PHP29

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.

PHP32

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.

PHP33

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.

PHP34

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

prior and after the implementation of 5 selected policies of the HTP. The analysis was conducted for total imported pharmaceutical (IP) sales and total locally manufactured pharmaceutical (LMP) sales in the A0. 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:** All policies effected the LMP sales more positively than IP sales except FP. However, the difference of impact was moderately positive for LMP sales, there was not any statistically significant change. **CONCLUSIONS:** Policy changes may effect at differently direction and amount the cost sales of LMPs and IPs. Non significant effect of these policy changes may partly explained by limited oberservation time and by other market dynamics.

PHP35

CHARACTERISTICS OF THE MEDICINES WHICH HAVE ANNUAL AVERAGE HIGHEST AMOUNT OF SALES OF BETWEEN YEARS 2008-2013

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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. Health implications of these developments in the medicine market have not been analyzed in a comprehensive manner. 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. In this study we aimed to determine these first 100 medicine's, which have higher total sales amount, defining characteristics. **METHODS:** While pharmaceutical sales data were obtained from the IMS Health-Turkey data base, characteristics of medicines were obtained from the Turkish Medicine And Medical Devices Agency and the Social Security Agency data bases. **RESULTS:** While 78 medicines are original, 22 medicines are generic. 60 medicines are imported medicines, 40 medicines are manufactured medicines. 19 medicines are biotechnological medicines and all of these biotechnological medicines are original and imported. 96 medicines covered by Social Security payments. Equivalent of 65 medicines are available (each equivalent group from 1-30, an average of 13 generics available). 19 medicines and 15 medicines are respectively systemic anti-infectives and antineoplastics and immunomodulating agents. In this study, the license holders of the medicines are 40 firms in total. 15 firms have a market share of 75% and the medicines which, have 77,7% portion of total amount, are created by multinational firms. **CONCLUSIONS:** In the years which were the effects of reforms, price cuts and global budget implementation seen, the medicines which have higher total sales amount were mostly original, imported, covered by Social Security payments and created by multinational firms.

PHP37

IMPACT OF HEALTH POLICY CHANGES ON UNIT 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. 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 unit sales (US) 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 top 5 selling ATC1 groups were Systemic Antienfectives (J0), Cardiovascular System (C0), Alimentary and Metabolism (A0), Respiratory (R0) and Central Nerveous System (C0). 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 J0 were negatively impacted from all policies except for RF. The C0 group was negatively impacted from all policies except for RF and CMS. The A0 group was positively impacted from all policies. The N0 was positively impacted from all policies except MRDS and FP. The R0 group was positively impacted from all policies except GMP and FP. **CONCLUSIONS:** Policy changes were not sufficient to control unit growth of top selling pharmaceutical groups. The effect of other policies to control unit sales of these group should also be evaluated.

PHP38

APPLICABILITY OF TURKISH PRICING POLICY ON PRICE INCREASES

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OBJECTIVES: Turkey is using international reference pricing for the pharmaceuticals. An update for Turkish pricing decree is published in April 2012 and price increases became more applicable due to various reasons. We analyzed price lists to identify pharmaceutical products that had any price increase in 2013 and defined causes in the decree **METHODS:** We reviewed weekly cumulative price lists published in Turkish Medicines and Medical Device Institution and compared each list with the list published in the previous week to identify products that had price increase. We excluded "plasma-derived blood products" that has different pricing schemes for the cases they get an exchange rate related increase and also excluded the price corrections. Price increase reasons were grouped as defined in the current decree. We calculated mean percentage of price increases in overall and in original vs. generic, import vs. locally manufactured, products below and above 6.79 TL pack price (local definition of cheap products) and ATC1 level subgroups. **RESULTS:** 606 products and 274 molecules had price increase in 2013. The most frequent reasons for price increase were related critical product status (110 increases), increase in reference price (105 increases) and due to the rule of getting the highest reference for delisted or non-reimbursed products (89 increases). The average rate of price increases was 23.1%. 57% of the price increases were applied to imported products compared with 43% locally manufactured ones. Average rate of price increase in original and generic products were 24% and 21% respectively. Products with ex-factory price above 6.79 TL had more price increase compared with cheap products. The highest rate of price increases were in ATC1 groups A and B (81 increases each) **CONCLUSIONS:** With the pricing policy change in 2013, price increases were possible in Turkey for products from different groups.

PHP39

THE GRASS IS ALWAYS GREENER ON THE OTHER SIDE OR WHY THERE IS LITTLE MEANING IN INTERNATIONAL PHARMACEUTICAL PRICE COMPARISON

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OBJECTIVES: In many countries there is an ongoing debate about pharmaceutical pricing. Especially in Germany there is common belief that pharmaceuticals are more expensive than in other countries. Payers are making use of this belief when negotiating prices with pharmaceutical companies. We wanted to know if there is scientific evidence for this conception. **METHODS:** We conducted a systematic literature review in order to identify price comparison studies comparing Germany with at least three other countries. We searched Pudmed and six other databases to identify relevant articles published between 1998 and today. Furthermore we developed a quality rating tool based on the approaches from Andersson (1993) and Danzon/Kim (1998). **RESULTS:** Our review delivered 4.927 articles from which 28 met our inclusion criteria. Study quality was quite heterogeneous, ranging from 3 to 13 points with an average score of 8.8 out of 15. Some studies use old data back from 1992 and no study considers the recent changes in German legislation (AMNOG). In addition no study includes rebates and selection of compared pharmaceuticals is often arbitrary. Reviewed studies report German pharmaceutical prices slightly above international average. High quality studies (upper quartile, quality score: >9) find German prices below international average, whereas low quality studies (lower quartile, quality score: <7) find German prices above international average. **CONCLUSIONS:** Results of the review suggest that there is a misconception of pharmaceutical pricing in Germany. Within a price comparison study any desired result can be achieved by deliberately choosing different approaches. At the end of the day payers and policy makers should stop comparing prices with other countries. Instead resources should better be spent on making value based reimbursment decisions in the respective health care setting.

PHP40

TRANSFORMATION OF GREEN CARD PROGRAM FOR THE POOR: ONE STEP FURTHER TO UNIVERSAL HEALTH CARE COVERAGE IN TURKEY

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OBJECTIVES: Since January 2012, Turkish government started to implement a mandatory general health insurance law. The Social Security Institution (SSI) coverage which has been 86% in 2012 was expected to be 100% after this reform instead has declined to 82% in 2013. On the other hand, as Turkish Green Card Program - a state social scheme to ensure the provision of health services for the poor - was abolished and transferred from Ministry of Health to SSI, approximately 9 million people have been subject to income audit in order to be classified as eligible to pay premiums themselves and non-eligible ones for which the state will pay the premiums. In this regard; this poster presents this transformation and gives its current status in terms of contribution to Universal Health Coverage in Turkey. **METHODS:** Publications of SSI, World Bank Reports and online articles are utilized. **RESULTS:** The recent available data shows that 82% of the population is under the coverage of SSI. %2 of the population corresponds to the groups which are out of SSI coverage according to Law 5510, Article 60. Remaining population corresponds to 12 million people subject to income audit. Approximately 62% of those could not pass income audit and their premiums are paid by the state. **CONCLUSIONS:** Since 2012 there are increasing number of people taking income audit and have the capacity to pay premiums. It is also noteworthy to state that there were 8,865,470 people under Green Card scheme whereas after the transfer of Green Card to SSI; 11,357,306 people applied for the income audit in 2012, this reached to 12,266,043 people at the beginning of 2014. Findings show that as Green Card Scheme brought under SSI, coverage has been made available to all eligible people in a systematic and just way thus contributed the extent of coverage in Turkey.

PHP41

GENERIC PENETRATION WITHIN TOP-10 GENERICIZED MOLECULES – GREECE VERSUS MAJOR EUROPEAN COUNTRIES

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OBJECTIVES: In early 2010, Greece was placed under International Supervision (EU, ECB and IMF), as a result of a growing public deficit and its non-sustainable state expenditure. At the time, the retail pharmaceutical market had a size of c. a. €6.5 bn in retail prices (public pharmaceutical expenditure €5.2 bn). Within that framework,