Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
for burdens to accrue over a full lifetime. 3) disease burden should be high. 4) healthcare resource use should be high, with significant cost-savings expected in those who receive a gene therapy. 5) current treatment options should be limited and offer challenging benefit: risk profiles. 6) treatments currently approved for the disease should be expensive, setting a precedent for high pricing and offering a simple like-for-like cost offset. Conclusions: By evaluating case studies of currently approved gene therapies, we have devised a framework for assessing the economic viability of disease areas that may be used by developers as part of early decision making.

POSB220
BRIDGING THE EVIDENCE GAP FOR TUMOR-AGNOSTIC THERAPIES
Coker T, Chung F, Hunt M
1 CBPartners, New York, NY, USA, 2 CBPartners, London, UK
Objectives: With more innovative tumor-agnostic therapies coming to market targeting specific biomarker populations, regulators and payers are tasked with reviewing evidence packages that span across several tumor types. This analysis aims to quantify the differences in regulatory and reimbursement outcomes for tumor-agnostic therapies in the EU and Canada compared to the US in relation to evidence development and identify the risks associated with evidence collection of these therapies. Methods: Case studies were evaluated to understand how clinical trial designs, size and type of tumor types influence regulatory and HTA outcomes in Germany, France and Canada. A comparative analysis of HTA documents was performed to identify key regulatory and reimbursement risks compared to the US. Results: While there is no significant divergence of key regulatory risk factors observed between the EU and the US, Health Canada is more selective, only granting regulatory approval for individual tumor types that demonstrate robust efficacy outcomes. Beyond regulatory approval, access and reimbursement of tumor-agnostic therapies in Germany, France and Canada is challenging due to stringent evidence requirements. HTA cost-effectiveness bodies in the EU and Canada conduct subgroup analyses for individual tumor types and demand robust efficacy and safety data in each tumor type to drive positive reimbursement decisions. Heterogeneity of trial populations, small sample sizes within each tumor, and the lack of comparative data versus standard of care, as well as patient relevant outcomes (e.g., overall survival and quality of life) are the most cited barriers to positive HTA outcomes. Conclusions: Given the limitations of tumor-agnostic trial designs, prospective real-world evidence (RWE) collection should be conducted to bolster the evidence package of tumor-agnostic therapies and demonstrate beneficial clinical outcomes in specific biomarker populations.

POSB221
ASSESSING THE ASSOCIATION BETWEEN PHARMACEUTICAL PRICING AND DRUG SHORTAGES IN SAUDI ARABIA
Alowairdhi M
Saudia FDA, Riyadh, Saudi Arabia
Objectives: Drug shortage has become a serious global challenge given its complex nature and its possible disruption of the routine clinical daily care which leads to negative clinical, social and economic impacts. Studies suggested that drug pricing might be a risk factor of drug shortage; however, none of these studies was conducted to quantify this possible causal association. The primary objective of this study was to quantify the causal association between drug prices and the probability of drug shortage through the following: -Determining prices of drugs with shortage in a comparative context of the foreign-to-Saudi (FTS) price ratio. -Modeling the causal association between FTS and drug shortage incidents adjusting for external determinants. Methods: This retrospective database analysis conducted using local and international price data of drugs with shortage incidents from Jan-2017 to Dec-2020. These data were retrieved from the Saudi Food and Drug Authority (SFDA) databases and from the IMS MarkitTM database. The included drugs were classified based on the FTS price ratio into three groups: Group 1 (ratio >1), Group 2 (ratio =1), and Group 3 (ratio <1). The primary outcomes were the ratio of mean counts (mCR) between the three groups with Group 3 as the control group. These outcomes were analyzed using a Poisson regression model adjusting for the measured confounders. All statistical analysis were computed using Rstudio Version 1.4.1103.
Results: A total of 1,095 drug shortage reports were identified. The interim analysis of 401 drugs showed that both the mean counts (mCR) of Group 1 and Group 2 were higher than Group 3. Conclusions: The results of this interim analysis showed that drug shortages could be linked to drugs that are more expensive internationally (or have consistent international and local prices). These finding are conditional on the results of the final study.

POSB222
CAN GENE THERAPY PRICES REMAIN THE SAME? WHAT WE HAVE LEARNED FROM THE COVID-19 VACCINES
Sigurðardóttir K, Solá-Morales O
The iHT Foundation, Barcelona, Spain
Objectives: Gene therapies (GTs) have been progressively reaching the market in the past years, despite the often high per-patient costs associated. This high cost has in part been justified by the small target patient population and the high research and development cost associated with GTs. However, in the light of newly approved, low-cost gene therapies, with a vast addressable market, such as the Moderna Covid-19 mRNA vaccine, the question becomes, what impact will this have on the future of GT pricing. The objective of this study was to analyse the pricing of marketed gene therapies, and if there is a link between their price and their addressable market. Methods: We identified all EMA approved GTs in the United Kingdom up to the year 2021. We analysed the addressable market for each treatment, and where possible, found their list prices as cited by the NHS and/or NICE. Then we analysed the correlation between the prices and the addressable market. Results: We found a clear trend where the prices of gene therapies to rise when the addressable market became smaller. We hypothesise whether new GTs arriving to the market can be priced according to the same price-volume correlation line, as it has been shown that the innovation can be provided at a small cost. Considering monogenic diseases, one could regard that providing and delivering genetic material is a me-too intervention now that mRNA vaccines have been effectively rolled out on a large scale and at an affordable cost. Conclusion: Novel mRNA vaccines have set a new standard for the pricing of GTs, and it could be that the willingness to pay for the replication of that innovation is low, thus killing the ‘hen of the golden eggs’.

POSB223
IMPACT OF THE 2019 COVID-PANDEMIC ON INFLUENZA VACCINATION POLICIES
Net P, de Renteria J, Blanca F
Snees Health, Montrouge, France, 2 Syness Health, Munich, Germany
Objectives: Since the COVID-19 pandemic occurred unique due to the co-occurring COVID-19 pandemic which exerted significant strain on populations and healthcare systems. On September 2020, the World Health Organization issued an interim guidance recommending countries to strengthen their national immunization programs (NIPs) against influenza. The objective of this study was to evaluate the impact of the COVID-19 pandemic on influenza vaccination policies. Methods: We conducted desk researches on Google and Google Scholars to identify changes in vaccination policies for the 2020/21 season in France, Italy, the UK and US. Public health agency and governmental websites were consulted on May 3rd, 2021. Results: Substantial changes following the COVID-19 outbreak were observed in France, UK and Italy, with all countries extending eligibility criteria for immunization and expanding their time window for vaccination. French authorities established a stockpile of two million doses and opened vaccination to children with the inclusion of intranasal influenza vaccines in their NIP. A stockpile was also constituted in the UK, whose NIP was extended to four new population categories such as individuals aged 50 to 64 years. Targets in vaccine coverage rate (VCR) were also increased from 55% to at least 75% in at-risk individuals aged below 65 years. Similarly, Italy extended vaccination to all individuals aged 60 to 64 years and estimated vaccine supply based on demographics rather than Objectives: in VCR. In comparison, no significant changes were observed in the US compared to previous seasons. Conclusions: It is likely that the COVID-19 pandemic has led to significant adjustments in country NIPs for influenza to limit the potential for additive burden on healthcare systems. As the pandemic is still ongoing, it will be of interest to confirm whether the changes observed in this study are just temporary or if they will be upheld in the long term.

POSB225
DIFFERENCES AND SIMILARITIES IN THE METHODS OF PRICING OF PRESCRIPTION DRUGS IN BULGARIA, FRANCE, GERMANY, BELGIUM, AND THE UK: A COMPARATIVE ANALYSIS
Vutova Y, Djambazov S, Dacheva A, Slovachev G
1 HTA Ltd, Sofia, 23, Bulgaria, 2 Medical University Pleven, Sofia, 23, Bulgaria, 3 HTA Ltd, Sofia, Bulgaria
Objectives: The objective of this study is to evaluate the methods of pricing of prescription drugs in selected countries. This study highlights some of the differences and similarities in pricing negotiation approaches in Bulgaria, France, Germany, Belgium, and the UK. Methods: A comparative analysis of the published pricing methods regarding reimbursement of prescription drugs was conducted for Bulgaria, France, Germany, Belgium, and the UK (England). The choice of countries was founded on the condition for external reference pricing when including a prescription drug in the Positive Drug List (PDL) in Bulgaria. Bibliographic databases, online sources, and government/HTA organization websites were searched. The collected data was synthesized in Excel and used for qualitative comparative analysis. Results: The pricing methods are very similar in the analyzed countries. External reference pricing is used in all countries and it is the most commonly used method in Bulgaria. Germany uses a variety of methods including free pricing, internal reference pricing, price based on additional therapeutic benefit. The UK (England) has a descending pricing mostly on cost-effectiveness requirements, while France and Belgium base drug prices on additional therapeutic benefit. Even though similarities of methods between countries exist, pricing levels may vary. Conclusions: This study reviews the differences and similarities of pricing strategies. External reference pricing is still the most commonly used approach which highlights the importance of correct drug launch sequencing to avoid price erosion.