HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer, Medicine Shortages and Borderline Classification (MSBC) – Compliance

ROLE SUMMARY

Reporting to the Medicine Shortages Coordination Lead, the role of the Scientific Officer is to support the MSBC section in its function, including exempt medicinal products, borderline classification and with the co-ordination of the management of medicine shortages.

Other key aspects of the role of Scientific Officer includes:

- Reviewing signals and reports of potential, pending and current medicine shortages received from multiple stakeholders, such as the pharmaceutical industry (including wholesalers), healthcare professionals and patients, to identify where actions are required.
- Liaising with relevant external stakeholders and internally with other sections and departments within the HPRA to arrange for the implementation of actions that are needed to prevent or mitigate the impact of medicine shortages.
- Where appropriate, arranging for the communication of information in relation to medicine shortages to stakeholders, such as healthcare professional and patients.
- Maintaining records of notified shortages including key details such as the cause of the shortage, the timeframe associated with the shortage and how the shortage was resolved.
- Assisting in the development and implementation of preventative measures to reduce the likelihood of medicines shortages occurring and optimising the current shortages framework.
- Supporting the HPRA's participation in initiatives to manage and prevent shortages at an EU and global level.
- Assisting in the management of the HPRA Exempt Medicinal Product Notification System to ensure that all wholesalers or manufacturers bringing such products into Ireland for supply on the Irish market are notifying receipt of EMPs correctly. This involves liaising closely with such wholesalers to set up such notification accounts and dealing with any problems with product information notified as they arise.
- Analysing EMP notification data to understand the usage of EMPs in Ireland and the factors that may lead to fewer EMPs being required.
- Working closely with the individual members of the Compliance Department with regard to traceability of Exempt Medicinal Products on the Irish market and also members of the Human Products Monitoring team in relation to any safety concerns that may arise.
- Providing support to the Quality Defects and Recall group within the Compliance Department in relation to quality defect and recall issues with Exempt Medicinal Products and use of the EMP database.

- Provide support to the Medicine Shortages and Borderline Classification Section generally and to other Sections within the Compliance Department and across the HPRA, when required.

The Scientific Officer maintains effective working relationships with colleagues in other sections and departments of the HPRA and with external stakeholder groups, to ensure that activities requiring cross-functional and external input are effectively managed and that the impact on patients and healthcare professionals is limited.

The role requires excellent communication skills, a high degree of flexibility and the ability to respond to changing priorities.

KEY RESPONSIBILITIES

Operational Activities

- Assisting the Medicine Shortages and Borderline Classification Manager and the Medicine Shortages Coordination Lead in the operation of the MSBC section.
- Working with the Quality Defects and Recall group in relation to quality defect and recall issues with Exempt Medicinal Products as well as with regard to use of the EMP database.
- Assisting in co-ordination of the HPRA's activities related to the management of shortages, borderline classification and EMPs, including working directly with colleagues across the relevant departments.
- Ensuring clear, appropriate, and timely communication of shortages, borderline classification and EMPs to all relevant stakeholders – this may include targeted communications to key stakeholders and/or the publication of information on the HPRA website.
- Supporting the development of a website page (and a technical support process) to manage the communications referred to above.
- Assisting in the preparation of management reports on the progress of work in the MSBC section.

Stakeholder interaction

- Supporting the MSBC Manager and Medicine Shortages Coordination Lead in meetings with all relevant stakeholders such as the HSE, healthcare professional representatives, industry representatives and patient representatives to discuss topics related to medicines shortages.
- Co-ordinating the inputs from the relevant internal departments that have an involvement in the management of shortages, borderline classification and EMPs.

Strategic objectives

- Support the MSBC team in the management and ongoing development of the section.

- Support evolving business needs and requirements, of the section in undertaking any new areas of technical responsibilities in line with these developments.

Representation

- Attending relevant national, European, and international fora as required.

Quality Management:

- Ensuring that the procedures and policies of the HPRA quality management system are deployed and adhered to.
- Ensuring that appropriate standard operating procedures (SOPs) and technical guidelines for shortages, borderline classification and EMPS are implemented, updated and communicated on an ongoing basis to the relevant parties.
- Participating in any internal audits, including the identification and implementation of any required corrective actions.

Communications/Customer Service

- Promoting a strong customer service focus taking account of broad stakeholder needs (internal and external).
- Providing responses to queries in line with the HPRA service charter.

General

- In consultation with colleagues, as appropriate, responding to queries from stakeholders, as may be required
- Working with colleagues in the relevant departments and across the HPRA to facilitate the implementation of the strategic and operational goals
- Perform such other duties as the HPRA may reasonably require

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - Third level degree in a relevant scientific or life sciences discipline
  - A minimum of one years' relevant experience working in pharmacy, healthcare, research, industry, a regulatory environment position, in another relevant healthcare or scientific discipline
  - Possess the requisite knowledge and ability, suitability and administrative capacity for proper discharge of the duties of the office
  - Proven ability to gather information and apply analytical skills to reach decisions on technical issues
  - Proven ability to work unsupervised
  - Highly motivated and with the ability to manage deadlines
  - Demonstrated initiative and team working capabilities
  - Excellent computer skills
  - Proven ability to work effectively as part of a multi-disciplinary team
  - Excellent communication skills with the proven ability to deliver appropriate information to the right people using a range of written, verbal and presentation skills

- Proven ability to work with others in a collaborative and solutions focused manner

- In addition, the following would be considered an advantage:
  - A post-graduate degree in a relevant pharmaceuticals-related discipline
  - Recent experience in a hospital pharmacy setting
  - Demonstrated understanding of the role of Exempt Medicinal Products on the Irish market
  - A proven track record of working in an environment requiring a high degree of flexibility

REMUNERATION

Salary: €42,392 – €70,800 per annum (incremental scale)
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.

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.

LOCATION

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 during or after the review period. 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.

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.

DURATION OF POST

This is a 3-year contract post.
Note: The issuing of a 3-year contract is standard HPRA practice prior to moving to permanency for long term roles, such as this.

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.

ANNUAL LEAVE

Annual leave (exclusive of usual public holidays) is 22 days per annum.

DUTIES OF POST

The duties set out in the role profile (above) are indicative of responsibilities related to this role. As with all posts, the nature of HPRA business is evolving and flexibility is required in order to adapt to changing business needs.

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. All new entrants are required to complete a declaration of interests prior to commencing employment in the HPRA. The HPRA's Conflicts of Interest Assessment 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 Assessment.

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 the time of application.

CLOSING DATE

The closing date for applications for this post is **4th August 2024.**

INTERVIEWS

Applicants attending for interview may be required to prepare a presentation or take part in a practical test - details will be notified to applicants who are shortlisted.

It is anticipated that interviews for this post will take place on the **14th August 2024.** The HPRA is not in a position to reimburse expenses incurred by candidates attending for interview.

HOW TO APPLY

Applications should be submitted directly to job@hpra.ie

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 opportunities employer. We are committed to equal employment opportunity regardless of gender, civil status, family status, sexual orientation, religion, age, disability, race or membership of the travelling community. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process and can be notified in the course of the interview correspondence.