ABSTRACT BOOK

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EDUCATIONAL PROGRAM TO BRAZILIAN PARLIAMENT DURING COVID-19 PANDEMIC

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The Covid-19 Pandemic in 2020 and 2021 mobilized the society and caused a sudden change in the common life from a social, economic and political point of view. The topic became a major subject in discussions involving politicians, journalists and other professionals. Long reports occupied space in the media. A great gap in knowledge about the development of vaccines and drugs in general, from the preclinical phases to access, was observed. The misinformation and preconceptions about the role of the Pharmaceutical Industry in society became a theme that needed to be urgently clarified. Based on that, SBMF organized a course "Connection with the Parliament for Development", with the support of Interfarma (Association of Brazilian Research Based Industries) and the Brazil - US Business Council. This initiative was tailored for politicians elected and present in the Parliament. Five virtual sessions were planned, every 15 days: 1) From the discovery of new molecules to the regulatory approval; 2) Ethics and regulatory environment; 3) Innovation and intellectual property; 4) Regulatory rigor and safety; 5) Access to medicines in Brazil.

The general population had little knowledge about the main steps needed before authorization to commercialize medicines: the importance of good manufacturing practices in the quality of medicines, the quality of clinical research, from ethical procedures to analysis of results. International and national laws on research ethics and the involvement of regulatory agencies were exposed. The accelerated process of vaccine approval in the exceptional case of COVID-19 pandemic was also addressed. The process of incorporation of drugs into the Brazilian Health System (SUS), the pricing definition, budget impact analysis, and general concepts of access and regulation were explained.

This initiative led by SBMF and Interfarma contributed to increase the transparency of the way medicines and vaccines are developed. Other courses like this were recommended, aimed mainly for journalists and lay public, for elucidation of several little-explored aspects in the development of medicines.

ABSTRACT BOOK

PHARMACEUTICAL MEDICINE

RESULTS OF THE FIRST EDITION OF A MEDICAL INFORMATION IN THE PHARMACEUTICAL INDUSTRY UNIVERSITY EXPERT COURSE IN SPAIN

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OP02

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The MI Working Group (MIWG) of AMIFE (Spanish Association of Medicine of Pharmaceutical Industry) and the University San Pablo-CEU (Madrid) implemented the first postgraduate course on medical information (MI) in pharmaceutical companies (PC) in Spain to close the training gap identified among the MI professionals [1,2] and as an option for graduates with health sciences profile interested in the MI area in PC.

The course, organized into 9 modules, finished in May 2022, and consisted of 100 hours of formal classes, 3 days a week from 5:30pm-8:30pm, both online and face to face, taught by members of the MIWG-AMIFE (n=14) and other prestigious professionals (n=13) in the fields of searching, communicating and analyzing scientific/medical data. Students could apply for 3 months of optional internship in MI areas of PC. Members of MIWG-AMIFE had the option to choose to attend only selected modules.

In total, 20 people from 3 different countries registered and attended the entire course (15 professionals in PC, 1 documentalist and 4 health science graduates). Additionally, 11 MI professionals chose to attend 3 specific modules. All students attended at least 80% of required classes [media (range)]: 93% [80%-100%], and 100% responded the questionnaires submitted to evaluate them. Participants rated 5 (highest score): content structure [media (range)]: 62% [50%-79%], usefulness of training material: 59% [45%-71%], lesson utility: 61% [48%-79%] and teachers' communication skills: 67% [57%-83%]. Five students applied for internships. As positive aspects of the course, participants highlighted: confidence, motivation, and knowledge; they suggested to increase practical work vs. theory classes.

The success of the course encourages to MIWG-AMIFE to plan new editions in which to implement the suggestions proposed by the participants in this first edition.

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ABSTRACT BOOK

THE IMPORTANCE OF LATIN AMERICA IN GLOBAL CLINICAL TRIALS: EXPANDING CLINICAL RESEARCH BEYOND BORDERS

Marlene Teresa Llópiz Avilés

Global Oversight Director for PPD

OP03

The dramatic increase in globalization—especially into conducting more trials in Latin America (LATAM)—may be attributed to greater competition in the USA and European markets; costs, patient recruitment, as well as looking for specific therapeutic indications and the demand for qualified clinical research professionals. The rapid economic growth and improved regulatory processes in emerging and growing regions, partly driven by wider adoption of ICH guidelines and principles are important factors considered.

LATAM has again come into the limelight for pharmaceutical, biotechnological and device studies. Biopharmaceutical and especially biotechnological companies have uncovered new opportunities in Central American, Caribbean, and South American countries.

The current population of Latin America and the Caribbean is 665,407,471, based on the latest United Nations estimates. LATAM and the Caribbean population is equivalent to 8.42% of the total world population. LATAM provides a large drug-naïve patient population with common and specific disease profiles, rapid compliant patient recruitment, motivated and experienced investigators, and USA and EC-equivalent medical standards, as well as highly trained monitoring and project management teams on GCP and ICH guidelines.

Partnering contract research organizations, regulatory businesses, patient recruitment companies and participating NGOs have contributed to conducting international global trials in LATAM. Conducting studies in LATAM provides sponsors with an array of countries for testing drugs, reduced costs for strategic multicenter studies, credible and objective submittals, and highly professional staff members at CROs who are bilingual, graduated in allied health and medical fields, often trained in the USA and Europe.

Large, urban populations in LATAM enable faster enrollment and easier patient follow-up. These populations often see clinical trials as viable healthcare options for gaining access to free medication and closely supervised and specific health care, which leads to high patient retention rates. Quality of data collected is comparable to that from any other country. LATAM is a viable and convenient option for global clinical trial conduction from the “get go”.

ABSTRACT BOOK

REGULATORY SCIENCE, REGULATORY AFFAIRS, ETHICAL, LEGAL, SOCIAL RELATED ISSUES

POST-TRIAL RESPONSIBILITIES, 15 YEARS OF DISCUSSION

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The first request in Brazil for a post-trial access to an investigational medicine was received in 2005 from National Ethics Committee, who required that a new insulin just evaluated in a multicentric international trial should be made available for the patients who still needed the treatment after the end of the study. It appears obvious that if the patient has benefit with the new drug, the treatment should continue. However, how to safely continue the treatment outside of a clinical research environment? How can you be sure the risk does not outweigh the benefit? For how long should the drug be provided? Who would be responsible for monitoring the patients if the trial was closed? Would off-label use be encouraged with this procedure?

The first publications regarding drug access after clinical studies were related to HIV trials conducted in Africa. Vulnerability of study participants was the big concern. The clinical research participation of Brazil sites in multinational trials was growing and this made the issue gain relevance in the country, becoming a valuable case study. Many international and national legislations mentioned the theme but without clarity, leaving room for misinterpretation. Since then, post-trial access has been discussed in some international panels by all clinical research stakeholders (investigators, sponsors, ethics committees, regulatory agencies, and patients). Continued access to experimental medications is indeed one way in which subjects may benefit from research participation but only furnish the drug is not enough. Medical care and follow-up are necessary, creating an additional burden to investigators and institutions, and more important, a confusion between research and clinical care. The evolution of this debate helped us to clarify that, before starting a trial, arrangements should be agreed, in order to plan a responsible transition to clinical care at the end of the research and, in some specific cases, access to the drug must be ensured if no treatment alternatives exist. The debate is still open.

ACCESS TO PEDIATRIC/ADOLESCENT MEDICINAL PRODUCTS IN GREECE

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Background: Access to treatment plays a major role in the provision of quality healthcare. The purpose of the present study was to examine the proportion of applications of medicinal products with pediatric/adolescent vs. adult indications, for inclusion in the Positive Reimbursement List in Greece, during a 4-year period, from 2018 to 2021.

Methods: Data were collected from the European Medicines Agency (EMA) and the Greek Ministry of Health websites, as well as from the Greek Health Technology Assessment (HTA) Committee's database. The dataset included all the medicinal products which received marketing authorization/extension of indication during the study period. Percentages of products with pediatric/adolescent indications were calculated according to their marketing authorization date, their submission to the Greek HTA Committee and their inclusion in the Positive Reimbursement List.

Results: Among 598 centrally authorized medicinal products/or extended indication products by EMA, 35.6% (n=213) included a pediatric/adolescent indication and 64.4% (n=385) were indicated for adults. Only 20.2% (n=43) of all centrally approved medicinal products with a pediatric/adolescent indication had been submitted to the HTA Committee by the end of the study period, from which 25.6% (n=11) have been included in the Positive Reimbursement List. In contrast, 37.9% (n=146) of all products which received marketing authorization or indication extension through the EMA for adults had been submitted to the HTA Committee by the end of the study period, from which 37% (n=54) have been included in the national Positive Reimbursement List.

Discussion: As expected, a greater proportion of medicinal products have been authorized for adults than for younger patients. Furthermore, HTA submission and reimbursement rates are lower for medicinal products authorized for children and adolescents than for adults. The needs of the pediatric/adolescent population should be taken into account in the marketing authorization procedure as well as in the overall HTA process.

ABSTRACT BOOK

EVALUATION OF CONSUMERS' KNOWLEDGE, BELIEFS AND RISK ASSESSMENT REGARDING PROTEIN

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Background: Protein supplements are consumed both by amateur and professional athletes. However, amateur athletes' knowledge, motivations, occurrence of consumption, benefits and potential health risks need to be investigated.

Objectives: This study investigates the state of protein supplements use among athletes in Greece and the sources of information, reasons of consumption and motivation and frequency of use.

Methods: The research was based on a survey. 928 people of random gender and age, of different athletic activities, from all around Greece participated. The questionnaire was shared anonymously both in person and online, mainly on gyms and other athletic fields. It consisted of 37 questions, on demographics, sources of information, regularity of use, purchasing habits, associated risk knowledge and beliefs on supplements. The data were categorized, analyzed using SPSS v15.0.

Results: Most responders were females 64.7% of mean age 27.7 years, whereas males were 35.3% of mean age 29.3 years, respectively. Mainly, they had a normal body mass index (BMI) (66.4%) and an educational level of BSc or higher (61.8%). A quarter of the participants, (24.8%) were consuming protein supplements and the majority were men. The main factor of use was the real action of this product, that means raise muscle mass (60%). In addition, users of protein supplements followed essentially Mediterranean diet (32.4%), while they also consumed other supplements such as vitamins, amino acids, carbohydrates, and creatine supplements. It was found that the most common source of information was the internet (70.4%), whereas 59.6% of consumers considered them as safe and of good quality and 47% of them preferred purchasing online due to lower costs. Regarding the form of protein supplements, powder was the first choice (90.9%). Furthermore, half of users utilized the supplements more than 2 times per week and after exercise. Finally, side effects have been observed in 6.3% of consumers.

PP01

Conclusions: Because of inappropriate information and products' wrong labelling, the majority of youth might be led to unwanted results with the consumption of protein supplements. That is why further education of athletes and coaches for responsible purchasing and use would be necessary.

ABSTRACT BOOK

HOW THE PHARMACEUTICAL MEDICINE WORLD WAS AFFECTED BY THE COVID-19 PANDEMIC: A LOOK BACK

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PP02

Global Oversight Director for PPD

On March 11th, 2020, the World Health Organization (WHO) announced the start of a pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus and disease were first identified in December 2019 in Wuhan, China – spreading rapidly worldwide.

The number of cases and deaths continued to rise rapidly in the following months, requiring countries to respond in an escalated way, as well as take action as soon as possible. Such actions were to help delay the pandemic, giving healthcare systems time to prepare and assimilate the impact. However, the virus was much faster and rampant.

Irrespective of the disease's trajectory in each country, there were several actions that needed to be taken. There was no one-size-fits-all approach across the world. The past two years have been full of incongruities occurring at all levels of health organizations, companies, governments, people, paradoxes and absurdities. Was / is COVID-19 a common enemy? Are we still at its mercy? In some ways it is or has been, and we are somewhat still at its mercy. However, each country has approached the pandemic differently, following their own timelines; facing difficulties with previously established budgets; and tackling the problem as swiftly as possible—although they had never contemplated or experienced this emergency. Was/is there worldwide solidarity? Were the pharmaceutical companies part of that solidarity? It is often said that confusion is often but a first step towards clarity. The world is/was/has been confused. Are we still confused? Have all our questions been answered? Far from it.

This presentation will cover the changes that were required to be made by the pharmaceutical medicine world in terms of the pandemic and how our lives have been at COVID-19's mercy and spread. It will also include a look at returning to "normality" —from home-based offices, family tragedies and losses, adjusting to new modalities of lifestyles and communications to hybrid conferences and meetings, companionship and new work scenarios. Included also will be pharmaceutical medicine development, vaccine strategies, worldwide collaborations, and continuous unity for a better place and life and overcoming an enemy never thought would exist.

ABSTRACT BOOK

PATIENT SAFETY & PHARMACOVIGILANCE

FIRST-LINE TREATMENTS FOR KIDNEY CANCER AND SECOND-LINE TREATMENTS FOR UROTHELIAL CANCER: SYSTEMATIC REVIEW, META-ANALYSIS OF SAFETY, COST ANALYSIS

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Background: Immune checkpoint inhibitor (ICI) combinations are currently first-line treatment options for clear-cell renal cell carcinoma (ccRCC). Moreover, ICIs are recommended for platinum-refractory urothelial carcinoma (PRUC). ICIs have been associated with a new type of toxicity, immune-related adverse events (AEs).

Aim: To compare the safety of first-line treatments for ccRCC and second-line ICIs versus chemotherapy for PRUC. Also, to estimate the economic impact of first-line ICI combinations for ccRCC, on the Greek National Health System (ESY).

Methods: CENTRAL, PubMed and clinicaltrials.gov were searched to identify randomized controlled trials (RCTs) with safety outcomes for the treatments studied. Review Manager software was used for statistical analysis. For the economic analysis, data were collected from the Price Bulletin of Medicines for Human Use.

Results: Nine RCTs were selected for the systematic review of ccRCC and two for the systematic review of PRUC. The meta-analysis of first-line treatments for ccRCC suggests that ICI combinations have a lower risk of "treatment-related AEs" than sunitinib (OR=0.53, 95%CI:0.38-0.73). The meta-analysis of second-line regimens for PRUC suggests that ICIs have a lower risk of "AEs" than chemotherapy (OR=0.32, 95%CI:0.17-0.60). The economic analysis estimated that pembrolizumab+axitinib included an additional cost of 55,154.74€ per patient per year compared with nivolumab+ipilimumab, for first-line treatment of patients with ccRCC, and an additional cost of 64,575.65€ per patient for the median progression-free survival of each treatment for the intermediate- and poor-risk population.

Conclusions: First-line regimens for ccRCC that include ICIs seem to have a lower risk of AEs than sunitinib. The ICIs, atezolizumab, pembrolizumab, seem to have a lower incidence of toxicity than chemotherapy in patients with PRUC, but more studies need to be conducted for safer conclusions. ESY expenditure seems to be lower with nivolumab+ipilimumab compared to pembrolizumab+axitinib for patients with ccRCC, without taking into account rebates applied.

ABSTRACT BOOK

PHARMACEUTICAL MEDICINE

EARLY SELECTION OF ORAL FORMULATION ACCEPTABILITY WITH A SCIENTIFICALLY SOUND COMPOSITE ENDPOINT ASSESSMENT METHOD – AN EFFICIENT STRATEGY TO OPTIMIZE PAEDIATRIC MEDICINES DEVELOPMENT

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Introduction: Paediatric medicine development needs to be facilitated and shortened. Justification of the formulation selection is a challenging element in paediatric development negotiations with authorities as no—scientifically sound, with broadly recognised acceptability—assessment methods exist.

Objective: Enabling frontloading of oral formulation selection with a standardised, statistically sound acceptability assessment method before entering the paediatric efficacy and safety studies.

Methods: In statistically powered paediatric patient studies with placebo-containing oral formulations, performed with standardised investigator-observed assessment methods and defined evaluation criteria for swallowability and palatability in children, statistically significant differences between the acceptability of several oral formulations were detected (Klingmann et al. [1-6]). To further strengthen discrimination, a new composite endpoint acceptability method was established combining a deglutition score and palatability assessment. The data from studies [5,6] investigating mini-tablets, oblong tablets, orodispersible films and syrup were used to evaluate the suggested acceptability assessment tool for the composite endpoint and to demonstrate its validity, expediency and applicability. A factor analysis was applied for each formulation and the results for acceptability defined as composite endpoint were calculated for the different formulations. Each outcome category of acceptability was then related to the outcome of the factor analysis as expressed by the linear combination for the main component.

OP07

Results: A high association between acceptability categories and the results from factor analysis was recognized. Comparison of the acceptability categories with regard to the main component by analysis of variance yielded a p-value < 0.0001. All formulations showed highly consistent results.

Conclusion: The suggested acceptability as composite endpoint can be regarded as a valid approach representing the result of the factor analysis and providing high validity and reliability of the suggested approach for assessing acceptability as composite endpoint. It is highly suitable and efficient to select different preferences of oral formulations before entering indication-specific efficacy or safety studies.

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ABSTRACT BOOK

REGULATORY SCIENCE, REGULATORY AFFAIRS, ETHICAL, LEGAL, SOCIAL RELATED ISSUES

GAPS AND CHALLENGES RAISED BY THE DIGITAL TECHNOLOGY USE IN THE PHARMACEUTICAL INDUSTRY

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Pharmaceutical companies have been challenged either with regards to the rising development costs or the satisfaction of the need to discover new approaches in differentiating the candidate drugs. Digitalization has been spreading with a rapid pace throughout Europe affecting both healthcare and pharmaceutical sectors. Recent advances in digital health technology, including wearables, sensors, in-home clinical devices, have given space to several data endpoints leading these devices to be proved as a valuable tool in clinical trials' programs of the modern era. Specifically, vast amounts of data are being collected, processed and analyzed, coming either from the phase of development and production of medicines or from patient treatments and its subsequent outcomes. Due to covid-19 pandemic and social distancing measures, a huge demand in alternatives for in-person care, including virtual trials, telemedicine and remote patient monitoring, has been promoted, as multiple stakeholders seemed to be benefited at a wide range. Therefore, there is an urgent need for the "capitalization" of pharma industry in the new digital era of healthcare and for the integration of digital technologies across its value chain, contributing to the overall support of its clients. However, several issues, emerging from the digital transformation in healthcare, need to be tackled. Despite the offered opportunities, this study aims to address the gaps and challenges raised by the digital technology use in drug developers, being gathered from a philosophical perspective.

ABSTRACT BOOK

RWD / REAL WORLD EVIDENCE/ BIG DATA/ PHARMACOEPIDEMIOLOGY

REAL-WORLD DATA STUDY ON THE USE OF PSYCHIATRIC DRUGS IN GREECE: INVESTIGATING THE IMPACT OF COVID-19 PANDEMIC IN MENTAL HEALTH

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Background: The outbreak of COVID-19 pandemic had a severe psychological impact on the Greek population due to the fear of COVID-19 disease, death, the social isolation, and the extended periods of quarantines during the period 2020-2021.

Aim: The significant negative impact of COVID-19 pandemic crisis on the mental health of Greeks has enforced the execution of a study focusing on psychiatric drugs' (antidepressants (N06A), anxiolytics (N05B) and hypnotics/sedatives (N05C)) consumptions and the investigation of the mental disorders being responsible for this.

Methods: We analyzed community pharmacies' sales data of 31 psychiatric medicines, provided by the IQVIA HELLAS database, to calculate their annual consumption for the years 2019 and 2020, expressed in "Number of Daily Doses (DDDs) per 1,000 inhabitants per day". Furthermore, for the same time period, we estimated their use per diagnosis of mental disorder (ICD-10 codes) using the National Organization of Health Care Provision (EOPYY) database.

Results: The consumption of antidepressants, anxiolytics and hypnotics/sedatives increased in 2020 compared to 2019 by 7.2%, 8.1% and 2.6%, respectively. In 2020, the highest use (51,6 DDDs/1,000 inhabitants/day) was observed for the selective Serotonin Reuptake Inhibitors (N06AB) and more specifically for the active substance escitalopram (N06AB10). Regarding anxiolytics, benzodiazepines (N05BA) showed the highest consumption (37.3 DDDs/1,000 inhabitants/day) in 2020. Alprazolam (N05BA12) was the most widely prescribed medicine and recorded an increase of 13,6% from 2019 to 2020. Furthermore, by analyzing the reason of these psychiatric drugs' prescriptions, it was found that Depressive disorders F32 and F33, Other anxiety disorders (F41) and Sleep disorders not due to a substance or known physiological condition (F51) were the most common diagnoses on the prescriptions of psychiatric drugs. Finally, the number of patients with Anxiety disorders (F41), who received anxiolytics and sedatives/hypnotics was increased 5% and 3% respectively from 2019 to 2020.

Conclusions: We observed an increasing trend in the consumption of antidepressants, anxiolytics, and hypnotics/sedatives during the COVID-19 pandemic (2020) compared to pre-pandemic period (2019). Moreover, we observed that four mental disorders were the main reason for the higher consumption of psychiatric medicines.

ABSTRACT BOOK

TRANSLATIONAL RESEARCH & PRECISION MEDICINE

VALUE CREATION IN CELL AND GENE THERAPIES FROM A HEALTH-ECONOMIC PERSPECTIVE

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OP10

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Background: Cell and gene therapies (CGTs) are highly specialized one-time technologies with curable potential targeting rare diseases, previously difficult-to-treat, or untreatable diseases.

Objective: The scope of this study was to promote objective value assessment of CGTs by investigating three rare diseases: spinal muscular atrophy (SMA), hemophilia A (Hem A), and sickle cell disease (SCD).

Methods: A systematic review of reports published between January 1, 2000, and September 30, 2021, was conducted on PubMed. For the set criteria 25 eligible studies on 17 interventions were found.

Results: Hem A with inhibitors (for patients developing inhibitors against rFVIII) reported the highest SOC costs: While lifetime cost-estimates per patient reached up to USD 99.21 million for SOC with BPA Prophylaxis (at 21.28 LYs, 15.21 QALYs), they were only USD 9.27 million for intervention with Hypothetical Gene Therapy (at 21.28 LYs, 15.41 QALYs), generating per-patient-cost-savings of roughly USD 90 million in favor of the US health system. Cost-savings per patient without inhibitors were less but still reached up to roughly USD 9.8 million (rFVIII Prophylaxis $23.47m vs $13.69m for Valoctogene Roxa-parvovec gene therapy [at 23.56 LYs, 17.31 QALYs vs 26.53 LYs, 19.09 QALYs, respectively]). Similarly, in SCD the per-patient cost-savings with CGTs reached up to roughly USD 6.4 million (Hydroxyurea $8.75m vs $2.37m hypothetical gene therapy [at not reported LYs/QALYS vs 26.4 LYs, 29.9 QALYs for gene therapy]). Finally, in SMA, CGTs generated cost-savings of roughly up to USD 2.4 million per patient (Nusinersen $6.32m vs $3.93m gene therapy Onasemnogene Abeparvovec [at 7.11 LYs, 5.29 QALYs vs 20.09 LYs, 13.33 QALYs, respectively]), see Table 1.

Conclusion: The results demonstrate that CGTs are significantly less expensive (up to $90m per-person) compared to lifelong chronic SOC treatments while generating significantly more health gains (SMA: +14.18 LY/+12.18 QALYs, BSC vs Onasemnogene).

ABSTRACT BOOK

MEDICINAL PRODUCTS ASSESSED BY THE HEALTH TECHNOLOGY ASSESSMENT COMMITTEE IN GREECE OVER 4 YEARS (2018-2022)

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Objectives: The purpose of the present study was to evaluate the type of medicinal products and the pace of recommendations issued by the Health Technology Assessment (HTA) Committee in Greece over 4 years, from its establishment in 2018 until 2022.

Methods: Data regarding new medicinal products/extensions of indications were collected from the HTA Committee's database and other publicly available sources. Analyses were carried out with respect to the legal basis of approval of the medicinal products. A secondary analysis by ATC1 level was also performed.

Results: During the study period, 140 new active substances, 37 orphan medicinal products, and 44 vaccines/biosimilars were submitted to the Greek HTA Committee. Another 92 applications referred to known/well established/hybrid products, whereas 36 applications pertained to fixed combinations. Most medicinal products belonged to the category of antineoplastic and immunomodulating agents (ATC-1 L) (25.98%) followed by alimentary tract and metabolism agents (ATC-1 A) (14.2%). Total recommendations during the study period were 216 (36.1%, 29.2%, 18.1%, 10.6%, and 6%, for new active substances, known/well established/hybrid products, biosimilars/vaccines, fixed combinations, and orphans, respectively).

Conclusions: The majority of HTA recommendations referred to new active substances, with antineoplastic and immunomodulatory effects. These findings corroborate the products' assessment plan outlined in the European HTA regulation and underline the emergence of the new era of immuno/oncology treatments.

ABSTRACT BOOK

TRANSLATIONAL RESEARCH & PRECISION MEDICINE

HEALTH TECHNOLOGY ASSESSMENT OF TWO CAR T-CELL-BASED THERAPIES, TISAGENLECLEUCEL AND AXICABTAGENE CILOLEUCEL, FOR THE TREATMENT OF PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA AND RELAPSED OR REFRACTORY LYMPHOMAS

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Background: Most European countries have adopted Health Technology Assessment (HTA) practices to support decision-making processes in health care at a policy level. Two CAR T-cell therapies have been recently approved in Greece for the treatment of patients with acute lymphoblastic leukemia (ALL) and relapsed or refractory lymphomas (DLBCL, PMBCL), tisagenlecleucel and axicabtagene ciloleucel.

Aim: To study the phase III clinical trials on which the approval of the CAR T-cell therapies was based, and critically evaluate the benefits and risks of both treatments. Also, to estimate the total cost of CAR T-cell treatment in Greece and review reimbursement schemes, proposed or implemented by health organizations worldwide, and to propose a suitable reimbursement model for Greece.

Methods: Efficacy and safety data on tisagenlecleucel and axicabtagene ciloleucel from EMA evaluation reports and published clinical trials were collected. Completed studies were assessed for the magnitude of clinical benefit of each therapy (ESMO-MCB scale) and the risk of bias (Cochrane Collaboration tool). Finally, the cost of each therapy was estimated.

Results: Only 7 of the 49 clinical trials found in the literature had published results. ALL patients showed a positive response to treatment (ORR 33.9%-81.3%), but ultimately the magnitude of the clinical benefit was moderate (Grade 2) and the clinical trials were of low quality. The cost of therapy per patient for ALL with tisagenlecleucel, and DLBCL or PMBCL with axicabtagene ciloleucel, was estimated to be high, but comparable (295,282.47€ and 286,260.78€, respectively). The lowest cost was for DLBCL treatment with tisagenlecleucel (278,815.24€).

ABSTRACT BOOK

Conclusion: Both CAR T-cell therapies provide an important actual clinical benefit and a moderate improvement in added benefit over conventional chemotherapy regimens. Outcomes-based staged payments, in line with other European countries, may be the most acceptable reimbursement approach for these therapies in Greece. Despite their high cost these health benefits might be cost effective.

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