Trends in EMA-Approved New Medicines 2015-2024: New Mechanisms of Action and Regulatory Shifts

HPR225

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Objectives

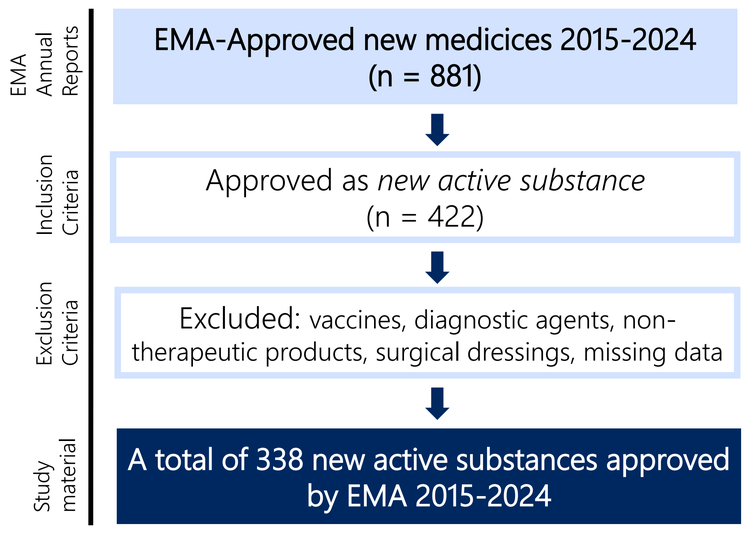
To assess how recent trends in medicines development are reflected in the approvals by the European Medicines Agency (EMA). Emphasis was given to evolution of regulatory pathways and the emergence of new mechanisms of action.

Materials and Methods

Data on new medicines were collected from the EMA's Annual Reports. Medicines approved as "new active substance" (NAS) were included. **(Figure 1).**

The number of new medicines in anatomic-therapeutic-chemical (ATC) classification system belonging to fourth-level class X ("other") was used as a proxy for new mechanism of action. The analysis compared subperiods 2015-2019 and 2020-2024.

Figure 1: Data selection



Results

A total of 338 NASs met the inclusion criteria (147 in 2015-2019 vs. 191 in 2020-2024).

The dominance of ATC main group L (antineoplastic and immunomodulating agents) continued to grow, increasing from 38% to 43% of approvals. This trend was largely driven by subgroup L04 (immunosuppressants), which increased from 7% to 12%.

The proportion of NASs with a new mechanism of action increased from 23% (2015-2019) to 32% (2020-2024). Within this subset, the share of medicines belonging to group L increased from 26% to 36%, and the proportion of subgroup L01FX (other monoclonal antibodies and antibody drug conjugates) increased from 9% to 18%. **(Figures 2-3)**

A notable shift in regulatory strategy was observed. The use of *accelerated assessment* decreased from 12% (2015-2019) to 1% (2020-2024). In contrast, the role of other regulatory pathways increased. These included *conditional marketing authorisations* (3% vs. 16%), approval under *exceptional circumstances* (4% vs. 7%), and *PRIME designations* (1% vs. 15%) **(Figure 4).**

Conclusions

Antineoplastics and immunomodulating agents have increased their share both overall and among innovative therapies, highlighting their growing importance in medicines development. The transition from accelerated assessment to more sophisticated regulatory pathways signals a broader shift in how innovation is managed within the regulatory system.

Figure 4: Shifts in EMA's regulatory pathways 2015-2019 vs. 2020-2024.

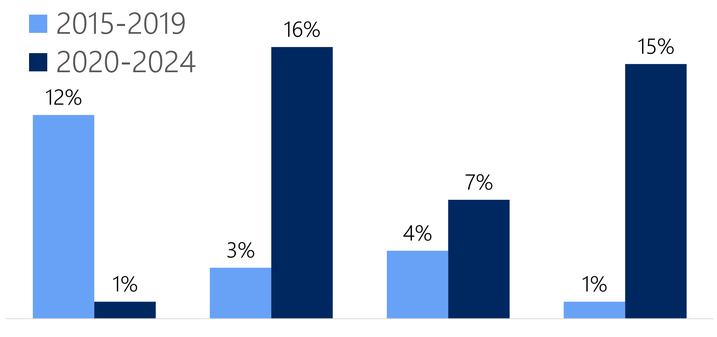
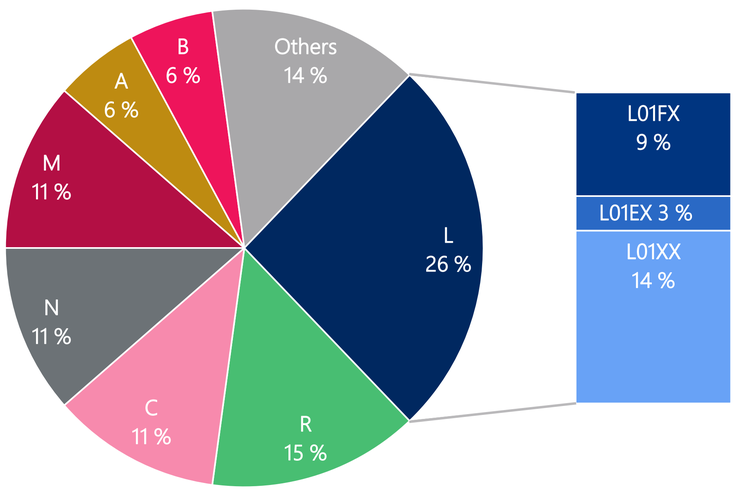
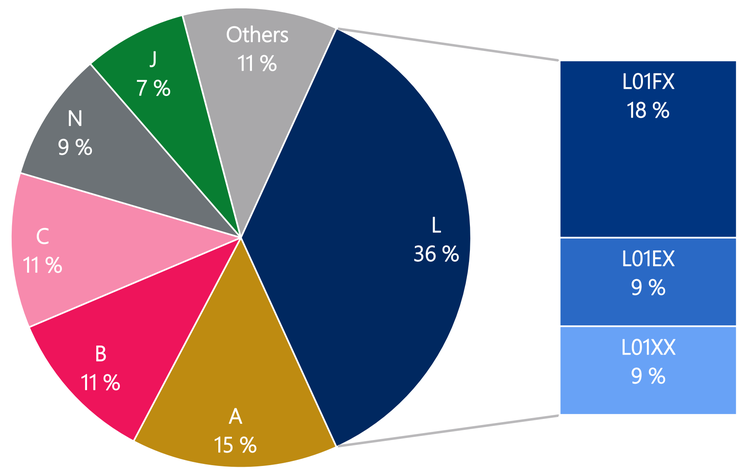


Figure 2: New active substances with a novel mechanism of action 2015-2019



Anatomic-Therapeutic-Chemical classification main groups:
A: Alimentary tract and metabolism
B: Blood and blood forming organs
C: Cardiovascular system
J: Anti infectives for systemic use
L: Antineoplastic and immunomodulating agents
M: Musculo-skeletal system
N: Nervous system
R: Respiratory system

Figure 3: New active substances with a novel mechanism of action 2020-2024



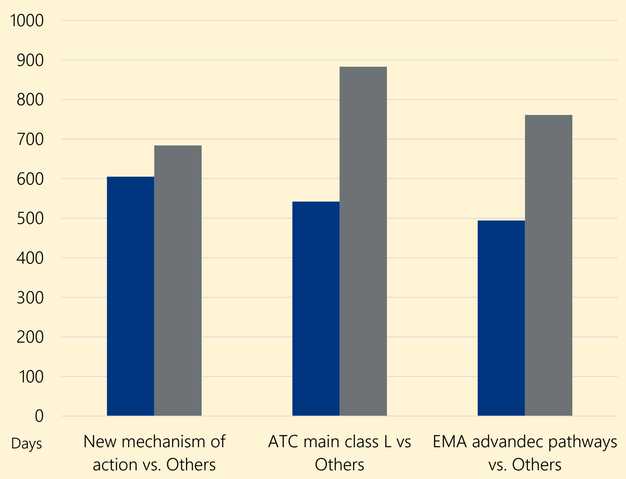
Subgroups of the main group L:
L01FX: Other monoclonal antibodies and antibody drug conjugates
L01EX: Other protein kinase inhibitors
L01XX: Other antineoplastic agents

Which factors accelerate the market entry of new EMA-approved medicines in Finland?

Based on registry data from the Finnish Medical Agency, we investigated how factors such as ATC main group, novelty of the mechanism of action, and EMA's regulatory pathways influence the speed of adoption of new medicines in Finland. A shorter interval between EMA approval and market entry in Finland was associated with ATC main class L, the use of advanced regulatory pathways/designations*, and to a limited extent, a novel mechanism of action **(Figure 5).**

*Accelerated assessment, Conditional approval, Exceptional circumstances, PRIME priority medicines, Orphan medicines, Additional monitoring.

Figure 5: the avarage time between EMA approval and market entry in Finland



Key findings

The proportion of new medicines with a novel mechanism of action is increasing.

Anticancer and immunomodulating agents, particularly antibody-based therapies, play an increasingly central role in pharmaceutical innovation.

EMA's regulatory pathways designed for advanced therapies are becoming more widely utilised, and they may be associated with a faster market entry.

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