the decision to consider further information from treatment guidelines and drug use data on doses used in current practice.

The three-year revisions of DDDs included in the ATC/DDD index from January 2021 were considered by the Working Group. All DDDs, except the DDD for budesonide, were kept unchanged. The DDD for budesonide (A07EA06) was reduced to 1.5 mg to reflect the average maintenance dose.