immunochemical tests for colorectal cancer were more expensive than the current SoC (guaiac-based Faecal Occult Blood Tests (FOBTs)); The average cost per test for each of the OC Sensor assay (£4.53), the HM-JACKarc assay (£6.04) and the FOB Gold (£1.96) assay was greater than for a guaiac-based FOBT (£0.78). But additional analysis shows that the OC Sensor and HM-JACKarc assay tests are more sensitive than the guaiac-based FOBTs, detecting 100%, 92% and 50% of colorectal cancers respectively; Therefore, these new tests can provide long-term cost savings for the NHS, due to allowing earlier diagnosis of patients' colorectal cancer. The FOB Gold assay was not included in this analysis but was shown to have an Incremental Cost-Effectiveness Ratio of £4, 725 per Quality Adjusted Life Year (QALY) gained compared with guaiac-based FOBTs. ***Conclusions:*** Products do not have to be lower cost than current SoC in order to gain AAC rapid uptake status in NHS England. Instead other characteristics, such as improvement in treatment pathways, are considered by the AAC.

PMU63
FRENCH HEALTH TECHNOLOGY ASSESSMENT OF DRUGS APPROVED UNDER EXCEPTIONAL CIRCUMSTANCES

Qiu T,[1] Hanna E,[2] Marre C,[2] Toumi M[1]
[1]*Aix Marseille University, Marseille, France,* [2]*Creativ-Ceutical, Paris, France*

Objectives: In Europe, approval under exceptional circumstances (EC) could be granted to drugs that are unable to provide comprehensive efficacy and safety data due to disease rarity or unethical issues. Therefore, these drugs may reach the market with only limited clinical evidence. This study aims to investigate how the drugs approved under EC are evaluated in terms of actual benefit (AB) and improvement in actual benefit (IAB) by the French health authority (HAS). ***Methods:*** Drugs granted a European marketing authorization under EC until June 2019 were identified from European Medicines Agency (EMA) website. HAS reports of these drugs were reviewed to extract reimbursement decision and recommendations. ***Results:*** A total of 34 drugs were approved under EC in Europe, among which 6 were withdrawn, and 8 were not assessed by HAS, thus 20 HAS reports were reviewed for analysis. AB was appraised as important for 12 drugs, moderate for 5 drugs, weak for 1 drug and insufficient for 2 drugs. Only 2 drugs received negative recommendations: Kolbam® due to limited patient number (N=13) for efficacy evaluation, and Raxone® with insignificant efficacy versus placebo. Among the 12 drugs rated with important AB, 9 had non-comparative trials, 2 had double-blinded placebo controlled trial, and 1 had before-after study as pivotal studies. IAB was rated as major for 1 drug, important for 3 drugs, moderate for 2 drugs, minor for 5 drugs and no improvement for 1 drug. ***Conclusions:*** Products approved under EC have high likelihood of reimbursement despite scarce clinical evidence, but the incremental added benefit is challenging. In France, single arm trial does not seem an obstacle for reimbursement of drugs indicated for rare diseases with no available alternatives.

PMU64
UNLOCKING ACCESS FOR TRANSFORMATIONAL CAR-T CELL AND GENE THERAPIES. ARE BIOSIMILARS THE KEY?

Ivanova H,[1] Macaulay R[2]
[1]*Parexel International, London, UK,* [2]*Parexel International, London, HRT, UK*

Objectives: We are embarking upon an era of innovative new therapies e.g. CAR-T cell and gene therapies that offer transformational benefits for patients with severe unmet needs. However, their potentially curative benefits mean they can be cost-effective at very high per-patient prices and their affordability is a key payer challenge. This research aims to contextualise their affordability by comparing their budget impact to potential budget savings anticipated/experienced through the introduction of biosimilars, using the UK as a case study. ***Methods:*** List prices of the two currently licensed CAR-T cell therapies: tisagenlecleucel and axicabtagene ciloleucel were sourced from the relevant NICE guidance documents. The NHS England website was also screened to identify information on savings experienced through the use of biosimilar therapies on 07/06/2019. ***Results:*** In 2017, the UK NHS saved £200 million from the introduction and uptake of three biosimilar classes alone: infliximab, rituximab, and etanercept. In Autumn 2018, five Humira® biosimilars were launched, with expected savings of £300 million by 2021. Up to 200 patients a year are anticipated to be eligible for either tisagenlecleucel and axicabtagene ciloleucel in their currently licensed indications, with their list prices at £300,000 and £282,000 per patient, respectively. Cumulatively, the budget impact of treating all eligible patients with a CAR-T cell therapy comes up to £116 million/year. ***Conclusions:*** The anticipated budget impact for currently available CAR-T cell therapies in their licensed indications (even based on their list prices and assuming no overlap of their indications, i.e. this is likely to represent a substantial overestimation of their net budget impact) is significantly outweighed by the potential budgetary savings that can be realized through utilisation of biosimilars. Affordability of transformational new therapy classes may be achievable by focusing on initiatives to encourage savings through biosimilars.

PMU65
PRICE ANALYSIS OF NEW MEDICINAL PRODUCTS REIMBURSED IN ITALY AND GERMANY

Casilli G,[1] **Lidonnici D,**[1] Isernia M,[1] Morichi M,[1] Konstanski M,[2] Kuchenbecker U,[2] Mittendorf T,[2] Lanati E[1]
[1]*MA Provider Srl, Milano, MI, Italy,* [2]*Xcenda GmbH, Hannover, Germany*

Objectives: With innovative, high-priced drugs, it becomes more relevant to timely plan the launch sequence and submission to HTA authorities, which could affect pricing strategies. Aim of this study was to analyse the impact of price negotiations and compare outcomes of process in Italy vs. Germany. ***Methods:*** Price information of 82 new medicinal products (January 2015 to June 2019) were available for Italy and Germany. Analyses were conducted according to their orphan status, therapeutic area, innovative status and reimbursement class (based on Italian criteria). For Italy/Germany, published ex-factory prices at date of launch (Official Gazettes/Lauertaxe, including mandatory temporary reductions) were compared with net prices including confidential discounts after price negotiation (tracked by regional public tenders/Lauertaxe). Finally, we made a comparison of the ex-factory and net/reimbursed prices between countries. ***Results:*** Compared to Germany, the Italian ex-factory price was on average 22% lower. Subgroup analysis showed that Italian vs German ex-factory price was -27% for orphan drugs (n=25), -15% for innovative drugs (n=23), -20% for oncological drugs (n=27) and -26% for uncategorised drugs (n=32). Analysing prices after negotiation processes, Italian net price resulted on average 23% lower than German reimbursed price. Subgroup comparison (Italian vs. German net/reimbursed price) showed -21% for orphan drugs (n=25), -24% for innovative drugs (n=23), -19% for oncological drugs (n=27) and -24% for uncategorised drugs (n=32). Price negotiation yielded to additional price reduction of 25% on average in Germany and 24% in Italy. Italian reimbursement before G-BA assessment (n=14) resulted in net prices on average 55% lower than German launch price. ***Conclusions:*** Our analysis highlighted that negotiated discounts in Italy are higher than in Germany leading to lower prices of drugs. Companies should carefully plan their launch sequence and design accurate access scenarios, being difficult to reset the price afterwards.

PMU66
TIMEFRAME FOR DRUG MARKETING AUTHORIZATION IN EUROPE

Costa-Samarra J, Cuesta M, **Brosa M**
Oblikue Consulting and MEDVANCE Spain, Barcelona, Spain

Objectives: The aim of this study was to compare expected vs observed times of drug marketing authorization [MA] by European Commission [EC] for the European Medicines Agency [EMA] centralized evaluation procedure. ***Methods:*** A literature review was performed using INMEDIATA, a secondary database that contains the registration and follow-up of all centralized marketing authorization applications [MAAs] for human drugs evaluated by the EMA. All drugs that began the evaluation procedure between January 2015 and April 2019 were included for the analysis, except generics and hybrids. For authorized drugs, the median time between submission of the MAA and the EC MA was calculated, depending on standard and accelerated evaluation procedures by the EMA. The expected theoretical duration of MA was considered without clock-stop time, specifically 277 days for standard evaluations and 217 for accelerated procedures. For all MAAs, the European regulatory status was described. ***Results:*** In the study 601 MAAs were included. At the time of analysis, 394 (65.6%) were authorized, 58 (9.7%) were withdrawn, 13 (2.2%) were refused and in 136 (22.6%) the decision was still pending. Of all MAAs, 331 (55.1%) were new innovative medicines, 270 (44.9%) extensions of indication, 137 (22.8%) orphan drugs, 59 biosimilar medicines (9.8%), 9 (1.5%) advanced therapy medicinal products and 194 (32.3%) were anti-cancer medicines. For authorized drugs, the median (range) duration for MA was 325 (85-999) days and 224 (91-515) days for the standard and accelerated procedures, respectively. More than 60.9% MA decisions exceeded the expected theoretical duration of the European regulatory assessment. The deviation of expected vs median observed MA time was 48 days for standard procedures and 7 days for accelerated evaluations. ***Conclusions:*** Median durations of EC MAs exceeded the theoretical timelines, especially for drugs undergoing the standard procedures with an overall deviation of 48 days.

PMU67
PERFORMACE-BASED SCHEMES IN ITALY: IMPACT OF THEIR APPLICATION IN THE LAST 5 YEARS (2013-2017)

Prada M,[1] Mariano EE,[2] Mantovani M[2]
[1]*INTEXO Srl, Rome, Italy,* [2]*Intexo, Roma, Italy*

Objectives: This study aims to assess the impact of the performance-based schemes (PBS) in Italy, in the last 5 years, based on last updated data available. ***Methods:*** A review of the existing risk-sharing agreement in Italy has been performed by checking the data published on the annual Osservatorio Nazionale per l'Impiego dei Medicinali (Osmed) National Report (2013-2017). Data about Registries active at May 2019 has been also performed in order to observe the most recent evolution of Managed Entry Agreements in Italy. ***Results:*** In the considered timeframe, the number of Registries gradually increased from 90 Registries in 2013 to 167 in 2017 (including also 16 web-based Therapeutic Plans; + 85%). A similar tendency can be observed by looking at the number of patients (from 149.447 in 2013 to 1.463.548 in 2017; +1.064%) and treatments (from 143.012 in 2013 to 1.644.119 in 2017; +880%). The estimate reimbursement amounts increased from the estimated 41 MIO Euro in 2013-2014, to 204,6 MIO in 2015, until 693 MIO in 2016. In 2017 the estimate savings were 531,8 MIO. Despite the the efficiency of spending (pay only when work, top of allocative efficiency), it is interesting to note how the percentage of performance-based schemes in Italy on the total of the new Registries introduced in the last few years and still active at May 2019, significantly decreased: 30% (4/13) in 2013, 39% (11/28) in 2014, 24% (5/21) in 2015, 19% (3/16) in 2016, 19% (4/21) in 2017 and none