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Reimbursement of Antineoplastic and Immunomodulating Agents in Turkey: Comparison with Approvals of the FDA between 2010-2021

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OBJECTIVES

'Antineoplastic and immunomodulating agents' classification of the World Health Organization's (WHO) ATC system (L) includes drugs that alter activity of the immune system (immunomodulators) and anticancer (antineoplastic) drugs. The research and clinical trials for this group of molecules are growing due to the increasing incidence and prevalence rates of diseases treated by these drugs. The aim of this study is to elaborate the market approval and reimbursement status of new molecules and new indications for this group in Turkey in comparison to the approvals of the FDA. The research period covers the period between 2010-2021.

METHODOLOGY

The FDA's web sites were searched to list the approvals of new molecules and new indications for previously approved molecules between 2010-2021. The name of the approved molecule, indication and approval year were recorded. After having a comprehensive list for the 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 Turkish Social Security Institution (SGK).

RESULTS

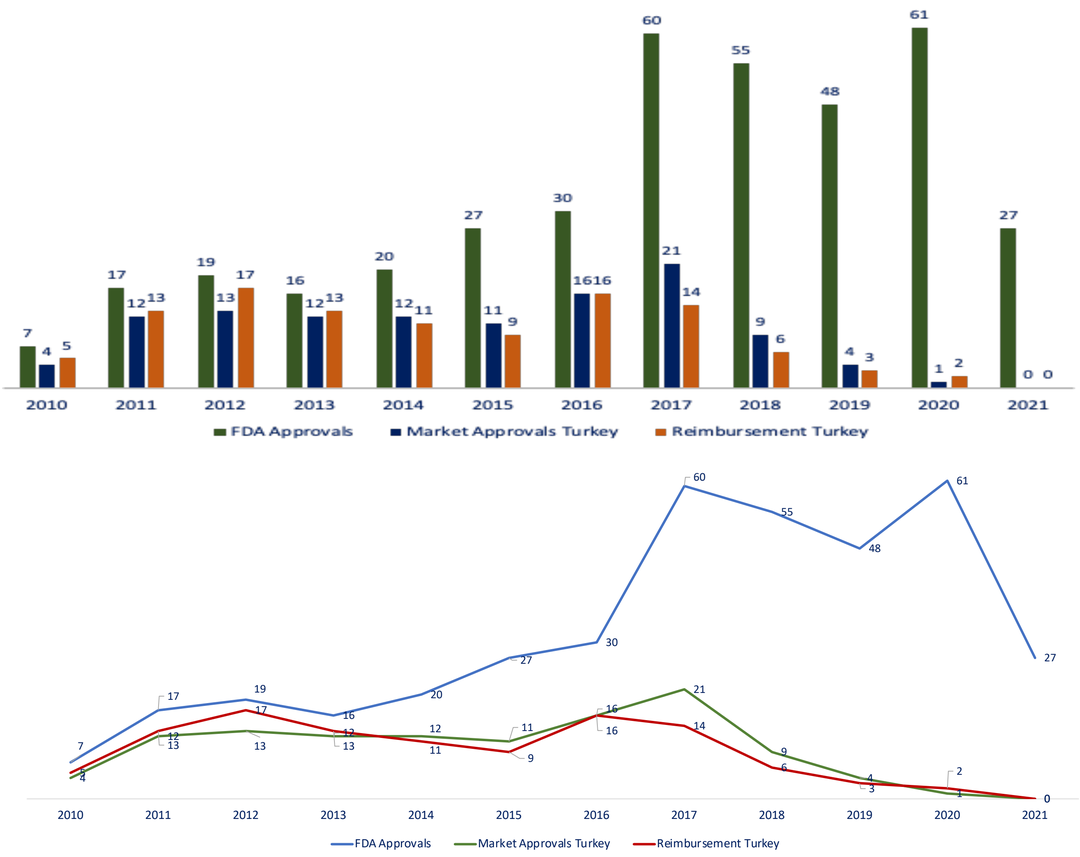
The FDA has approved 387 new molecules or new indications between 2010-2021 in this ATC group. Of these, 115 (29.8%) had market approval and 109 had (28.2%) reimbursement status in Turkey. There has been a steep decline in approvals after 2017. Among the diseases in the group with ≥ 10 approvals in the FDA, multiple sclerosis (55%), plague psoriasis (50%), CLL (%42), colorectal cancer (40%), breast cancer (37%), non-small cell lung cancer (37%), renal cell carcinoma (30%), multiple myeloma (30%) had the highest rates of positive reimbursement decisions in Turkey. Prostate cancer (1%) and melanoma (3%) had the lowest reimbursement rates.

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

	Market Approval	Reimbursement
2010	57.14	71.43
2011	70.59	76.47
2012	68.42	89.47
2013	75.00	81.25
2014	60.00	55.00
2015	40.74	33.33
2016	53.33	53.33
2017	35.00	23.33
2018	16.36	10.91
2019	8.33	6.25
2020	1.64	3.28
2021	0.00	0.00

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

FDA Approvals vs Market Approval and Reimbursement Status in Turkey



DISCUSSION

The highly regulated market in Turkey with low incentives for companies to launch new products may have a negative impact on the availability of new and effective treatments. The entry of new molecules for antineoplastic and immunomodulating agents to the Turkish market has slowed down since 2017. This raises concerns for the unmet need of the population and for delayed access to novel agents.