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IMPACT OF HEALTH POLICY CHANGES ON THE COST SALES OF 5 TOP SELLING ATC1 PHRAMACEUTICAL GROUPS IN TURKEY

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OBJECTIVES: Turkish Ministry of Health (MoH) initiated Health Transformation Program (HTP) in 2002. HTP impacted all clinical and economic outcomes of health including pharmaceutical sales by improving access to health services. Total pharmaceutical market reached US $ 8 billion in last 10 years. The objective of this study is to understand the differences in the impact of selected 5 policies on 5 top selling ATC1 groups in terms of cost sales (CS) in the respective periods. **METHODS:** 132 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 antienfectives (J0), alimentary and metabolism (A0) and Respiratory system (R0) Central Nerveous System (N0) groups were negatively impacted from all policies except for RF. All policies impacted negatively the trend in cardiovascular system (C0) group. Implementation of RF had a significant positive impact on A0 and R0 group. Impact of RF was positive on C0 however it did not reach signifcance level. **CONCLUSIONS:** Policy changes were very successful to control growth of top selling pharmaceutical groups while improving access to health. RF and CMS policies were the least effective cost containment measures

PHP30

SAVING MONEY IN HEALTH CARE: COST EFFECTIVENESS OF INDIVIDUAL DRUGS (AS BY NICE) OR BUDGET CUTS (AS UNDER PPRS)?

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OBJECTIVES: To compare the savings achieved by appraisal of the clinical and cost effectiveness of individual drugs by NICE'S Technology Appraisals for England & Wales with those due to price cuts under the Pharmaceutical Pricing Regulation Scheme 2000-2014. **METHODS:** Maximum and best estimates of savings attributable to the 512 technologies appraised and published by NICE to end 2013 with published reports of the PPRS. Published estimates of the cost of the Multiple Risk Sharing Scheme, the Cancer Drugs Fund and the End-of-Life criteria. **RESULTS:** Savings attributable to NICE were relatively low. Few drugs were not recommended and of these, special schemes, funds and exceptions required by the governments of the day, reduced savings that might otherwise have resulted. The bulk of the savings due to NICE resulted from price cuts under Patient Access Schemes from 2009. Higher savings resulted from cross the board price cuts in the PPRS. **CONCLUSIONS:** Health systems aiming to control pharmaceutical expenditure should consider both individual level appraisal of drugs as overall budget control of the branded prescription drugs budget.

PHP31

THE EFFECTS OF REFORMS, PRICE CUTS AND GLOBAL BUDGET IMPLEMENTATION ON ORIGINAL/GENERIC MEDICINE SALES WHICH HAVE ANNUAL AVERAGE HIGHEST AMOUNT OF SALES BETWEEN 2008-2013 IN TURKEY

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OBJECTIVES: In 2003 Health Transformation Program and in 2006 Social Security Reform were launched in Turkey. At the end of the years 2009 and 2011 price cuts were done by the Government and between the years 2010-2012, there was a global budget implementation in Turkey. The top 100 medicines, annual average highest amount of sales of between 2008-2013, had one to four of the total pharmaceutical market value in 2013. We aimed to examine the status of original and generic medicines in the first 100 medicine's and evaluate the effects of policy interventions on these medicine sales. **METHODS:** While pharmaceutical sales data were obtained from the IMS Health-Turkey data base, prices and characteristics of medicines were obtained from the Turkish Medicine and Medical Devices Agency data bases. Each group (original/generic medicines) was analyzed using TRAMO and SEATS method. **RESULTS:** 78 medicines are original, 22 medicines are generic. In 2009 compared to the previous year both generic and original medicine spending increased by respectively 16% and 20,9%. Between the years 2010-2012 compared to the previous year both generic and original medicines spending decreased by different ratios. In 2013 according to 2012, generic medicine spending decreased by 8.3% but original medicine spending increased by 7.9%. In 2013 total original medicine spending was 2888 million Turkish Liras (TL). This amount estimated to be 3050 million TL in 2014 and 3145 million TL in 2015. Generic medicines total spend was 501 million TL in 2013. This amount projected to be 510 million TL in 2014 and 515 million TL in 2015. **CONCLUSIONS:** Original medicines dominated the top 100 medicines. The total effect of the intervention is more negatively in generic medicines. At the end of 2013, it is understood that original medicines total amount have a tendency to increase.

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IMPACT OF HEALTH POLICY CHANGES ON THE GROWTH LOCALLY MANUFACTURED AND IMPORTED PHARMACEUTICAL MARKETS IN TURKEY

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OBJECTIVES: Turkish Ministry of Health (MoH) initiated Health Transformation Program (HTP) in 2002. 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 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:** 132 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. The analysis was conducted for total imported pharmaceutical (IP) sales and total locally manufactured pharmaceutical (LMP) sales. The Durbin-Watson d statistics of SPSS version 20.0 was used as serial correlation. 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 may effect at differently direction and amount the unit and cost sales of LMPs and IPs. Cost control mechnism such as RF has a more negative effect on imported product as expected.

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AN OVERVIEW OF THE BIOSIMILAR MARKET IN THE US

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OBJECTIVES: This study intends to provide an overview of the US biosimilar policies and its impact on the development of the biosimilar market in this country. **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 (2009) established an abbreviated Biologic License Application (aBLA) pathway/351 (k) for biosimilars in addition to the 1. 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 biologics under NDA/ANDA and one under BLA were previously approved. Product identity and therapeutic equivalence of some biologics (i. e. Lovenox, Copaxone) led to important debates for defining the application pathway. Currently, the FDA has no 351 (k) approvals. The lack of clear FDA guidance on data requirements 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 nearly the same amount of data required (i. e. Neutroval). The impact of the recently released FDA 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. Further debate is anticipated but an increase in applications is expected 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 biopharmaceuticals market. 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.

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IMPACT OF HEALTH POLICY CHANGES ON THE GROWTH LOCALLY MANUFACTURED AND IMPORTED PHARMACEUTICAL MARKETS OF TOP SELLING ATC1 PHRAMACEUTICAL GROUP (ALIMENTARY AND METABOLISM (A0) IN TURKEY

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OBJECTIVES: Turkish Ministry of Health (MoH) initiated Health Transformation Program (HTP) in 2002. HTP impacted all clinical and economic outcomes of health including pharmaceutical sales by improving access to health services. Total pharmaceutical market reached US $ 8 billion in last 10 years. The objective of this analysis is to understand the impact of selected 5 major policy changes by MoH on the growth locally manufactured and imported pharmaceutical markets of top selling ATC1 phramaceutical group, which was Alimentary and Metabolism (A0) with US $ 1.1 billion sales in 2012, in the respective periods in Turkey. **METHODS:** 132 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