Comparison of approval dates of new medications between Europe (European Medicines Agency, EMA), Japan (Pharmaceutical and Medical Devices Agency, PMDA), and the United States (US) of America (Food and Drug Administration, FDA)

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OBJECTIVES

A key factor for quality of medical care is early access to innovative pharmaceuticals. We investigated differences in approval dates of new active substances (NAS) between Europe, Japan, and the United States.

METHODS

Data of NAS approved by EMA, PMDA and FDA from 01.01.2018–31.01.2024 were retrieved from the respective websites [1, 2, 3]. Generic, biosimilar and hybrid approvals were excluded. We reviewed whether and when each product was approved by the other agencies. Subsequently, we calculated time differences between drug approval dates between the agencies.

RESULTS

As shown in figure 1, in total, n=516 NAS were approved since 2018 by EMA, PMDA and/or FDA. Of these, EMA approved 332, PMDA approved 271, and FDA approved 402. Of the 516, 169 (32.8%) were approved by all EMA, PMDA and FDA, 20 (3.9%) by EMA and PMDA only, 114 (22.1%) by EMA and FDA only, 17 (3.3%) by PMDA and FDA only, 29 (5.6%) by EMA only, 65 (12.6%) by PMDA only and 102 (19.8%) by FDA only (see figure 1).

Comparing NAS approved by both EMA and FDA (n=283), 50 (17.7%) are approved >1.5 years earlier by FDA and 21 (7.4%) >1.5 years earlier by EMA. In contrast when comparing products approved by both PMDA and FDA or EMA, respectively (n=186 and n=189), approval is earlier by >1.5 years by FDA in 42.5% and by EMA in 37.6% of the cases, while PMDA is earlier by >1.5 years in only 5.9% (FDA) and 8.5% (EMA) of the cases.

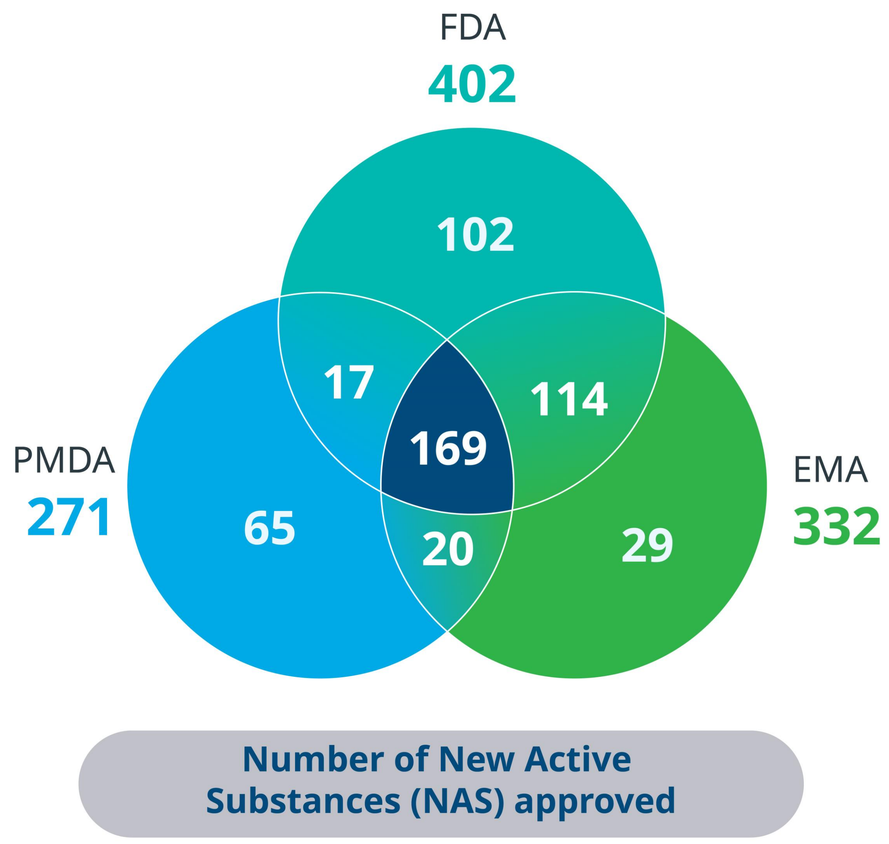
Of 283 medications approved by EMA and FDA, 96 (33.9%) were approved within 0.5 years. 104 (36.6%) were approved by FDA >0.5–1.5 years earlier, and 50 (17.6%) >1.5 years earlier. 12 (4.2%) were approved by EMA >0.5–1.5 years earlier and 21 (7.4%) >1.5 years earlier (see table 1).

Of 186 medications approved by FDA and PMDA, 51 (27.4%) were approved within 0.5 years. 37 (19.9%) were approved by FDA >0.5–1.5 years earlier, and 79 (42.5%) >1.5 years earlier. 8 (4.3%) were approved by PMDA >0.5–1.5 years earlier and 11 (5.9%) >1.5 years earlier (see table 1).

Of 189 medications approved by EMA and PMDA, 69 (36.5%) were approved within 0.5 years. 19 (10.1%) were approved by EMA >0.5–1.5 years earlier, and 71 (37.6%) >1.5 years earlier. 14 (7.4%) were approved by PMDA >0.5–1.5 years earlier and 16 (8.5%) >1.5 years earlier (see table 1).

This leads to a drug loss if not approved at all for both Europe and Japan compared to the US, which is especially noticeable in Japan.

Figure 1: EMA, PMDA and FDA NAS approvals (time range: 01.01.2018–31.01.2024)



In total, n=516 NAS were approved from January 2018 to January 2024 by EMA, PMDA, and FDA

Table 1: Time differences in approval dates for new active substances between EMA, PMDA and FDA

	Number	Percent
Approval by EMA and FDA	283	
Approval within 0.5 years	96	33.9
Approval by FDA >0.5–1.5 years earlier	104	36.7
Approval by FDA >1.5 years earlier	50	17.7
Approval by EMA >0.5–1.5 years earlier	12	4.2
Approval by EMA >1.5 years earlier	21	7.4
Approval by FDA and PMDA	186	
Approval within 0.5 years	51	27.4
Approval by FDA >0.5–1.5 years earlier	37	19.9
Approval by FDA >1.5 years earlier	79	42.5
Approval by PMDA >0.5–1.5 years earlier	8	4.3
Approval by PMDA >1.5 years earlier	11	5.9
Approval by EMA and PMDA	189	
Approval within 0.5 years	69	36.5
Approval by EMA >0.5–1.5 years earlier	19	10.1
Approval by EMA >1.5 years earlier	71	37.6
Approval by PMDA >0.5–1.5 years earlier	14	7.4
Approval by PMDA >1.5 years earlier	16	8.5

CONCLUSION

The results from the FDA, EMA, and PMDA confirm that Japan is currently experiencing a “drug loss” problem. US/EU-based biotech companies are contributing to New Active Substances (NAS), particularly in rare and pediatric areas, with the highest approval rates in the US. To close this gap, the Japanese government has been taking several actions and is awaiting results.

Abbreviations: EMA: European Medicines Agency; FDA: Food and Drug Administration; NAS: new active substance; PMDA: Pharmaceutical and Medical Devices Agency; US: United States

Sources:

[1] European Medicines Agency (2024). Available from: https://www.ema.europa.eu/en/medicines/download-medicine-data. Last access date: 18.04.2024

[2] Pharmaceutical and Medical Devices Agency (2024), Available from https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0002.html. Last access date: 18.04.2024

[3] Food and Drug Administration (2024). Available from: https://www.fda.gov/. Last access date: 18.04.2024

Poster presented at ISPOR Europe 2024 on 17-20 November 2024, Barcelona, Spain, Presentation Code: EPH246

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