Analysis Of Newly FDA Approved Medicines and The Licensing Status By TITCK in Türkiye

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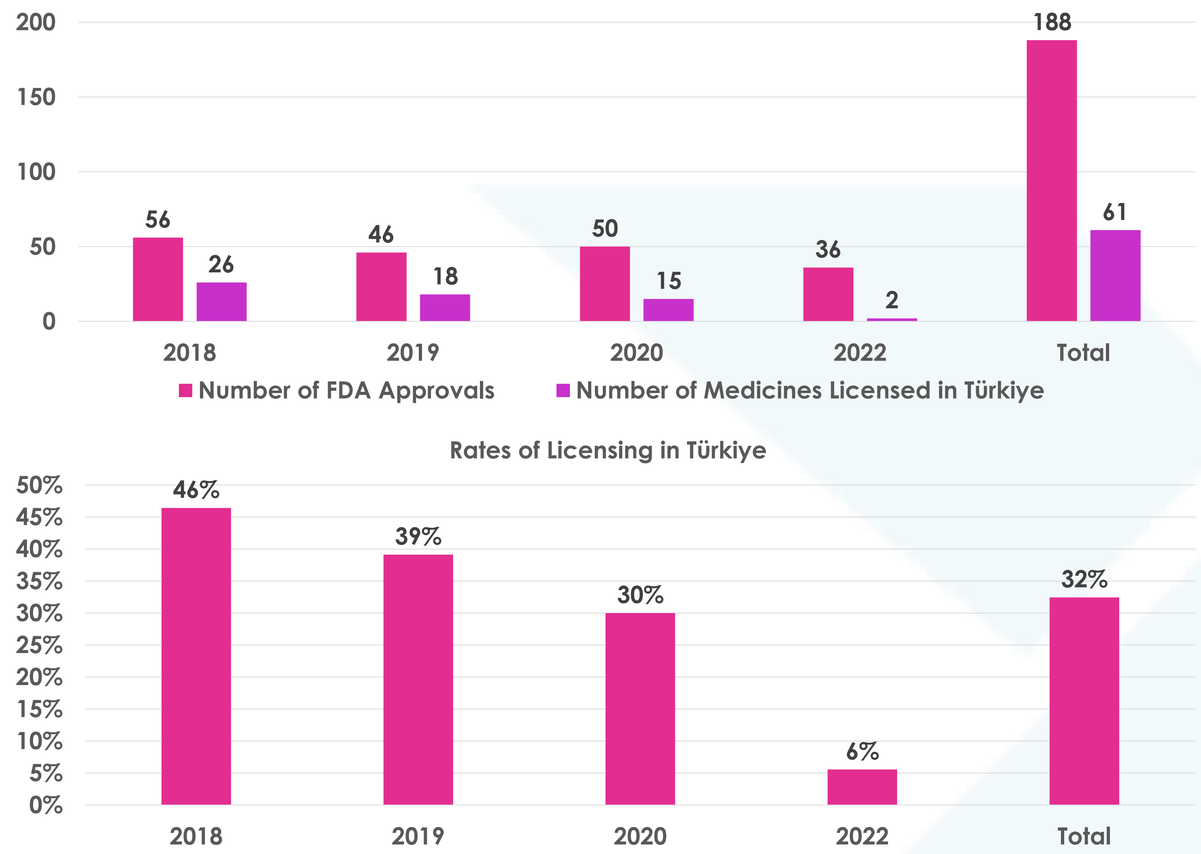
INTRODUCTION

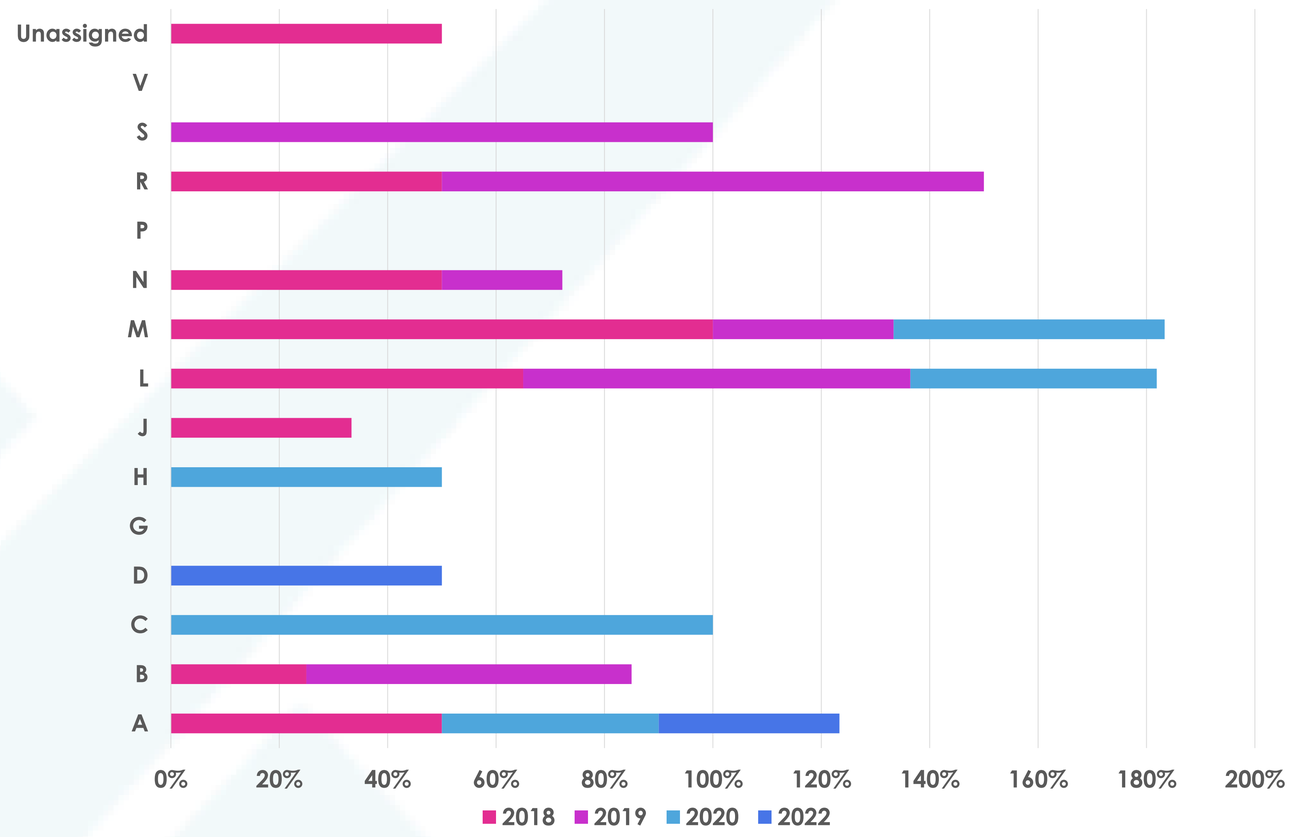
- The drug approval process serves as a critical mechanism to ascertain the safety and efficacy of pharmaceuticals prior to their dissemination to the general populace. It is important to note that the approval procedures established by the U.S. Food and Drug Administration (FDA) diverge significantly from those of other nations.
- The objective of this analysis is to undertake a comparative examination of the variances in drug approval protocols between the FDA in the United States and the Turkish Pharmaceutical and Medical Device Agency (TITCK) in Türkiye.

METHOD

- This study utilized data from two authoritative sources: the U.S. Food and Drug Administration's official website and the List of Licensed Products from the TITCK. The Microsoft Office Excel program was employed for conducting descriptive data analysis. This approach ensured data accuracy, reliability, and efficient analysis.

RESULTS





- Over the preceding years, a total of 188 pharmaceutical products received approval from the FDA. It was observed that 32.45% of these FDA-approved medications are also granted licenses by TITCK for distribution in Türkiye.
- When assessing the licensed medications in accordance with the Anatomical Therapeutic Chemical (ATC) classification, the approval rates within each respective category displayed variation. Specifically, approval rates were as follows: 36% for Category A, 36% for Category B, 50% for Category C, 17% for Category D, 33% for Category H, 18% for Category J, 49% for Category L, 43% for Category M, 24% for Category N, 67% for Category R, 25% for Category S, and 0% for Categories P, G, and V.
- It was determined that the average duration for FDA-approved pharmaceuticals to secure licensing in Türkiye stood at 20.9 months, with a minimum duration of 5 months and a maximum duration of 41 months.

CONCLUSIONS

- These findings suggest that a significant proportion of pharmaceutical products approved by the U.S. Food and Drug Administration receive licenses for distribution in Türkiye. However, it is evident that the procedures and the rates of success in obtaining these licenses differ across various ATC categories.
- As per the findings of the analysis, there exists a notable delay exceeding one year in the process for a recently FDA-approved drug to attain licensure from TITCK, the Turkish regulatory authority.
- Furthermore, a substantial proportion of these pharmaceuticals fail to secure the necessary licensing for distribution within the Turkish market.

REFERENCES

1 Dabrowska, agata and Thaul, S. (2013) How FDA approves drugs and regulates their safety and effectiveness. Washington, D.C.: Library of Congress, Congressional Research Service.

Abbreviations: FDA: Food and Drug Administration, TITCK: Turkish Pharmaceutical and Medical Device Agency, ATC: Anatomical Therapeutic Chemical

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