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Objectives: The present work aims to discuss the role of the economic evaluation in the new guidelines for pricing and reimbursement (P&R) of medicines adopted by the Health Medicines Agency (AIFA) in March 2021. Methods: A multidisciplinary scientific group were enrolled from Academia (2 researchers), Regulatory Agency (1 expert from AIFA), Regional Entities (2 pharmacists), Pharma Companies (2 access managers) and Healthcare Consultancy Firms (2 access leads). A systematic review of the literature was conducted in order to collect the main documents available in Europe about the role of economic evaluations in the P&R process. All the records were analysed in qualitative terms according to a pre-specified analytical framework. At the end of the analysis, a consensus questionnaire was developed to establish a standardised and transparent approach to economic analysis in healthcare for guidelines used in other European countries demonstrates the importance of a opportunity to improve the use of economic evaluations. Comparison with the were analysed in qualitative terms according to a pre-speci

Conclusion: The new AIFA guidelines provide an opportunity to improve the use of economic evaluations. Comparison with the guidelines used in other European countries demonstrates the importance of a standardised and transparent approach to economic analysis in healthcare for improving transparency of the economic modelling approach during the P&R process.

POSA210
DECENTRALIZED STUDY METHODS: A SUMMARY OF THE REGULATORY LANDSCAPE IN THE SARS-COV-2 ERA AND BEYOND
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Objectives: The adoption of decentralized (DCT) study methods including e-consent, eCOA, telehealth visits, home health and direct to patient (DTP) study supplies have been accelerated in the SARS-COV-2 pandemic to maintain research continuity. However, DCT approaches have not been universally accepted by regulatory authorities (RAs) and ethics committees (ECs). The aim is to summarize intelligence on the adoption of DCT study methods in order to characterize the current global regulatory landscape. Methods: Information on the acceptance of DCT methods was extracted from Pharmaceutical Product Development (PPD)’s regulatory intelligence system, which includes regulatory content and practical experience on DCT adoption across 72 countries, on 21-Jun-2021. Results: DCT supply for interventional studies was most commonly accepted DCT method, permitted in 70.8% of countries; however, 49.0% of countries only permitted this during the pandemic. Telehealth visits via video link were accepted in 59.7% and 50.0% of countries for interventional and observational studies respectively, with fewer countries restricting this measure to the pandemic period (interventional 25.6%, observational 33.3%). Overall, results for home health services were similar to telehealth (58.3% and 50.0% of countries permitting this for interventional and observational studies respectively); however, fewer countries limited this measure to the pandemic period (interventional 14.3%, observational 13.5%). Remote e-consent was the least accepted DCT method (permitted in 30.6% and 28.7% of countries for interventional and observational studies respectively), with 49.0% and 40.0% respectively permitting this only during the pandemic. Conclusions: Results demonstrate that the acceptance of DCT methods is variable and has been highly variable, with many countries restricting measures to the pandemic and several now removing these, signaling that the ability to maintain the momentum implementing DCT study methodologies post-pandemic will be reduced, unless RAs and ECs adopt a different stance.

POSA211
ARE ORPHAN DRUGS IN FRANCE PRICED ACCORDING TO INTERNATIONAL PRICES AND WHICH FACTORS COULD INFLUENCE THE NEGOTIATED PRICES?
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Objectives: The orphan drug status in the European Union aims to promote investment by creating incentives. The primary objective of this analysis is to compare the prices of orphan drugs in France to that of four other European countries: Germany (post-among), Italy, Spain and the United Kingdom. Methods: 17 orphan drugs priced in France between January 2016 and May 2021 were selected. Only products reimbursed first in an orphan indication and with public prices available were included. Daily treatment costs, first price publication date and price evolution in each country were collected. A one-to-one analysis was conducted to account for drugs not available in a country. Results: Out of the 17 products, 11 (65%) had their lowest price in France. The mean daily treatment cost in France was significantly lower than in the UK (-20.73%; P-value = 0.0123), Italy (-18.57%; P-value = 0.0109) and Spain (-15.98%; P-value = 0.0288). The difference with respect to France was not statistically significant. A trend appeared when observing the launch sequence of countries: the UK usually obtained a price first followed by other countries with a lower published price. The drop in price compared to the UK was substantial for Germany and France. In a linear regression model, the two best factors that explained the treatment cost were the population size and level of Added Medical Value (adjusted R² = 0.7085; P-value < 0.001). Conclusions: These findings suggest that France grants a lower listed price than its reference countries for orphan drugs. Pricing decisions seem influenced by a fixed discount on the reference price. However, the new 2021 framework agreement with the CEPS could change this. Indeed, orphan drugs will access European prices with an AMV level of IV. This status should guarantee a price at least equal to the lowest price in the four countries considered.

POSA213
PRODUCT DEVELOPMENT PARTNERSHIPS (PDPs) AND PHARMACEUTICAL INNOVATION
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Objectives: Product Development Partnerships (PDPs) are a rational economic response to the lack of incentives for private pharmaceutical R&D in areas of low expected returns but high unmet need (e.g., neglected tropical and infectious diseases, rare diseases). In this research, we examine how different types of PDP are associated with the likelihood of product approval, i.e., successful pharmaceutical innovation, and ii) whether some types of PDP stimulate drug development effectively in the early stages. Methods: We exploit the G-Finder database to collect data on PDPs for emerging infectious diseases between 2015-2019. Additionally, we extract data from various other sources such as the subscription-based PharmaIntelligence database and PubMed. We conduct simple OLS regression analyses that explore the relationship between the likelihood of approval of a product funded by different type of PDP, controlling for product and disease characteristics. Results: We find that an increase of PDPs R&D levels facilitates successful product development for all stages of development. Also, specific funder and product types stimulate innovation for infectious diseases products developed by PDPs, notably when public sector R&D funding to PDPs is used to develop risky products. The likelihood of approval of products in the early development stages is lower. The lack of scientific advances in sub-disease areas of infectious diseases is a barrier to innovation. Conclusion: Non-private funding is especially beneficial in the early stages of drug development for infectious diseases. PDPs play a significant role in developing new treatments for covering unmet need. Our findings can inform policymakers on i) how to optimally use PDPs to solve the market failures that characterize pharmaceutical innovation and ii) how to optimally balance the use of PDPs (such as pull strategies to tackle global health challenges and improve patients’ health and society’s welfare.

POSA215
PUBLIC AND HOUSEHOLD HEALTHCARE AND PHARMACEUTICAL SPENDING ANALYSIS IN BULGARIA IN FOUR YEARS PERIOD
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Objectives: To analyse the differences in household and public healthcare and pharmaceutical expenditures during 2016-2019 in Bulgaria. Methods: A comparative, retrospective, observational, and macroeconomic analysis was performed. National Statistical Institute (NIS) and National Health Insurance Fund (NHIF) databases were analyzed. Household and public healthcare and pharmaceutical expenditures were systematized and statistically proceeded. Results: Household spending is increasing more than twice in many of the observed categories. The pharmaceuticals’ spending has arisen from 229 to 280, those for herbal, homeopathic medicines and food supplements - from 3.57 to 7.65, medical devices and equipment - from 14.79 - 26.52, out-patient services - from 39 to 44, dental services - from 17 to 21, laboratory analysis and x-ray examinations increase from 5 to 6 euro, and hospital services - from 24 - 66 euro average per household annually. Overall growth of healthcare services cost is about 35 %. The public expenditures for reimbursed medicines, food supplements, and medical devices increased - from 365 in 2016 to 420 mln euro in 2019 with rate almost 15 %. All changes were found statistically significant. Conclusions: The households and public healthcare and pharmaceutical expenditures are progressively increasing with higher rate for public ones but still the burden on families is heavy. The introduction of cost containment measures could ensure more affordable medical services as well as better clinical Results:

POSA216
BIOSIMILAR ASSESSMENT FRAMEWORKS AND POLICY SHIFTS IN THE EU IN THE POST-COVID CONTEXT
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Objectives: Recent years have witnessed EU markets updating their biosimilar policies; however, there remain countries where the full cost-savings potential of biosimilars is yet to be realized. This research aims to review the current EU biosimilar