ISPOR Europe 2023

12 - 15 November

Poster Tour Guide Packet

Poster Session:	**Poster Session 2**
Tour Name:	**Pricing Reimbursement**
Tour Date/Time:	Monday, 13 November 2023 | 15:30 - 16:15
Tour Location:	Area B, Poster and Exhibit Hall, Hall C

Acceptance Code:	PT19
Board Number:	1B
Abstract Title:	Analysis of the Access to Medicines for Rare Diseases in Countries from the Balkan Peninsula: A Comparative Analysis
Presenting Author:	Mariya Kamusheva

Abstract Body:

OBJECTIVES: To analyze and compare the access of patients with rare diseases (RDs) to pharmacotherapy by monitoring the legislative procedures and the number of reimbursed orphan medicinal products (OMPs) in Bulgaria, Romania and Greece.

METHODS: A comparative analysis of the current legislation in these countries was performed. In addition, the national programs (NPs) of the three countries, the trends in the development of reimbursement and pricing policies for OMPs, the availability of national registers, the policy for neonatal screening and the development of centers of expertise for the last 10 years were analyzed.

RESULTS: Since joining the European Union (EU), all three countries have harmonized their legislation with the European one. There has been an increase in the number of national registries for RD and centers of expertise. The total number of medicines for RDs with orphan status authorized for use in the EU is 179 (163% increase in comparison with 2012). Out of them, 42 are included in the Positive drug list (PDL) in Bulgaria, 100 in Greece, and 61 in Romania. The percentage increase in availability compared to 2012 is 100%, 146.44% and 69.44%, respectively. The number of OMPs that have been authorized but lost orphan status is 103 (37.33% increase compared to 2012). In Bulgaria 89 are reimbursed, in Greece – 86, and in Romania – 39. The percentage increase in availability is 122.50%, 65.38% and -11.36%, respectively. The therapeutic group 'L - Antineoplastic and immune modulating agents' prevails among the OMPs included in all three countries.

CONCLUSIONS: The study found an increased number of reimbursed OMPs compared to 2012. The access to therapy has improved, as a result of hard work in the field of legislation, the goals set in the NPs, and the creation of organizations that aim to address the needs of patients with RDs.

Tour Guide's Questions for Starting Q&A (Each poster will have ~5 minutes for Q&A with attendees/Tour Guide)

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Tour Location:	Area B, Poster and Exhibit Hall, Hall C

Acceptance Code:	PT20
Board Number:	2B
Abstract Title:	Applications for Tolvaptan (JINARC®) Under a Managed Access Protocol in Ireland
Presenting Author:	Claire Gorry

Abstract Body:

OBJECTIVES: Tolvaptan (Jinarc®) capsules are reimbursed in Ireland under the High Tech Arrangement, for a subgroup of the licensed population: treatment of autosomal dominant polycystic kidney disease patients with chronic kidney disease (CKD) stage 2 or 3 at initiation of treatment, with evidence of rapidly progressing disease. Reimbursement, effective from 28 February 2020, is subject to a Health Service Executive (HSE)-Managed Access Protocol (MAP). This study provides an overview of applications for tolvaptan reimbursement, and utilization for the first three years of the protocol.

METHODS: All applications submitted to the HSE-Medicines Management Programme between 28 February 2020 and 27 February 2023 were reviewed. Utilisation data was extracted from the HSE-Primary Care Reimbursement Services national pharmacy claims database for the High Tech Arrangement, from 28 February 2020 to 31 May 2023. Data was compiled and analysed in Microsoft Excel™ and RStudio 1.1.447.

RESULTS: A total of 29 applications were received from six approved prescribers. The majority of applications (62.1%) were for males (n=18), with 37.9% applications for female patients (n=11). The average age of applicants was 42.1 years (range 23-57 years). Of the 29 patients, 3 (10.3%) had CKD stage 2 (estimated glomerular filtration rate (eGFR) 60-89 ml/min/1.73m2) and 25 (86.2%) had CKD stage 3 (eGFR 30-59 ml/min/1.73m2); eGFR was unknown for one applicant. Reimbursement was approved for 89.7% (n=26) of applications received. Further information relating to two applications (6.9%) was still outstanding at the end of year three. One application (3.4%) was not approved as it did not meet the reimbursement criteria. Treatment was initiated by 25 patients. The median duration of treatment is 2 years (95% CI 1.37, not reached).

CONCLUSIONS: The MAP ensures drug reimbursement is in line with the agreed terms by the HSE. Data collected may serve to inform future Health Technology Assessment and reimbursement decisions.

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Acceptance Code:	PT21
Board Number:	3B
Abstract Title:	Evaluation and Reimbursement of Digital Therapeutics in Germany, France, Belgium and England
Presenting Author:	Graham Foxon

Abstract Body:

OBJECTIVES: This study compares and contrasts the evaluation and reimbursement pathways for digital therapeutics (DTx) in Germany, France, Belgium and England.

METHODS: Four frameworks for DTx assessment: the German DiGA fast track, the French PECAN fast track, the Belgium mHealth Pyramid, and the English Early Value Assessment (EVA) were reviewed to compare and contrast their objectives, methodology, and eligibility criteria.

RESULTS: DiGA and PECAN fast tracks aim to accelerate reimbursement for eligible DTx. Both processes offer a one-year transitional reimbursement period to collect patient data that can be used in determining product value and achieving permanent reimbursement. The mHealth Pyramid focuses on informative function and categorizes DHAs based on functionality, compliance, and health-economic value, offering funding potential only to those meeting higher-level criteria. The English Early Value Assessment evaluates the clinical and cost-effectiveness of DTx among other medical technologies to inform local funding decisions and support the generation of meaningful real-world data. Across frameworks, assessed DTx must be CE-marked and meet safety and interoperability criteria. Reimbursement eligibility varies: Germany includes class I and IIa DTx, while France evaluates class IIb, III, and telemonitoring devices under PECAN, with DiGA focusing on potential positive health effects and PECAN prioritizing clinical benefits or improved care organization. In the mHealth Pyramid framework, only apps that enable remote diagnosis, therapy, or monitoring by healthcare providers are eligible for funding. NICE DTx out of those have Digital Assessment Criteria (DTAC) approval for evaluation in the EVA process based on their potential to address prioritized national unmet needs.

CONCLUSIONS: As a result of the distinct differences in the objectives and methodology employed to assess the value of DHAs across countries, companies need adopt a country-specific approach, resulting in increased costs and resources, in order to facilitate patient access across the EU.

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Acceptance Code:	PT22
Board Number:	4B
Abstract Title:	Exploring Reimbursement Disparities: A Comparative Study of Pharmaceutical Access in Hong Kong and Mainland China
Presenting Author:	Richard Macaulay

Abstract Body:

OBJECTIVES: Inclusion in the National Reimbursement Drug List (NRDL) is main route for public reimbursement of pharmaceutical products in mainland China. In Hong Kong, a special administrative region in China, only the Hospital Authority Drug Formulary is the primary route of public reimbursement. This research compares reimbursement outcomes between mainland China and Hong Kong.

METHODS: Reimbursement outcomes from the NRDL 2022 and the Hong Kong Hospital Authority Drug Formulary (version 23-May-2023) were identified with key information extracted (12-June-2023).

RESULTS: In the NRDL, 2,967 medicines are reimbursed, including 1,381 Traditional Chinese Medicines and 1,586 Western Medicines. In Hong Kong, on the Hospital Authority Drug Formulary, 924 general drugs are fully reimbursed, 403 special drugs are reimbursed with certain conditions, and 107 Safety Net Financial Assistance (SFI) drugs are exclusively reimbursed for patients facing financial difficulties. Notably, among the 111 new entrants in the NRDL 2022, only 39 (35%) are reimbursed in Hong Kong. Out of the 14 new oncology NRDL entrants, only 5 (36%) receive reimbursement in Hong Kong. Among the 7 new rare disease entrants, only 3 (43%) are reimbursed, with Evrysdi being reimbursed under special programmes for individual patients in Hong Kong when no reimbursement restrictions are applied in mainland China.

CONCLUSIONS: The comparison of pharmaceutical reimbursement between mainland China and Hong Kong reveals notable differences, with the NRDL providing broader access, while Hong Kong's coverage appears to be less diverse and more limited, particularly for high-cost drugs. While fewer innovative therapies are reimbursed in Hong Kong, the recent initiative of the Greater Bay Area offering an early access route may present opportunities for companies to explore accelerated market entry, enabling them to enhance market presence and maximize commercial opportunities in the region.

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Acceptance Code:	PT23
Board Number:	5B
Abstract Title:	Is It Possible to Estimate the Welfare Economic Loss to Society of Not Having Value-Based Differential Pricing for Multi-Indication Pharmaceuticals: An Empirical Analysis in Denmark, Norway, and Sweden
Presenting Author:	Lars Holger Ehlers

Abstract Body:

OBJECTIVES: By not having a value-based pricing (VBP) system that can reflect the differential value of pharmaceuticals across different indications, there is a risk that many EMA-approved multi-indication pharmaceuticals will not obtain reimbursement for all indications. Our aim was to evaluate whether it is possible to empirically estimate the welfare loss resulting from the absence of VBP policies for multi-indication pharmaceuticals in Denmark, Norway, and Sweden.

METHODS: We conducted a literature review to identify different types of potential measurable losses to society resulting from not having VBP policies. Three multi-indication pharmaceuticals, manufactured by different companies, with a total of 18 indications were selected for each country (n=54). Data from the national HTA organizations in the three countries (DMC, NoMA, TLV) were used to extract relevant outcomes including national reimbursement, annual number of patients, QALYs, and life years (LYs) compared to existing treatment i.e., the opportunity costs in terms of QALYs and LYs which could have been gained if indications were reimbursement.

RESULTS: We identified different measurable types of loss to society: a) EMA indications not applied for/withdrawn, b) non-reimbursed indications, and c) indications with longer time to reimbursement than average. The preliminary results, based on the three pharmaceuticals' non-reimbursed indications, revealed a total loss of 323 QALYs and 396 LYs per incident annual population in the three countries. Thirteen indications across countries were registered as 'not applied for/withdrawn' while ten indications were registered as still in process

CONCLUSIONS: The results demonstrate that not having VBP policies for multi-indication pharmaceuticals may result in a measurable welfare loss to society in terms of QALYs and LYs lost. However, the societal loss may be associated with other causes as well, emphasizing the need for further research. Implementing VBP policies has the potential to mitigate welfare loss and improve patient access to multi-indication pharmaceuticals.

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Acceptance Code:	PT24
Board Number:	6B
Abstract Title:	Reimbursement Decisions in Ireland; Utilising Text Mining to Assess Factors Contributing to Decision Making
Presenting Author:	Emer Gribbon

Abstract Body:

OBJECTIVES: In Ireland, as part of the Health Service Executive's (HSE) assessments on medicines for reimbursement, medicines undergo price negotiations with the Corporate Pharmaceutical Unit followed by assessment by the HSE Drugs Group. Data mining techniques can be utilised to extract relevant insights from HTA bodies. This research aims to identify factors which influence the Drugs Group decision to reimburse or not reimburse a medicine using a text mining approach.

METHODS: Text data containing the HSE Drugs Group minutes was obtained for a sample of assessments from 2020 – 2022 (n=65). Medicines under consideration were split into two subsamples, reimbursed or not reimbursed. Natural Language Processing (NLP) was utilised in RStudio® and Python® to prepare the data for text analysis. Descriptive text analysis was implemented using Python® to obtain output of the most common words that appear in each subsample to identify factors that influence the Drugs Group's decision to recommend a medicine for reimbursement.

RESULTS: From the 65 medicines, 43 (66.15%) were recommended for reimbursement from the Drugs Group's deliberations. There are similar trends observed across the most frequent words utilised in both positive and negative outcomes at Drugs Group. As expected, "clinical evidence" and "cost effectiveness" appear frequently in both subsamples. "Unmet need" appears frequently in only the reimbursed subsample (0.40 times per medicine), and "price" appears frequently in the not reimbursed subsample (0.54 times per medicine).

CONCLUSIONS: The ability to partake in price negotiations can often result in a medicine's positive recommendation from the HSE. As expected, unmet need and price are important considerations for reimbursement. Cost effectiveness and clinical evidence are likely to influence the Drugs Group's decisions, either way. Further regression analysis is required to understand the extent of which these factors influence decisions at Drugs Group.

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