OBJECTIVES: To assess the global economic consequences for French hospitals of the European Medicines Agency (EMEA) EC decision to strengthen administration conditions of intravenous iron products (IP) (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 IP. METHODS: We computed the French non-biotech medicines, surgery-obstetric (SO) hospitals, IP 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 (DRG) codes linked to iron sucrose (Technical Agency of Information on Hospitals data). RESULTS: 20 hospitals were included. Before they had a HRS, IP global consumption in volume increased by 9.6% (i.e. ±171,022 spent more) in a year. After IP had a HRS, the increase was 16.7% (i.e. ±338,338 spent more) in two 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. ±118,838 spent more) in 2014 compared to 2013 whereas IS consumption was 16.4% lower (i.e. ±91,668 spent less). CONCLUSIONS: DHA as part of the DRG-CNTD linked to iron sucrose increased by a factor of 1.8. Implications: The first step 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 to 6.5 years for those launched 1994-2003, and 7.5 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 had less time in clinical development than new anti-viral therapies (e.g. 7.2 to 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 of clinical development has increased remarkably since the 1980s, and the uncease is not related to increasing time taken for regulatory approval.

IMPACT OF HEALTH POLICY CHANGES ON TRENDS OF PHARMACEUTICAL MARKET 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 between 2008-2013, had one to four of the total pharmaceutical market in 2011. We aim to examine the impact of biotech-medicines development in the top 100 medicine’s and evaluate the effects of policy interventions on these medicines. METHODS: While pharmaceutical sales data were obtained from the IMS Turkey’s Health data base, prices and characteristics of medicines were obtained from the Turkish Medicines and Medical Devices Agency (TUGMEK) website, as case-study. Biotech-medicines (biotech) and non-biotech medicines (non-biotech) was analyzed using TRAMO and SEATS methods. RESULTS: 19 medicines are biotechnological. In 2009 compared to 2008 biotech-medicines consumption increased by 58.3%, number of non-biotech medicines consumption decreased 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 non-biotech-medicines. 2014 and 2015 for the consumption of biotechnological medicines was estimated to be 20% to 30% from the 2013-2014 average level 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 TL more in 2014 and 225 million TL for the year 2015. 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 lower.

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 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 time spent in clinical trials for new anti-viral drugs for HIV could be reduced as a case-study. METHODS: New anti-viral drugs launched in the UK between 1981 and 2013 were identified from the National Formulary. Initiation of clinical development was determined from Pharmaprojects (Informa Healthcare) and Medline (National Library of Medicine). RESULTS: The time from first clinical trials to approval of 6.4 years. This period increased from 4.8 years for drugs launched 1981-93, to 6 to 6.5 years for those launched 1994-2003, and 7.5 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 had less time in clinical development than new anti-viral therapies (e.g. 7.2 to 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 of clinical development has increased remarkably since the 1980s, and the uncease is not related to increasing time taken for regulatory approval.

RESEARCHING 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, BioCentury (www.biocentury.com), EMA (www.ema.europa.eu), national websites, Medline® database, and available grey literature. RESULTS: To date, 17 biosimilars were granted marketing authorization through the European Union and Switzerland. Biosimilars are authorized for all proportion of European countries. 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 area, the uptake is still relatively limited (around 20% to 30% of 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