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FDA vs EMA a comparison of new chemical entity approvals: the role of start-ups

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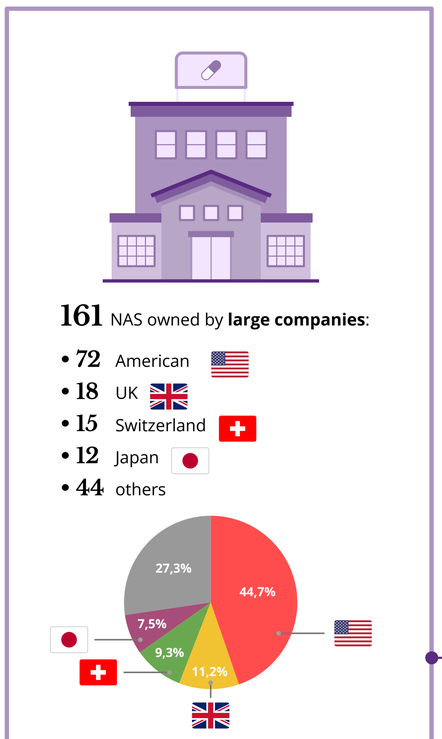
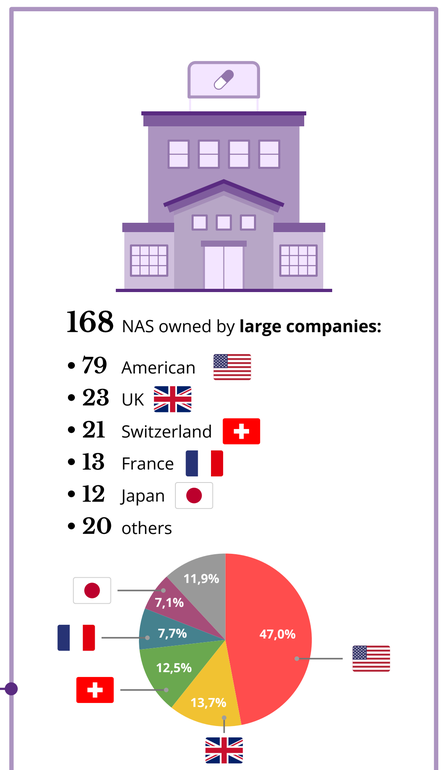
Objectives

The EMA and the FDA regulate drug approvals in the European Union and the United States, respectively. Although they collaborate, their approvals for new active substances often differ. This analysis aims to identify the variables influencing approvals of new chemical entities, with particular attention to company size and the role of start-ups.

Methods

Annual publications from the EMA and FDA between 2020-2023 on new chemical entity approvals were analysed. Variables included designations like Breakthrough Therapy, PRIME, orphan drugs, and the company holding the marketing authorization, distinguishing between large companies and start-ups.

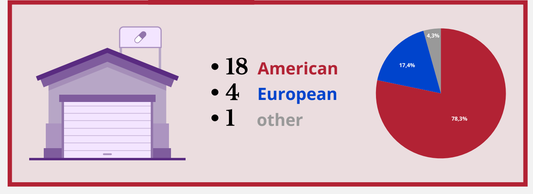




20 NAS approved by both agencies but approved by EMA before 2020

4 active substances approved by both agencies but only considered NAS by FDA

73 NAS approved **only by FDA**
- **16** Breakthrought Therapy
- **35** Orphan drugs
- **23** Owned by **START-UP**



99 NAS approved **by both FDA and EMA**

37 NAS approved **only by EMA**
- **3** Prime
- **9** Orphan drugs
- **3** Owned by **START-UP**

38 approved by both agencies but approved by FDA before 2020

15 active substances approved by both agencies but only considered NAS by EMA (ATMP, vaccines)

Results

Between 2020 and 2023, the FDA approved 196 new chemical entities, while the EMA approved 189. Differences included, 37 new chemical entities, of which 3 were from start-ups, approved in the European Union but not in the United States, and 73 new chemical entities, of which 23 were from start-ups, approved in the U.S. but not in the European Union. In the United States, 161 approved molecules are owned by large companies, with around 50% being American. Following them are 18 companies from the UK, 15 from Switzerland, and 12 from Japan. Additionally, among the 35 start-ups that received approval, 85% are American-owned. In the European Union, U.S. companies received 79 approvals, followed by 23 from the UK, 21 from Switzerland, 13 from France, 12 from Japan. Of the 21 start-ups that obtained approval, 50% are American-owned.

Conclusions

The analysis suggests that designations by the EMA and FDA do not significantly impact new active substances approvals between the agencies. However, large companies dominate approvals in both markets. U.S. start-ups face challenges in accessing the European market, likely due to their smaller structure and the complexity of the European market, which is fragmented across different member states, particulary from a regulatory perspective.

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