

EphMRA/Intellus Worldwide Classification Committee

WHO WE ARE.

WHAT WE DO.

2019



Background

- Pharmaceutical products worldwide are grouped into categories in sales, medical, and promotional audit services according to the **EphMRA/Intellus Worldwide Anatomical Classification System**
 - Virtually all 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 standardization, enabling market researchers to analyze 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 approving the classification of individual products **lies with the Classification Committee**
- **The World Health Organization (WHO)** adapted the system for its own needs to create a separate ATC classification for clinical use.

COMMITTEE MEMBERSHIP

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 organizations 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 ten members from pharmaceutical companies
- The Committee consists of individuals from EphMRA full member companies in Europe plus one full member from Intellus Worldwide
 - There is a position for Liaison members from Japan and China
 - IQVIA is represented on the Committee as a non-voting member
- The primary qualifications for membership are knowledge of the international pharmaceutical market and its products, and current experience with global secondary databases
 - Within the Committee, there are two categories of membership: full position and apprentice position (determined by level of experience)

Committee Membership

- The Committee meets four times each year for approximately 1.5 days.
 - Members of the Committee rotate hosting the meeting
- 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 (in person) at least 3 meetings per year and their organization must be prepared to fund their T&E
- When positions on the Committee are available, nominations for members who meet the qualifications are sought from member companies
- Industry member volunteer who ask to join the Committee are also considered

DETAILED INFORMATION

Schedule of Committee Meetings/Activities

- Q1 WHO Harmonization Meeting – Review annual changes to both classifications, seek areas of alignment, review future anticipated developments
- Q1 Classification Meeting – Review new/existing investigations and finalize 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 – Finalize 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 Worldwide members, non-EphMRA/Intellus Worldwide 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 finalizes the proposal
 - The finalized proposal with background information is sent out to the full EphMRA/Intellus Worldwide 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 Worldwide membership
- Industry members of EphMRA and/or Intellus Worldwide 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

Harmonization 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 teaching, clinical trials, health organizations, and governments
 - The EphMRA/Intellus Worldwide Anatomical Classification system aims to meet the needs of marketing research and marketing
 - The WHO ATC classifies substances while the EphMRA/Intellus Worldwide Anatomical Classification system classifies products
- Since 1991, EphMRA and WHO meet annually to harmonize the systems in order to avoid confusion between the two systems
 - A high level of harmonization has been achieved

Access to the EphMRA/Intellus Worldwide 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 Worldwide and EphMRA websites
- The Guidelines and annual changes can be obtained through the EphMRA internet site (www.ephmra.org) or the Intellus Worldwide internet site (www.intellus.org/Member-Resources/Ephmra-Classification), or by writing to the General Manager of EphMRA or the Chief Financial Officer of Intellus Worldwide

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THANK YOU!

- See EphMRA (www.ephmra.org) and Intellus Worldwide (www.intellus.org) websites for :
 - Directory of Committee members and their responsibilities
 - Contact information to inquire further