from which ATMPs could benefit to get early access. ATMPs may be the next source of major impact on payers' drug budget.

PHP21

POLICY IMPLICATIONS OF AFFORDABLE CARE ACT ON US MARKET ACCESS

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OBJECTIVES: The Affordable Care Act (ACA) has introduced several major changes which can impact product pricing, access and uptake in the United States. The objective of this analysis was to review all major new changes due to ACA and develop implications for market access for medical products. **METHODS:** The new pricing, access and coverage changes impacting the pharmaceutical and devices products were reviewed using the bill for ACA (H. R. 3590), 2011-2015 policy publications, reports by the Congressional Budget Office and Government Accountability Office, and the latest Centers for Medicare & Medicaid Services (CMS) guidelines for Essential Health Benefits (EHBs). Primary discussions with US private payers and ex-CMS policy experts were conducted to understand key issues for medical products. **RESULTS:** The ACA has introduced major changes for product pricing, deductible, coverage and uptake. For pricing, major changes are a 50% discount for Part D population and an increased rebate of 23.1% for the Medicaid population. For deductibles, the patient costs are capped at $12,700. For uptake, an additional population is eligible based on expanded access to 30 million uninsured Americans, with more than half of them being under the age of 35 years (~59%). For access, the 2014 definition of Essential Drug Benefits is likely to either expand or reduce coverage depending upon the state and class of drugs. For example, for NSAIDs in CA only 20 drugs are covered, while in NY, 40 drugs are covered. During 2012-2014 Accountable Care Organizations (ACOs) have increased to ~600 organizations covering ~18 million lives, which has created a new stakeholder of an integrated provider-payer partnership. **CONCLUSIONS:** ACA has introduced major changes which will have a significant impact on converge, pricing and access of pharmaceutical and device products.

PHP22

HOW REDUCING THE EQUIVALENCE BAND CAP TO BASE PRICE FOR SELECTED 15 GROUPS IMPACTS SAVING AND PRICE EROSION IN TURKEY: PRELIMINARY RESULTS

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OBJECTIVES: Turkey applies molecule-based equivalence grouping and Social Security Institution (SGK), the sole public payer of pharmaceuticals, pays a cap which is at most 10% over the lowest (base) price of each group. As of October 1 2014, SGK lowered the cap to base price for selected 15 groups. The objective of this study is to analyze the preliminary impact of this policy change and compute whether it provides necessary saving and price reduction. **METHODS:** Claims data from SGK for all drugs included in the selected groups were collected monthly for June and July 2014, denoted as pre-policy change period; October and November 2014, defined as post-policy change period. Price changes, saving impact, patient contribution rate, and utilization rates were compared and analyzed. **RESULTS:** Among 212 drugs in those groups, the price of 180 drugs stayed the same whereas 6 increased and 26 decreased. With this policy shift, SGK generated a saving of nearly 10%; base price, prescription substitution, and price erosion impacts contributed by 7, 1, and 2 percentage points respectively. Besides, cost per unit, weighted average of total sales value divided by total sales volume, reduced by 9% compared to pre-policy change period. Base-priced drugs' sales volume (value) climbed by 3 (6) percentage points. Although it was estimated that patient contribution rate would rise by 8 percentage points on average after the new policy, in reality it reached 18% with an increase of 5 percentage points, thanks to price reduction due to competition and higher utilization of base-priced drugs. **CONCLUSIONS:** Based on primary data, it seems the new policy provided the desired effect on price reduction and utilization increase of base-priced drugs, hence saving with minor impact on patient contribution.

PHP23

HAVE INFLIXIMAB DISCOUNTED PRICES IN NORWAY HAD AN IMPACT ON PRICES AROUND THE WORLD?

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OBJECTIVES: Following the availability of biosimilars of Remicade (infliximab, Janssen Cilag) - which target severe pathologies - a national tender was launched in Norway in order to negotiate discounts. Orion, manufacturing the biosimilar Remsima, won the national tender by offering a 72% discount compared with Remicade in February 2015. Hospira, manufacturing the biosimilar Inflectra, offered a 51% discounts. Given the extent of the discounts and wide publicity of the prices, the goal of this survey was to assess if list prices of infliximab were impacted in Norway as well as in countries using Norway in their International Reference Pricing (IRP) rules. **METHODS:** Ex-manufacturer list price changes over time for Remicade and biosimilars of infliximab were analysed in Norway as well as in countries using Norway in their IRP rules and for which list prices are available, namely: Denmark, Finland, Iceland, Poland and Slovenia. **RESULTS:** Our results show that while the tender led to significant discounts, list prices (since biosimilars are available) of either the biologic product or biosimilars have remained constant in Norway. Additionally, prices have remained constant in all countries using Norway in their IRP rules except for Iceland, where prices have regularly decreased. The change is however not linked to IRP rules. **CONCLUSIONS:** The research indicates that prices around the world for Remicade and infliximab biosimilars have not been impacted by price changes in Norway. Whilst the new prices generated significant global attention, they have not been formally incorporated into pricing negotiations elsewhere, at least for the time being. This is partly because certain countries may not have had time to conduct IRP against Norwegian prices yet, but also because the list prices remain unchanged, and IRP at the discount level remains rare.

PHP24

DEFIBROTIDE IN VENO-OCCLUSIVE DISEASE IN PUBLIC HOSPITALS OF PARIS: FUNDING ISSUES AND PERSPECTIVES

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OBJECTIVES: Defibrotide had market authorization (MA) in treatment of severe veno-occlusive disease (VOD) and negative opinion for VOD prevention (October 2013). Before, in France, defibrotide get in 2009 a compassionate use (temporary use authorization) in VOD treatment and prevention with a specific financing. Since the MA, the high cost of defibrotide remains a major problem for hospital budgets. Assessment of economic impact of defibrotide treatment and perspectives to frame indications to reduce costs were purposed for the 37 hospitals of the Public Assistance–Hospitals of Paris. **METHODS:** Data collected were: i) consumptions/expenditures in défibrotide from 2011 to 2014 and extrapolated values in 2015; ii) 2014 medical information from PMSI hospital database (French medical information system program); iii) Diagnostic Related Group (DRG) tariff and part of drugs cost; iv) experts in hematology opinions. **RESULTS:** Since 2011, consumptions increased to reach 15,750 vials for 5.2M€ in 2014. In contrast, extrapolated values in 2015 have showed decreasing amounts which could be explained by a self-regulation of prescribers in front of the economic impact and practices changes. In 2014, eighty patients received defibrotide (mean: 19 years), main diagnosis was acute myeloblastic leukaemia. 90% of these patients who received defibrotide were attributed to the DRG corresponding to hematopoietic stem cell transplantation levels 3 or 4 (tariff DRG cost: 51,725.20-71,948.73€). Portion of attributed to drugs (3,544-4,084€) cover a small part of treatment cost (97,524€ for an adult). Experts recommended harmonization of indications, improvement of pre-transplant cares (reduction of the liver damage and conditioning regimen intensity), optimization of vials numbers per patient (centralized preparations, limitation of treatment duration). **CONCLUSIONS:** Aware of economic impact, experts have initiated a change of practice and they recommend a restrictive use of defibrotide specially limitation the off-label use in preventive (only patients with very high risk of VOD).

PHP25

EFFECT OF PARALLEL REVIEW PROCESSES FOR THE MARKETING AUTHORIZATION AND REIMBURSEMENT TO PATIENTS AND BUDGET

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OBJECTIVES: To Improve patient access toward new drugs, parallel MFDS(Ministry of Food and Drug Safety) and HIRA(Health Insurance Review and Assessment service) review processes have been introduced in South Korea since 2014. In parallel processes, submission for reimbursement to HIRA is allowed during marketing authorization process in MFDS. This study reports on evaluation of two years' experiences and current issues. **METHODS:** We investigated reimbursement appraisal results of drugs submitted before their approval from 2014 to June 2015. The reduction of the length of time for patients' access to new drug was calculated by the time between the submission to HIRA and authorization of MFDS. And extra budget impact of parallel processes was calculated. **RESULTS:** Total six drugs were assessed for reimbursement upon parallel MFDA and HIRA processes. HIRA decided all six drugs to be reimbursed. The reduction of the length of time for patient access was average 61 days in parallel processes comparing with the prior sequential process that submission for reimbursement was required to complete its marketing authorization process of MFDS. In case of two drugs of six reimbursed drugs, an estimated total drug cost expected to increase approximately three million USD per year comparing with the estimated total drug cost assuming that if the 2 drugs were assessed in sequential review process. It resulted from the price of comparators of the two drugs scheduled to be discounted in the near future. Because of a patent expiration of the comparators, their price will be disounted after the listing date of the two new drugs. **CONCLUSIONS:** Parallel MFDS and HIRA processes could contribute to patient access toward new drugs by 61 days earlier in South Korea. But in some drugs, it can be expected to change the budget compared with former sequential review process considering comparators' patent expiration.

PHP26

MARKET ACCESS OF ATMPS: OVERVIEW AND EXPECTED CHALLENGES

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OBJECTIVES: Advanced therapy medicinal products (ATMPs) are a class of innovative and regenerative therapies. As of May 2015, only 5 ATMPs were granted a marketing authorisation (MA) in European Union (EU): three cell therapies, Provenge® (for advanced prostate cancer), Chondrocelect® and MACI® (for cartilage defects); one tissue engineering product, Holoclar® (for damaged cornea); and one gene therapy, Glybera®(for lipoprotein lipase deficiency). The aim of this study was to review the ATMPs assessments by EU HTA bodies. **METHODS:** EU big 5 HTA body websites were searched for their decisions on ATMPs: France (HAS), UK (NICE, SMC), Italy (AIFA and regions), Spain (MSSSI and regions), Germany (IQWiG, G-BA). Grey literature was also searched for further details. **RESULTS:** Chondrocelect® was only assessed in Spain and France; reimbursement was granted in Spain, rejected in France as efficacy/adverse effects ratio had not been clearly established. Provenge® and MACI® were only assessed in the UK and Germany. NICE concluded that Provenge® did not demonstrate additional benefit nor cost-effectiveness against best supportive care; IQWiG/G-BA concluded "non-quantifiable" added benefit. MACI® was not recommended by NICE due to uncertainty in cost-effectiveness analysis and lack of long-term data, while its assessment has been suspended in Germany until further publication of randomised clinical trials. Only G-BA assessed Glybera® but could not conclude on its benefits due to limited data submitted by manufacturer. Holoclar®