OBJECTIVES: With the formation of Clinical Commissioning Groups (CCGs) GP Practices will come together to commission services for their local populations. However, decisions are now being made by 195 independent CCGs, instead of the Competition and Choice Commissioning board may that considerable ‘command and control’ will still be exerted from the centre. Secondary and primary research was undertaken to gain insight into how devolved locality based commissioning is likely to impact on access to medicines. Method: The CCGs in the England, financial stability and current Primary Care Trust (PCT) activities in relation to Practicing based commissioning. We then interviewed 5 NHS Experts to assess how this CCGs would be allowed the aspirational freedoms referred to in the 2012 Healthcare and Social Care Act - including prescribing in primary care. Under the guidance of PCTs. Various information sources were used Care Quality Commission, Audit Commission, and Health Select Committee reports to support the interpretation of the findings. RESULTS: The selected CCGs represented an homogeneous set of GP practices in that they had previously demonstrated successful and collaborative working with their ‘host’ PCTs. Many CCGs had been devolved the Commissioning budget by their PCTs and were routinely involved in setting up medicines management protocols with their provider hospitals. Almost half of the CCGs had coterminous medicines management contracts shared with their PCTs. NHS experts raised issues around corporate and clinical governance and how practices would fundamentally want to take on the devolved financial responsibilities. CONCLUSIONS: The NHS reforms mean that £60 Billion of the total health care budget will be under the control of CCGs. PCTs and Strategic Health Authorities will be abolished and with a watered down role for NICE postcode variation may be rife, access to medicines will continue to be fraught with many layers of decision making and further delays.

PHP2

PHARMACOVIGILANCE IN QATAR – A PHARMACIST SURVEY
Wilbur K
Doha University, Doha, Qatar
OBJECTIVES: Active domestic pharmacovigilance programs are necessary as adverse drug reaction (ADR) data from other countries may overlook safety patterns in local populations. The success of any surveillance system relies on active participation of reporters. The objective of this study was to describe pharmacist reporting of suspected ADRs in Qatar to inform policy recommendations to the Supreme Council of Health. METHODS: A 27-item survey was developed following comprehensive literature review of relevant published research. Questions encompassed broad domains including pharmacist knowledge of and experiences in reporting suspected ADRs, attitudes towards health professional pharmacovigilance roles; perceived barriers and facilitators to reporting; and recommendations for improvements in this process. The web-based survey was formatted for electronic delivery and response for self-administration in English or Arabic by a convenience sample of over 500 Qatar pharmacists. RESULTS: The survey remained open for two months between April 30 and June 30, 2011. Of the 142 (25%) total responses, 116 (81.6%) surveys were completed beyond demographic data and included information about prior suspected ADR reporting experiences. Knowledge of ADR terminology and reporting purpose among the 116 (20%) responding pharmacists was high, but only 34 (30%) had ever made a suspected ADR report in Qatar. Most respondents expressed positive attitudes towards pharmacist roles in pharmacovigilance activities, but inability to recognize a potential ADR or subsequently access a reporting form were perceived barriers, with enhanced training and efficacy in report submission corresponding identified facilitators to future participation. Hospital pharmacists were 7 times more likely than ambulatory-care based pharmacists to have reported a suspected ADR in Qatar. CONCLUSIONS: Pharmacists in Qatar are willing to engage in pharmacovigilance activities if supported by increased training and transparency in the reporting process. A national infrastructure with capacity to collect and manage suspected ADR reports and promote patient and medication safety is exigent.

PHP3

THE EARLY BENEFIT ASSESSMENT OF NEW PHARMACEUTICALS IN GERMANY (“AMNOG”): A STRUCTURED SURVEY ANALYSIS ONE YEAR AFTER ENACTMENT
Stockel Fab1, Neubauer AS2
1University of Bayreuth, Bayreuth, Germany, 2IGF Institute for Health Economics, München, Germany
OBJECTIVES: In January 2011, the act for restructuring the pharmaceutical market (“AMNOG”) was introduced in Germany. We analyzed the effects one year after AMNOG’s implementation in an empirical study. The research focused on surveying affected stakeholders, systematically summarizing their experiences, and identifying the dynamics of controversy and political framing. Method: 17 stakeholders were involved in statements during the AMNOG legislation: Payers, Pharmaceutical Industry, National Regulatory Bodies, Scientific Experts, Patients, Care Providers, Politicians, Pharmacies and External Service Providers. The benefit assessment process was structured into 6 topics: Market Access; Early Benefit Assessment; Cost-Benefit Analysis; Arbitration Procedure, Cost-Benefit Analysis and Process. 45 experts participated in the structured survey (26% response rate), which consisted of closed questions supplemented by optional open-ended questions (total 47 items). Descriptive and statistical analysis methods were performed. RESULTS: The 9 stakeholder groups, several items were highly controversial: negotiation position of statutory health insurances (“GKV-Spitzenverband”) in rebate level negotiations (L2=0.95). Different response profiles were observed between stakeholders but they yielded relatively low dissimilarities on cost-benefit assessment. VAlue in Health 15 (2012) A277-A575

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Overall, the topic areas "Market Launch", "Price Negotiations" and "Process" were most controversial. Regarding stakeholder groups, the experts belonging to Pharmaceutical industry displayed the largest differences to those of the Payor group. 16 experts answered the open-ended question about "costs of dossier process" ranging between €100,000 and €500,000 per drug assessed. CONCLUSIONS: We performed a structured survey analysis with experts to assess the new German reimbursement process and to determine the value of measures regulating the pricing and reimbursement decisions of pharmaceuticals in European Union Member States. TD establishes a number of fundamental principles including strict timelines for the pricing and reimbursement (P&R) process. Our study focuses on the implementation of the Transparency Directive in Hungary with special focus on time limits for P&R decisions. METHODS: We analyzed official decisions in 103 P&R submissions (positive cases with decisions only) made by the National Health Insurance Fund Administration (NHIFA) between 2005 and 2010. Most of the cases belonged to pharmaceuticals with new active ingredients and without reimbursement at the time of submission. We excluded generic drugs and cases without P&R decision from the analysis. In order to determine the market access time we calculated the time period between the registration date of the drug by the European Medicines Agency (EMA) or by the National Institute of Pharmacy (NIP) and the P&R decision. RESULTS: The average time period from registration to P&R decision was 721 days (min: 46 days, max: 2696 days); from registration to P&R submission was 481 days (min: 1 days, max: 2581 days); from the P&R submission to public decision was 214 days (min: 7 days, max: 990 days). Hungarian patients get access later to those medicines with centralized EMA registration compared with medicines with national registration procedure by NIP (average elapsed time from registration to positive decision was 827 days by EMA, 513 days by NIP). CONCLUSIONS: Periods needed to reach a P&R decision are in accordance with the 90–90 days recommendation of the TD. There is a positive change in pricing and reimbursement process in Hungary; decision procedure was shorter in 2010 than it was in 2004. Hungarian patients get new, better medicines later if the registration was done by EMA.