HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Pharmacovigilance Risk Communication & Assessment (PvRCA) Manager - Human Products Monitoring (HPM)

ROLE SUMMARY

The Human Products Monitoring (HPM) department of the HPRA is responsible for post-market surveillance activities and operating a system of pharmacovigilance to fulfil tasks associated with monitoring the safety of authorised health products, including medicines and vaccines, and for detecting any change to their risk-benefit balance. The department also has a number of vigilance responsibilities associated with investigational medicinal products, blood/tissues and cells and organs (BTO).

The PvRCA manager is a new post being introduced to the HPM department to enable delivery on the HPRAs strategic plan, and in particular our goals to strengthen partnerships with the health system and to develop our approach to patient/public engagement, as it relates to medicines safety issues and national risk management.

Reporting to the Director of HPM, the PvRCA manager will establish and manage a new section within the HPM department. They will lead our communication and engagement strategy with health care professionals, the health system, academia, patient/public organisations and industry to promote the role of HPRA in safety monitoring and risk management of medicines in clinical use. This includes advocating for the adoption and implementation of important safety recommendations, and ensuring the needs of the Irish health system and the public are fully integrated into our national risk management assessment approach.

The PvRCA manager will also provide leadership, motivation, encouragement and effective management for their team as well as more broadly across the department and organisation by ensuring development and maintenance of a positive working environment. The PvRCA manager will be a member of the HPM leadership team, as well as part of HPRAs section management level, who together develop and deliver our strategic, operational, people and quality goals, working collectively to achieve the HPRAs mission and vision.

The post will suit an individual passionate about the role of medicine safety and risk management in public health protection, with an outward facing perspective and particular interest in communications and stakeholder engagement. In establishing a new section, the post holder will be involved in a significant change management programme, with the objective of delivering on our strategic goal to develop regulatory approaches to how we engage with stakeholders on medicine safety issues. The post holder will be a leading voice in the HPRA and Ireland on medicines safety issues, and will be responsible for building relationships at a senior level across stakeholders and for raising the profile of HPRAs role in safety monitoring and risk management. This dynamic role will require drive and tenacity, excellent decision-making and influencing skills, with an ability to build relationships and to design innovative processes and systems in line with developing scientific approaches.

KEY RESPONSIBILITIES

- Representing the HPRA to senior leadership across the health system and learned societies, building meaningful relationships that can advance HPRAs strategic plans, and work towards a cohesive and joined up response to adoption of regulatory advice on risk management of medicine safety issues.
- Ensuring HPRAs role in safety monitoring of medicines in clinical use is promoted across the health system, including as part of the HPRAs education policy and as part of outreach and engagement and proactively seeking opportunities to present and engage with relevant key stakeholders.
- Developing intelligence and relationships across key partners in relation to above, including building on novel partnerships and approaches to support a coordinated and cohesive response to medicine safety issues.
- Developing national approach to evaluating effectiveness of risk minimisation, building existing academic partnerships and the role of HPRA as a collaborator.
- Leading the response to HPM related media queries and engagements, together with HPRA corporate communications team.
- Developing the approach to risk minimisation nationally, from communication to implementation, taking account of relevant advances in the area of risk management and implementation science.
- Ensuring up-to-date awareness and knowledge of Irish health system practices and regard to same during national assessment of risk management approaches.
- Overseeing evaluation of educational materials and DHPCs, including engagement with licence holders and health system partners to improve and develop distribution modalities and systems in line with technical advices and with due regard to GDPR.
- Following up post PRAC as appropriate with the health system/HCPs to raise awareness of new safety advice.
- Embedding patient engagement as part of the national risk minimisation evaluation system and processes including development of appropriate methodologies (e.g. in development of patient facing educational materials).
- Facilitating clinical readiness in relation to new medicines with significant risk minimisation requirements.
- Responsibility for HPRAs Drug Safety Newsletter, including developing the communication modalities and styles used.
- Assisting in the coordination of the HPRAs patient forum, leading on topics related to medicine safety and risk management.
- Working with VGA and PV sections to ensure coordinated approaches as regard to communication and engagement activities.
- Working across monitoring functions within the HPRA, including Compliance and Medical Devices to find synergies and ensure consolidation and efficiency in approaches and cohesiveness for external stakeholders.
- Ensuring appropriate representation at relevant European, international and national committees/ working groups, including communication, follow up and implementation on any relevant issues that may arise.

- Ensuring appropriate liaison with pharmaceutical industry in relation to the provision of guidance and case assessment follow up/outcomes.
- Managing the overall performance of the PvRCA section, ensuring the delivery of service which meets best international practice both for scientific robustness and customer service, and for leading on implementation of any relevant reform measures or change initiatives, in line with HPRA organisational strategy.
- Maintaining effective working relationships with other HPM sections, including the vigilance assessment and pharmacovigilance sections, as well as other departments, in particular with staff of other departments within the human medicines function (HPAR and Compliance).
- Ensuring appropriate levels of communication, integrated planning of resources, achievement of joint objectives and contributing to the development of an overall strategy for the department.
- Leading staff through a significant change and development initiative in establishing the new section and more generally to make effective contributions to development of systems, processes, resources and capabilities to ensure effective and timely implementation of new legislation and Good Vigilance Practices (GVPs).
- Contributing to the strategic, operational, performance and quality leadership across the HPRA as a member of the HPM leadership team and as a HPRA section manager.
- Performing other such duties as the HPRA may reasonably be required.

QUALIFICATIONS AND EXPERIENCE

- The successful candidate must have:

    - A relevant degree in any one of the following areas: medicine, pharmacy, pharmacology or another relevant healthcare or life sciences discipline.
    - Significant experience (e.g. 5 years) of working in a clinical, pharmacy, vigilance, regulatory or health system setting, for example, a regulatory authority, government authority, pharmaceutical company, academic or clinical setting.
    - Demonstrated leadership capability in establishing and building relationships with external stakeholders to focus on common goals and deliver on results.
    - Demonstrated capacity of working collaboratively with multidisciplinary teams both cross-organisational and externally identifying solutions to address complexity in a solution focussed manner.
    - Excellent communication skills, oral and written.
    - Demonstrated ability to lead and manage a team(s).
    - Working knowledge of relevant EU and national legislation relating to medicines, and understanding of risk management principles and their application in healthcare delivery.
    - A self-starter, with developed influencing, negotiation and decision-making skills.
    - An ability and tenacity to work within changing conditions in a dynamic environment and display ability to generate effective and pragmatic solutions to new situations and problems, both strategic and operational.

- The ideal candidate will also have one or more of the following:
    - A relevant postgraduate qualification.
    - Experience of EU regulatory assessment procedures for pharmacovigilance.
    - Experience in risk management and communication procedures.
    - Experience in the implementation of EU pharmacovigilance guidelines and legislation.
    - Experience of regular high-level representation of organisational/national positions at National/European level.
    - Experience in presenting externally and/or dealing with the media

REMUNERATION

Salary: €95,466 (Incremental scale).

SUPERANNUATION

The new Single Public Service Pension Scheme ("Single Scheme") commenced with effect from 1 January 2013. All new entrants to pensionable public service employment on or after 1 January 2013 are, in general, members of the Single Scheme.

HOURS OF DUTY

The hours of duty are fixed by the HPRA from time to time. The current arrangements are Monday-Friday (minimum 35 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

The HPRA are operating a hybrid model where work is carried out partly from the office (a minimum of 2 days per week) and partly using a remote working arrangement. This model permits an employee to carry out some of their duties at the HPRA offices and some from a remote location. This hybrid working model is subject to review.

DURATION OF POST

This is a three year fixed term contract.

HEALTH

A candidate must be fully competent and capable of undertaking the duties attached to the position and be in a state of health such as would indicate a reasonable prospect of ability to render regular and efficient service.

LOCATION

This role is being offered as part of our hybrid working model. The successful candidate will be working in the HPRA offices a minimum, of two days per week and can avail of working

remotely up to a maximum of three days per week subject to the terms of the policy. The specific days each week when you work at each location will be determined by your manager.

The HPRA reserves the right to cease, vary or change the office/home location split. Notwithstanding any applicable hybrid working arrangement, you may be required to work at any specified location as may be reasonably required by the HPRA from time to time.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 25 days per annum.

DUTIES OF POST

The duties set out in the role profile (above) are indicative of responsibilities related to this role. The Manager will have to demonstrate flexibility and anticipate that the role, activities and responsibilities will change as the HPM department develops and changes progresses.

The Manager will need to demonstrate the ability to lead the team through any such change and development initiatives.

CONFIDENTIALITY AND CONFLICT OF INTEREST

Employees are prohibited from having any personal or financial interest in any industry that the HPRA regulates from the date of appointment with the HPRA. All HPRA employees are required to declare any matter that could affect their impartiality or that could reasonably be perceived as affecting their impartiality. The HPRA's Conflicts of Interest Policy provides guidance on the types of interests to be declared. Any interests declared will be evaluated and any potential conflicts will be addressed in line with that policy.

The HPRA deals with highly confidential matters including identifiable details pertaining to healthcare professionals, patients and commercially sensitive information. Employees are prohibited from disclosing any information in relation to the business of any person obtained in his/her capacity as an officer of the HPRA.

DATA PROTECTION

The General Data Protection Regulation and Data Protection Acts 1988-2018 apply to the processing of personal data and the HPRA is committed to complying with its legal obligations in this regard. For information on how we process your information during recruitment, please see our privacy notice.

REFERENCES

The names and addresses of two referees to whom the applicant is well known but not related must be submitted with the application. Reference may be made to current and former employers

without further notification of the applicant. Applicants having any reservations on this matter should so state at time of application.

CLOSING DATE

The closing date for applications for this post is **12.00 noon on 30th March 2023.**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation/complete a practical test - details will be notified to applicants who are shortlisted.

It is anticipated that first round interviews for this post will take place **in the week commencing 10th April 2023.**

Note: The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

COLLECTIVE AGREEMENT: REDUNDANCY PAYMENTS TO PUBLIC SERVANTS

The Department of Public Expenditure and Reform introduced, with effect from 1st June 2012, a Collective Agreement which had been reached between the Department of Public Expenditure and Reform and the Public Services Committee of the ICTU in relation to ex-gratia Redundancy Payments to Public Servants. It is a condition of the Collective Agreement that persons availing of the agreement will not be eligible for re-employment in the public service by any public service body (as defined by the Financial Emergency Measures in the Public Interest Acts 2009 – 2011) for a period of 2 years from termination of the employment. Thereafter the consent of the Minister for Public Expenditure and Reform will be required prior to re-employment. People who availed of this scheme and who may be successful in this competition will have to prove their eligibility (expiry of period of non-eligibility) and the Minister's consent will have to be secured prior to employment by any public service body.

DECLARATION

Applicants will be required to declare whether they have previously availed of a public service scheme of incentivised early retirement and/or the collective agreement outlined above. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Public Service employment and/or where they have received a payment-in-lieu in respect of service in any Public Service employment.

EQUAL OPPORTUNITIES

The HPRA is an equal opportunity employer. The HPRA will not discriminate against an employee or prospective employee in relation to the nine discriminatory grounds as per the Employment Equality Acts, 1998-2015

* Candidates should note that entry will be at the minimum of the scale and the rate of remuneration may be adjusted from time to time in line with Government pay policy.