EphMRA/PBIRG Classification Committee

WHO WE ARE

WHAT WE DO

2017

CLASSIFICATION COMMITTEE

Background

- Pharmaceutical products worldwide are grouped into categories in sales, medical, and promotional audit services according to the **EphMRA/PBIRG Anatomical Classification System**
  - Virtually all pharmaceutical audits around the world are based on this system
  - IMS 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 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.

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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

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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

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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 PBIRG
  - There is a Liaison member from Japan
  - A member from Asia/Pacific would also be welcome
  - IMS 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)

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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
- When positions on the Committee are available, nominations for members who meet the qualifications are sought from member companies
- Volunteers for the Committee are also considered

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DETAILED INFORMATION

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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

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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.
  - Products are usually classified according to their main therapeutic indication if they have multiple indications
  - Each product is assigned to one category

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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/PBIRG members, non-EphMRA/PBIRG 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 opinion leaders
  - 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/PBIRG membership for voting in the second quarter of the year

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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/PBIRG membership
- Full members of EphMRA and/or PBIRG 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

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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 teaching, clinical trials, health organisations, and governments
  - The EphMRA/PBIRG Anatomical Classification system aims to meet the needs of marketing research and marketing
  - The WHO ATC classifies substances while the EphMRA/PBIRG Anatomical Classification system classifies products

- Since 1991, EphMRA and WHO meet annually to harmonise the systems in order to avoid confusion between the two systems
  - A high level of harmonisation has been achieved

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Access to the EphMRA/PBIRG 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 PBIRG and EphMRA websites
- The Guidelines and annual changes can be obtained through the EphMRA internet site (www.ephmra.org) or the PBIRG internet site (www.pbirg.com/member services), or by writing to the General Manager of EphMRA or the Executive Director of PBIRG

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THANK YOU!

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

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