EPHMRA/Intellus Worldwide Classification Committee

WHO WE ARE.
WHAT WE DO.
(last updated Oct 2023)

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Background

- Pharmaceutical products worldwide are grouped into categories in sales, medical, and promotional audit services according to the **EPHMRA/Intellus Worldwide Anatomical Classification System**
  - Pharmaceutical audits around the world are based on this system
  - IQVIA and other secondary data suppliers use this classification

- The Anatomical Classification brings order and standardisation, enabling market researchers to analyse therapeutic markets and to compare similar products

- **Responsibility for maintaining** the integrity of the system, meeting the demands of the evolving marketplace, and reviewing and deciding the classification of products **lies with the Classification Committee**

- **The World Health Organisation (WHO)** adapted the system for its own needs to create a separate ATC classification for clinical use

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COMMITTEE MEMBERSHIP

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Benefits of Committee Membership

Committee membership provides colleagues with unique developmental opportunities and interaction with other industry colleagues. The Committee is a global working group from multiple organisations and multiple companies.

- Provides colleagues from member companies a seat at the table to review and discuss classification issues that may impact their business:
  - While Committee members are expected to be unbiased in their assessments, it is acknowledged that each member can present their corporate interests where applicable
  - The Classification Guidelines are the principles that determine classification issue outcomes

Benefits of Committee Membership (continued)

- Allows colleagues very early insight into new developments and to have an impact on how market classifications are structured in the future
- Contributes to broadening drug class and overall industry knowledge
- Provides an opportunity to contribute in a meaningful way to the continued evolution of the Pharmaceutical Industry

Committee Membership

- The Anatomical Classification Committee is made up of approximately eight to ten members from pharmaceutical companies

- The Committee consists of individuals from EPHMRA full member companies plus one full member from Intellus
  - There are positions for Liaison members from Japan and China
  - IQVIA is represented on the Committee to provide support and expertise

- The primary qualifications for membership are knowledge of the international pharmaceutical market and its products, and some experience with global secondary databases
  - Apprentice positions are also available for newer industry colleagues

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Committee Membership

- The Committee meets four times each year
  - One hybrid virtual/face-to-face meeting per year is held at the EPHMRA conference
  - There are also 3 meetings per year that are held virtually
  - Additionally, the Committee Leadership meets annually with the WHO to harmonise the two classifications systems

- Each member has a primary responsibility for one or more therapeutic categories
- In order to add value to the industry and the Committee, members are encouraged to be part of the Committee for at least two years
- This medium to long-term commitment will also enhance the experience for the Committee member
- Members are expected to attend at least 3 meetings per year with funding for T&E provided by their company for any face-to face meeting
- When positions on the Committee are available, nominations for members who meet the qualifications are sought from member companies
- Industry members who volunteer to join the Committee are also considered

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DETAILED INFORMATION

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Schedule of Committee Meetings/Activities

- Q1 WHO Harmonisation Meeting – Review annual changes to both classifications, seek areas of alignment, review future anticipated developments
- Q1 Classification Meeting – Review new/existing investigations and finalise proposals ready for voting
- Annual Voting (May/June) of new classes
- Q2 Classification Meeting – Review outcome of annual voting on new classes; review new/existing investigations
- Q3 Classification Meeting – Refine detailed rules of newly voted classes; review progress on new/existing investigations
- Q4 Classification Meeting – Finalise new class guidelines; review progress on new/existing investigations; determine list of proposals ready for voting the following second quarter

History

- Pharmaceutical sales audits were introduced in the 1950s
  - Most of these audits were based on similar classification systems but there was some variation

- There was therefore a need to have one unified classification system for comparability
  - Development of the current Anatomical Classification began in 1968
  - It was developed by market researchers of many European-based international pharmaceutical companies
  - Market researchers from international pharmaceutical companies in Europe and USA participated in translating the old system into the Anatomical System

Anatomical Classification System Overview

- The Anatomical Classification System is based on a cascade:
  - Products are grouped by anatomical site of action, indication, mechanism of action or composition
  - The 2nd level gives details of the 1st, the 3rd of the 2nd, and the 4th of the 3rd

- Importantly, individual products are classified, not substances
  - "Product" is defined as a pack or unit that can be dispensed, prescribed, etc.
  - Each product pack (SKU) is assigned to one category

Creating New Classifications

- To create a new class within the system, there must be:
  - a compelling need for a new class
  - and a substance with an approved indication launched in at least one country
  - and a second, different substance in registration and expected to be launched soon

- A one-substance class will not be created

- New classes can be suggested by EPHMRA/Intellus members, non-EPHMRA/Intellus members, or the Committee
  - Proposals should be clearly stated and the impact of the change to the system should be outlined
  - The proposal is carefully reviewed by the entire Committee, which consults, as needed, with appropriate involved member companies and sometimes with medical input
  - The purpose is to find out if there is general consensus that the system should be modified and what the changes should be
  - The responsible Committee member finalises the proposal
  - The finalised proposal with background information is sent out to the full EPHMRA/Intellus membership for voting in the second quarter of each year

Classification Restructure Proposal: Voting Requirements

- Proposals for a restructure of the classification are prepared by the Committee
  - Proposals are then voted on by the EPHMRA/Intellus membership
- Industry members of EPHMRA and/or Intellus are entitled to vote
  - Each member company is entitled to one vote
  - A “company” is defined as a corporate entity
  - This means there is one vote per corporation, regardless of the number of affiliates or subsidiaries
- The proposals need the approval of a 2/3 majority of the voting companies to pass
- If approved, the new classes are implemented in the first audit of the following year

Harmonisation with WHO

- In the 1970s, WHO adapted the EPHMRA system for its own needs. This became the system that the WHO calls the Anatomical Therapeutic Chemical system (ATC)
  - At the present time, the two systems are similar but are designed to meet two different goals
  - The purpose of the WHO ATC is to meet the needs of clinicians, academia, governments and health organisations for drug utilisation with the aim of improving drug use
  - The purpose of the EPHMRA/Intellus Anatomical Classification system is to meet the needs of marketing research and marketing
  - The WHO ATC classifies substances while the EPHMRA/Intellus Anatomical Classification system classifies products

- Since 1991, EPHMRA and WHO meet annually to harmonise the systems in order to ensure consistency between the two systems
  - A high level of harmonisation has been achieved and an EPHMRA/WHO Comparison Document is published annually

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Access to the EPHMRA/Intellus Guidelines

- The Guidelines to the Anatomical Classification System describe the types of products included in each class
  - Annual Classification changes are also available in an annual report posted on the Intellus and EPHMRA websites

- The Guidelines and annual changes can be obtained through the EPHMRA internet site (www.EPHMRA.org) or the Intellus internet site (www.intellus.org/Member-Resources/EPHMRA-Classification), or by e-mailing the General Manager of EPHMRA or the Executive Director of Intellus

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