Comparison of approval dates of new substances between the United States of America (Food and Drug Administration, FDA) and Europe (European Medicines Agency, EMA)

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OBJECTIVES

Early access to innovative medications is a key factor for the quality of medical care. We investigated differences in approval dates of new active substances between the United States (US) and Europe.

METHODS

Data of new active substances approved by the US FDA and EMA from 01.01.2018 – 26.05.2023 were retrieved from FDA and EMA websites [1, 2]. Generic, biosimilar and hybrid approvals were excluded from evaluation. We reviewed whether and when each drug was approved by the other agency. Subsequently, the time difference between the drug approval dates between the agencies was calculated.

RESULTS

As shown in Table 1, in total 353 new active substances were approved since 2018 by FDA or EMA. Of these, 101 (28.6 %) were only approved by FDA compared to 31 (8.8 %) only by EMA (see Table 1 and Figure 1). From the 221 (62.6 %) active substances approved by both agencies, 70 (31.7 %) were approved with 0.5 years difference. 85 (38.5 %) substances were approved by FDA 0.5 – 1.5 years earlier, 33 (14.9 %) 1.5 – 3 years earlier and 10 (4.5 %) >3 years earlier. On the other hand, 7 (3.2 %) substances were approved by EMA 0.5 – 1.5 years earlier, 5 (2.3 %) 1.5 – 3 years earlier and 11 (5.0 %) >3 years earlier (see Figure 2).

Therefore, US patients on average get access to innovative medicines earlier than European patients.

CONCLUSION

More than 25 % of new active substances approved by the FDA within the last five years are not yet approved in Europe whereas only less than 10 % of new active substances approved by EMA are not yet approved by FDA. In total these results show that European patients get later access to innovative medicines than US patients. Potential reasons for this may be strategic market and pricing decisions of the pharmaceutical industry or differences in data requirements, evaluation criteria and timelines between the two jurisdictions.

Table 1: Time differences in approval dates for new active substances between FDA and EMA (time range: 01.01.2018 – 26.05.2023)

	Number	Percent
Approval only FDA	101	28.6 %
FDA-approval more than 3 years earlier	10	2.8 %
FDA-approval between 1.5 and 3 years earlier	33	9.3 %
FDA-approval between 0.5 and 1.5 years earlier	85	24.1 %
FDA- and EMA approval with up to 0.5 years difference	70	19.8 %
EMA-approval between 0.5 and 1.5 years earlier	7	2.0 %
EMA-approval between 1.5 and 3 years earlier	5	1.4 %
EMA-approval more than 3 years earlier	11	3.1 %
Approval only EMA	31	8.8 %
Number of medicines approved in at least one region between 01.01.2018 and 26.05.2023	353	100 %
Number of medicines approved in both regions	221	62.6 %

Figure 1: Time differences in approval dates for new active substances between FDA and EMA as percentage of medicines approved in at least one region (time range: 01.01.2018 – 26.05.2023)

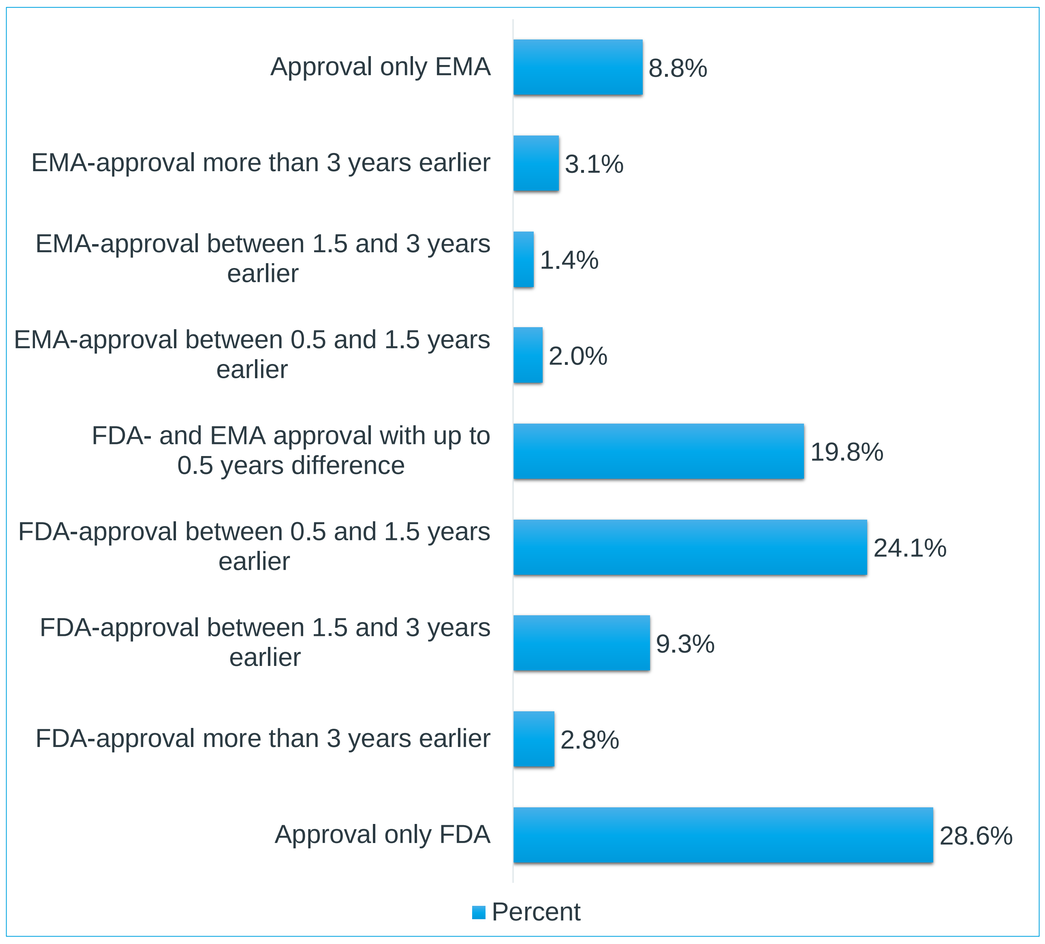
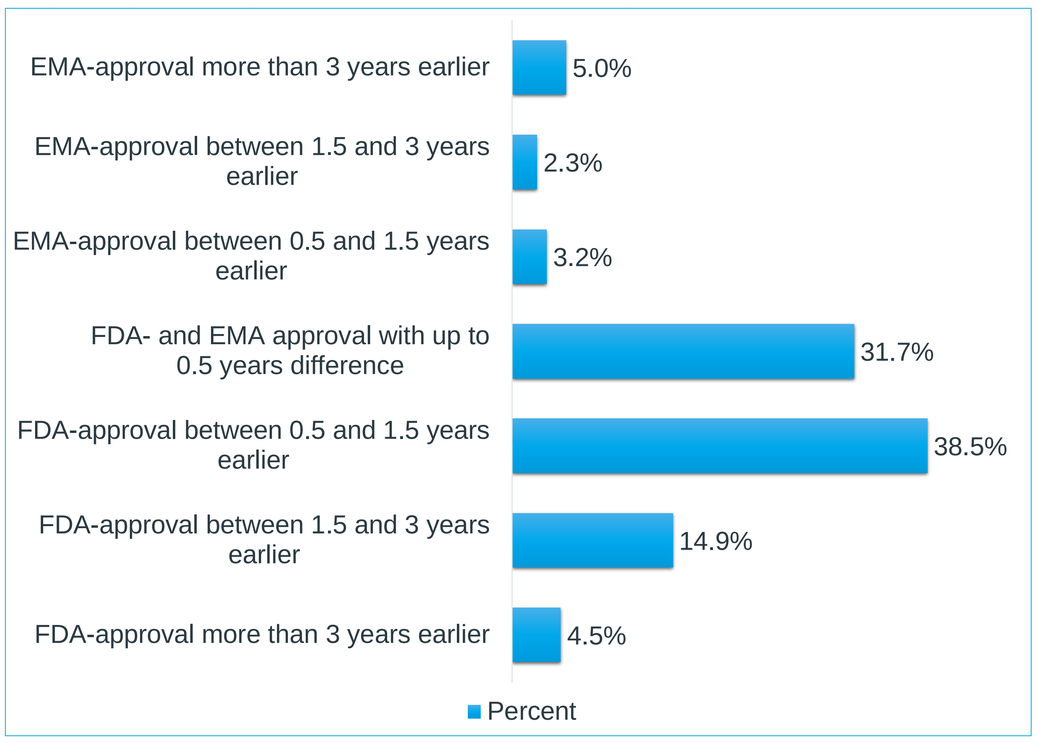


Figure 2: Time differences in approval dates for new active substances between FDA and EMA as percentage of medicines approved in both regions (time range: 01.01.2018 – 26.05.2023)



Abbreviations: EMA: European Medicines Agency; FDA: Food and Drug Administration; US: United States

Sources:

[1] Food and Drug Administration (2023). Available from: https://www.fda.gov/. Last access date: 26.05.2023

[2] European Medicines Agency (2023). Available from: https://www.ema.europa.eu/en. Last access date: 26.05.2023

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