A growing number of health technologies are coming to market with limited, yet promising, clinical data. Coverage with evidence development (CED), a conditional interim reimbursement scheme linked to research to reduce uncertainty, has been increasingly explored by payers worldwide. The objective was to summarize CED programs worldwide, and report final reimbursement decisions.

**METHODS:** A search was conducted using published literature, websites, and grey literature to identify CED programs worldwide from 1998 to 2012. **RESULTS:** Seventy-four CED schemes were identified in Canada (n=23), Sweden (n=16), United States (n=14), UK (n=11), Australia (n=6) and Europe (n=6). CED schemes were found in oncology (n=21), heart disease (n=12), diabetes (n=10), Neurological disorders (n=7), addiction (n=7), mental health (n=3), rheumatoid arthritis (N=3), and other (N=18). Drugs, imaging techniques, surgical procedures, and devices were most commonly evaluated. Most CED programs aimed to address more than one type of uncertainty. The most commonly encountered uncertainty was clinical benefit, followed by value for money, adoption and diffusion, and affordability. Study designs included interventional, clinical, observational, and economic studies. CED programs were generally managed by independent, government-funded non-profit research organizations, university-based academic centers, or professional societies. In only 39% (N=28) of the identified CED schemes, study outcomes and funding decisions were reported. In 74% (N=17) of reported cases, the technology evaluation was successfully funded. One technology (lung volume reduction surgery) was ceased due to identified failures, and one technology, and one CED program, was ceased due to lack of evidence. On many accounts CED has proven challenging to implement. **CONCLUSIONS:** Although a large number of CED activities were identified, detailed information, and other (N=17) could be classified according to the Carlson’s approach. The most common propositions were related to pay-back of a part of the reimbursement obtained for each reimbursed package and did not include any risk sharing. There is a strong need for further research.

**PHP268**

**MANAGED ENTRY AGREEMENTS IN UK, ITALY AND SPAIN**

Tolley C.1, Palazzolo D 2

Quintiles Consulting, Reading, UK

**OBJECTIVES:** To compare Managed Entry Agreements (MEAs) in the UK, Italy, and Spain, and analyse the type of MEAs, number of agreements, and therapeutic areas in which they exist. Finally, to determine MEA impact on market access delay in these countries. **METHODS:** HTA databases were searched for types and quantities of MEAs (publicly available). The data were analysed by indication, and country specific knowledge applied to quantify the average delay to market access. **RESULTS:** All types of MEA have been granted previously in the UK, the majority were non-outcomes based (76%). In Italy, and Spain, all MEAs were outcomes based, with Italy focused purely on risk-sharing agreements. UK has 42 MEAs since 2000, Italy has 44 MEAs since 2006 and Spain has 9 MEAs since 2010. Of 95 MEAs, 56% were for oncology drugs, 12% musculoskeletal, 10% ophthalmology, 7% CNS, 5% respiratory and 10% other therapy areas. Nice average time to HTA decision is 21 months, and is delayed up to 10 months depending on the type of MEA. AIFA average time to HTA decision is 8 months; however MEAs are part of the pricing negotiation, so it may be a way to gain market access faster. In Spain, the average time to HTA decision is 8 months. With MEAs for drugs with promising results taking on average 14 months. For high cost hospital or orphan drugs, the delay can be up to a year. **CONCLUSIONS:** Negative reimbursement decisions can have a significant impact on achieving market access, and revenue generation. MEAs represent an average 25% to 50% negative deviation from the price of new medicines. Companies aiming for MEAs in UK, Italy, and Spain, should be aware of the potential market access delay and the precedence of MEAs that the payers in these countries are amenable to.

**PHP270**

**THERE IS NO PLACE FOR RISK-SHARING AGREEMENTS IN THE CURRENT ECONOMIC SITUATION**

Germanenko A1, Fraulisen JM2

1University of Copenhagen, København N, Denmark, 2University of Copenhagen, København, Denmark

**OBJECTIVES:** The aim of this project was to evaluate risk-sharing agreements that are currently being negotiated in Europe between health care authorities and the pharmaceutical industry. **METHODS:** A literature review of the grey literature (reports of the Organization for Economic Co-operation and Development and WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies) as well as peer-reviewed literature (PubMed) was done to explore the background of this topic. Semi-structured interviews were conducted with representatives of the pharmaceutical industry, consultant agencies and health care authorities to get their opinions about the current state of risk-sharing agreements. **RESULTS:** The study identified several problems in risk-sharing agreements such as insufficient terminology and methodology, the absence of adequate infrastructure for implementation and a lack of trust and dialogue between the establishing parties: health care authorities and the pharmaceutical industry. These issues question the crucial concept of sharing the risks equally and disagre the agreements, even though it would be of great value to overcome current challenges. Such agreements could help the health care authorities to keep within their budget while still providing innovative pharmaceuticals to patients. **CONCLUSIONS:** The agreement between the pharmaceutical and the healthcare industries would not just benefit from the same costs and benefits for pharmacists and patients, but would also benefit from the satisfaction of being able to supply the most effective treatment to the patients. In conclusion, the health care system would benefit from adequate pricing and reimbursement. **CONCLUSIONS:** In spite of the current problems, the popularity of risk-sharing agreements in Europe is growing fast and the future is bright. For this reason there is a strong need for dialogue between health care authorities and the pharmaceutical industry to create true risk-sharing agreements.

**PHP271**

**RISK-SHARING SCHEMES IN POLAND - ANALYSIS AND CLASSIFICATION OF RSS PROPOSED IN REIMBURSEMENT APPLICATIONS RECEIVED BY AHTAPol IN 2013**

Swanuck T1, Zawodnik S1, Hermanowski TR1, Matusewicz W1

1Agency for Health Technology Assessment in Poland (AHTAPol), Warszaw, Poland, 2Medical University of Warsaw, Warszawa, Poland

**OBJECTIVES:** To analyze and classify the Risk-Sharing Schemes (RSSs) proposed in reimbursement applications received by Agency for Health Technology Assessment in Poland (AHTAPol) in 2013. **METHODS:** Risk-Sharing Schemes proposed in reimbursement applications received by AHTAPol in 2013 were quantitatively and qualitatively analyzed. The classification of the RSSs was conducted based on both Carlson’s approach and the Polish Act on the reimbursement of medicinal products. In the study, we distinguished the reimbursement schemes into 3 categories: making the official sales price dependent on a pay-back of a part of the reimbursement obtained for each reimbursed package or medical technologies, they were classified into 5 categories according to the Act on the reimbursement. The most common risk-sharing agreement that benefits both the payer and the manufacturer is the one of a part of the reimbursement obtained to the entity which is obliged to finance benefits with public funds (48.08%). Further categories were: making the official sales price dependent on the applicant providing supplies at a reduced price as specified in the negotiations on the price of the medicine (15.38%), making the official sales price dependent on the level of turnover of the medicine (11.54%) and making the level of the applicant’s revenues dependent on the health effects achieved (1.92%). Other, non-compulsory RSSs constitute 10.06% of all. Among 52 proposed RSSs only 17 of them could be classified according to the Carlson’s approach. As a results, 10 Price Volume Agreements, 6 Manufacturer funded treatment initiation and 1 Conditional treatment continuation were identified. **CONCLUSIONS:** Most of the propositions are not considered to be RSS according to the Carlson’s approach. The most common propositions were related to pay-back of a part of the reimbursement obtained for each reimbursed package and did not include any risk sharing. There is a strong need for further research.

**Health Care Use & Policy Studies - Conceptual Papers**

**PHP272**

**WHAT HAPPENED TO NICE VALUE-BASED PRICING? WELCOME, VALUE-BASED ASSESSMENT**

Langham S1, Gemmell E1, KERRIGAN M1, Wright AJ1, Cherry M1

PFMR Associates, London, UK, 1PFMR Associates, Newcastle upon Tyne, UK

For some time the central role the National Institute for Health and Care Excellence (NICE) would play in the move to value-based pricing (VBP) of drugs in England and Wales as part of the new Pharmaceutical Price Regulation Scheme (PPRS) scheduled to start in 2014. To date, there is no VBP model, but NICE and the PPRS have been disentangled, and NICE is currently consulting on a proposal to include new terms of reference for value based assessment (VBA) in its Technology Appraisal Methods Guide. This would change the way in which it makes recommendations to the NHS and could become policy within a short time frame. Therefore, manufacturers need to be aware of the implications of VBA and they need to prepare for potential changes to VBA. The discussion will be of great value to overcome current challenges. Such agreements could help the health care authorities to keep within their budget while still providing innovative pharmaceuticals to patients. **CONCLUSIONS:** The agreement between the pharmaceutical and the healthcare industries would not just benefit from the same costs and benefits for pharmacists and patients, but would also benefit from the satisfaction of being able to supply the most effective treatment to the patients. In conclusion, the health care system would benefit from adequate pricing and reimbursement. **CONCLUSIONS:** In spite of the current problems, the popularity of risk-sharing agreements in Europe is growing fast and the future is bright. For this reason there is a strong need for dialogue between health care authorities and the pharmaceutical industry to create true risk-sharing agreements.