Objectives: This systematic literature review aims to: (i) review strategies that have been applied and/or tested for minimizing the nocebo effect in clinical practice, within and outside the context of biosimilar switching, and (ii) propose recommendations for effective mitigation strategies to minimize the nocebo effect in the context of biosimilar switching. ***Methods:*** Biomedical databases PubMed and Embase were screened up to end of April 2023 with a search string consisting of the following search terms "nocebo", "biosimilar", "mitigation", "strategy", and "prevention" and related synonyms. The search strategy was supplemented by snowballing of the included studies. The quality of the studies was assessed using the Joanna Briggs Institute Critical Appraisal Checklist for Systematic Reviews and Research Syntheses, the Scale for the Assessment of Narrative Review Articles, and the Mixed Methods Appraisal Tool. ***Results:*** Out of 1617 screened records, 60 met the inclusion criteria. Among these, 10 (17%) were conducted within the biosimilar switching context, with seven testing specific mitigation strategies. Among the remaining 50 studies conducted outside the biosimilar switching context, 46 tested mitigation strategies. In total, 13 distinct mitigation strategies were identified, which can be employed within the context of biosimilar switching: (i) open non-verbal communication, (ii) positive framing, (iii) empathic communication, (iv) validating communication, (v) shared decision-making, (vi) self-affirmation, (vii) education of patients and healthcare professionals about the nocebo effect, (viii) education of patients and healthcare professionals about biosimilars, (ix) soft-skills training for healthcare professionals, (x) personalized information, (xi) supporting information, (xii) multidisciplinary approach, (xiii) organization of the switch. ***Conclusions:*** This review has identified a comprehensive set of strategies to mitigate the nocebo effect, which can be applied by healthcare professionals in the context of biosimilar switching. We suggest implementing a combination of mitigation strategies for patients and healthcare professionals to utilize before, during, and after a switch.

HPR65
DECISION-MAKING IN NICE, SMC, AND NCPE: ASSESSING TIME FROM REGULATORY APPROVAL TO HTA DECISION OUTCOME

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Objectives: Health Technology Assessments (HTA) on new medicines are conducted in Ireland by the National Centre for Pharmacoeconomics (NCPE) and in the UK by the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC). This research aims to evaluate the variations in time from market authorisation (MA) to the publication of HTA outcome across the three assessment agencies in Ireland and the UK. ***Methods:*** Regulatory approval data and HTA outcomes from publicly available sources including the NCPE, SMC, NICE, European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) websites were collated in Excel®. A sample of 48 medicines with a HTA submitted to all three assessment agencies (NCPE, NICE and SMC) were identified between 2022 and 2024 and selected to assess the time to HTA outcome from original MA. For NICE and SMC, where the MA predates the MHRA conversion, the original EMA authorisation date is utilised. ***Results:*** The average time to HTA outcome from original MA was 1247.3 days for NICE, 1252.1 days for SMC, and 1652.3 days for NCPE. The proportions of outcomes below 1247.3 days were 46.94% (NCPE), 61.22% (NICE) and 55.10% (SMC). Similar cyclical patterns were observed for NCPE and SMC, which differed from NICE. ***Conclusions:*** Time to HTA outcome from original MA in Ireland is significantly longer than that of the UK, taking on average 4.5 years in Ireland compared to 3.4 years in the UK. The results for NICE are longer than expected, due to the utilisation of original MA for medicines. Potential factors further influencing these results include the mandatory NCPE Rapid Review (RR) submission, the ability for NICE processes to commence pre-regulatory approval, and the different regulatory bodies between the jurisdictions as of 2021. Further analyses will include more data and MA extensions, where appropriate.

HPR66
READINESS ASSESSMENT FOR CERVICAL CANCER ELIMINATION IN EUROPE

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Objectives: Human papillomavirus (HPV) is a well-established cause of cervical and other cancers. The World Health Organization (WHO) and European Commission released strategies and recommendations to facilitate cervical cancer (CC) elimination with a special focus on broad HPV vaccination, screening, and CC treatment availability, program implementation, and surveillance systems. We intended to assess readiness of 31 European countries to eliminate CC by defining status of programmes and policies, implementation, and existing data systems essential for decision-making. ***Methods:*** The scoring framework used for this assessment comprised of three domains: vaccination, screening, and treatment, each comprising of two subdomains: decision- making and implementation. Countries were assigned scores based on availability of predefined parameters and tiered into one of four archetypes: low readiness (0-25% of maximum points collected), moderate-low readiness (26-50%), moderate-high readiness (51-75%), and high readiness (76-100%). ***Results:*** Sweden, Ireland, and the United Kingdom achieved the highest overall scores, demonstrating the highest readiness for CC elimination (93%, 89%, and 87%, respectively). Western countries generally outperformed Eastern European countries, with Bulgaria, Cyprus, and Greece showing lowest readiness. Vaccination domain scores were generally higher than screening and treatment domain scores with Sweden, Portugal, and Ireland showing highest readiness (91%, 88%, and 88%, respectively) and Czechia, Greece, Croatia, Poland, and Bulgaria showing lowest (50%). Across all three domains, countries generally scored lower across the implementation subdomain compared to the decision-making subdomain. One third of countries have limited/no vaccination and screening uptake monitoring systems or publicly reported rates essential for informed decision-making. ***Conclusions:*** Our assessment highlights the diversity in decision-making and implementation of vaccination, screening, and treatment programmes across European countries. This framework illustrates current progress and highlights key areas for improvement to strive towards CC elimination as a public health problem.

HPR67
GLOBAL ASSESSMENT OF PRE-MARKET APPROVAL PATHWAYS FOR MEDICAL DEVICES: HIGHLIGHTING THE NEED FOR HARMONIZATION ACROSS 55 JURISDICTIONS

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Objectives: The objective of Pre-Market Approval Pathways (PMAP) for medical devices (MDs) is to guarantee MD safety and efficacy through generation of robust clinical evidence. As part of the Harmonised Approach to Early Feasibility Studies for Medical Devices in the European Union (HEU-EFS) project funded by IHI, this study aims to identify the key PMAP features that sponsors must consider when applying for pre-market clinical investigation approval in different jurisdictions. ***Methods:*** A comprehensive database (DB) on PMAP was developed through systematic review of public sources. Data collected includes information on national legislation, procedures and rules (required documentation, timelines, language of submission, fees, reimbursement of investigational devices), existence of performance monitoring system, stakeholder involvement. PMAP-DB covers 55 countries (27EU+3EEA+25non-EU). A comparative analysis of approval pathways was conducted. ***Results:*** Data collection revealed high availability of information: national reference legislation was found in 53 countries (96.4%) and links to designed competent authority websites were universally available (100.0%). Submission procedures range from 1 to 6 across jurisdictions depending on class risk and other MD characteristics. Approval pathways are heterogeneous in terms of modes of sponsor-competent authority interaction, requirements, testing, documents, approval times and submission fees. The submission (of all or some documents) is permitted in English in almost all countries. Public databases for pre-market clinical investigations were found in only 17 countries (30.9%), performance monitoring systems in 5 (9.1%). Reimbursement of investigational devices is allowed in only 2 jurisdictions (3.6%). Stakeholder involvement (HTA bodies, patients, expert panels) in the design of pre-market clinical investigations was reported in only one country. ***Conclusions:*** The significant variability in PMAP features across jurisdictions highlights the need for urgent harmonization to streamline global market access for medical devices. Improved alignment and standardization of approval pathways will facilitate more efficient and consistent regulatory processes, benefiting both sponsors and patients worldwide.