OBJECTIVES: In Turkey, a medicine pricing reference system has been in use since 2004. The price of pharmaceuticals is determined by the acceptance of the lowest ex-factory price in the reference countries (France, Greece, Italy, Portugal, Spain). We aimed to examine the first 100 medicines, having the annual maximum amount on the average Turkish Lira (TL) based medicine sales between the years 2008-2013 which have 15% value in the total pharmaceutical market, reference price changes in these medicines. METHODS: While pharmaceutical sales data were obtained from the IMS Health-Turkey data base, medicine prices were obtained from the Medicine Price List published by Turkish Medicines and Medical Devices Agency. RESULTS: In 2008, 100 medicines were subjected to EPR, in determining the reference price in most of the medicines, the reference country was following France and Greece. In 2013 while Greece is taken as the reference country more common, France and Italy are to follow. In 2008, only one medicines reference price had increased and only one medicine's price decreased because of the implementation of substitution rules, even if still raising some reluctance, might contribute to boost biosimilar uptake in Europe. Price competition will impose necessary benefits to all stakeholders.

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IF THE LISTS EN-SUS STILL SUPPORTING ACCESS TO INNOVATIVE MEDICINES?

OBJECTIVES: The "liste-en-sus" was implemented within the framework of the HPST [1] law. One of its objectives was to ensure access to highly-priced innovative medicines in hospital settings without distorting the Diagnostic-Financing mechanism (DFM). The goal was to create a reference list of innovative medicines included in the "liste-en-sus". METHODS: Starting from the ATH [2] database, an initial analysis consisted of identifying all the Health Technology Assessments (HTAs) for each protected list the "liste-en-sus". We included all the HTAs approved after the 1st of January 2008. Then, for each HTA, the following key information was collected: assessment date, SMR [4] and ASMR [5] scores. RESULTS: The "liste-en-sus" includes 123 medicines. 21% have no HTA. Another 19% were last evaluated before 2004. Among the medicines which had undergone a HTA since 2004, 7% were granted an ASMR I, 27% an ASMR II, 22% an ASMR III, 8% an ASMR IV, 36% an ASMR V. In other terms, amongst the medicines which have undergone a HTA in the last 10 years, 65% of them were deemed non-competitive (ASMR IV/V). The medicines mainly consist in antiepileptics (27%), antianemics (18%), antineoplastics (15%) and immune sera and immunoglobulins (15%) [6]. Although they are not innovative, these medicines are only used in a proportion of patients and are thus likely to distort DRG. To put these results into perspective, since 2005, 92% of evaluated medicines were granted an ASMR IV/V [7]. CONCLUSIONS: Looking at the list-en-sus' objectives, the most conclusive study seems to be more stability of the DRG rather than access to innovative medicines, however a higher proportion of the medicines in the liste-en-sus are innovative.

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A MULTISTAKEHOLDER PHYSICIAN, PATIENT, PATIENT, AND INDUSTRY QUALITATIVE ANALYSIS OF THE POLICIES THAT WOULD SUPPORT A SUSTAINABLE EUROPEAN BIOMEDICINE MARKET COMBINED WITH A QUANTITATIVE ANALYSIS OF THE MULTI-STAKEHOLDER BENEFITS A SUSTAINABLE MEDICINES MARKET WOULD DELIVER

OBJECTIVES: To establish the key policy areas that will drive the establishment of a sustainable and biosimilar medicines market. To outline the benefits that these policies will bring to Physicians, Patients, Payers, and Industry, with particular focus on the benefits for European National Health systems. METHODS: 71 qualitative in-depth interviews were conducted across 7 European markets: France, Germany, Hungary, Italy, Poland, Spain and the UK, collecting insight from experts and policy influencers at pan-European, National and Regional levels, Physicians, Payers, Pharmacists, Patients, and Industry. Quantitative modelling used a systems dynamics approach with in-depth analysis of 3 representative biologic products: trastuzumab, bevacizumab, and adalimumab. Dynamics were based on a delphi panel of expert opinions. The five forces of supplier power, buyer power, impact of new entrants, impact of substitutes, and competitive rivalry were addressed. A ranking of the attractiveness of policy combinations from a sustainability and benefit perspective was made based on a biosimilar medicines market “Sustainability Index” and the calculation of the magnitude of the benefits. RESULTS: DPB policy guidelines, supporting additional patients treated, that the policy combination was likely to produce. RESULTS: The qualitative analysis has shown that a European biosimilars medicines market based on stakeholder and policy alignment in four key areas: Education and Understanding, use, substitution, sustainable pricing, 4 rational decision making will be sustainable and deliver benefits to all stakeholders. The quantitative analysis demonstrated that the most efficient policy combination, measured in terms of the sustainability index, was the same for all the countries and was cumulative 10 year cost saving of between 24% and 26%. CONCLUSIONS: Greater stakeholder alignment and the combination of specific policies will increase the sustainability of the European biosimilar medicines market. A sustainable biosimilars medicines market will deliver significant benefits to all stakeholders.
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 2003. 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 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. 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 antiinfective (J0), alimentary and metabolism (A0) and Respiratory system (R0) Central groups have a tendency to increase. 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 different impact at different levels of pharmaceutical products and showed different effects on sales of LMPs and IPs. Cost control mechanism such as RF has a more negative effect on imported product as expected.