previous and current policies and regulations in the grey literature was conducted for this research. **RESULTS:** 17 articles were included in the systematic review. The three most crucial issues in the regulatory process have been analyzed in detail and relate to products technical requirements, the type test report and the clinical trials evaluation. Concerning the 'products technical requirements' and the 'type test report', the main challenges are related to the lack of sufficient legal status and openness for interpretation. A new Regulation governing the Supervision and Administration of medical devices introduced in June 2014 now includes improvements regarding specification of requirements. In addition, if a medical device fulfills certain requirements, it should be exempted from clinical trials, which signifies a major simplification for manufacturers. **CONCLUSIONS:** Getting a medical device registration certificate in China is a complicated, time-consuming process. The new regulatory policies in place focus more strongly on the clinical effectiveness and safety of medical devices. However, some major structural problems remain, i. e. the lack of technical standards for manufacturers, with major policy planning and changes currently underway in order to address these problems.

PHP64
THE BENEFITS AND CHALLENGES OF SUBMITTING TO THE NICE MEDICAL TECHNOLOGIES EVALUATION PROGRAMME-MANUFACTURER PERCEPTIONS AND EXPERIENCES
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OBJECTIVES: The Medical Technologies Evaluation Programme (MTEP) was set up by NICE in 2009 to identify new medical devices and diagnostics that could improve patient experience and outcomes whilst driving health care efficiencies. Innovative products are submitted by manufacturers for evaluation, requiring confidence in the programme and its methods. The purpose of the study was to examine the experiences of manufacturers whose products have been assessed by MTEP, to review the challenges of the submission process, the resources required for the submission, NICE support for further evidence generation, and the impact of NICE recommendations on product uptake in the UK and elsewhere. **METHODS:** A systematic review of published literature on MTEP and products/companies that have been through this process was completed. Qualitative interviews were then undertaken with a representative sample of senior team members from manufacturers whose products have undergone MTEP review to elicit insight on their perceptions and experiences of the programme. Findings were collated and analysed thematically. **RESULTS:** Manufacturers have identified the benefits of submitting to MTEP in terms of value communication in the NHS, however key issues are: the significant time and resource burden of completing the submission, the lack of funding for additional data generation where this is required, the challenges of adhering to the stringent timescale, and the questionable benefits of submitting for larger companies with extensive sales teams. There is also a recognised need for greater efforts to influence practice and prescribing decisions in the NHS based on the MTEP guidance. **CONCLUSIONS:** Manufacturer experience of the MTEP process is largely positive, however as MTEP is dependent on manufacturers to initiate submissions, key actions can be taken to incentivise future submissions. Priorities will be ensuring that MTEP recommendations have a tangible and proven impact on prescribing decisions and that support is available for the submission development.

PHP65
AVAILABILITY OF RISK SHARING AGREEMENTS IN THE TURKISH PHARMACEUTICAL SECTOR
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OBJECTIVES: Risk sharing agreements are among the new trends in pharmaceutical sector as a tool for reducing the drug expenditures and increasing patient access to innovative drugs. The objective of this study is to elaborate the availability of risk sharing agreements in the Turkish pharmaceutical sector. **METHODS:** A literature review was undertaken to identify the existing risk sharing schemes in the European countries using "risk sharing agreements", and risk sharing schemes" as key words. **RESULTS:** Risk sharing agreements are mainly classified as financial based and performance based schemes. The vast majority of those agreements are implemented in oncology area, others are mostly implemented in ophthalmology, blood diseases and multiple sclerosis areas. Countries mostly prefer financial based schemes as they are easier to implement and track. Performance based agreements are relatively rare as they are more complicated due to the long length of follow up, lack of reliability of data generation/registration, administrative burden for all stakeholders. **CONCLUSIONS:** Taking into account that original drugs to be reimbursed in Turkey need to grant a compulsory statutory discount which is generally 41%, it can be stated that Turkey is already implementing a financial based scheme. On the other hand, when availability of performance based risk sharing agreements is assessed, there is a lack of infrastructure to track drugs or non-responders and also it seems to be difficult to make this kind of agreements in Turkey without making any amendments in current regulations. In addition to these regulation issues, transaction and administrative costs should also be taken into account. On the other hand despite these difficulties, these schemes could provide budget control and patient access to highly innovative and expensive treatments.

PHP66
IMPACT OF COST- CONTAINMENT POLICIES ON BIOSIMILARS MARKET
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OBJECTIVES: The expiration of biotech drugs patents has led to the creation of drugs copies of originator products, defined biosimilars. The automatic substitutability between the originator and the biosimilar is not allowed in Europe with the exception of France. In Italy, in the absence of a national legislation, some Regions have issued directives to the spread of the biosimilar use. Campania was the first Region to legislate on the matter, supporting the prescription of the biosimilar to the naive patient. The aim of this study was to evaluate the impact of cost-containment policies about biosimilars in Campania between 2009 and 2013. **METHODS:** IMS Health regional database was used to carry out this descriptive retrospective drug-utilization for the years 2009 through 2013. Information was retrieved about different distribution channels (retail, direct distribution, hospital). Consumptions are expressed in Counting Units (CU) and trends have been calculated using Compound Average Grow Rate (CAGR). **RESULTS:** In 2013, a total consumption of 930.859 CU of biosimilar drugs was registered in Italy (CAGR 13/09 68,8%). The penetration rate of biosimilar was 23,9% with regard to expenditure and 25,3% with regard to consumption. Analyzing the consumption of biosimilars by therapeutic category in Italy, the consumption of erythropoietin and filgrastim has an index of annual growth respectively equal to 153.4% and 174.7%. In Campania, the penetration rate of all biosimilars was 31.4% of total expenditure and 35.9% of consumption. Analyzing the trend in consumption for single therapeutic category, it can be seen that penetration is due to erythropoietin (297.5% CAGR); with regard to filgrastim, however, the average annual growth rate is around 54%. **CONCLUSIONS:** The results suggest that Campania Region records an index of market penetration of biosimilars higher than the national. This trend could be attributable to the cost-containment policies implemented in the region.

PHP67
ECONOMIC IMPACT OF DRUGS DE-FUNDING AND PHARMACEUTICAL CO-PAYMENT
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OBJECTIVES: to assess the consequences in terms of outpatient pharmaceutical expenditure, that accounted for changes in state law on de-funding of medicines and the introduction of pharmaceutical co-payment in 2012 in Spain. **METHODS:** Cross-sectional study during 2012. Two health regions of Spain (*Comunitat Valenciana* with 5,129,266 inhabitants and *Extremadura* with 1,108,130. Total population: 6,237,396) where analysed to determine the evolution of outpatient pharmaceutical expenditure after a change in state law (July 1,2012). We compared the first over the second half of 2012 by age and gender distinction. **RESULTS:** The total spending was reduced by 16.80% after the new law. By gender, the reduction was greater in women (17.47% versus 15.25%). By age, the decrease was seen most sharply in the stretch of paediatrics (0 to 14 years). In older people, the stretch mostly affected was the one from 66 to 70 years old. The stretches with fewer changes in terms of outpatient pharmaceutical expenditure were 21-25 years (reduced by 5.42%) and 46-50 years (reduced by 6.07%). **CONCLUSIONS:** After the de-funding of 400 drugs and the increase of pharmaceutical co-payment (40% previously and now variable, 40%, 50% and 60% depending on income levels), a drastic drop in the amount of pharmaceutical outpatient expenditure is observed. Further analysis is required in order to assess whether that decline is sustained over time or, on the contrary, a new phase of positive growth begins.

PHP68
WHEN GENDER MATTERS: IMPACT OF FDA SAFETY WARNING ON DISPENSED ZOLPIDEM DOSE
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OBJECTIVES: The Food and Drug Administration (FDA) issued a safety announcement on January 10,2013 requiring manufacturers to lower the recommended dose of zolpidem for women. Lower dose recommendations for elderly patients were already labeled. This analysis describes the impact of the FDA safety announcement on the initial dose dispensed to new zolpidem users. **METHODS:** Patients >=18 years old with an immediate- (IR) or extended-release (ER) zolpidem prescription between July 2012 and July 2013 were evaluated using MarketScan Commercial and Medicare Supplemental Databases. The first zolpidem prescription during the *pre-warning* (July 1, 2012 – Jan. 9, 2013) and *post-warning* (Jan. 10, 2012 – July 31, 2013) time periods was evaluated. Chi square tests were used to examine differences in the proportion of new users dispensed low dose zolpidem during each of the time periods. **RESULTS:** Overall a significantly higher proportion of patients in all age gender groups received low dose IR zolpidem during the post-warning compared to the pre-warning period. Similar results were found for the ER formulation except among males 65 years or older. Before and after the FDA safety warning, the highest proportion of patients receiving low dose zolpidem (any formulation) for their first prescription was among elderly women (46% pre-warning; 53% post-warning). Even after the FDA warning, a large proportion of women 18 to 64 years old (63% IR; 65% ER) and women 65 years or older (46% IR, 55% ER) received high dose zolpidem for their first prescription. **CONCLUSIONS:** For all age and gender categories, the proportion of patients receiving low dose zolpidem increased after the FDA safety warning issued in 2013. The highest proportion of low dose zolpidem use was seen in elderly females. However, the proportion of women and elderly who received low dose zolpidem even after the FDA safety warning was still relatively low.

PHP69
NON-STEROIDAL ANTI-INFLAMMATORY DRUGS IN HOUSEHOLD DRUG SUPPLIES IN SERBIA
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OBJECTIVES: Medications in households offer a variety of opportunities for irrational consumption and development of adverse drug reactions (ADR). One of the medicines most commonly associated with ADR are non-steroidal anti-inflammatory drugs (NSAIDs), one of the most frequently used medications in Serbia. Therefore, the aim of this study was to analyze the amount and structure of