

Important Classification Committee Update:

Major Restructuring of ATC L-Class Impacting Oncology and Immunology

The EPHMRA/Intellus ATC Classification Committee is embarking on a pivotal reorganization of the L-class within the Anatomical Classification (ATC) system. This significant change aims to better distinguish antineoplastic (oncology) therapies from immunological products, creating a clearer and more adaptable framework for emerging innovations in both therapeutic areas.

Addressing Current Challenges

Currently, oncology drugs and immunological products are grouped under the same ATC1 level (L-class). While convenient in the past, this classification has become increasingly restrictive given the rapid development of novel therapies, particularly monoclonal antibodies (L1G) and protein kinase inhibitors (L1H). This grouping limits the availability of subcategories, making the classification less able to respond to market evolution.

The Proposed Change

The committee's proposal introduces a new, dedicated ATC1 F-class for immunological products, allowing oncology drugs to exclusively occupy the restructured L-class. Antineoplastic subclasses within the L-class will be promoted to higher levels, such as L5 for alkylating agents and L10 for monoclonal antibody antineoplastics, among others. Immunology-related products will transition to new classifications (F1 for immunostimulants and F2 for immunosuppressants) to ensure separation from oncology drugs.

This streamlined approach will enhance clarity in drug classification, separate oncology and immunology, and future-proof the ATC system to accommodate emerging therapies.

CURRENT				
L: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS				
L1: ANTINEOPLASTICS		L2: CYTOSTATIC HORMONE THERAPY	L3: IMMUNOSTIMULATING AGENTS	L4: IMMUNOSUPPRESSANTS
L1A: ALKYLATING AGENTS	L1H: PROTEIN KINASE INHIBITOR ANTINEOPLASTICS	L2A: CYTOSTATIC HORMONES	L3A: IMMUNOSTIMULATING AGENTS EXCLUDING INTERFERONS	L4B: ANTI-TNF PRODUCTS
L1B: ANTIMETABOLITES	L1J: PROTEASOME INHIBITOR ANTINEOPLASTICS	L2B: CYTOSTATIC HORMONE ANTAGONISTS	L3B: INTERFERONS	L4C: INTERLEUKIN INHIBITORS
L1C: PLANT-BASED ANTINEOPLASTICS	L1K: LIDOMIDE ANTINEOPLASTICS			L4D: JAK INHIBITORS
L1D: ANTINEOPLASTIC ANTIBIOTICS	L1L: PARP INHIBITOR ANTINEOPLASTICS			L4X: OTHER IMMUNOSUPPRESSANTS
L1F: PLATINUM ANTINEOPLASTICS	L1X: ALL OTHER ANTINEOPLASTICS			
L1G: MONOCLONAL ANTIBODY ANTINEOPLASTICS				

Within oncology, there are limited free sub-levels available for expansion to reflect new therapies. Especially in the MAb and PKI classes, L1G and L1H respectively.

The proposal creates a new ATC1 for immunological products and therefore separates them from oncology products.

This allows the promotion of existing L1 antineoplastic ATC3 classes to ATC2 level, providing scope for new class creation in line with market developments.

L2 Cytostatic Hormone Therapy
classes would remain unchanged.

Benefits of the Change

The restructuring of the L-class offers multiple benefits:

- **Clarity:** Distinct classifications for oncology and immunology products.
- **Adaptability:** The updated framework can better accommodate market changes and new therapeutic innovations.
- **Future-Proofing:** The system will be positioned to manage therapies yet to be developed, ensuring long-term relevance.

Implementation Timeline

Voting on the restructuring proposal is scheduled for May/June 2026, with implementation planned for January 2027. This timeline provides ample opportunity for stakeholders to provide feedback and prepare for the transition.

Stakeholder Engagement and Support

To ensure a smooth transition, the ATC Classification Committee is encouraging feedback from industry professionals and organizations. Oncology and immunology teams are urged to review the proposed changes and align accordingly. Comprehensive materials and resources will be available on the EPHMRA and Intellus websites.

Additionally, the Committee will host a webinar to discuss the proposed restructuring in detail, answer questions, and provide further guidance. This event will serve as an opportunity to familiarise stakeholders with the proposed change and answer any questions.

Get Involved

- Look out for the upcoming webinar to explore the changes and their implications further.
- Alert your oncology and immunology colleagues of this proposal.
- Share your questions and feedback by contacting Bernadette Rogers, (generalmanager@ephmra.org)
- And finally, vote on the proposal in May/June 2026.

Together, we can ensure the ATC system remains a robust and effective tool for classifying therapies in the evolving healthcare landscape.