PHP94  CRITICAL EVALUATION OF LABELING REQUIREMENTS OF NUTRACEUTICAL BRANDS

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OBJECTIVES: This study focuses on the regulations made by government of India for Nutraceuticals labeling requirements and the need of the change in the monitoring system in the use of Nutraceuticals in India. 2. To study labels of selected Nutraceutical products from health care market. METHODS: For objective first we have studied the regulations made by TDA of India regarding Nutraceuticals labeling requirement, for which we have used secondary data collection method. For second objective we have collected 30 samples randomly from Nutraceutical segments from local Pharmacies and studied the labels carefully. RESULTS: The follow-up by Nutraceuticals manufacturer to labeling regulations found very moderate in our study. We found that regulations about list of ingredients, nutritional value, declaration regarding veg non-veg, declaration of ingredients, nutritional value, declaration regarding veg non-veg and other crucial parts of label are poorly followed by Nutraceutical Manufacturer in India. CONCLUSIONS: As we have studied the regulations regarding labeling of Nutraceuticals, we found that these regulations are sufficient and appropriate. Again through this research work we have come to make this conclusion that Nutraceuticals manufacturer are not much serious regarding labeling which is threaten in some aspects so they used to make mistakes in labeling knowingly or unknowingly.

HEALTH CARE USE & POLICY STUDIES – Regulation of Health Care Sector

PHP95  DEVELOPING A DRUG PRICE REFERENCE INDEX IN THE PHILIPPINES

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OBJECTIVES: To develop a method of setting a Drug Price Reference Index (DPRI) in the Philippines to ensure good value for money in the procurement and reimbursement of essential medicines. METHODS: A database of prevailing drug procurement prices was created from actual purchase orders submitted in 2012 by government procuring entities in the Philippines. The database includes information on the unit cost, volumes of procurement, source/supplier/manufacturer, brand, mode of procurement and location of the hospital for each formulation and strength of all drugs in the National Formulary. Uni-variate regression analyses were performed for commonly sourced essential drugs exploring possible determinants of drug costs, which include quantities procured and hospital bed capacity. Further cost- comparison with other methods and for other potential formulations such as mode of procurement, supplier/manufacturer and distance of distribution. RESULTS: Price data was analyzed for 20 drug products with the highest share of procurement in terms of volume and for 13 highly fragmented formulations, such as mode of procurement, supplier/manufacturer and distance of distribution. RESULTS: Price data was analyzed for 20 drug products with the highest share of procurement in terms of volume and for 13 highly fragmented formulations. Data was compared for all drugs analyzed. The price differentials, i.e. high/low ratio, was found to be up to 60 times when comparing the highest to the lowest priced drugs. The variations in prices were not associated by volumes procured, distance of distribution and hospital bed capacity. Suppliers were also observed to charge different prices for the same brands to different public hospitals, indicating information asymmetry on reasonable prices of drugs. CONCLUSIONS: Based on the observed wide variations in drug procurement prices in the Philippines, setting the DPRI at the median value for most drugs was found to be an appropriate method to set ceiling prices for public sector procurement. For monopolized pharmaceutical products, other methods may be more appropriate such as value-based pricing, price negotiations and external reference pricing to relevant countries.

PHP96  ANALYSIS ON POLICIES OF BIOSIMILAR MARKET IN CHINA

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OBJECTIVES: To review relevent policies with regards to biosimilar products in China, and further understand the external environment that shapes the biosimilar market. METHODS: A literature review on laws, regulations and policies released by key government stakeholders and other additional documents to fully capture the current environment of the biosimilar market in China. RESULTS: Multiple policies have been issued at central government level to encourage the development of biologics industry in China. Nevertheless, rather than in, this market wide variations in costs for biologics, those policies are more R&D and manufacturing quality control focused. There is no clear regulatory pathway for biosimilars in China to date. Due to the lack of clear standard for biosimilars to prove their bioequivalence to the originators, biosimilars are treated as new drugs at each stage of market access, resulting in a delay of getting approval in China market. Currently, local biosimilar developers are actively building their capabilities in innovative biologics such as monoclonal antibodies, while MNC players are continuing to bring in new molecules. As original product patent expiry peak period is coming, biosimilars, whose prices are relatively affordable, have potential huge opportunities to grow. On the other side, the fierce competition among biosimilars with the same reference biologics and upcoming MNC’s next generation antibody therapies are also putting a threat to biosimilar market as a whole. CONCLUSIONS: If pathways cannot be tailor-made for biosimilars in the future, thus hinders the fast launch of biosimilar products in China, population may not be able to enjoy more cost-effective treatments and government may also lose the chance to benefit from the saving of the total health care expenditure.

PHP97  CURRENT SITUATION OF HEALTH CARE ORGANIZATIONS’ WASTE MANAGEMENT

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OBJECTIVES: There are challenges to assess the current situation of health care organizations’ waste management by the level and to formulate methods for further improvement. Thus, this research assesses the importance of this assessment for reference about methods to improve current situation of health care organizations’ waste management. METHODS: Study was done by the descriptive method among 39 health care organizations using study forms, as questionnaires, checklist and test results. RESULTS: In Ulaanbaatar waste disposal company is 100% responsible for hazardous waste of health care organizations, but 50% of domestic waste are taken care by hospitals themselves. However, in rural areas 48.7-64% of hospitals and 57.1% of health care centers are responsible for both their domestic and hazardous waste. 50% of hospitals drain the liquid waste into main sewage and liquid waste from laboratory are drained into central sewage after disinfection. Waste management team works in 64.6% of hospitals, and nurses and dry-nurses are responsible in collecting of waste in 39.6% of hospitals. The team consists of 1-3 people in 50% of hospitals, 4-6 people in 39.5% of hospitals but more people in tertiary level hospitals. CONCLUSIONS: Legal documents about waste management of health care organizations are approved, most secondary and tertiary level health care organizations have workers responsible for waste. They have developed plans to improve the “waste management” and installed waste registration system. Despite making disposal temporary for hospitals, they still need improvement. Although any equipment with mercury has been prohibited to use in health care organizations, 50% of hospitals are still using and it has been difficult to collect, transport and dispose mercury containing waste.

PHP98  COMPARISON ON THE CONCEPT OF MARKET ACCESS OF CHINA AND WESTERN COUNTRIES

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OBJECTIVES: This study is designed to review and to compare the concept and content of market access in both China and Western countries, and further endeavor to clarify the responsibilities of each stakeholder in China to help providing better drug accessibility and affordability for the people. METHODS: A literature review was undertaken to understand comprehensively the current market access protocols in mature markets as well as in China. Industry interviews, consulting surveys and data analysis were also conducted to collect first-hand data for comparison. RESULTS: Unlike developed countries, where drug market access includes reimbursement and lots of patient access schemes, the market access of pharmaceuticals in China has a much broader scope, ranging from pricing, reimbursement, tendering, to hospital listing, etc which indicates drug market access in China is more complex. China has its own characteristic of drug market access, which involves a lot of different government departments. The centralized government market management style, a historical consequence of the transformation from planned economy to市场经济, is a key attributable to this phenomenon. As a result, civil society, such as NGOs and academia, is relatively weaker compared to western countries, and they are not able to take intrinsically influential roles during market access decision-making process. This further leads to a huge administration-oriented and low market-oriented drug market access present circumstance. Consequently, the timeline of drug market access in China is much longer than that of the mature market. CONCLUSIONS: The definition of market access in China needs to be reconsidered with global perspectives to be incorporated. A re-structured concept will better serve China’s changing environment.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

PHP100  EVIDENCES AND CRITERIA RELATED TO THE HOSPITAL SERVICE QUALITY AND SAFETY

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OBJECTIVES: Even the Ministry of Health is taking its attention to improve quality and safety of medical services, developing and implementing relevant policy and directions, quantity of complaints and occupational mistakes coming from citizens and medical staff services are still not going down. Therefore it is very necessary for every health organizations to analyze the situation. METHODS: To study processes for evidences and requirements of quality, information is collected by quantitative methods and the cross sectional survey form was used. RESULTS: On the service standard survey, 93.5% in level III hospitals, 50.0% in level II hospitals and 73.3% in level III hospitals are replied as they follow certain standards for their services. But respondents replied as 47.4% of the standards for medical services, which is the most percent, are not incompatible for wards. When summarizing the results, we can say it is not clear what service standards the medical staffs...