

(89%). On average, participants were 42 (± 13) years old, 47% being female. In all 3 waves, self-reported anxiety and depression were significantly higher in young adults (18-34) compared with older adults (35+) ($p < 0.01$). Anxiety scores were 42%, 53%, and 33% in waves 1-3 respectively for young adults, whereas 33%, 40%, and 22% were reported by adults 35-64 and 19%, 20%, and 12% were reported by adults 65+. Similar trends were observed for depression, with younger adults reporting 39%, 54% and 35%, compared with 27%, 38% and 22% for those aged 35-64 years and 14.5%, 16% and 14.85% for 65+. EQ-5D-5L utility in waves 1-3 were 0.82, 0.75, and 0.82 ($P < 0.01$) and 74.7, 78.7, and 76.4 for EQ-VAS ($P < 0.01$). Age and employment status were significant predictors for anxiety and depression outcomes. **Conclusions:** Mental health deterioration during COVID-19 was pronounced among young adults for all waves, especially in wave 2. Findings suggest although people adapt over time, the US was ill-prepared for a mental health crisis, especially among young adults.

Informing the Decision-Making Process in Real Time

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REIMBURSEMENT OUTCOMES FOR COMBINATION THERAPIES VS MONOTHERAPIES IN LUNG CANCER AND MULTIPLE MYELOMA IN THE TOP FIVE EUROPEAN MARKETS

Izmirlieva MA,¹ Reinaud F,² Taiyeb M,³ Ando G¹

¹IHS Markit, London, UK, ²IHS Markit, Paris, France, ³IHS Markit, Bangalore, India

Objectives: Theoretically, combination therapies would face greater difficulty in demonstrating cost effectiveness because the backbone therapy is often priced close to the relevant country's cost-effectiveness threshold. Unless the backbone therapy's cost is reduced, the combination may not be cost-effective even if the add-on therapy is priced at zero. We set out to verify if this is true in practice by assessing reimbursement outcomes for combination therapies vs monotherapies in lung cancer and multiple myeloma. **Methods:** Reimbursement status and level of reimbursement for all drugs in lung cancer and multiple myeloma, which were first priced between 1 January 2011 and 31 December 2020, were assessed in France, Germany, Italy, Spain and the United Kingdom using data from the IHS Markit POLI database. The reimbursement status review was supplemented by Amélioration du Service Médical Rendu (ASMR) ratings in France, Federal Joint Committee (G-BA) ratings in Germany and NICE guidance in the UK to assess the likely pressure on prices for those combination therapies that gained reimbursement. **Results:** In lung cancer combination therapies were more likely to be rejected for reimbursement compared to monotherapies. Across the five countries, 20 out of the 56 combination therapy presentations (equivalent to 35.7%) were rejected for reimbursement compared to 11.4% (31 out of 271) for monotherapy presentations. In multiple myeloma, 5.3% of combination therapy presentations (7 out of 132) were rejected for reimbursement, while every single monotherapy was approved for reimbursement. Combination therapies also had less favourable ASMR and G-BA ratings. **Conclusions:** This review of reimbursement decisions and cost-effectiveness assessment outcomes for drugs approved over a 10-year period in the top five European markets confirms that combination therapies in lung cancer and multiple myeloma face greater difficulty in demonstrating cost-effectiveness compared to monotherapies. Even when approved for reimbursement, combination therapies are subject to greater pressure on prices.

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POTENTIAL IMPACTS OF THE NEW MHRA POLICY FOR BIOSIMILAR APPROVAL FOR THE INDUSTRY AND PATIENTS

Ribeiro A, Walker A, Walsh K

Lifescience Dynamics Ltd, London, UK

Objectives: To understand the potential impact of the new MHRA guidance for biosimilar licensing in the UK and other key markets, in terms of accelerating biosimilar development, time to market, prescribing limits (e.g. automatic substitution) and, patient access to biologics. **Methods:** We reviewed the MHRA guidance on biosimilar licensing, alongside that from the FDA/EMA, and country-specific guidance on biosimilar use. We also analysed FDA/EMA approvals for biosimilars approved without confirmatory efficacy trials. Finally, a virtual iAdBoard was organised with payers/KOLs from France, the UK and US to capture different perceptions on the new policy and downstream impacts on biosimilar access. **Results:** The MHRA has discontinued the requirement for biosimilars to undergo confirmatory efficacy trials as a licensing condition. Although the new policy was celebrated by the biosimilar industry, one must note the FDA and EMA do not explicitly state a Phase 3 trial requirement for biosimilar approval, and to date, two pegfilgrastim biosimilars have been approved without a Phase 3 trial (Udenyca, Nyvepria), given their robust chemical characterization and Phase 1 trials' Results: Additionally, the new MHRA guidance contemplates exceptions where comparative trials are required, leaving uncertainty around for how many biosimilars, particularly monoclonal antibodies, chemical characterization plus PK/PD trials will suffice. The virtual iAdboard revealed payer differences in opinion regarding impacts on biosimilar development timelines (vs agreement on economic viability), and in future policies encouraging biosimilar uptake, with EU payers more receptive to the change

than US counterparts, but concerned with backlash from HCPs. **Conclusions:** If the FDA/EMA endorse the MHRA decision, in the future, a strong CMC/Phase 1 package could replace Phase 3 studies for biosimilar licensing. However, it is yet unclear whether this abbreviated data package will result in faster times to market or if it will have negative impacts on prescribing freedom and patient access to biosimilars.

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IMPACT OF COVID-19 ON HTA/PRMA OF MEDICINAL PRODUCTS IN EUROPE: A PAYER PERSPECTIVE

Mycka J,¹ Dellamano R,² Lobb W,¹ Dalal N,¹ Dellamano L,² Pereira E¹

¹Medical Marketing Economics LLC (MME), Montclair, NJ, USA, ²ValueVector, Milan, Italy

Objectives: Assess payer perceptions of COVID-19 pandemic's impact on health systems, focusing on HTA, pricing, reimbursement and market access (PRMA) of new, branded medicines in the EU4 and UK. **Methods:** In June 2021, MME Advisors conducted a virtual, national payer / advisor board with representatives from France (2), Germany (2), Italy (1), Spain (1), and the UK (2) - to discuss key topics within the pandemic's context, such as:

- Disruption to healthcare systems
- HTA impact: backlog, re-prioritization, framework
- PRMA impact: net price pressure, conditional pricing/RWE and time to market
- Differences and similarities within oncology, rare diseases, ATMPs and general medicines

Results: Unlike the significant disruptions seen during the height of the pandemic in 2020, payers saw impact ranging from moderate (Italy) to high (Spain) as of June 2021. Disruption by disease state varied: oncology was highly disrupted everywhere but Germany. Most payers did not anticipate shifts in long term priorities or budget cuts to healthcare post pandemic. HTA impact was minimal, with no need to re-prioritize by therapy area or alter plans to adjust frameworks. Likelihood of stricter HTA criteria varied with payers in Italy anticipating more scrutiny for oncology and in Germany for rare diseases/ATMPs. While time to market was expected to remain mostly stable, delays anticipated in Spain. Majority of payers anticipated increasing pressure on drugs' net prices; however, they were divided on increases in conditional pricing/RWE. **Conclusions:** Perceived COVID-19 impact varied by country based on infrastructure and adaptability. Germany less impacted, whereas in other markets (e.g., Spain) COVID-19 seemed to have accelerated changes, rather than drive PRMA policy. Given the importance of healthcare, overall budget cuts were not anticipated, although the need to deploy funds to diverse areas (e.g., healthcare worker salaries, hospital capacity) could complicate future scenarios, especially for high-cost therapies. Therefore, continued monitoring is warranted.

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PRICE ANALYSIS OF CANCER THERAPIES FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE HEPATOCELLULAR CARCINOMA

Williams A,¹ Anderson N,² Gwon YG,³ Wifler W²

¹Boston Scientific, Marlborough, MA, USA, ²Boston Scientific, Maple Grove, MN, USA, ³Boston Scientific, Kuala Lumpur, MN, Malaysia

Objectives: The price of cancer therapy for the treatment of adult US patients with hepatocellular carcinoma (HCC) remains unknown. This study estimated the price of systemic therapies (ST) compared to selective internal radiotherapy (SIRT) for the treatment of HCC from the payer and provider perspectives. **Methods:** The National Comprehensive Cancer Network (NCCN) Guidelines were used as a framework to model the treatment strategies for HCC. The associated drug prices as of May 2021 for ST and SIRT were obtained from the IBM Micromedex Redbook (Average Wholesale Price [AWP]), (Wholesale Acquisition Cost [WAC]), Medicare's Average Sale Price (ASP), and Decision Resources Group (DRG) ASP. Clinical parameters, such as treatment duration and FDA-recommended daily dose (DDD), were obtained from randomized controlled trials and FDA-approved labels. The total price/DDD was calculated for each treatment therapy and treatment duration over a short-term (<12 months) horizon. Sensitivity analysis was conducted to explore the impact of treatment duration uncertainty on model Results: Because drug rebates are unknown, these price estimates did not account for drug rebates or patient assistance programs negotiated directly with manufacturers by Pharmacy Benefit Managers. **Results:** 11 STs and 3 SIRTs were included in our analysis. The median price/DDD of ST varied by perspective: Medicare ASP: \$97,466 (IQR: \$341-\$205,393); Provider WAC: \$123,322 (IQR: \$18,475-\$305,615); Provider AWP: \$186,389 (IQR: \$22,170-\$366,738). The median price for SIRT was estimated; Medicare ASP: \$21,877 (IQR: \$21,877-\$22,269) and Provider ASP: \$21,873 (IQR: \$21,316-\$21,873). The price differences are greater than SIRT when considering patients who progress through first-line and second-line ST. **Conclusions:** The price of cancer therapy for HCC varies widely by payer-provider perspective. The availability of alternative cancer therapies, such as locoregional (non-surgical) approaches, may offer clinical meaningful benefit and reduce the total costs of HCC care from the payer-provider perspectives.