OBJECTIVES: Turkish Ministry of Health (MoH) initiated Health Transformation Program (HTP) in 2003. HTP impacted all clinical and economic outcomes of health including pharmaceutical sales by improving access to health services. The objective of this analysis is to understand the impact of selected 5 major policy changes by MoH to sales of locally manufactured and imported pharmaceutical products in the respective periods. METHODS: 123 months sales data with segmented regression analysis for interrupted time series were used. International reference pricing of pharmaceuticals (RF), mandatory reimbursement dossier submission for new molecules, new indications and line extensions with medical and economic evaluations (MRDS), auditing for good manufacturing practice (GMP), family physician system (FP) and compulsory medical service for physicians (CMS) were selected as five major policies that may affect cost, demand and supply of pharmaceuticals. We analyzed possible breaks in trends prior and after the implementation of 5 selected policies of the HTP. The Durbin-Watson d statistics of SPSS version 20.0 was used as a test for serial correlation of error terms. Shift in slope with p<0.05 was considered as statistically significant. RESULTS: There was an increasing trend for all ATC1 groups prior the implementation of policies. The trends in systemic antientfisds Policy changes were very successful to control growth of top selling pharmaceuticals. The Durbin-Watson d statistics of SPSS version 20.0 was used as a test for possible breaks in trends prior and after the implementation of 5 selected policies that may affect cost, demand and supply of pharmaceuticals. We analyzed possible breaks in trends prior and after the implementation of 5 selected policies of the HTP. The Durbin-Watson d statistics of SPSS version 20.0 was used as a test for serial correlation of error terms. Shift in slope with p<0.05 was considered as statistically significant. RESULTS: The negative effect of RF policy change on CS trends was more prominent for IP than LMP sales. However, the shift in CS due to other 4 policy changes was lower for IP when compared with LMP sales. The differences reached statistical significance level except for CMS policy. Although not significant, positive shift of US due to RF policy change was higher for LMP than IP sales. There was a decreasing slope of LMP unit sales following MRDS and GMP policies but an increasing slope of IP unit sales. CONCLUSIONS: Policy changes had differential effect at different time periods and different savings were generated by IP and LMP sales. Cost control mechanism such as RF has a more negative effect on imported product as expected.

OBJECTIVES: To compare the savings achieved by appraisal of the clinical and cost effectiveness of individual drugs (as by NICE) or budget cuts (as under PPRS)?

METHODS: A literature review was conducted from the US Food and Drug Administration (FDA) website, Generics and Biosimilars Initiative (GaBi) websites, Medline database, and available grey literature. RESULTS: The Biologics Price Competition and Innovation Act (BPCI) established a Biologic License Application (aBLA) pathway/351 (k) for biosimilars in addition to the 3. Non-abbreviated biologic license application (BLA)/351 (a); 2. New Drug Application (NDA)/505 (b) (2), or 3. Abbreviated New Drug Application (ANDA). 10 follow-on biosimilars under NDA/ANDA and one under BLA were previously approved. Product identity and therapeutic equivalence of some biosimilars (i.e. Lovenox, Copaxone) led to important debates for defining the application pathway. Currently, the FDA has no 351 (k) guidance for biosimilars. The lack of guidance of FDA on the criterion for biosimilarity in aBLA was a limiting factor for manufacturers to go through aBLA pathway. They preferably opted for a classical BLA pathway due to its longer exclusivity period and lower data requirements (i.e. 10 years). However, the FDA recently released draft guidance on designing clinical studies for biosimilarity (5/13/14) is yet to be seen but should address issues on proving biosimilarity in aBLA. Another debate is on the need for new molecules, new indications and biosimilars savings are projected at $250 billion by 2024. CONCLUSIONS: The biosimilars market is still lagging, specifically compared to the EU, with no 351 (k) approvals despite the US’ leading position in the biopharmaceutical markets. However, the US’ high prices for innovative products and history of generic utilization can signify a positive market projection after a transition period, as was seen in Germany and Sweden. Further, the new FDA guidance by addressing biosimilarity issues may ease biosimilar market entry.