model was employed to estimate factors associated with where a new drug was reimbursed by its health body (e.g. reimbursement through insurers). While attention has been paid to 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 NHI. Companies, including their types of therapy, and institutional and international 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 list price, 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

THE POTENTIAL IMPACT OF PRICE ADJUSTMENTS OF A NEW THERAPY IN GERMANY ON OTHER COUNTRIES: A SIMULATION MODELING EXERCISE

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OBJECTIVES: In Germany, the reimbursement and pricing of innovative in-patient drugs is based on the International Reference Pricing (IRP) system. For NUB applications, the IRP rules are a key tool for healthcare 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 the IPR body. In the context of the German AMNOG price negotiation, this study was to collate and compare published HTA guidance on the use and acceptability of non-randomized evidence. Although the majority of HTAs request that a systematic search for non-RCT data be conducted, few HTAs considered non-randomized evidence relevant to clinical effectiveness outcomes. Observational data were submitted to HTA bodies in order to complement and extrapolate RCT evidence, test the integrity of evidence synthesis networks, and inform long-term safety outcomes. Feedback regarding the appropriateness of observational data was minimal or absent in many EK reports. CONCLUSIONS: There is a need for HTA bodies to provide clearly defined guidance regarding the use of non-randomized evidence. Technology appraisals and reports from evidence review groups (ERGs) (published 2004–2014) on the oncology setting, were assessed to identify circumstances in which non-randomized evidence was submitted in HTAs, and to understand how this evidence was considered by ERGS. RESULTS: A lack of clear guidance was found regarding when and how non-randomized evidence can be used to support HTAs. Although the majority of HTAs request that a systematic search for non-RCT data be conducted, few HTAs considered non-randomized evidence relevant to clinical effectiveness outcomes.

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 the USA and EU for several products that are unique, meet previous unmet medical needs, and yield important reductions in morbidity and mortality. 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 study aimed to simulate a hypothetical scenario of pricing of these unique products (including trends) and explored alternative funding strategies that have been negotiated (e.g. outcome contracts) and/or 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-