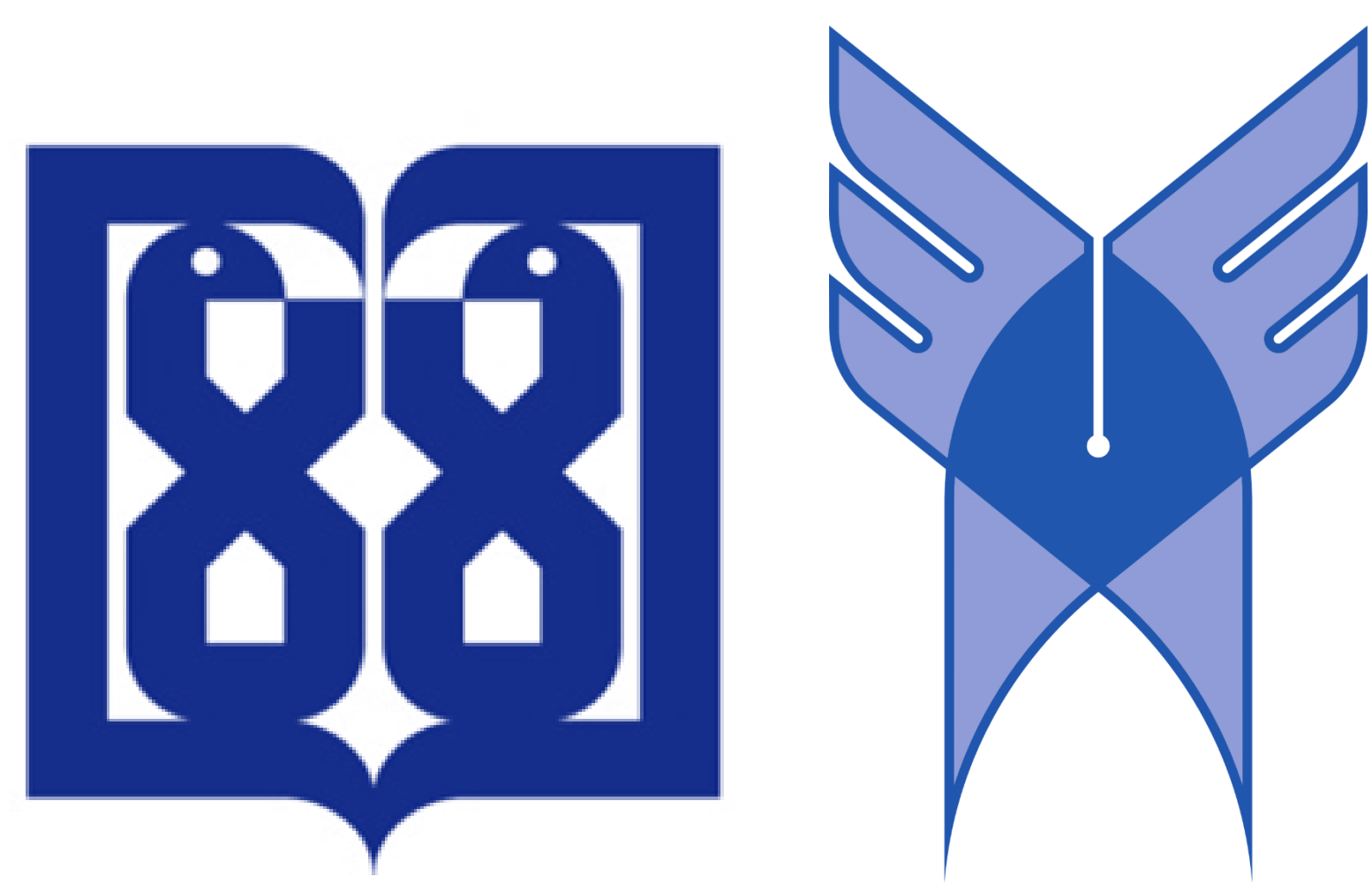


ORPHAN DRUG EXPENDITURES IN IRAN: A HISTORICAL AND PROSPECTIVE ANALYSIS, 2000–2022



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INTRODUCTION

Orphan medicines (OMs) are often very costly due to small market. OM's expenditure grew over the years and its market is expected to reach one-fifth of the total worldwide pharmaceutical market. This study aims to show total expenditure of orphan medicines in Iran as a proportion of the total pharmaceutical market within the period 2000-2018 and to forecast its expenditures in the next 4 years.

METHODS

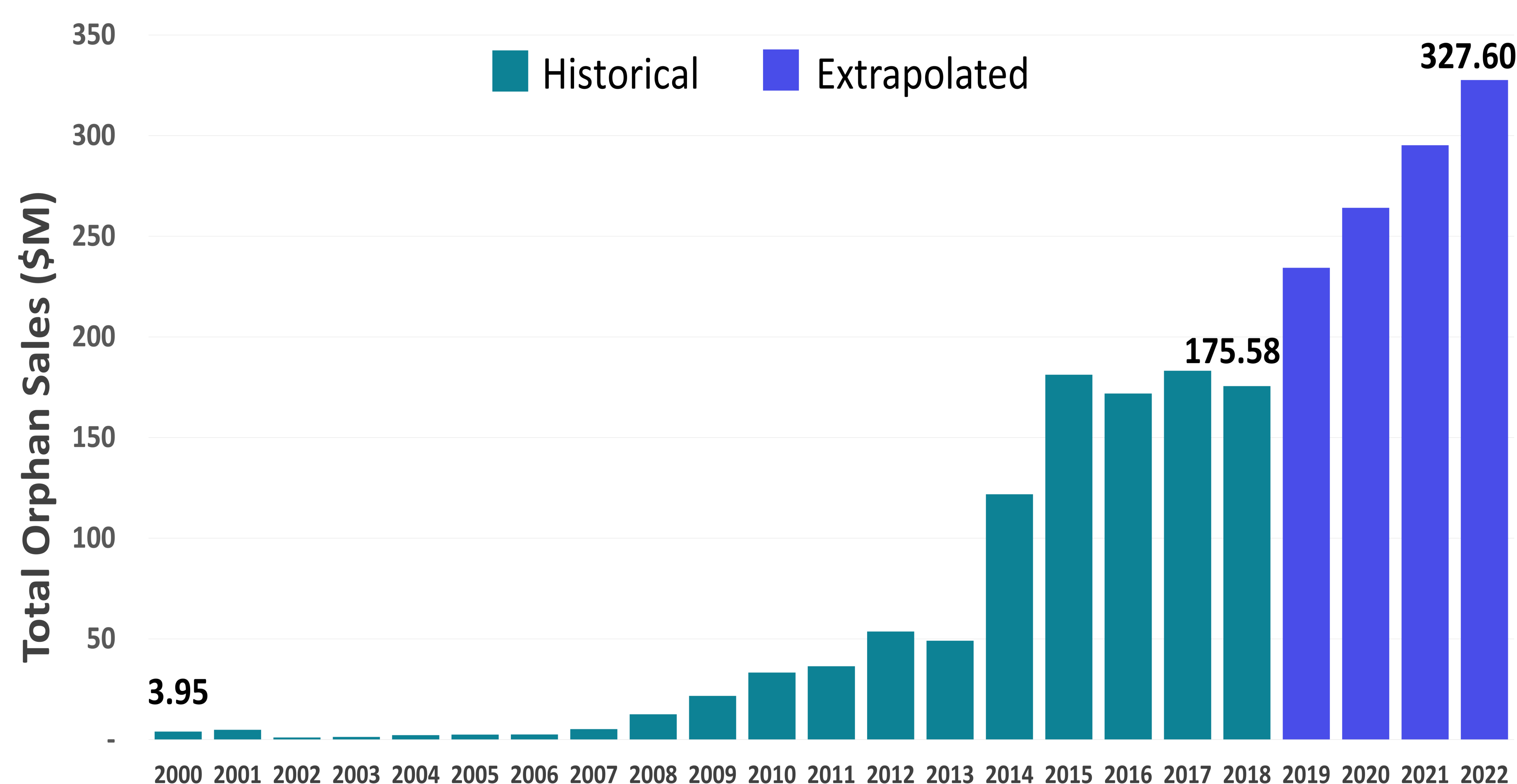
- A list of authorized OMs has been extracted from the Iran official Drug List (IDL) and classified on the basis of their respective ATC codes.
- Annual statistical datasheet published by the Iranian Food and Drug Administration (IRFDA) (2000-2018) was used to estimate historical spending trends.
- Future expenditures up to 2022 also forecasted using regression analysis based on previous years information.
- In order to verify the reimbursement status, National Health Insurance's tariffs were also reviewed to set public expenditure for OMs.

RESULTS

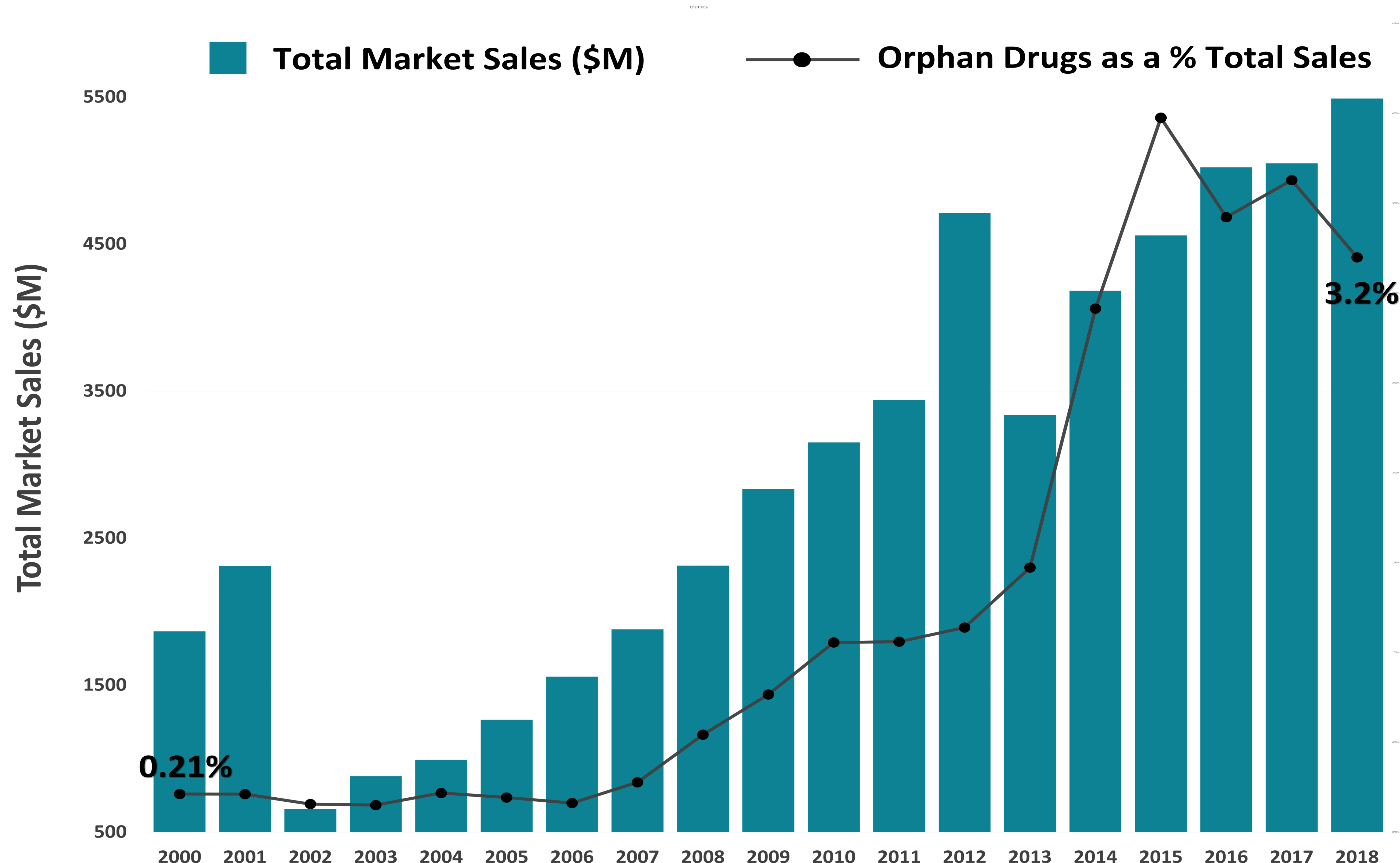
In total, we identified 73 drugs that received the orphan drug designation within 19 years (2000- 2018), while 63 drugs' market information was available to analyze. Total expenditure of orphan drugs increased from \$3.95 million in 2000 to \$175.58 million in 2018 (15 and 52 drugs, respectively). OM expenditures as a share of total Iranian pharmaceutical expenditure increased from 0.21% in 2000 to 3.2% in 2018. CAGR for OMs (23.46%) is much greater compared with the total Iranian pharmaceutical market (6.18%). Our future trend analysis for 2019-22 showed that orphan drug expenditure is estimated to reach around \$330 million.

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Historical and future expenditures of orphan drugs in Iran



Orphan drugs expenditures as a proportion of total Iranian pharmaceutical expenditure from 2000 to 2018

CONCLUSIONS

Considering the potential market growth of OMs, this study attempts to provide information to health policy-makers, to implement a special pricing and reimbursement process, and consider the cost burden forced on the pharmaceutical system by these drugs.