

Reimbursement of Pharmaceuticals in Turkey: Comparison with Approvals of the FDA between 2010-2021

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OBJECTIVES

Turkey has a highly regulated pharmaceutical market with profound challenges for market approval, pricing and reimbursement decisions. The external and internal reference pricing procedures, low value of exchange rate used in pricing, high statutory discounts required from companies during reimbursement applications, the complex system with imported drugs and alternative reimbursement mechanisms have contributed to the decreased willingness of companies to launch new molecules or new indications for already available molecules. This study’s main aim is to have a picture of the new molecule and indication reimbursement trends of Turkey in comparison to the FDA approvals between 2010-2021.

METHODOLOGY

A thorough search was made on the FDA’s web sites and all new molecules or new indications for previously approved molecules were listed from 2010. For each case, the name of the approved molecule, indication, ATC class and approval year were recorded. After having a comprehensive list for FDA, the reimbursement status of each molecule and indication was checked with the two positive lists (Attachment 4/A and Attachment 4/C) of the Social Security Institution (SGK).

RESULTS

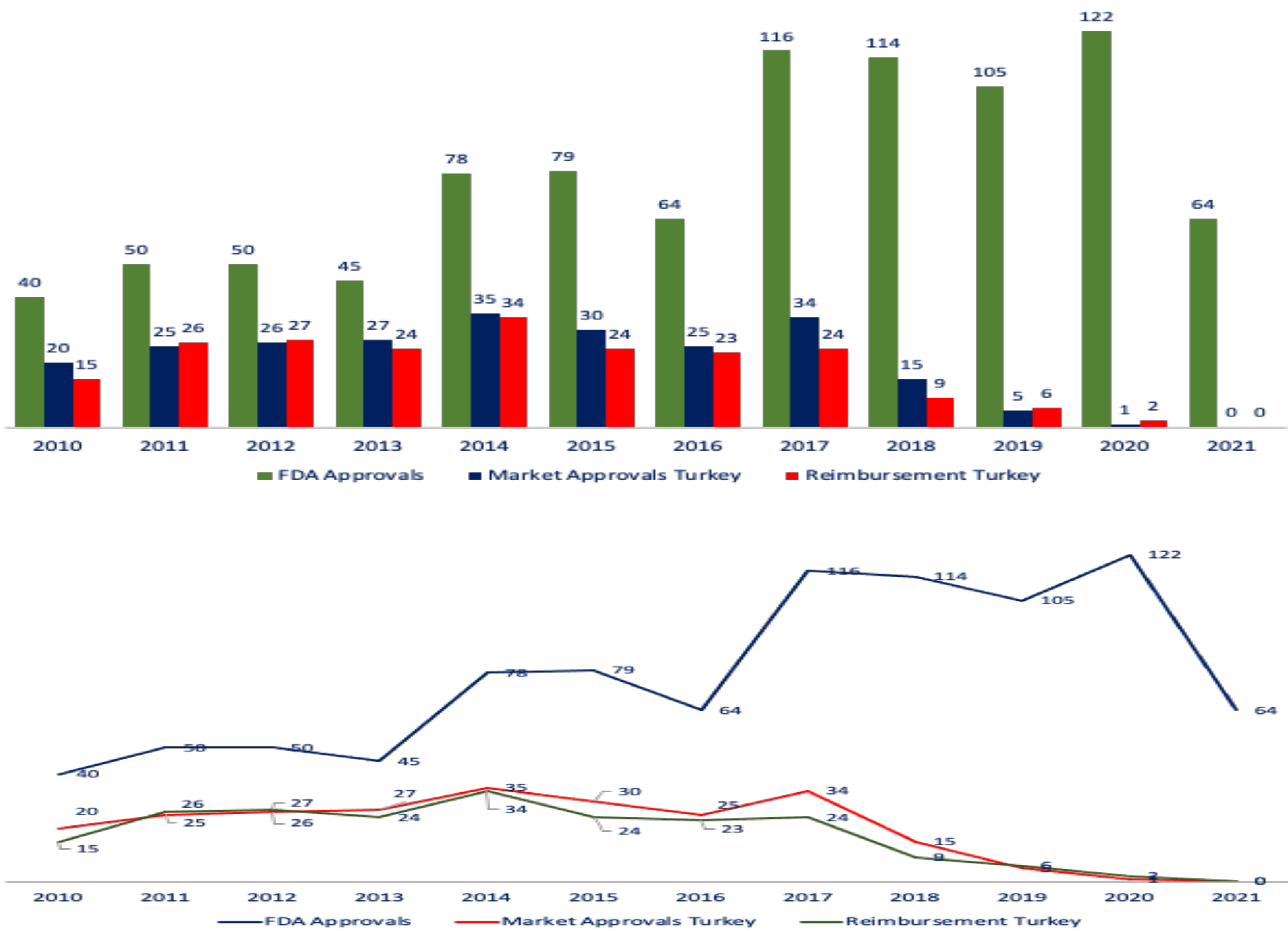
Between 2010-2021, 927 new molecules or indications were approved by the FDA. Only 26.2% of these molecules or indications had market approval from the Turkish Ministry of Health (MoH) and 23.1% had reimbursement status from the SGK. There was a steep decline in reimbursement decisions starting from 2017 when the pricing and reimbursement rules became very stringent. The reimbursement rates are 43.59%, 30.38%, 35.94%, 20.69%, 7.89%, 5.71% and 1.64% for 2014, 2015, 2016, 2017, 2018, 2019 and 2020 respectively.

Market Approval and Reimbursement in Turkey Compared to FDA Approvals (%)

Year	Market Approval	Reimbursement
2010	50.00	37.50
2011	50.00	52.00
2012	52.00	54.00
2013	60.00	53.33
2014	44.87	43.59
2015	37.97	30.38
2016	39.06	35.94
2017	29.31	20.69
2018	13.16	7.89
2019	4.76	5.71
2020	0.82	1.64
2021	0.00	0.00

Percentages show the % of molecules/indications with market approval and positive reimbursement decision in Turkey compared to molecules and indications approved by the FDA in the relevant year.

FDA Approvals vs Market Approval and Reimbursement Status in Turkey



DISCUSSION

Our analysis has shown that as of 2022, only 25% of molecules or indications approved by the FDA since 2010 are available or reimbursed in Turkey. The decline in approval and reimbursement percentages from 2017 reflects the impact of market access rules.