on media to dispute sofosbuvir price considered as scandalous, while compliant with French regulation. French Health Minister organized a European coalition to control its price. Under tremendous media, political and administrative pressure, the manufacturer accepted significant price decrease, early entry agreement in France and later in most EU countries. Following this saga, to ensure drug budget will remain under control, most EU countries issued regulation or law to cap drug budget expenditure for HCV. **CONCLUSION:** This case highlights limit of current pricing policies which are unable to match affordability and drug prices. Even if cost effectiveness remains important information for efficiency assessment, sofosbuvir case confirms the inability of cost-effectiveness analysis to address affordability issue. Budget impact in supporting decision making will become more and more critical in the future.

PHP340

IS ONCOLOGY DRUG FINANCIAL TOXICITY A SPECIFIC US ISSUE?

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BACKGROUND: Cancer imposes enormous financial burden to society. Direct medical costs were estimated at around €51 billion across European (EU) countries (2009) and $88.7 billion in the United-States (US) (2011). The concept of "financial toxicity" has been first reported by US academic oncologists, Zafar and Abernathy in 2013. It refers to financial distress linked to out-of-pocket payments of costly oncology drugs (OD). This critical concept led to the development of a patient-reported outcome questionnaire by de Souza et al. This conceptual research aimed to address aspects of oncology drug financial toxicity (ODFT) and how the US and European Union countries cope with high OD prices. **DISCUSSION:** ODFT has been reported to affect patient's quality of life and treatment adherence. In US, ODFT is related to the positioning in specialty care tier (fourth or fifth tier), leaving a high co-pay for the patients. Moreover, 13% of the US population is uninsured (2013). This issue is not new; in 2007, a study reported that 16% of oncologist did not propose expensive products to some patients based on their perception of patient affordability. In EU, the coverage system is quite different and operates as an on/off system, protecting patients from ODFT. Patients are either 100% covered for all reimbursed drugs (France, UK, Germany, Spain, Italy), or drugs are not recommended/reimbursed and then not proposed to the patients nor requested by the patients. The level of availability of these treatments might substantially differ between countries; high access of cancer drugs seen in France and Germany, while more restricted access seen in Spain, Italy and the UK. **CONCLUSIONS:** EU inhabitants will remain protected from ODFT as long as reimbursement process remains an on/off system (100% or 0% coverage) and off-reimbursement use is exceptional. ODFT will remain specific to the US and possibly to emerging countries.

PHP341

THE SOUTH AFRICAN GUIDELINES FOR PHARMACOECONOMIC SUBMISSIONS: A REVIEW IN CONTEXT OF EXISTING LEGISLATION AND CHALLENGES TO IMPLEMENTATION

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BACKGROUND: The South African Pharmacoeconomic Guidelines were published in February 2013, with the intention for application to newly approved medicines in the privates sector. However, uptake has been poor and the number of submissions negligible. **OBJECTIVES:** This study aims to examine the pharmacoeconomic guidelines in the context of existing legislation, policy and incentives in the private sector in South Africa to make explicit the reasons for the poor uptake and challenges to implementing the guidelines. **METHODS:** A review of existing legislation regulating reimbursement of medicines in the private sector was undertaken in relation to the implementation of the guidelines, as well as interviews with key stakeholders in the pharmaceutical industry, ministry of health and health insurance industries to understand attitudes to and challenges to adopting the guidelines submission criteria and results. **RESULTS:** Existing legislation means that results of pharmacoeconomic submissions are not enforceable – funders are not required reimburse for products should the ministry of health evaluations process deem them cost-effective. Pharmaceutical companies are thus at risk of a negative finding on reimbursement with no assurance that a positive finding will improve reimbursement for new products. As submission is currently not mandatory, this is something they will be unlikely to do. The level of strict application or flexibility within the requirements of the guidelines is also not clear. **CONCLUSIONS:** Uptake and engagement with the South African Pharmacoeconomic Guidelines has been poor, with no submissions formally evaluated since the guidelines were finalised. Several existing policy and legislative barriers exist which make the success of these guidelines in this current environment unlikely. Building capacity for submitting analyses as well as within the ministry of health to evaluate submissions will be critical.

PHP342

NEED FOR NEW PHARMACOECONOMICS POLICY FOR REGULATING PRICES OF MEDICAL DEVICES IN INDIA

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In India, medical device industry is a multi-product industry covering the entire gamut from disposable gloves and syringes to high-end machines like CT scans and robotic surgery machines and worth $5 billion approximately growing at a Compound Annual Growth Rate (CAGR) of 15%. Over 75% of medical devices market is dependent on imports, mostly by multinationals that have no manufacturing facility in India. According to a survey conducted by us, the disposables ($1.57 billion), consumables ($0.83 billion) and surgical instruments ($0.06 billion) market depends on around 40-50% of imported products while the medical electronics ($1.57 billion), hospital equipments ($0.39 billion), implants ($0.20 billion) and diagnostics ($0.09 billion) categories on around 85-90%. Due to more dependency on imported products as well as absence of regulations for prices in India, doctors, hospitals and retailers overcharged the patients almost three to four times for certain devices e.g. Drug eluting stents (DES) manufactured by Abbott imported at $640 and sold at $2000, a mark-up of over 250% and that manufactured by Medtronics imported at $485 and sold at $2600, a mark-up of more than 400%. Recognising this policy deficit, the Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers, has published draft proposals which is National Medical Device Policy-2015 for the medical devices approval & pricing regulations. These proposals have recommended creating an autonomous body, the National Medical Devices Authority (NDMA) for pricing control of medical devices by including them under the Essential Commodities Act or through a Medical Devices Prices Control Order(MDPCO) and creating a separate pricing division in the National Pharmaceuticals Pricing Authority(NPPA). Ispor-India chapter has developed Pharmacoeconomic guidelines which will also include the above mentioned devices and the same will be presented in this presentation along with our survey data.

PHP343

PRICING AND REIMBURSEMENT POLICIES OF TURKEY AND UKRAINE

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Recently, the need for health services has increased gradually and the limitations in sources allocated for this area have been recognized.According to Danzon (2001), arrangements towards controlling the expenses through price,profit controls and reimbursement methods This study examines;current situation in Turkey and Ukraine, pharmaceutical pricing methods, reimbursement methods and basic health indicators within the scope of changing pharmaceutical policies in Turkey and Ukraine. It was detected that the pharmaceutical pricing in Turkey has been performed on the basis of the reference pricing system that takes Italy,Portugal,Spain,Greece and France as reference. The regulations regarding the reimbursement process are determined by SSI. In Ukraine there are margin control and reference pricing methods only for the medicines that may be public purchased and are included in the National list of medicines and the list of medicines "On the procedure of procurement of medicines by health institutions financed from the public budget". Reimbursement method was applied only for one pilot project on antihypertensive medicines in 2012 because state health insurance system has not yet implemented. Due to the resolution of Cabinet of ministers of Ukraine "On reference pricing for medicines and medical products, purchased by the state and local budgets reference pricing is implemented for medicines, which are included in the list of medicines that have margin control and may be purchased within public budgets. Reference pricing is based on the international comparison with prices in mainly eastern Europe countries. Coverage of government was 13% of the Ukrainian pharmaceutical market The reimbursement system of Turkey has been changed numerous times and the discount rates has incrementally risen. Ukraine has just began implementing pricing and reimbursement for medicines. It is understand that Turkey has been done policies already but Ukraine has just began implementations. Our study shows impact of Turkish reforms and expected from Ukraine.

PHP344

HEALTH PROFFESSIONALS INVOLVEMENT IN POLITICS A MEANS TO IMPROVING HEALTHCARE DELIVERY AND HEALTHCARE LEGISLATIONS FOR HEALTHCARE SEEKERS IN AFRICA

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OBJECTIVES: Health Professionals in Africa in an attempt to improve healthcare delivery have brought up well thought out ways to offer better health care service, but for their lack of involvement in Politics and Legislation in their countries, efforts to implement their proposals have been met with brick walls. The Objective of this conceptual paper is to emphasis the need for Healthcare providers to be involved in Policy making in their countries, to champion health care policies that will improve health care delivery. **METHODS:** Using Nigeria as case study. I sort the views of several health professionals through their articles on Improving Healthcare delivery in Nigeria published in popular Journals and magazines. I consulted magazines and Journals from more advanced countries to seek out ways through which they have improved their health care system. **RESULTS:** Of all the views presented by these health professionals (Pharmacist and Medical Doctors), most pointed towards the role of the government in improving the healthcare sector, others suggested a need for health professionals to be involved in Politics without emphasizing on it. While in my analysis of the systems in the developed countries, I discovered that healthcare providers were involved in the government not as executive but as legislatures, this way they sponsor health related bills and policies and were able to improve the value of healthcare delivery. **CONCLUSIONS:** To improve healthcare delivery and patient care in Africa, Health care givers (pharmacist and doctors) should be part of the countries policy makers (legislatures) so as to drive the needed transformation in the health sector.

PHP345

HEALTH CARE POLICY AND COST AFTER EARTHQUAKE IN NEPAL

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Nepal is a topographically vulnerable country for many life threatening disasters like earthquake, landslides, avalanche, floods etc. Health care policy should focus on the disaster management plan and quick relief programs following major disasters. According to National consensus, 8151 people have been killed and 17,886 left injured. Nepal's earthquake economic toll is massive in the health sector too. Many hospitals

are completely damaged where others have been left with endangered to work in. The damaged infrastructure has left with inability to store essential drugs and vaccines. The cost of building new health care facilities is expected to reach billions of dollars. The cost required for the acute trauma is estimated very high. As homeless people are living in improper shelter, they have been presenting with other health related problems. For the short term relief, disaster management team should be formed in major government hospitals and medical colleges taking help of army and police health care personnel. Immediate enrolment of medical officers at the level of primary health centers should be done. A blend with major government and non-government organizations like International Red Cross, United Nations Organization, World Health Organization, USAID etc. should be made to meet the health care equipment, trained manpower and all other expenses. For the long term relief, trauma centers should be established in regional levels. As most of the remote villages even don't have primary health centers, the health and sub health posts should be upgraded to meet the demands. Health posts and sub health posts should engage at least medical officers backed up by supportive staffs and basic investigations.

PHP346

MARKET ACCESS FOR PHARMACEUTICALS IN EUROPE: FUTURE PERSPECTIVES

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BACKGROUND: Market access for pharmaceuticals is evolving in a fast-changing environment : (1)Pressure of European Union (EU) Member States (MS) on health insurance budgets; (2) Dramatic technological advances; targeting new biological pathways, advanced therapy medicinal products, personalized medicines, expansion of digital medicine; (3) Initiatives from regulators and payers to develop synergies, e.g., collaborations between HTA agencies and multi-HTA/parallel early advice; (4) Increased payer risk-aversion and increasing products with limited information at launch; (5) Healthcare organisations moving towards integrated healthcare services (6) Ageing population and growing prevalence of chronic conditions, co-morbidities, and life threatening diseases; (7) Increased access inequity between EU MS. **DISCUSSION:** Cost-containment measures will increase under close supervision of parliaments. Fast development of electronic communication will allow online monitoring of drug utilisation. Adaptive licensing and limited evidence at time of launch will lead to generalization of coverage with evidence development. A more pragmatic approach in clinical trial designs should be considered to cope with concomitant development of companion diagnostics, segmentation of treated patients with targeted therapies; adaptive pathways should evolve from pilot to standard approach. Post-launch observational studies will become unavoidable to meet regulators and payers' expectations. Pan-European HTA coordination could lead to one single European HTA body assessing drugs prior to national HTA and pricing and reimbursement process. Managed entry agreements, ambulatory DRG, and bundled payments might become standard models. Integrated health services will expand, shifting payers role to health care providers. Differential pricing will address access inequity. **CONCLUSION:** Sustainability of healthcare systems will remain at the heart of drug funding decisions. Drug market access will evolve through extended collaborations and interactions between key stakeholders. Drug licensing, pricing and reimbursement decisions will be increasingly coordinated to enable fast patient access to innovative therapies. Real-world data will be central to switch from initial restricted access to progressive wider coverage.

PHP347

ADAPTIVE PATHWAYS MAY EXPAND THE GAP BETWEEN REGULATORS AND PAYERS

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BACKGROUND: Adaptive pathways (AP) are prospective planned approaches to regulation and coverage of drugs. Through iterative phases of evidence gathering, it aims to reduce uncertainties while balancing timely access for patients and level of available evidence. The concept assumes that all phases from development to clinical routine use through reimbursement are integrated. If AP did develop from regulatory perspective, many payers remain resistant. The aim of this research is to discuss payer's position on AP. **DISCUSSION:** Payers show an increasing resistance to uncertainty and their decisions are mainly driven by evidence robustness. Regulators are integrating foregone alternative treatment opportunities in decision making and increasingly registering drugs with limited evidence and larger benefit estimates. Time from development initiation to marketing authorization (MA) decreases overtime (compassionate use, accelerated assessment, conditional MA, MA under exceptional circumstances); On the opposite, time from MA to reimbursement expand with an increasing number of products denied reimbursement due to limited evidence. This gap between regulators and payers continues to increase and AP may widen this gap. While managed entry agreements were thought to help managing uncertainty, it happens, in most of the cases, to be used as disguised cost-containment tools. Only coverage with evidence development (CED) with escrow agreements remain an appropriate tool to address uncertainty, but is rarely used. The difficulty to reverse reimbursement decision makes payers very sensitive to uncertainty. AP is unlikely to address the payers concern unless they are directly involved in identifying risk, designing mitigation plan, and monitoring the uncertainty. **CONCLUSION:** AP may contribute to widen the gap between regulators and payers. Only CED with escrow agreement may be an appropriate tool to address payers' uncertainty. However, AP pilot projects with expected high benefit will exercise pressure on payers to issue reimbursement.

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TRENDS OF IMPLEMENTATION OF HTA IN KAZAKHSTAN

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Kazakhstan is an upper-middle-income country with per capita GDP of nearly US$13 thousand in 2013. Kazakh's public healthcare system – UNHS (Unified National Health System) – aims to deliver healthcare coverage to the whole population. The political desire of authorities to provide broader access to healthcare for its populations, along with the growing prevalence of non-communicable diseases (NCDs) such as cardiovascular disease, cancer and diabetes, are placing a strain not only on government budget but also on the healthcare infrastructure in Kazakhstan. Increasing life expectancy is giving rise to the greater burden associated with ageing populations, while governments struggle to balance growing costs with a need to expand healthcare provision to all. At the heart of any cost-containment strategy is a set of tools, ranging from complex risk-sharing schemes and health technology assessment (HTA) through to more simplistic mechanisms, such as prescribing controls and mandatory price cuts. Analysis of cost-management trends in Kazakhstan, relative with international experience, suggests a leaning towards less complex approaches. One reason for this is that before being able to even contemplate more sophisticated initiatives, governments must first address basic infrastructure needs. These include having sufficient doctors and clinics to diagnose and treat patients. There is growing appreciation that cost containment can only be effective when implemented in a systematic manner. Kazakhstan already have informal guidelines in place and are now considered «mature» markets in terms of HTA adoption. Despite the obvious challenges, some would argue that the time for HTA has arrived in Kazakhstan. Implemented correctly, it can play a role in the future of the region, not only as a key component of cost containment but also as a pivotal enabler for the efficient use of resources, as governments look to provide broader access to affordable healthcare for all.

PHP349

A CONCEPTUAL PAPER ON STEPS NEEDED TO REACH INTEGRATED HEALTHCARE SYSTEM IN EGYPT

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OBJECTIVES: This conceptual paper aims to build a roadmap to reach integrated healthcare (HC) system in Egypt for optimum efficiency and utilization of resources among the different insurance bodies. The roadmap will help fill in the gaps evolved from the fragmented system having 5 different types of insurance coverage. **METHODS:** Gap analysis between the desired integrated HC system that achieves; Equity, Solidarity and Free access to entire population, and the current situation of the HC system which was obtained from interviews and discussions with the HC payers and decision makers inside the public sector. **RESULTS:** A ten year roadmap was built with eight action steps that were identified to reach integrated HC system: 1- Task Force Committee: from inside and outside the public sectors, 2- Research and Data centre: responsible for Epidemiological and Pharmacoepidemiological studies, 3- Prioritization plan: prioritize coverage plan based on budget and strategic diseases burden , 4- Treatment Protocols Flowchart: ensuring unified treatment guidelines across different HC bodies 5-Unique Patient ID: thus all insured patients are traceable without double counts, 6- Health Information System: connecting all HC units for optimum resources utilization, 7- Primary Care Physicians Development Plan: continuous education programs for optimizing their utilization and freeing time to the over-utilized specialists, 8- Health Economics Unit: that will be the nucleus of establishing a Health Technology Assessment body responsible for economical strategic planning of the HC. **RECOMMENDATIONS:** Although some action steps were taken in some of the mentioned points however they were executed as separate initiatives inside the public sector; therefore it's of high importance that the taskforce committee takes the accountability of executing the project as a single mission, and make sure the executed action steps are utilized and integrated with the rest of action steps as per the roadmap timetable.

PHP350

HEALTH SYSTEM RESEARCH OPPORTUNITIES FOR ASSESSMENT OF THE NATIONAL HEALTH CARE SYSTEM

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OBJECTIVES: The health care system reforms, which in many countries, particularly in the Eastern Europe, started in the 1990s, affected Latvia as well. The directions of the reforms can be divided into two basic segments – health care system organisation and health care system financing. Within the framework of this research, the author evaluates the health system research opportunities to assess the efficiency of the health care system reform in Latvia. **METHODS:** To achieve the goal of the research, the methods of the theoretical research are used alongside the methods of empirical research. The methods of statistical analysis and methods of economic analysis are used for data processing and analysis. **RESULTS:** To perform the research, the author uses a three-level performance evaluation model based on macro-level evaluation, meso-level evaluation, and micro-level evaluation. The appropriate measures of the macro impact results, policy outcomes and performance outputs are defined to evaluate the effectiveness of the performed health care system reform. The author assumes that the macro impact results are specified for public health, the policy outcomes are determined for the health care, as well as the pharmacy, while the performance's outputs are representative for all areas. **CONCLUSIONS:** The general conclusions show, for example, that the economic efficiency of the reimbursement system is sufficient and at the same time there is a tendency to move towards technical efficiency rather than total economic efficiency (technical and allocative efficiency). The allocative efficiency in health economics is also associated with the market efficiency and effectiveness of the treatment process. However, the author notes that there are no perfect competition market conditions for health care products and services, so it is necessary to use alternative methods of economic analysis.