

## PHP35

## FACTORS RELATED TO OUTPATIENT ANTIBIOTIC DRUG CONSUMPTION IN TURKEY

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**OBJECTIVES:** Turkey is currently a European leader in antibiotic consumption. To fight against increasing consumption, it is necessary to understand factors related to antibiotic drug consumption. To fill this gap in the literature, this study intends to probe factors related to outpatient antibacterial drug consumption in Turkey. **METHODS:** Data from the National Antibacterial Drug Consumption Surveillance report and the Turkish Statistical Institute were assessed. The number of physicians; socio-economic development index (SEDI); endocrine, nutritional, and metabolic disease mortality; employment; education; and geographic region were used as factors related to outpatient antibacterial drug consumption. Euclidean distance measure and complete linkage methods were used to draw a heatmap. A hierarchical cluster analysis was performed to visualize factors related to outpatient antibacterial drug consumption. Additionally, 81 provinces of Turkey were used as a decision-making unit in the analysis. Sensitivity analysis of province group differences in terms of study variables were examined using independent sample “t” and Chi-square (“X<sup>2</sup>”) tests. **RESULTS:** Study results revealed a close link between education and outpatient antibiotic drug consumption in Turkey. In addition, 81 provinces were categorized into two groups representing rural and urban regions of Turkey. The differences in province group sensitivity results – according to the number of physicians (t=2.522, p<0.05); SEDI (t=4.986, p<0.05); endocrine, nutritional and metabolic diseases, mortality (t=3.317, p<0.05); employment (t=1.684, p<0.05); antibacterial drug consumption (t=6.470, p<0.05); and education (t=3.544, p<0.05) – were statistically significant. **CONCLUSIONS:** The study results highlight the need to raise awareness in Turkey regarding appropriate consumption of antibacterial drugs. Antibiotic awareness campaigns, consideration of increasing cost, communication among stakeholders, and strong sustainable use policies are essential to combat increasing antimicrobial resistance in Turkey.

## PHP36

## HEALTHCARE INTERVENTIONS FOR IMPROVING QUALITY USE OF ANTIBIOTICS IN THE HOSPITAL SETTING: A SYSTEMATIC REVIEW

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**OBJECTIVES:** The purpose of this study is to systematically review the healthcare interventions aimed at improving quality use of antibiotics in the hospital setting. Specific emphases were placed on the study design, objectives, types of interventions, methodology and major results. **METHODS:** A systematic search of relevant publications concerning healthcare interventions aimed at improving quality use of antibiotics in the hospitals published during the years 2006–2016 was conducted through Pubmed, Scopus, Google Scholar, and bibliographies. Articles were selected for the final review if they met the inclusion criteria of reporting the healthcare interventions employed in the hospital for improving quality use of antibiotics. **RESULTS:** A total of 49 studies were included in the final review. Majority of the studies were conducted in the USA (22%). Most of them were conducted in the general hospitals (53%) with the study period ranged from seven months to two years. Majority of the studies were experimental pretest-posttest study in one sample group (65%), followed by randomized control trials (RCT) and non-RCT in two sample groups (25%), and cross-sectional study in one sample group (10%), respectively. Concerning the healthcare interventions employed, most of the studies employed professional intervention, followed by technology intervention, policy/guideline intervention, and education intervention, respectively. Of 49 studies, 20% employed more than one type of intervention. Outcomes measured included mainly the reduction rate of antibiotic use, cost savings, and the decline in the treatment duration. **CONCLUSIONS:** This study revealed that multifaceted interventions were appropriate to apply in the hospital setting where healthcare professionals work together as multi-disciplinary team. Multifaceted interventions obviously showed to significantly improve the quality use of antibiotics. From this point, there is a need to encourage all hospitals to adopt this concept for rational use of medicines so that the ultimate goal of patient safety could be obtained as a result.

## PHP37

## PROBABILISTIC SENSITIVITY ANALYSIS AND ITS ROLE IN ASSESSMENT OF PROFITABILITY IN POLAND

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**OBJECTIVES:** In August 2016, guidelines for conducting Health Technology Assessment in Poland were updated. Since then, the Agency for Health Technology Assessment and Tariff System (AOTMiT) has required manufacturers to conduct a probabilistic sensitivity analysis (PSA) or provide an adequate justification for lack of it. The objective of this review is to assess whether current decisions made by AOTMiT depend on the results of PSA. **METHODS:** Submissions from 1 August 2016 up to 26 May 2017 with AOTMiT assessment reports and recommendations of the President of AOTMiT were identified and analysed, if probabilities of cost-effectiveness were publically available. If several probabilities were provided, appropriate ranges were used and graphically presented. **RESULTS:** A total of 32 submissions were identified within the analysed timeframe. PSA was performed in 21 (65.5%) cases and justification for lack of PSA in pharmacoeconomic analysis was only presented in 3 out of 11 (27%) remaining cases. Finally, only 14 out of 21 submissions were taken into consideration, since probability of cost-effectiveness was undisclosed in the 7 remaining cases. The recommendation of the President of AOTMiT was positive in 5 and negative in 9 cases. To assess a relationship between the PSA outcomes and recommendation character, the results were plotted on a graph. **CONCLUSIONS:** It can be assumed that technologies with a probability of being cost-effective lower than 30% tended not to be recommended. However, this

analysis should be treated with caution as it was limited by a small number of appraisals with PSA results available. There is a need for greater transparency of PSA outcomes to assess their role in the decision-making process in Poland. To assess a correlation between results of PSA and character of the recommendation of the AOTMiT President, more samples need to be reviewed and analysed.

## PHP38

## PROVIDING A FRAMEWORK FOR ASSESSING ACCESS TO MEDICINE

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**OBJECTIVES:** One of the main goals of all health systems is to improve access to safe and effective medicines. Assessment is a very important phase of national medicine programs of access improvement. The goals of this study are to collect and compile suitable indicators and provide a comprehensive framework for assessing access to medicine. **METHODS:** A literature review with systematic search was conducted using Pub Med/ Medline, Scopus and Google Scholar databases in order to investigate the published materials on access to medicines framework or indicators. The results of systematic search were completed with comprehensive government documents search. All the articles and documents were reviewed with two researchers and related indicators were extracted. Then the collected data were cleaned of duplicate entries or unnecessary concepts in focused group discussion consisting of academics and IRFDA (Iran food and drug administration) experts. Then a Delphi questionnaire was sent to the 17 experts from academia, Social Security Insurance, IRFDA, Ministry of Health and Iran Pharmacist Association. The Delphi technique has finalized with an expert panel. **RESULTS:** According to the results of systematic search, 126 indicators have been found. After primary cleaning, 77 indicators were sent to the 17 experts in a Delphi form. Delphi finalized in expert panel and 67 indicators were approved in 5 categories including physical availability and geographical accessibility (19 indicators), affordability (23 indicators), human resources (4 indicators), quality and safety (5 indicators), information and rational use (16 indicators). **CONCLUSIONS:** Full access to medicine has been composed of different aspects of access from providing national medicine list until rational use which have been categorized in five categories in this study. All the categories have several indicators to assessment and further local surveys are necessary to describing the access status in each country.

## PHP39

## PHARMACEUTICAL ASSISTANCE PUBLIC FUNDING IN A BRAZILIAN CITY AND ITS IMPLICATIONS FOR THE UNIVERSAL ACCESS TO ESSENTIAL MEDICINES

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**OBJECTIVES:** To ensure the constitutional right to health, a national health system was created in Brazil, in 1988, appointing municipalities as the main executors of health actions and services. The universal access to basic essential medicines is cities' responsibility, while the federal government and the states dispense high-end drugs. However, an alternative way to get access to public funded medicines is being consolidated: a phenomenon called "Judicialization of Health". It happens when an individual judicially claims healthcare provision. In 2015, the Health Ministry's expenditure on drugs judicialization was USD 281,704,610.00 – 8% of the federal pharmaceutical assistance budget. Since municipalities have smaller funds, this research aims to analyze judicialization's budget impact in a small Brazilian city and its implications for the universal access to essential medicines. **METHODS:** "Ouro Branco" was chosen due to its small population size (estimated at 38,601 residents in 2016) and the availability of detailed expenditure records within the City Hall's website. All the medicines purchase expenses using municipal resources were analyzed for 2015 and 2016. The amount disbursed in both the universal pharmaceutical assistance policy and the drugs judicialization was calculated for each year and for the whole period. **RESULTS:** Ouro Branco invested USD 28,486.17 in its universal policy for the 2015–2016 period (around USD 19,000 less than established by regulation) while USD 27,991.68 were destined to judicialization. In 2015, the judicialization expenses equated to 40% of the universal policy investment. In 2016, this ratio rose to 173%. Records show that, in 2016, all judicialization expenditure benefited only five citizens. **CONCLUSIONS:** Once all government levels answer to all price drugs judicialization, this phenomenon damages mostly small cities' budgets and consequently their universal pharmaceutical assistance policy. Despite judicialization is based on the "right to health" argument, it harms the right's universality when it reallocates public funds to benefit a few individuals.

## PHP40

## ACCELERATED UPTAKE OF INNOVATIVE HEALTH TECHNOLOGIES: A LITERATURE REVIEW

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**OBJECTIVES:** The Accelerated Access Review made recommendations to speed up access of patients to innovative technologies (medicines, devices and diagnostics), but evidence on how best to achieve this is not readily available. We conducted a literature review of measures to accelerate uptake of health technologies after regulatory approval. This encompasses identification of markets in which pace of adoption has been reported as an issue, initiatives/mechanisms implemented to overcome delays or to accelerate uptake, and their outcome. **METHODS:** A systematic search of Embase, Medline, Cochrane and the grey literature published in English in 2011–2016. Combinations of search terms such as 'health care', 'innovation', 'uptake', 'scheme' and 'reimbursement' were used. Identification of relevant articles and data extraction was performed by two independent reviewers with differences resolved by consensus. The evidence was synthesised using a narrative approach. **RESULTS:** Thirty-two articles met the inclusion criteria. A wide range of themes emerged,

including horizon scanning; price negotiation; health technology assessment consideration of 'innovation'; managed entry agreements (such as conditional approval and financial risk-share); health service financial flows; and leadership around promotion of evidence-based medicine. The most prevalent theme was conditional access. Many papers described the issues and conceptual solutions, rather than reporting implementation of measures and their outcome. **CONCLUSIONS:** The evidence base on accelerating innovation uptake is limited, from studies with varied designs and quality, and often specific to individual market and policy contexts. Nevertheless, a wide range of factors limiting uptake of innovative technologies is evident, and numerous potential solutions have been proposed. This suggests that multi-factorial interventions that are market and policy specific with pilot testing are required.

#### PHP41 CAN EARLY ACCESS SUPPORT CONTINUED ACCESS? THE RELATIONSHIP BETWEEN EAMS AND NICE

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**OBJECTIVES:** The Early Access to Medicines Scheme (EAMS) launched in April 2014 with the aim of providing patients with severe, life-threatening diseases without adequate treatment options to access to medicines prior to their marketing authorization. Thus, for products with an EAMS designation, there will be real world evidence (RWE) with the product prior to health technology assessment (HTA) decision-making by the National Institute for Health and Care Excellence (NICE). This research aimed to assess if, and how, EAMS data is being utilised in the NICE appraisal process. **METHODS:** All EAMS designations as of 26/06/2017 were identified from the MHRA website. For products with final NICE guidance, the full manufacturer submission, as well as all publicly available NICE documentation was reviewed. **RESULTS:** 16 product/indication pairings with an EAMS designation were identified, of which 6 have received final NICE guidance. 6/6 were recommended and 6/6 included references to EAMS. 6/6 used the EAMS designation to support the product's innovation status. The number of patients who received access to the assessed drug through EAMS was referenced in 3/6 submissions, and the number of sites with product access via EAMS was referenced in 1/6 submissions. No submissions referenced any RWE outcomes data collected during the EAMS period. References to EAMS not originating from manufacturers included: a patient advocacy group providing a "patient voice" of someone who had received a therapy under EAMS scheme, and public commentary from an NHS professional who reported experience of using a drug as part of the EAMS scheme. **CONCLUSIONS:** Our research shows that experience of products under EAMS has primarily been used to support patient and physician advocacy during the appraisal process. Currently, no RWE outcomes data has been collected while a product was available through the EAMS scheme has utilised to support NICE submissions.

#### PHP42 THE INFLUENCE OF PHARMACEUTICAL REFORM IN KOREA A DECADE AGO: WHAT WE WALKED

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**OBJECTIVES:** Korea had reformed the pharmaceutical listing/pricing system in 2007 according to the governmental DERP (drug expenditure rationalization plan) policy. It has brought innovative changes on the National Health Insurance (NHI) drug reimbursement including the transition into the Positive List System. The aim of this study was to look back the outcome of 10-years' of it. **METHODS:** Total 15 literatures were selected and data from governmental published reports and internal data of HIRA were included. Impacts of the reform was categorized into 1) pharmaceutical benefit decision, 2) access to affordable drugs, 3) national drug expenditure corresponding the intermediate measures as quality, access, and efficiency to assess health-system performance (Marc Roberts et al. 2008). **RESULTS:** It has institutionalized evidence-based decision-making for medicines; acceptable only if clinically effective and cost-effective. Benefit decision is supported by the Committee equipped with advisory and sub-committees. Appraisal results are disclosed to the public from 2008 transparently. Although the concern on high-cost new drug entry is not only of Korea, the acceptance rate of new medicine (HIRA) is 60.7%–82.7% in 2011–2015 and lower than the UK but greater than Australia or Canada. For severe and rare disease treatments, equitable access was contributed by (i) the risk-sharing scheme for 9 products since 2013 (ii) more flexible ICER level comparing to common drugs (iii) economic evaluation exemption (2015). To streamline access, it reduced statutory period twice. The reform contributes to stabilize pharmaceutical expenditure; as a share of total healthcare expenditure has stopped increasing and maintained the level of <30% (2007–2011). There is no evidence it may strengthen or weaken industrial market or R&D. **CONCLUSIONS:** The reform has led to the improvement of the quality of drug benefit decision, reinforcement of the access to the appropriate medicine, rationalization of the national drug expenditure and more efficient allocation of resources.

#### PHP43 EXPENDITURE ON NON-PHARMACEUTICAL PRODUCTS IN IRELAND DURING A PERIOD OF HEALTHCARE COST CONTAINMENT

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**OBJECTIVES:** Total expenditure on reimbursed pharmaceuticals in Ireland has fallen since the impact of the economic recession in 2008. However, data used to represent these figures typically contain both pharmaceutical and non-pharmaceutical products. The objective of this analysis is to delineate spending across these two different sectors over the past 14 years in Ireland and assess their relative trends. **METHODS:** Nationwide Primary Care Reimbursement Service (PCRS) data was used for 12 years between 2002 and 2015. The total expenditure across schemes

that contain both pharmaceutical and non-pharmaceutical schemes was calculated, and non-pharmaceutical expenditure items were identified and subtracted to produce a total pharmaceutical and non-pharmaceutical expenditure estimates and calculate their relative proportions. **RESULTS:** For non-high-tech medicine, total expenditure decreased from €1.66bn in 2012 to €1.4bn in 2015 (15.7% decreases). For non-pharmaceutical items reimbursed under PCRS, the decrease in expenditure during this period was 0.68m (<0.5% decrease). In 2015, total expenditure on non-pharmaceutical products reimbursed under PCRS was €173m. **CONCLUSIONS:** Since the impact of the economic recession, the total cost of medicines reimbursed in Ireland has decreased. The decrease in expenditure, at a time of increasing demand, was supported by the introduction of mandatory rebates for innovative pharmaceutical medicines. This analysis shows that for non-pharmaceutical items, expenditure reductions over this period were not proportional.

#### PHP44 POTENTIAL FUNDING SOURCES FOR BREAKTHROUGH THERAPIES

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**OBJECTIVES:** Chronic diseases constitute a worldwide public health issue with important clinical unmet needs. Novel breakthrough therapies such as advanced therapy medicinal products (ATMPs) are in development to fulfill those unmet needs. ATMPs are expected to have high upfront costs. A key remaining question is the funding options of these new high cost therapies giving the large target population, and therefore the large budget needed. The aim of this study was to identify new funding sources for novel breakthrough therapies. **METHODS:** A systematic review was conducted in Ovid Medline and Embase to identify innovative funding sources for novel therapies. Studies published between January 2000 and January 2017, written in English or French were included. **RESULTS:** Four funding sources were mainly proposed in the literature: pooled funding, international transaction taxes, front-loading and debt reduction. Pooled funding is a combination of funding from multiple groups or multiple payers (in the case of the United States) to pay for a specific therapy. Another suggested solution is collecting funds through placing taxes and levies on specific transactions (e.g. plane tickets). Funds could also be provided through frontloading mechanism; some donors offer aids and resources to fund novel therapies like the International Finance Facility for Immunization that provided stable funding to achieve immunization goals. Furthermore, an international cooperation by debt reduction can constitute another solution, where a country creditor agrees to write off debt for a country debtor if the latter commits counterpart funding to an account that had been approved for a breakthrough therapy. **CONCLUSIONS:** The suggested methods may be a potential source of additional funds for novel advanced therapies. Those methods have already been used for communicable diseases. A worldwide cooperation is needed to adapt these methods for non-communicable diseases in order to ensure the patient access to innovative therapies while maintaining the health care system sustainability.

#### PHP45 NEW DRUGS APPROVAL IN ITALY: ANALYSIS OF THE APPLIED NEGOTIATION CONDITIONS 2015-2017

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**OBJECTIVES:** This study aims to track and analyse, using Official Journal publications, the negotiation conditions (Managed Entry Agreements [MEAs], monitoring registries, discounts) of novel drugs reimbursed in Italy. **METHODS:** Publicly available Official Journal (OJ) of 47 new active principles approved through European centralised procedure were screened since May 2015 to April 2017. These 47 drugs have completed the P&R process and have been reimbursed. Categorization by drug type and by therapeutic area. For each drug analysed, the kind of MEAs negotiated, the application of confidential discounts and monitoring registries have been tracked. **RESULTS:** Based on these criteria, 47 new drugs were reimbursed in Italy. The 31.6% of these drugs were assessed as innovative, the 15.8% were orphan and the 10.5% hybrid. The 26.3% were oncological drugs and the 10.5% haematological. 40% (19) of the total sample had a MEA as approval condition agreed between the Marketing Authorisation Holder and AIFA. 3 drugs (15.8%) had 2 MEAs simultaneously applied (1 payment-by-results + budget cap and 2 price-volume + budget cap). One drug had a MEA applied but not disclosed in the OJ. Analysing the 22 MEAs tracked, the 82% were non-outcome based and the 14% were outcome-based. The only outcome-based MEA applied was the payment-by-results, while non-outcome-based MEAs were cost-sharing (6%), budget cap (39%) and price-volume agreements (56%). The 38% of the 47 screened drugs had monitoring registries and 32 (68%) out of these drugs had a confidential discount (13 also had a MEA). **CONCLUSIONS:** A broader use of non-outcome based (financial) MEAs emerged, highlighting the attention showed by AIFA to economic issues. Price-volume agreements appears as the mostly applied MEA, with a monitoring registry as measure to track appropriateness. Publicly available analyses of these tools would be of great help in understanding the real value of their application.

#### PHP46 NEW DRUGS APPROVAL TIMING IN ITALY (2015-2017)

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**OBJECTIVES:** This study aims to track the Italian P&R timing step by step, to verify the trends in approval timings of reimbursed drugs assessed by AIFA from dossier submission (Start) to decision publication on the Official Journal (OJ). **METHODS:** Publicly available agendas and reports of all monthly decisional meetings of the Technical Scientific Committee (CTS) and the Price and Reimbursement Committee (CPR) were screened since January 2015, focusing on new active principles approved through European centralised procedure. Analysed drugs, divided into categories,