SFI Public Service Fellowship 2023

1. **Name of Governmental Department or Agency**
Health Products Regulatory Authority
2. Title of the Project
HPRA1 The effectiveness of regulatory recommendations on risk management of medicines safety issues and impact on healthcare practice in Ireland
3. Description of the Project
A key aim of pharmacovigilance is to optimise the safe and effective use of medicines through the provision of evidence-based recommendations to healthcare professionals and patients to minimise risk. Through the EU system of pharmacovigilance, national competent authorities such as the HPRA, coordinated by the European Medicines Agency (EMA), oversee the assessment of the benefits and risks of medicines throughout the product lifecycle, with proactive planning and management of risks from the time of first authorisation through to use in clinical practice. For each authorised medicine, there is a risk management plan, through which there is proactive planning to reduce the burden of adverse reactions on patients and to optimise clinical benefit. Typically, risks relating to medicines are adequately addressed using routine risk minimisation measures, such as information and advice contained in product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)), packaging or labelling, and through the method of sale and supply (e.g. prescription-only). However, when routine measures alone are not considered sufficient to address an important safety issue for a particular medicine, additional risk minimisation measures are recommended as a complement to product information. Additional risk minimisation measures focus on the most important, preventable risks, with the feasibility and impact on the health system of implementing additional risk minimisation carefully balanced with the anticipated benefit for patients. Additional risk minimisation measures can include Direct Healthcare Professional Communications (DHPCs) and/or educational materials. DHPCs are used to deliver important safety information directly to a healthcare professional (HCP). The pharmaceutical company that holds the licence for the medicine, following approval by the HPRA, distributes DHPCs in Ireland. All DHPCs are published on the HPRA website. Educational materials then usually focus on one or more specific safety concerns (e.g. hepatotoxicity, cardiovascular risk, teratogenicity) related to use of that medicine, and provide clear information on the nature of the specific risk(s) and actions required to prevent and/or minimise the

risks, thereby optimising the risk-benefit balance for patients. Educational materials and tools may be intended for HCPs (e.g. doctors, pharmacists and nursing staff) and/or be made available to HCPs to provide to patients and caregivers.

Examples of educational materials for HCPs include healthcare professional guides, dosing and administration guides, prescriber checklists and monitoring charts. These may outline considerations before prescribing, e.g. prescriber checklist for combined hormonal contraceptives (to minimise the risk of venous thromboembolism), or the prescriber guide for valproate (to advise on pregnancy prevention and mitigate risk of exposure in utero).

Research into the effectiveness of such tools plays a fundamental part in medicines risk management and can inform the need for new or amended measures, as well as identifying when specific tools may no longer be needed.

Available research, including that conducted nationally, indicates that awareness and knowledge of specific tools, and of regulatory risk management approaches generally could be improved. There are gaps in the understanding of the factors which impact a HCPs awareness and knowledge of these issues and the barriers to this. Understanding of how measures could be more effectively implemented is also lacking.

The purpose of this project would be to evaluate awareness, knowledge, preferences for regulatory risk communications, as well as perspectives on factors relevant to behavioural change of HCP groups, in relation to HPRA communications, including DHPCs and Educational materials.

4. **Project Scope**
Medicines risk management as set out above.

5. **Skills/Expertise Required**
• Life science or healthcare professional background. • Experience in developing and conducting surveys. • Data analysis and write up skills.

6. **Expected Outputs of Project**
• Identify key perceived or actual barriers to knowledge, awareness and implement of additional risk minimisation measures. • Consider impact for existing regulatory policy and procedures for regulatory risk management and communications nationally and propose recommendations for revisions, as appropriate. • Consider appropriate initiatives to increase awareness and knowledge amongst key target groups. • Understanding of key factors that impact behavioural change in the health care setting in Ireland.

7. **Working Arrangements**
Hybrid – HPRA offices are located at Earlsfort Terrace, Dublin 2

8. **Expected Timeline**
12-months part-time (3 days per week- 21 hours)
9. **Contact Details**
Sinead Curran, Director of HPM