

the reduction of pharmaceutical expenditure was one of the main targets for fiscal adjustment. The purpose of this study was to assess the usage of generic medicines in Greece, as a key driver for savings from the pharmaceutical market, and compare it with that of other major European countries. **METHODS:** IMS data from several European countries was collected in terms of the overall retail pharmaceutical market and the consumption of generic medicines in each of them. Focus was placed on the top-10 genericized molecules for Greece including alendronic acid, atorvastatin, carvedilol, clarithromycin, clopidogrel, donepezil, fluconazole, olanzapine, omeprazole and simvastatin. To ensure an "apples-to-apples" comparison across countries, the study focused on the retail market only (excluding hospitals) given that, in Greece, there is no publicly-available data for pharmaceutical consumption within the hospital setting. **RESULTS:** The analysis indicated that, in Greece, the penetration of generic medicines within the top-10 genericized molecules was 65% in terms of volume, with off-patent medicines holding the remaining 35%. According to IMS data, Greece had a lower penetration of 21 percentage points (-24%) versus the weighted European average and -8.2 percentage points (-11%) versus the cluster of Southern European countries plus Ireland for calendar year 2013. **CONCLUSIONS:** Generic penetration within the 10 largest genericized molecules, in Greek retail-pharmacy setting, is significantly lower versus the weighted average of major European countries but also compared to that of countries in similar economic situation with Greece.

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PROMOTING QUALITY USE OF GENERIC MEDICINES: KNOWLEDGE, ATTITUDES AND PRACTICES OF COMMUNITY PHARMACISTS IN A MIDDLE EASTERN COUNTRY

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OBJECTIVES: The practice of generic medicines prescribing, dispensing and substitution in developing countries has been controversial among health care professionals, particularly due to issues on quality, safety and efficacy. These controversies are as a result of inter-country differences in policies and laws as well as individualized knowledge and attitudes of pharmacists pertaining to generic medicines. This study primarily aims to assess the knowledge, attitudes, and practices of community pharmacists in Qatar towards generic medicines. **METHODS:** A cross-sectional study using a pretested paper-based survey was conducted among a random sample of community pharmacists in Qatar. The data were analyzed using IBM-SPSS® version 20. Both descriptive and inferential statistical analyses were applied. **RESULTS:** A total of 160 surveys were distributed to community pharmacists of which 118 were returned (response rate, 74%). The mean total score of generic medicines knowledge among the pharmacists was 6.8 ± 1.6 (maximum possible score was 10). Years of practice as well as place of obtaining academic degree did not influence knowledge score. Approximately 72% of the pharmacists supported generic substitution for brand name drugs in all cases where a generic medicine is available and the majority (93%) agreed that pharmacists should be given generic substitution right. Nearly 61% of the pharmacists considered lack of proven bioequivalence to original brands as an important barrier for selecting generic medicines and 55% rated "lack of policy for directing the practice of generic medicine" as an important barrier. **CONCLUSIONS:** In order to enhance the quality use of and to promote the practice of generic medicines in Qatar, an educational program should be implemented. A national generic medicine policy and guidelines are warranted in the State of Qatar.

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EVALUATING RATES OF POTENTIAL GENERIC SUBSTITUTION FOR PRESCRIPTION DRUGS: CAN WE IMPROVE ON EXISTING INCENTIVE SCHEMES?

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OBJECTIVES: Encouraging generic drug use has reduced health care costs for payers and consumers, but the rate of branded medications therapeutically interchangeable to generic is not equal across medications disease states. The extent to which different systems of care are able to substitute towards generics is not well understood. This study defined and measured the maximum generic rate (MGR) of currently prescribed drugs and illustrated differences across drugs associated with selected underlying diseases. **METHODS:** Using information in prescription claims data, drugs were classified into "potentially generic substitutable" or not based on clinical consensus regarding the following algorithm: 1. They did not have a narrow therapeutic index (NTI) as defined by the Food and Drug Administration (FDA); 2. Did not belong to one of six protected classes of drugs in Medicare D; 3. They were substitutable with a generic medication of the same chemical entity; 4. They were therapeutically interchangeable with a generic in the same class which was thought clinically to have class effect benefits and minimal risk of harm in switching. A maximum generic rate (MGR) was defined as the percent of prescriptions that could be generic. This rate was examined overall and across drugs known to be associated with illustrative diseases including hypertension, diabetes mellitus, and obstructive lung disease. **RESULTS:** The MGR ranged from 100% for drugs used in hypertension to 26.7% for drugs used in obstructive lung disease. The overall maximum possible generic rate (MGR) was 83.6%. **CONCLUSIONS:** Payers wishing to promote generic substitution should incorporate the potential for substitution toward clinically appropriate generic medications as part of incentives for generic utilization to avoid unintended consequences of using a fixed target rate. A practical methodology for determining a MGR is offered here.

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PREVENTION AND MANAGEMENT OF MEDICINE SHORTAGES IN BELGIUM, FRANCE AND FROM THE PERSPECTIVE OF THE EUROPEAN UNION

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OBJECTIVES: Medicine shortages are a global phenomenon. A growing number of reports indicate the problem is increasingly affecting the European pharmaceutical market. The present study aims to investigate the characteristics, determinants, legal aspects and management of medicine shortages in Belgium, France and from the perspective of the European Union. **METHODS:** A review of scientific and grey literature was performed. The legal framework on European and national level was reviewed. Primary qualitative data was collected through 22 semi-structured interviews with key representatives of health care systems' stakeholders on the national and European level. **RESULTS:** France reported three times more shortages than Belgium. However, the main therapy area, the major cause and the dynamics of medicine shortages were analogous between the two countries. Determinants of medicine shortages were categorised in manufacturing problems, distribution and supply issues, and economic-related challenges. Manufacturing problems were most frequently reported as the primary cause of medicine shortages. Laws and regulations related to medicine shortages are more extensive in France than Belgium. Several preventive and responsive measures were identified to address such shortages. **CONCLUSIONS:** Although medicine shortages are country-specific, the underlying mechanisms of medicine shortages appear to be similar in Belgium and France. Economic aspects seem to play a central role in the phenomenon of medicine shortages, as it influences stakeholders' business decisions. The impact of the legal framework around medicines on the occurrence of medicine shortages may be limited. Collaboration, communication and coordination are key to any effective approach to address medicine shortages.

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EXPEDITED REGULATORY REVIEW AND AUTHORISATION OF MEDICINES AND THEIR SUBSEQUENT APPRAISAL BY HTA AGENCIES IN THE EUROPEAN UNION

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OBJECTIVES: Firstly, to review whether medicines that have received expedited regulatory approval in the European Union (EU) subsequently received positive recommendations from selected Health Technology Assessment (HTA) agencies in the EU. A second objective was to understand the reasons for negative appraisals of these medicines by EU HTA agencies. **METHODS:** Medicines that have received Conditional Marketing Authorisation (CMA) by the European Medicines Agency (EMA) were identified from the EMA website. Websites of HTA agencies in the United Kingdom (NICE, SMC); Ireland (NCPE), France (HAS) and Germany (IQWiG) were searched to ascertain whether these medicines had been appraised. Appraisal reports were reviewed. For medicines with at least one negative appraisal, reason (s) for the negative appraisal were identified. **RESULTS:** 13 medicines have received CMA in the EU. 10 of these medicines have received a negative appraisal by at least one HTA agency (either 'not recommended' or deemed to offer 'no additional benefit' over existing treatment). Of the 10 medicines with at least one negative appraisal, 8 are oncology medicines. The most common reason for a negative appraisal (relevant to 9 of the 10 medicines) was insufficient or uncertain clinical effectiveness. Uncertain cost-effectiveness in relation to the proposed treatment cost was mentioned as a source of uncertainty for 5 of the 10 medicines. **CONCLUSIONS:** Despite receiving expedited regulatory approval, patient access to innovative medicines in the EU may be delayed due to negative appraisal of these medicines by HTA agencies (most often due to a relative lack of data on clinical effectiveness). Such delays obviate the intention of expedited regulatory review of medicines.

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CHALLENGES: IN IMPLEMENTING HTA IN THE REIMBURSEMENT DECISIONS IN ALGERIA / A COMPARTIVE ANALYSIS

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OBJECTIVES: To provide a comprehensive description of the current Drug Reimbursement Systems in Algeria and to compare it to two archetypes drug reimbursement systems in France and UK and to a system in a middle income country: Turkey where the HTA has been recently implemented. **METHODS:** We collected and reviewed relevant information to describe the health care and drug reimbursement systems in these countries; we reviewed the legal framework and procedure documents. For Algeria, in addition to the data and information collected, we conducted informal interviews supplemented by a survey among key stakeholders. **RESULTS:** Compared to the UK, no similarities were found. This is probably due to the cultural differences and the lack of expertise in the use of cost-effectiveness approaches. Compared to the France, we didn't find similarities, except the final decision which is taken at the Ministry level. This is due to the administrative nature and the lack of transparency of the assessment in Algeria especially where the methods as well as the results of the assessment are not explicitly expressed. Compared to Turkey, we found some similarities in terms of process, but not in terms of methods as this country is now more familiar with the HTA approach. **CONCLUSIONS:** Our study shows that the implementation of HTA differs according to cultural and financial factors and to expertise capacity in data collection, analysis and use in the decision making process. The use of HTA in the drug evaluation and reimbursement system in Algeria is underestimated and underdeveloped. That's why before adopting HTA approaches in the pharmaceutical sector, the Algerian authorities should consider these factors and improve the data quality and decision process transparency. This is becoming vital as cost of drugs is increasing and the fiscal space will be more constrained in the near future.

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AN ANALYSIS OF THE 2014 MOROCCAN DRUG PRICE CUTS

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