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differences in the WTP for curative treatments across different therapeutic areas, which is particularly low for antibacterials. Further research is required to better understand the reasons and implications of such findings.

POSA221
5-YEAR EVALUATION OF THE CANCER DRUGS FUND
Critchlow S, Lilley C

Objectives: In June 2016, the Cancer Drugs Fund (CDF), an important mechanism for managed access in England, underwent significant reform. Between June 2016 and June 2021 NICE considered the evaluation of over 300 individual single technology appraisals (STAs). During these 5-years, the CDF has played a pivotal role in supporting cancer medicines by promising further data are collected with the aim of reducing uncertainty. This research evaluated the CDF recommendations made during this period and reflects on the role of the CDF in the context of the imminent 2021 launch of the new ‘Innovative Medicines Fund’ (IMF), which will expand the role of the CDF to include non-cancer diseases.

Methods: A targeted literature review was conducted to identify STAs where the treatment under evaluation was recommended for use within the CDF with additional research undertaken to understand which of those STAs had subsequently been reappraised on exit from the CDF. Results: The review identified 198 STAs conducted between June 2016 and June 2021 in an oncology setting. 40 recommendations were made using the results of new evidence. Of those, nine have been fully reappraised following submission of new evidence. Of those, nine have been reappraised following submission of new evidence. Of those, nine have been fully reappraised following submission of new evidence. There are an additional 11 appraisals for which there remains a relatively low number of reappraisals. There are an additional 11 appraisals for which there remains a relatively low number of reappraisals. This research evaluated the CDF recommendations made during this period and reflects on the role of the CDF in the context of the imminent 2021 launch of the new ‘Innovative Medicines Fund’ (IMF), which will expand the role of the CDF to include non-cancer diseases.

Results: This study provides an overview of the exclusivity status of 173 OMPs with 213 OD indications granted MA from 2000-2020. The majority of OMPs are still patent protected, whilst a small proportion (~10%) benefit from OD market exclusivity after loss of patent exclusivity. Approximately one fifth of OMPs have no exclusivity protection and generic entry has occurred in around half of these OMPs. The study identifies a small trend for higher likelihood of generic entry for oncology and non-oncology OD-products. Analysis shows that non-OD products are more likely to experience generic entry than OMPs, with a higher number of generics approved also.

Conclusions: This study shows that OD status protects OMPs from generic competition beyond the 10-12 year market exclusivity period, with generic entry less likely after the lapse of market exclusivity than observed with non-OD products.

POSA222
CRITICAL REFLECTIONS ON REIMBURSEMENT AND ACCESS OF ADVANCED THERAPIES
Simoens S, De Groot K, Boersma C

Objectives: The health economic literature has questioned the cost-effectiveness and affordability of advanced therapies, proposed adjustments to value assessment frameworks, and discussed the use of outcome-based managed entry agreements and staggered payments in the last few years. The aim of this study is to critically reflect on recent developments in health technology assessment agencies, advanced therapy organisations, government, advanced therapy innovation programmes, consultancy agencies; ISPOR conference abstracts and presentations. Results: Based on the available evidence, this study argues that: a) advanced therapies can be cost-effective at high prices set by manufacturers; b) the narrow economic evaluation framework adopted by many payers under-values these products; c) advanced therapies can be affordable and may not require spread payments; d) outcome-based managed entry agreements are theoretically attractive, but challenging in practice; e) the cost-effectiveness of advanced therapies depends on the outcome-based managed entry agreement and payment approach; f) there is a role for pan-European collaborations to manage reimbursement and access of advanced therapies. Conclusions: This study shows that there is no single approach to reimbursement and access of advanced therapies. Instead, we support a more tailored assessment of health economic aspects of advanced therapies, which takes into account the heterogeneity of these products and their target populations.

POSA223
DYNAMICS OF EU MARKET EXCLUSIVITY: THE IMPACT OF ORPHAN DESIGNATION ON GENERIC OR BIOSIMILAR ENTRY
Collins S, Patel B, Saada R, Kelly S

Objectives: Orphan designation (OD) status was introduced to encourage development of therapies for rare disease. Products that fulfil the OD criteria benefit from a 10-12 year market exclusivity period from market authorisation (MA), which can extend protection from generic competition beyond patent expiry. In this study we explore the impact of OD market exclusivity on the likelihood of generic and biosimilar entry. Factors which may influence the attractiveness of generic entry are also analysed. Methods: A database containing all products with an OD status were granted MA from 2000-2020 were collected from the European Medicines Agency (EMA) database. The database was curated to distinguish paediatric vs. non-paediatric and oncologic vs. non-oncologic orphan medicinal products (OMPs). Patent expiry dates were collected from Lexipharma and other publicly available sources. An EMA database was used to identify the earliest date of centralised MA for generics and biosimilars, and the numbers of these competitors that were approved. Results: This study provides an overview of the exclusivity status of 173 OMPs with 213 OD indications granted MA from 2000-2020. The majority of OMPs are still patent protected, whilst a small proportion (~10%) benefit from OD market exclusivity after loss of patent exclusivity. Approximately one fifth of OMPs have no exclusivity protection and generic entry has occurred in around half of these OMPs. This study identifies a small trend for higher likelihood of generic entry for oncology and non-oncology OD-products. Analysis shows that non-OD products are more likely to experience generic entry than OMPs, with a higher number of generics approved also.

Conclusions: This study shows that OD status protects OMPs from generic competition beyond the 10-12 year market exclusivity period, with generic entry less likely after the lapse of market exclusivity than observed with non-OD products.

POSA225
COMPARING THE US DRUG DEVELOPMENT, PRICING, ACCESS, AND REIMBURSEMENT STRATEGIES FOR COVID-19 VACCINES AS A POTENTIAL MODEL FOR NOVEL ONCOLOGY THERAPIES
Lee Y, Lee K, Park H, Neese M, Khan Z

Objectives: With the development and launch of COVID-19 vaccines and pricing, access, and reimbursement (PAR) barriers often prevent innovative therapies from reaching patients in a timely manner. Rapid R&D and PAR strategies have allowed COVID-19 vaccines to become widely available. This study aims to explore the impact of OD market exclusivity on the likelihood of generic and biosimilar entry. Factors which may influence the attractiveness of generic entry are also analysed. Methods: A database containing all products with an OD status were granted MA from 2000-2020 were collected from the European Medicines Agency (EMA) database. The database was curated to distinguish paediatric vs. non-paediatric and oncologic vs. non-oncologic orphan medicinal products (OMPs). Patent expiry dates were collected from Lexipharma and other publicly available sources. An EMA database was used to identify the earliest date of centralised MA for generics and biosimilars, and the numbers of these competitors that were approved. Results: This study provides an overview of the exclusivity status of 173 OMPs with 213 OD indications granted MA from 2000-2020. The majority of OMPs are still patent protected, whilst a small proportion (~10%) benefit from OD market exclusivity after loss of patent exclusivity. Approximately one fifth of OMPs have no exclusivity protection and generic entry has occurred in around half of these OMPs. This study identifies a small trend for higher likelihood of generic entry for oncology and non-oncology OD-products. Analysis shows that non-OD products are more likely to experience generic entry than OMPs, with a higher number of generics approved also.

Conclusions: This study shows that OD status protects OMPs from generic competition beyond the 10-12 year market exclusivity period, with generic entry less likely after the lapse of market exclusivity than observed with non-OD products.

POSA226
ANALYSIS OF REQUIREMENT OF IMPLANTABLE CARDIOVERTER DEFIBRILLATOR IN THE RUSSIAN FEDERATION
Seryapina Y, Pustovalov D, Fedyaev D, Musina NZ

Objectives: Sudden cardiac death (SCD) is one of the leading causes of death in people of working age. Implantable Cardioverter Defibrillator (ICD) should be considered as the primary means of preventing SCD. The number of ICDs in Russia is 9.4 per 1 million people (2,841 implantations in 2019), but in the countries Western and Eastern Europe, this indicator is approximately 10 times higher. This study aims to estimate the number of patients requiring ICD treatment due to SCD-associated diseases in Russia. Methods: The calculations were carried out using information on the population of Russia. Incidence was estimated based on the hospital bills data in 2019 and expert assessment of the proportion of patients with SCD-associated diseases who potentially required ICD.