OBJECTIVES: Competition within therapeutic drug classes from “follow-on” drugs has been an important issue in many drug markets. Many medications in existing drug classes have often been criticized for inflating health systems’ expenses, but it has been argued that such drugs increase therapeutic options. Economic theory suggests that follow-on drugs induce price competition. We contribute to this debate by addressing the quality of a new product using a novel method: MAAK, a new metric for medicine. Our aim was to judge the price development in the German market with the distinct focus on competition within already existing drug classes. METHODS: We measure determinants of price strategy of follow-on drugs using MAAK, the theoretical quality of a new product using Fricker-Klaus as a proxy for innovation. RESULTS: We identify price correlations with therapeutic value at market entry. While the first two molecules engage in quality competition, later molecules are more price-oriented. The market price can be observed from the third entrant on. Price discounts are even more distinct in development races with several drugs entering the market within two years and in classes with a low degree of therapeutic differentiation. Prices remain relatively constant over time. CONCLUSIONS: This study contributes to assessments of competition in pharmaceutical markets focusing on price strategies of new market entrants. After an initial phase of market building, further follow-on products induce price competition. Largely unchanged prices after 4 years are a result of quality competition and can be attributed to prices in Germany being anchor point for international price referencing.

PHP28
THE IMPACT OF GENERIC SUBSTITUTION ON HEALTH OUTCOMES AND COSTS: A SYSTEMATIC REVIEW
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OBJECTIVES: Although generic drugs are considered to be therapeutically equivalent to their off-patent (branded) counterparts, the overall impact of generic substitution on clinical and economic outcomes has not been comprehensively evaluated. The goal of this study was to test whether 3) brands and branded products yield equivalent clinical effects; and 2) generic therapies save economic resources versus branded therapies for de-novo patients and patients on maintenance therapy. We conducted a systematic review of the literature and stakeholder interviews. As EPR has been most common in Europe, the study focused on this region. RESULTS: The systematic review identified 104 relevant articles. The results were categorised according to study characteristics and four major themes were identified; these findings were confirmed by the interviewees. The evidence suggests that EPR schemes often generate disproportionate price levels leading to non-uniform participation, this is likely due to the pricing on foreign list prices which do not reflect negotiated discounts. If manufacturers apply launch strategies to exert upward pressure on prices (e.g. launch delays or product bundling) it could lead to non-uniform incentives. In addition, the bureaucratic complexity of many EPR schemes may undermine the objectives of EPR use (i.e. cost containment and macroeconomic efficiency). Finally, widespread EPR application may stifle pharmaceutical and biomedical innovation. CONCLUSIONS: A national pricing policy should provide an effective, predictable, transparent, and stable pricing environment for pharmaceutical products. It should internalise national priorities for health and industrial policy, including outcomes, employment, innovation, and trade promotion. EPR is associated with important short- and long-term issues. If EPR is going to continue to be applied by EU Member States and other countries, then it is necessary to establish guiding principles to govern EPR use across jurisdictions. Still, different EPR and risk-sharing agreements may represent more sustainable policy options.

PHP31
DOES EUROPE REWARD REFORMULATIONS? A DATA DRIVEN ANALYSIS OF VALUE PRESERVATION THROUGH REFORMULATION
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OBJECTIVES: Reformulating existing drugs can improve patient convenience, compliance, and the total health of a patient, but the cost of the product. However, reformulations cost millions of Euros - a risk investment without guaranteed exclusivity or returns. This study assessed whether markets reward incremental value creation through reformulation by comparing sales performance close to patent expiry for reformulated and non-reformulated products. METHODS: IMS MIDAS data was interrogated to identify 829 small molecule, non-generic products which had peak sales above $5M and lost patent protection between 2001 and 2010 in EU-5 (France, Germany, Italy, Spain and UK). Ex-manufacturer sales value ($) 2 years after patent expiry was compared with sales value 4 years earlier to calculate percentage value erosion for each of the 829 products. A subset of 133 products which launched at least 1 reformulation close to patent protection expiry (launch between 3 years before and 1 year after patent protection expiry) were analysed to assess whether value erosion varied across countries or therapy areas. RESULTS: Mean ex-manufacturer sales value erosion of reformulated products (24%) was significantly less than non-reformulated products (37%, P<0.01). Reformulated product value erosion varied with country and therapy area. Germany saw highest number of reformulations launched yet only reformulations launched in Italy showed significantly less value erosion than non-reformulated products (P<0.01). Across therapy areas, reformulations were most common in nervous system, metabolism and anti-infective categories. However, reformulated anti-infective product value erosion was pronounced while musculoskeletal and nervous system products experienced significantly less value erosion than for non-reformulated products (both P<0.05). CONCLUSIONS: Overall, reformulated products do maintain more value than non-reformulated products following loss of patent protection. Chronic diseases with long life expectancies and relatively steady product demand appear to be the most promising areas for reformulating. Future reformulation potential is tightly linked to country-specific pricing and market access policy decisions to recognise incremental value products.

PHP32
CONSTRUCTING AN INDEX OF INTERNATIONAL PHARMACEUTICAL PRICES: A COMPARISON OF PHARMACEUTICAL PRICES IN 56 COUNTRIES
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OBJECTIVES: To construct a number of pharmaceutical price indices for a broad set of countries, covering a range of regions, including countries with different levels of economic development.

The margin index was 21% in 2009 and 20% in 2010. Since all drugs were Rx medicines, Rx was set up to 12%, VAT was fixed to 8%), which was completely expected. At the end of the 2010, two medicines: levonorgestrel (1.5mg) and olistat (60mg), were authorised as OTC medicines (free pricing, margin 25%, VAT 18%). CONCLUSIONS: “Lifestyle-medicines” are difficult to define. Market success depends on product innovation, effectiveness, market access (addressing the competitive price setting), simplicity of administration, good safety profile, first-to-market position, premium prices, sustained media attention, Rx-to-Otc switch potential and reimbursement potential. Although more than “lifestyle-medicines” will be authorised in Serbia, market share is expected to decrease because of low purchasing power and low reimbursement potential.