chronic (e.g., diabetes, hypercholesterolemia, schizophrenia) rather than life-threatening conditions. The study demonstrates the importance of considering medical benefits and ultimately leave medication decisions to specialists. Patients are cautiously examining potential savings and were willing to institute modest management for genomics (tier 1) while keeping branded FDCs on preferred tier 2 (branded preferred copy). Patients were unwilling to institute high cost-sharing co-insurance, prior authorizations, or require failure for members to access branded HIV medications presently or in the near future. CONCLUSIONS: Patients recognize the complexity of treatment regimens and role of adherence, the high cost of failure and the public health component of preventing resistance. We found patients to cautiously look at potential cost savings in medication management until all FDC components become generic. We found no widespread desire to drive generic adoption in HIV treatment, and little interest in the “de-simplification” of currently available FDCs.

PIN135 THE HEALTH AND ECONOMIC EFFECTS ON PUBLIC HEALTH DUE TO PATIENTS’ DEFAULT IN TUBERCULOSIS TREATMENT IN MALAYSIA

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OBJECTIVES: Inadequate or partial treatment of Tuberculosis (TB) is a known factor that would promote drug resistance, thus increasing the overall cost of TB management. The study objectives are to identify the general characteristics of defaulting patients and to estimate the cost impact on health authorities as compared to non-defaulting patients. A retrospective case-control study was conducted to compare drug treatment adherence in two treatment centres in Selangor, Malaysia. Defaulters is defined as TB patient who has interrupted treatment for two consecutive months or more and did not complete their treatment. All subjects were strictly selected from general practice clinics. Patients’ medical case notes and baseline characteristics were reviewed and analyzed. The direct costs of TB management were estimated from public health cost references. The cost was then compared to government-covered free TB treatment. Mean cost of the non-defaulter group is higher than the defaulter group following a complete treatment (RM 1,259.62 vs. RM 575.58; p < 0.05). Other significant findings were observed between the two groups including age, ethnicity, severity of x-ray changes, type of TB and overall medical risk factors. Mean cost of the non-defaulter group is higher than the defaulters group due to a complete treatment (RM 1,259.62 vs. RM 575.58; p < 0.05). No significant cost treatment difference was observed in foreign-born defaulters as compared to local Malaysians (mean: RM 576.43 vs. RM 573.78; p > 0.05). CONCLUSIONS: Data from this study suggests government management should be a potential huge waste of resources. More attentions are required for foreign-born defaulters due to overall consequence in public health and management cost. Additional costs would be required if susceptible TB strains of the defaulters turned into more virulent strains for the FDA, IMA, Health Canada and Australia the Australian Therapeutic Goods Administration, the Notified Bodies and other regulatory agencies are influences by the FDA in the studies they consider, as illustrated by at least six cases in which other agencies used studies commissioned by the FDA after approval. This is easier to see in the last five years, but may be older than that due to improvements in published reports.

PIN138 ATTITUDES, BELIEFS AND BEHAVIOURS OF GENERAL PRACTITIONERS REGARDING VACCINATION: DEVELOPMENT OF A CHARACTERISATION TOOL – QUALITATIVE STUDIES

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OBJECTIVES: General practitioners (GPs) play an essential role in France in the prescription and administration of vaccines. Understanding factors that influence GPs’ attitudes towards vaccination and determining strategies to improve vaccination coverage in the general population. The study objectives were to understand and describe GPs' attitudes, beliefs and behaviours regarding vaccination, to develop a self-report tool to assess GPs’ characteristics, the prevalence and determinants of vaccination behaviours and to identify the modifiable barriers regarding vaccination. METHODS: Focus groups with French GPs (n=36) were conducted following a semi-structured interview guide. Main themes of the guide were identified through a literature review and through qualitative茴ycin frame (68% vs. 31%; p<0.01). No other significant findings were observed between the two groups. CONCLUSIONS: Data from this study suggests government management should be cautious about the potential misuse of resources. More attentions are required for foreign-born defaulters due to overall consequence in public health and management cost. Additional costs would be required if susceptible TB strains of the defaulters turned into more virulent strains for the FDA, IMA, Health Canada and Australia the Australian Therapeutic Goods Administration, the Notified Bodies and other regulatory agencies are influences by the FDA in the studies they consider, as illustrated by at least six cases in which other agencies used studies commissioned by the FDA after approval. This is easier to see in the last five years, but may be older than that due to improvements in published reports.

PIN139 A CASE STUDY OF FDA PRACTICES AND ITS INFLUENCE ON REGULATORY AND REIMBURSEMENT DECISIONS FOR DARUNAVIR


OBJECTIVES: It is assumed that agencies influence one another but little has been written on the extent of this influence. This analysis aims to explore how regulatory decisions affect reimbursement decisions within one HIV drug, darunavir. METHODS: Documents from the FDA, European Public Assessment Report (EPAR), Health Canada, and the Australian Register of Therapeutic Goods together with the reimbursement decisions from France, Scotland, Canada and Australia were analyzed. The clinical trials found in these documents were compared. RESULTS: The FDA approved darunavir ethanolate on June 23, 2006 based on the POWER 1, 2 and 3 clinical trials. After approval, the FDA also required further reports (to be completed by December 31, 2007) on two Phase II studies, ARTEMIS and TITAN. Health Canada approved darunavir on July 28, 2006 and used the POWER studies along with the ARTEMIS and TITAN studies in its decision. The EMA approved darunavir on December 2, 2007 but gave conditional authorization a year earlier. EPAR also used the TITAN and POWER studies to make its decision. The French reimbursement agency used the ARTEMIS and TITAN studies in two recommendations. Scotland and Canada cited the ARTEMIS study in their recommendations. Australia used the POWER studies in its recommendation for funding. The UK NICE used the POWER studies but in its one negative recommendation, citing an inappropriate comparator for the population under review. CONCLUSIONS: Studies that required further review by the FDA after approval were key in determining regulatory decisions by Health Canada, EMA and Australia. The reimbursement decisions of France, Scotland, Canada and Australia also relied on these commissioned studies.

PIN140 CLINICAL GUIDELINES EVIDENCE AS A CRITERION FOR CHANGES IN THE LEGISLATION COMBATING TUBERCULOSIS

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For instance, the State Expert Center of the Ministry of Health in Ukraine, Kyiv, Ukraine examined 15 regulatory decisions and reasons for reimbursement decisions. The EMA approved darunavir on December 2, 2007 but gave conditional authorization a year earlier. EPAR also used the TITAN and POWER studies to make its decision. The French reimbursement agency used the ARTEMIS and TITAN studies in two recommendations. Scotland and Canada cited the ARTEMIS study in their recommendations. Australia used the POWER studies in its recommendation for funding. The UK NICE used the POWER studies but in its one negative recommendation, citing an inappropriate comparator for the population under review. CONCLUSIONS: Studies that required further review by the FDA after approval were key in determining regulatory decisions by Health Canada, EMA and Australia. The reimbursement decisions of France, Scotland, Canada and Australia also relied on these commissioned studies.