HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer- Exempt Medicinal Products, Market Compliance

ROLE SUMMARY

Reporting to the Quality Defects & Recalls Manager, the role of the Scientific Officer in the Exempt Medicinal Products area is to ensure compliance with Irish regulations of wholesalers and manufacturers that supply Exempt Medicinal Products (EMPs) to Ireland, by providing guidance in this area as needed.

Other key aspects of the role of Scientific Officer – Exempt Medicinal Products includes:

- 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 in order to understand the usage of EMPs in Ireland and the factors that may lead to fewer EMPs being required.

- A decrease in supply of high-risk or high-volume exempt medicinal products and products with an authorised alternative is a key HPRA objective and, in conjunction with other HPRA Departments, this role has involvement in achieving this.

- Liaising with the Human Products Monitoring Department in relation to potential safety issues with EMPs.

- Liaising with the Medicinal Products Shortages team in relation to the role of Exempt Medicinal Products in the event of potential or actual medicine shortage scenarios

- 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.

- Provide support to the Market Compliance Section generally and also to other Sections within the Compliance Department and across the HPRA, when required.

- On an ongoing basis liaise with Healthcare Professionals to address queries or concerns they may have in relation to EMPs. Consideration is given to patient needs, balanced against the legislative requirements when handling such requests or queries.

- 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 Quality Defects & Recalls Manager in managing the HPRA's EMP Notification system from a compliance perspective
- Working with the HPRA IT & Change Management Department to further develop the Notification System in order to identify high volume EMPs supplied to Ireland
- Identifying and reacting to compliance-related issues with the supply of EMPs
- Identifying and reacting to compliance-related issues with the notification of EMP importations to the HPRA
- Ensuring the effective mechanisms are in place for ongoing contact and collaboration on product supply issues with the Department of Health, Health Service Executive, healthcare professionals and suppliers
- Ensuring that there is improved understanding and knowledge among relevant healthcare professional groups about the legislative requirements in relation to the supply of exempt medicinal products and a stated preference for using authorised products, where possible
- Working with Irish wholesalers and manufacturers to improve their understanding of the supply route and the importance of accurate EMP notifications
- Preparing interim updates and presentations for discussion with HPRA colleagues, committees, with the Advisory Committee on Human Medicines and the Board and with the Department of Health
- Assisting in the compilation of data and preparation of management reports as required
- Submitting reports as required and maintaining appropriate records of meetings and activities
- Promoting a positive, open, friendly and professional working environment

Technical Activities

- Advising the Department of Health and the HSE of EMP usage in Ireland when requested
- Participating in inspections of wholesaler activities, when required
- Determining the extent to which EMPs are used in Ireland via discussions with the various stakeholders and examination of actual supply and usage
- Continually investigating the reasons for the use of EMPs in Ireland
- Reviewing schemes for supply of EMPs in other countries and considering their applicability and adaptability to the Irish situation
- Providing annual figures to the HPRA's Finance and Corporate Affairs Department in relation to EMP Notification charges
- Compiling and analysing EMP statistics for monthly and annual reports
- Providing technical support to other colleagues within the Market Compliance section, where required.

Quality Management

- Working with colleagues to develop and implement quality management policy and practice. Assist in work to ensure that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained through the Exempt Medicinal Products program.
- Developing and updating SOPs for all areas of EMP work
- Participating, as required, in internal audits, and working on the implementation of any required corrective actions

- Participation in the adoption and implementation of any new EMP-related scheme into the quality management system
- Ensuring that quality management practices and policies in relation to EMPs reflect relevant developments in national legislation and guidelines

Performance Management

- Working with the relevant line manager to agree appropriate performance related targets
- Taking measures to identify and resolve issues impacting performance
- Reporting regularly on progress against specified objectives, goals and performance targets
- Effectively communicating objectives, goals and performance targets within the team
- Promoting a positive, open, friendly and professional working environment
- Participation within HPRA's Performance Development Programme (PDP)

Communications/Customer Service

- Attending and contributing to Departmental and organisational meetings as appropriate
- Ensuring that HPRA policies and procedures are communicated in a consistent way to stakeholders
- Liaising with relevant external organisations in relation to activities and processes relevant to the Exempt Medicinal Products area
- Liaising with HSE in relation to advice sought regarding reimbursement of certain EMPs
- Participating in Medication Safety Forum meetings and other projects in relation to EMPs when requested
- Attend external meetings as deemed appropriate by the Quality Defects & Recalls Manager
- Ensuring that appropriate mechanisms are in place to support interactions with other areas of the HPRA
- Providing support to other areas of the HPRA where appropriate
- Communication of key issues with stakeholders including wholesalers and manufacturers

General

- Performing such other duties, as the Board may reasonably require.

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - 3rd level degree in Pharmacy or in a related discipline
  - A minimum of one years' relevant experience working in a pharmacy, in a regulatory affairs position or in another relevant healthcare-related position.
  - 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: €34,077 per annum (*new entrants - 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 37 hours). Appointees are eligible to participate in the flexitime arrangements after a period of six months.

DURATION OF POST

This is a one-year contract post.

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 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 **23rd September 2019.**

INTERVIEWS

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

It is anticipated that interviews for this post will take place on **11th October 2019.**

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

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

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.

* 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.