guide their evaluation and use. While a need to stimulate pharmaceutical innovation is widely recognized, cost containment is significant in decision-making. The objective of this research is to identify how members of the EU5 assess the innovative value of pharmaceuticals; understand the policies surrounding their market access and highlight potential drivers. **METHODS:** We assessed publicly available country guidelines and regulations to understand the evaluation and reimbursement process for innovative medicines. Findings were considered in light of definitions of innovation, market access conditions, reimbursement agreements and sources of funding. **RESULTS:** Across the EU5, definitions for innovative medicines vary. In Italy, the approach involves an algorithm which forms the basis of the assessment and reimbursement process for innovative medicines at national level. In Spain, although innovation is considered alongside clinical and economic parameters in the evaluation of drugs, there are no special considerations for reimbursement. France and Germany are both found to value innovation as a core criterion in the standard appraisal process with opportunities to facilitate market access in France and with prospects for price negotiations in Germany. In the UK, innovation is included as a modifying factor; however, the recently introduced Early Access to Medicines Scheme, allows the UK to present a landscape facilitating the development of innovative medicines. **CONCLUSIONS:** There are similarities and differences in the approaches used by the EU5 country members in their assessment and reimbursement of innovative medicines. While in some countries, innovative medicines benefit from lowered hurdles for market access; in other countries, innovation proves less impactful.

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NICE PATIENT ACCESS SCHEMES – A WHO, WHAT, WHY, WHEN AND HOW

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OBJECTIVES: Patient Access Schemes (PAS) are agreed between pharmaceutical companies and the Department of Health (DoH, with input from National Institute of Health and Care Excellence [NICE]) that enable companies to offer discounts or rebates that reduce the cost of a drug. PAS proposals are made in the context of a NICE technology appraisal, with the aim of improving cost-effectiveness to enable a positive NICE recommendation. This research aims to systematically analyse all PASs for NICE- approved technologies with respect to the type of scheme agreed, indication, company and how these have varied over time. **METHODS:** Publically available technologies with approved PASs were identified from the NICE website and the date, treatment, indication, company, and type of scheme were extracted. **RESULTS:** 49 PAS were identified involving 25 different companies. 51% (25/49) were for oncology medicines, 16% (8/49) rheumatology, 12% (6/49) ophthalmology, 6% (3/49) MS, and 14% (7/49) other. 76% (37/49) of PASs were simple discounts, 14% (7/49) for free stock, 6% (3/49) dose caps, 2% (1/49) rebates, and 2% (1/49) response schemes. An average of 5.4 new PASs are agreed every year, but these have risen from 3 between 2007-2008 to 23 in 2013-2014. There is also a notable time trend in the type of PAS, with 97% (32/33) of PASs agreed since November 2011 being simple discounts versus only 31% (5/16) of those agreed beforehand. **CONCLUSIONS:** PASs have been utilised by many pharmaceutical companies to help gain NICE approval primarily in oncology. Their utilisation has notably increased in recent years alongside a very strong trend to almost exclusively be simple discount schemes, perhaps reflecting DoH aversion to managing more complex schemes. Nevertheless, the recent dose capping PAS agreed with GSK for Tafinlar in October 2014, illustrate that other types of schemes will still be considered acceptable by the DoH.

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OFF-LABEL USE OF INTRAVENOUS IMMUNOGLOGULINS (IVIGS): FUNDING MECHANISMS IN FRANCE, GERMANY, ITALY, SPAIN AND THE UNITED KINGDOM (EU5)

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OBJECTIVES: IVIgs are used off-label in a number of patients with rare diseases which is thought to be mostly responsible for their increasing use. We propose here to describe the market access framework set in the EU5 for IVIgs' off-label use and determine if the level of evidence supporting off-label use influences its funding. **METHODS:** A literature review has been carried out in May 2015 using Pubmed and Datamonitor databases as well as websites of European Health authorities using the following terms: [off-label use OR unlicensed] AND [intravenous immunoglobulin] AND [funding OR reimbursement]. **RESULTS:** Despite its common practice, there is little regulation for off-label use and is generally funded when no approved therapeutic alternative exists. Schemes allowing pragmatic solutions for the funding of off-label use have been recently implemented in France through the granting of Temporary Recommendations for Use (RTUs), in Italy through pre-authorisation by AIFA (lista farmaci off label), in Germany with the implementation of BfARM off-label expert group. Funding through these schemes is granted if evidence of treatment success are shown and that there is no therapeutic alternatives. However, these schemes do not currently cover all drugs, including IVIgs. There is evidence of funding for IVIgs' off-label use in Spain but no specific schemes are set up. In the UK, the Department of Health implemented a Demand Management Programme for IVIgs. Their indications are colour-coded according to their level of priority and funding is linked to the colour granted. We found that IVIg's off-label use is funded if judged of a high priority. **CONCLUSIONS:** IVIgs' off-label use funding is not equally regarded in the EU5. Harmonisation of off-label use funding, dependant on the level of evidence available, may be considered in the future to ensure equal access to IVIg therapy amongst European patients.

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MARKET ACCESS ENTRY AGREEMENTS IN THE ITALIAN MARKET BETWEEN JANUARY 2006 AND APRIL 2015

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OBJECTIVES: Market access entry agreements (MAA) are vital to access the Italian Market. MAAs, monitored by an AIFA registry, are divided into outcome based (cost-sharing) and non-outcome based (risk-sharing and payment-by-results) agreements. The objective is to understand the MAA adoption, evolution and utilization variability among Therapeutic Areas. **METHODS:** The desk-based research was carried out by integrating different information sources, from AIFA and Gazzette Ufficiali to Regional HTA studies. Data was gathered for all the 82 products/indications belonging to an open registry signed up to a MAA since January 2006 up until April 2015. **RESULTS:** 59% products/indications have an outcome based MAA, 33% a non-outcome based and 1% both. A third of outcome based and a quarter of non-outcome based MAAs have an additional volume agreement or spending cap. A maximum peak of 30 products/indications with MAA is recorded in 2014, compared to an annual average of 8. In 2006-2007 cost-sharing MAAs were predominantly adopted; in 2008-2011, outcome based MAAs were negotiated in approximately half of the cases (57%), becoming since 2012, the preferred conditional reimbursement scheme (78%). Focusing on Antineoplastic products, Leukemia drugs have only non-outcome based agreements, Lymphoma, Melanoma, Breast, Colorectal and Ovary Cancer drugs have a prevalence of outcome based, whereas Renal Cell and Lung Cancer drugs have both. **CONCLUSIONS:** Throughout the years there has been an increase in the adoption of a MAAs as they are considered a valuable strategy to manage payer budget impact and drug clinical benefit uncertainties. Since their introduction, the choice of MAA schemes utilized has witnessed an evolution, with an increasing preference for outcome based MAAs, though often applied together with additional financial saving schemes. Due to the model adoption variability of MAAs within the Therapeutic Areas, the study of their structure plays a key role in accessing the Italian Market.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

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MEASURING HEALTH CARE PERFORMANCE ON EQUITY: A FRAMEWORK USING NATIONAL ADMINISTRATIVE DATA FROM 2004/5 TO 2011/12

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OBJECTIVES: We assessed NHS progress between 2004/5 and 2011/12 in reducing inequality in healthcare access and outcomes, with the aim of developing the first systematic approach to monitoring socioeconomic inequalities in NHS access and outcomes. **METHODS:** Indicators of healthcare access and outcomes at different stages of the patient pathway were constructed for all English small areas (2001 LSOAs) from 2004/5 to 2011/12 using GMS, QOF, HES and ONS mortality and population data – (1) GP supply: full time equivalent (FTE) GPs per 100,000 population, need-weighted adjustment, (2) primary care quality: quality and outcomes framework performance, weighted by public health impact, (3) hospital waiting time: days from referral-to-treatment, allowing for patient-level casemix, (4) post-hospital mortality: 12-month mortality after discharge, allowing for patient-level casemix, (5) amenable mortality: deaths from causes amenable to health care per 100,000 population, indirectly age-sex-standardised. Slope and relative indices of inequality were calculated through small-area-level regression using all 32,482 Index of Multiple Deprivation 2010 ranks, with regression-based tests of change over time. **RESULTS:** Nationally, all unadjusted relative indices of inequality fell from 2004/5 to 2011/12 (with 95% CIs in brackets, where negative indices represent "pro-poor" inequality): (1) for GP supply from -2.2% [-2.9% to -1.6%] to -9.5% [-10.2% to -8.8%], (2) for primary care quality from 4.1% [3.6% to 4.6%] to 1.1% [0.6% to 1.6%], (3) for hospital waiting time from 3.2% [2% to 4.4%] to 2.7% [1.5% to 3.8%], (4) for post-hospital mortality from 0.6% [2.3% to -1.2%] to -4.5% [-2.6% to -6.4%], and (5) for amenable mortality from 34% [36.5% to 31.4%] to 11.9% [14.6% to 9.2%]. **CONCLUSIONS:** Socioeconomic inequality in healthcare access and outcomes in the English NHS reduced between 2004/5 and 2011/12 in both relative and absolute terms on all our indicators (unadjusted), though all indicators except GP supply and post-hospital mortality continue to exhibit "pro-rich" inequality.

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METHODOLOGICAL GAPS IN THE ASSESSMENT OF THE UTILITY AND BURDEN OF RISK MINIMISATION INTERVENTIONS

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OBJECTIVES: Risk minimization interventions (RMIs) implemented by drug manufacturers aim at optimizing the benefit-risk of medicines when important safety concerns related to product have been identified. In some situations, strict RMIs, such as controlled distribution programs or mandatory certification, may be required. Although aiming to improve patient's safety, RMIs could be costly, time-consuming, challenging and therefore, generate an undue burden on stakeholders. In some instances, regulatory agencies request that burden of RMIs be evaluated but no methodological guidance is available. The objective of the present study is to identify current methodologies used to evaluate the utility and burden associated with RMIs and to identify methodological gaps. **METHODS:** A non-systematic literature review was conducted using Medline and Embase in order to identify relevant publications that include an assessment of the utility and/or burden of RMI. Pragmatic searches using Google and Google Scholar search engines completed this analysis. Regulatory agencies websites were also consulted to identify potential existing guidelines related to the evaluation of the burden associated with RMIs. **RESULTS:** A total of 362 relevant publications were identified in the literature. Among the methods used, surveys and focus groups appeared to be the most frequent as they allow to gather participants' opinions providing a better understanding of the burden and potentially identifying optimization opportunities. Mixed-method evaluations were also currently employed as they include