OBJECTIVES: To assess the global economic consequences for French hospitals of the European Commission (EC) decision to strengthen administration conditions of intravenous iron products (IIP) (iron sucrose (IS) and ferric carboxymaltose (FC)) due to safety concerns. Following this EC decision, in February 2014, French Health Authorities decided to give a hospital-restricted status (HRS) to IIP. **METHODS:** We compared, in acute care (medicine, -surgery-obstetrics) hospitals, IIP consumption and expenditure (extracted from SAP software) before (2012 vs. 2013) and before-after (02/2013-04/2013 vs. 02/2014-04/2014) they had a HRS, and the number of diagnosis-related group "sessions of chemotherapy for non-tumor disease" (DRG-CNTD) linked to anemia (Technical Agency of Information on Hospitals data). **RESULTS:** 20 hospitals were included. Before they had a HRS, IIP global consumption in volume increased by 9.6% (i. e. €171,022 spent more) in a year. After IIP had a HRS, the increase was 16.7% (i. e. €164,338 spent more) in 3 months (02/2013-04/2013 vs. 02/2014-04/2014). 23.7% of the increase was attributable to day hospital admissions (DHA) and 4.4% to dialysis units. FC consumption was 23.9% higher (i. e. €188,838 spent more) in 2014 compared to 2013, whereas IS consumption was 16.4% lower (i. e. €24,500 spent less). DHA in DRG-CNTD linked to anemia increased by a factor of 1.8. **CONCLUSIONS:** DHA as part of the DRG-CNTD is the only way to finance this additional hospital activity (no additional funding for traditional hospital care). FC's cost of daily treatment (€120 to €150) is about 20 times IS's (€5.2 to €7.8), while a single tariff is allocated for the DRG-CNTD (drug case-mix: €62, whatever the drug). Costs of the FC increasing use to manage anemia may be offset by administration of other drugs, or the DRG-tariff should be adjusted. Another alternative would be to implement a tender between IIP, taking into account the cost-effective ratio of each drug.

PHP19

THE IMPACT OF COST CONTAINMENT REFORMS TO THE PHARMACEUTICAL BENEFITS SCHEME (PBS) ON PRESCRIBING VOLUMES AND EXPENDITURE IN AUSTRALIA: 1992 TO 2011

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OBJECTIVES: The increase in PBS expenditure over the past two decades led to the Australian Government implementing several cost containment measures. The objective of the present study was to investigate the impact of these reforms on PBS prescribing volumes and expenditure. **METHODS:** Data retrieved from Medicare Australia's PBS Statistics database provided monthly government expenditure (benefit) and prescription volume (service) data. Segmented linear regression models were used to analyse the time series data starting from 1 January 1992 to 31 March 2012. In each segment, between implementing the cost containment measures, two parameters, the level and trend were used to estimate the impact of the intervention. A lag of 12 months was applied to adjust for seasonality and forward stepwise eliminations were applied to obtain a parsimonious model. Seven cost containment measures were investigated: the economic evaluation requirement for drug listing (1/01/1993), re-supply limits (1/11/1994), two co-payment increases (1/01/1997 & 1/01/2005), therapeutic group premium (TGP) policy (1/02/1998), safety net 20-day rule (1/01/2006), and price reductions in multiple brand drugs in Formulary 2 (F2) (1/08/2008). **RESULTS:** All interventions except the re-supply limits policy were found to have a significant impact on PBS services or benefits. Reductions in the services and benefits trend were observed in two measures, the TGP policy and safety net 20-day rule while a reduction in the services trend was observed for the economic evaluation requirement measure. No significant trend changes were observed in the post F2 price reductions while higher co-payments resulted in a reduction in the level of services followed by an increase in the trend of services and benefits. **CONCLUSIONS:** Many of the cost containment measures implemented in Australia have been effective in containing cost. Among these measures, the safety net 20-days rule was estimated to be the most effective in reducing drugs utilisation and expenditure.

PHP20

THE EFFECTS OF REFORMS, PRICE CUTS AND GLOBAL BUDGET IMPLEMENTATION ON BIOTECHNOLOGICAL 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 biotech-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 (biotech/nonbiotech-medicines) was analyzed using TRAMO and SEATS method. **RESULTS:** 19 medicines are biotechnological. In 2009 compared to 2008 while biotech-medicines amount increased by 43.8%, nonbiotech-medicines amount increased by 14.2%. In subsequent years, an increase over the previous year is observed at lower rates for biotech-medicines. This total amount has decreased compared to previous years for nonbiotech-medicines. 2014 and 2015 for the consumption of biotechnological medicines was estimated to be around 9 million boxes, expenditure for 2014 of 1360 million Turkish Liras (TL) and 2015 million TL for the year 2015. On the other hand, non-biotechnological medicines consumption would be approximately 185 million boxes and for the year 2014 2225 million TL, for the year 2015 2280 million TL are projected. **CONCLUSIONS:** Biotechnological medicines have high unit costs and these costs are increasing compared to year to year. Policy interventions did not effected biotechnological medicine sales negatively. While big differences between the biotechnological and non-biotechnological medicine box sales will continue, the gap between the biotechnological and non-biotechnological medicines total amount will be closer.

PHP21

TRENDS IN CLINICAL DRUG DEVELOPMENT TIMEFRAMES, 1981-2013 – AN EXAMPLE FROM VIROLOGY

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OBJECTIVES: There are concerns that the time taken to develop innovative new drugs is increasing, delaying access to and increasing the costs of new medicines. Both the clinical trial stage and regulatory approval stage for new drugs are important components of overall development time, and we sought to determine whether the length of either of these stages is increasing, using new anti-viral drugs launched in the UK as a case-study. **METHODS:** New anti-viral drugs launched in the UK between 1981 and 2013 were identified from the British National Formulary. Initiation of clinical development was determined from Pharmaprojects (Informa Healthcare) and Medline searches; the Investigational New Drug Application or first report of phase I trials was taken as the start of clinical development, whichever was earlier. Regulatory submission and approval dates were obtained from the European Medicines Agency and UK Medicines and Healthcare Regulatory Agency. **RESULTS:** 43 new anti-viral drugs were launched in the UK between 1981 and 2013, with a mean time from start of clinical trials to approval of 6.4 years. This period increased from 4.8 years for drugs launched 1981-93, to 6.0 years for those launched 1994-2003, and 7.9 years for those launched 2004-2013; and a statistically significant positive linear trend was observed (r= 0.47). The mean time from regulatory submission to approval was 1.1 years, but no significant linear trend was seen for this time period (r=0.20). New drugs for HIV typically spent less time in clinical development than other anti-viral drugs (mean 5.7 vs 7.3 years, p=0.049). However clinical development times for HIV and other anti-viral drugs increased at a similar rate. **CONCLUSIONS:** For anti-viral drugs launched in the UK, the time spent in clinical development has increased markedly since the 1980s, and this increase is not related to increasing time taken for regulatory approval.

PHP22

IMPACT OF HEALTH POLICY CHANGES ON TRENDS OF PHARMACEUTICAL MARKET 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. HTP improved health coverage and access to health services, additional policies are implemented by MoH for controlling this increasing trend on pharmaceutical consumption. The aim of this analysis is to understand the impact of selected 5 major policy changes to total pharmaceutical consumption in between 2002-2012. **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 cost (CS) and unit sales (US) for all pharmaceutical products. 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, except for RF policy changes, had a negative impact on the trends for CS. RF policy did not reverse the trends in CS and US however it slowed positive trend in CS significantly down. All policies hindering impact on the increasing trend in US. However, only RF and CMS policies reached statistically significant level. **CONCLUSIONS:** Policies within the HTP framework were successful to control pharmaceutical expenditures while improving access to health care. International reference pricing has a limited impact on controlling growth of pharmaceutical market.

PHP23

BOOSTING BIOSIMILARS UPTAKE IN EUROPEAN COUNTRIES

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OBJECTIVES: To provide an overview of biosimilars uptake in Europe and assess policies and initiatives that might boost uptakes of biosimilars in European countries. **METHODS:** A literature review was conducted from European and national health authorities websites, Generics and Biosimilars Initiative (GaBi) website, Medline® database, and available grey literature. **RESULTS:** To date, 17 biosimilars were granted marketing authorization throughout the European Union and the European Medicines Agency released 9 product-specific biosimilar guidelines. Recent approval of the first monoclonal antibody biosimilar of infliximab demonstrates the evolution of the European regulatory framework over time allowing approval of structurally complex molecules. Despite Europe has been a pioneer in this regulatory path, biosimilars uptake still remains limited (about 30% to 50% volume uptake) with modest price discounts from the originators (15% to 30%). If Germany authorized substitution of biological products produced by a same manufacturer in 2011, none of the Members States had allowed substitution of biological products from different manufacturers so far. With adoption of the 2014 social