

SFI Public Service Fellowship 2023

1. Name of Governmental Department or Agency
Health Products Regulatory Authority
2. Title of the Project
HPRA2 The identification and evaluation of supply chain vulnerabilities and their role in the risk of human medicine shortages which impact public health
3. Description of the Project
<p>The World Health Organisation recognises medicine shortages are a global problem. They represent an increased focus for governments given their potential public health impact.</p> <p>Whilst supply chains extend beyond finished product manufacturing, in addition to global integration, manufacturing and quality issues account for over 60% of shortages in Ireland.</p> <p>This project aims to further elucidate supply chain vulnerabilities and dependencies in the Irish health system context with a view to focusing on actions to increase supply chain resilience as part of a focus on medicine supply chain security in the Irish context.</p> <p>The project aligns at a point of European focus for Medicines Supply and Access. The European Commission has published (26th April 2023) its proposal for the revision of the general legislation for human medicines. The proposal aims to implement strategic objectives identified in the Pharmaceutical Strategy for Europe published by the European Commission in November 2020, a main strand of which is 'Security of Medicines Supply' which deals specifically with the prevention and management of medicines shortages. Continuing to objectively and accurately define key issues through measurement and analysis at this time is of key strategic and tactical importance, both at a national and European level in the improvement and correction of challenges.</p>
4. Project Scope
<p>The main tasks of the project will be:</p> <ul style="list-style-type: none"> • Task1: Analysing high impact shortages to identify their supply chain dependencies and vulnerabilities. • Task 2: Analysing potential commonalities in the root causes of shortages, quality defects and manufacturing deficiencies to identify potential areas of future focus leading to more resilient supply chains. • Task 3: Identifying potential medicines within therapeutic groups for which there are significant structural vulnerabilities with a view to developing, in collaboration with key stakeholders, a health system approach to ensure systemic health system resilience should a

shortage of one product occur.
5. Skills/Expertise Required
<ul style="list-style-type: none"> - Life science or healthcare professional background. - Strong research and analytical skills with excellent attention to detail. - Excellent communication and interpersonal skills.
6. Expected Outputs of Project
<p>The expected outputs of the project are:</p> <ul style="list-style-type: none"> • Identification of supply chain vulnerabilities and dependencies relating to medicines supplied to Ireland with a view to increase supply chain resilience and security. • Recommendations for areas of future regulatory focus with regard to decreasing manufacturing and quality issues. • Development of a health system approach to ensure resilience for medicines in therapeutic groups with identified significant vulnerabilities.
7. Working Arrangements
Based in the HPRA offices (Earlsfort Terrace, Dublin 2), using hybrid working arrangements.
8. Expected Timeline
12 month timeline; full time.
9. Contact Details
Darren Scully, Medicine Shortages and Borderline Classification Manager