model was employed to estimate factors associated with where a new drug was reimbursed by multinational health insurers. While the reimbursement lag was 11.83 months in the US and 26.84 months in Europe, reimbursements were obtained within 6 months for new drugs in Taiwan, the median of marketing lag was 26.84 month while the median of reimbursement lag was 11.83 months. About 84% of new drugs were reimbursed by NHI. The reimbursement decision was mainly associated with the characteristics of manufacturers, including their types of therapies and innovation categories. The price-related factors were significantly related with the reimbursement lag but not whether medications were reimbursed. CONCLUSIONS: By examining the barriers at different stages from drug approval to listing and reimbursement, this study provided different perspectives for health policy makers to examine issues on drug approval, health care resource allocation, and quality of medical care.

PHP100

OVERVIEW AND IMPORTANCE OF NUB PROCESS FOR MARKET ACCESS OF IN-PATIENT DRUGS AND DEVICES IN GERMANY

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OBJECTIVES: In Germany, the reimbursement and pricing of innovative in-patient drugs and devices are evaluated through the NUB (National Use-Based) application process. These applications are submitted by the hospital stakeholder and are approved or rejected by the Institute for the Hospital Remuneration System (InEK). The objective of this research was to assess the NUB trends in Germany in 2012-2014. METHODS: We developed a database of NUB approvals and rejections based on the Institute for the Hospital Remuneration System’s (InEK)’s reports. All information was extracted into Excel format. The following data was extracted: product name, indication, year of submission, number of NUB applications submitted, status score, type of evidence available and lack of evidence for NUB rejection. Additionally, the number of re-applications and re-rejections were also analyzed. RESULTS: In 2013 and 2014, a total of 21264 and 2564 NUB applications were submitted for 612 and 613 medical products, respectively. Of these applications in 2013 and 2014, 10% and 16% were approved for NUB (as Status 1) and 82% and 75% were rejected (as Status 2), respectively. In 2014, 25% of the new hospital applications (5 of 20) and 27% of the reapplications (2 were 37 and 3, demonstrating the importance of hospital participation for seeking NUB approval. Among approved NUBs, 37% of the applications were for drugs and 63% were for devices. Interestingly, the median NUB hospital applications for approved drugs were 0 and for devices, the median was 3. In 2014, 447 NUB applications for products were re-submitted, of which 5 were approved and the remaining 442 were rejected. The evidence requirements analysis suggests the need for hospital focused economic data. CONCLUSIONS: The NUB process plays a critical role in market access for in-patient drugs and devices. For approval, two key components are: hospital focused economic evidence and provider stakeholder involvement.

PHP110

THE POTENTIAL IMPACT OF PRICE ADJUSTMENTS OF A NEW THERAPY IN GERMANY ON OTHER COUNTRIES: SIMULATION MODELING EXERCISE Sivkovsky B1; Walter S2, DrscheI D2, Zah V3
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OBJECTIVES: International Reference Pricing (IRP) is a key tool for health care payers across the world. IRP may apply either fixed or flexible rules to calculate the price of branded drugs. Typically there is no negotiation between manufacturers and payers in the context of IRP. The German AMNOG regulations and the role of Germany as a key referenced country, there is dearth of real-life evidence on the international impact of the AMNOG law. METHODS: The publicly available AMNOG data were gathered and evaluated systematically. Based on these findings an IRP model was developed to simulate the impact of a new drug between the German Head Association of the Statutory Health Insurance Companies and the manufacturer. The impact of the price agreement on other countries was analyzed based on the existing IRP rules. RESULTS: We simulated a hypotheti- cal price dataset for a branded drug X with all prices set at 100 euro to limit the impact to Germany only. A 25% price drop in Germany would lead to a range of 32.5% reduction in Egypt and almost 1% in Austria. The largest impact in Europe would be in France, Romania, Russia, Slovenia, Luxembourg (-25%), followed by Norway and Greece (-8.33), the Netherlands (-6.25%), Switzerland, Ireland and Denmark. A price drop of 50% in Germany would double the impact with the exception of Egypt (-55%). However, a limited impact was observed if the price increase in Germany was 25%. That would lead to 6.25% increase in the Netherlands, 4.17% in Switzerland, 2.78% in Ireland and Denmark, and about 1% increase in Austria. CONCLUSIONS: Price negotiations in Germany could potentially impact the price of new branded therapies in other countries. This could ultimately lead to a price-downward spiral with a negative impact on innovation and drug development in Europe.

PHP111

CURRENT TRENDS IN US AND EUROPEAN PRICING OF UNIQUE BIOPHARMA PRODUCTS

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OBJECTIVES: In recent years, the pharmaceutical industry has received approval in both the US and Europe for several products that are unique, meet previously unmet medical needs, and yield important reductions in mortality and morbidity. Frequently, these products are orphan and even ultra-orphan drugs targeted at very small patient populations. It is common for these products to be priced up to $500,000 per annum. This paper reviews the unique pricing of these unique products (including trends) and explored alternative funding strategies that have been negotiated (e.g. outcome contracts) and/or are being proposed (e.g. reimbursement methods) by payers to manage their budgets. METHODS: We conducted research on the publicly available data on unique biopharma products and their pricing through literature and inter-