RESULTS:

Product changes can be divided into three groups: generic changes, identical active ingredient but different brand name, and complex drug changes with different active ingredients or changed drug formulation. The later change is associated with a higher demand for information, which is reflected in higher process costs. Relevant costs arise during the process of product purchase and on the ward. The cost per product change inclusive operating expenses at the MRI range (3) from EUR2,300 to EUR6,420 and depend on the frequency of prescription and the complexity of the product.

CONCLUSIONS:

This Health Technology Assessment (HTA) shows that main costs for a drug product change arise due to additional staff costs on the ward. Reasonable thresholds can aid in decision making when considering cost effectiveness and potential risks of the medication or patient safety.

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PP076 Research On Drug Policy Change In China Since 2009 New Medical Reform

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INTRODUCTION:

Drugs are a special commodity for treating diseases and protecting health. There are problems in China's drug research, production, distribution and use (1) thus the national drug policies, including government long-term frameworks and specific policies, play an important role (2). This study summarized and analyzed drug policies in China since the New Medical Reform, to determine patterns of policy change, and aiming to provide theoretical support for drug policy making for the world.

METHODS:

We downloaded all drug policies issued between April 2009 to December 2016 on State Council, National Development and Reform Commission, National Health and Family Planning Commission, China Food and Drug Administration websites. These documents were combined with academic articles to extract data, which was processed in Microsoft Excel 2013. We also use the Advocacy Coalition Framework to analyze dynamic factors for drug policy change in China.

RESULTS:

There are 113 drug policies during last 8 years on 4 websites; 76 of them are released by a single ministry. Thirteen, ten, ten, fifteen, seven, fourteen, twenty-six and eighteen policies are issued each year, respectively**.** Fifteen are classified in long-term frameworks, while the other ninety-eight are specific policies. And fourteen of ninety-eight policies are focusing on basic drug systems, while six are on centralized purchases, nine on public hospitals reform, seven on drug safety, sixteen on prices, fourteen on distribution, twelve on administration, five on traditional medicine, and fifteen on specific drugs.

CONCLUSIONS:

After the basic drug system was built in 2009, the government started to focus on its distribution over the next 7 years. Policies on centralized purchases are mainly issued in 2010 and 2015, and creative modes have been coming up since 2015. The Government cares not only about production safety, but also safety in sales. Prices were decided by government at first but then follow the market forces. Work focus shifted from the above contents to drug distribution, price,

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management and traditional medicine after 2012. The peak of policy releases occurred when the great reform took place, such as 2009 when reform began, and in 2012 the Twelfth Five-year plan began. There was a decrease in 2013 due to national leadership change (3). Overall, dynamic factors for policy change mainly are social conditions, public issues and opinions, and feedback on former policy effects.

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PP077 Intravitreal Corticosteroids In Macular Edema: Quality Of The Evidence

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INTRODUCTION:

Treatment options for macular edema include intravitreal corticosteroids (1). Traditionally, an injectable suspension of triamcinolone acetonide (TA) had been employed off-label (2); in recent years, authorities have approved sustained-release drug delivery systems (DDSs) for corticosteroids (3). Considering the hypothesis that the use of these drugs is based on widely variable evidence in terms of methodological quality and robustness, the purpose of this analysis is to compare the quality of the evidence on efficacy and safety of three different formulations of intravitreal corticosteroids: the dexamethasone (DEX) implant, the fluocinolone acetonide (FA) implant, and the preservative-free injectable suspensions of TA, in the management of two retinal pathologies: diabetic macular edema (DME) and macular edema secondary to retinal vein occlusion (RVO).

METHODS:

A search of clinical trials on MEDLINE from 1 January 2000 to 16 December 2015 was performed. Studies were included in the analysis if they met the following criteria: (i) related to at least one of the preparations of interest in patients with DME or macular edema secondary to RVO; (ii) included a control group treated with placebo, observation, sham procedures or conventional treatments; and (iii) included visual acuity, retinal thickness and/or safety parameters as outcomes. Results were summarized in a narrative manner.

RESULTS:

Twenty-five publications from nineteen RCTs were included. We observed increased attention of researchers towards TA compared to DEX and FA; however, studies for TA are less robust. Scientific publications related to DEX and FA implants are of higher quality, especially in terms of randomization and masking procedures.

CONCLUSIONS:

Even though each of the three considered corticosteroid-containing medicines are approved for marketing and included in clinical guidelines for treatment of macular edema, a high degree of heterogeneity in terms of quality of evidence has been noticed among them. This observation underlines the need to review the requirements for drug approval and their inclusion in clinical recommendations, as well as the importance of post-markeing monitoring to generate new evidence.

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