HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Scientific Officer, Veterinary Assessment – Veterinary Sciences

ROLE SUMMARY

The role of the Health Products Regulatory Authority (HPRA) is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The HPRA is the national competent authority with responsibility for the assessment of applications relating to veterinary medicinal products.

The Veterinary Sciences department within the HPRA wishes to appoint a Scientific Officer within the Safety & Efficacy assessment team of the Veterinary Sciences Department.

The Scientific Officer reports to the Veterinary Assessment Manager and will contribute to the technical functions of the Safety and Efficacy Assessment team and support risk based assessment activities through data analysis and data management activities.

The Scientific Officer will:

- Assist in the processing and evaluation of reports of suspected adverse reactions associated with the use of veterinary medicinal products.
- Assist in the assessment and processing of certain types of safety and efficacy related variation applications.
- Contribute to the compilation of data and report writing, as necessary.
- Assist in maintenance of the computer databases and information systems relating to veterinary medicinal products.
- Liaise with reporters and stakeholders in relation to reporting of suspected adverse reactions.
- Attend meetings of the European pharmacovigilance network, when required.
- Carry out pharmacovigilance inspections, as necessary.
- Work closely and maintain effective working relationships with the other members of the Safety and Efficacy Assessment team and other members of the Veterinary Sciences department to ensure that departmental objectives are met.
- Maintain effective working relationships with Marketing Authorisation Holders to ensure that pharmacovigilance issues are reported, effectively investigated and followed up.
- Work with colleagues from other Member State authorities in relation to matters of common interest.

KEY RESPONSIBILITIES

- Strategic Objectives:
  - Assisting the Veterinary Assessment Manager in meeting the goals and objectives of the Veterinary Sciences department.
  - Supporting the Safety and Efficacy assessment team in its work.
  - Support evolving business needs and requirements of the section in undertaking new areas of technical responsibilities in line with needs.

- Operational/Technical Objectives:
  - Processing and reviewing pharmacovigilance data in an efficient and competent manner.
  - Performing or participating in pharmacovigilance inspections, when required.
  - Processing and evaluating periodic safety update reports (PSURs), reports of suspected adverse reactions to veterinary medicinal products and undertake signal management, including follow-up communications with the marketing authorisation holder and, where necessary, the provision of advice for follow-up regulatory action to the Veterinary Assessment Manager.
  - Undertaking data monitoring in pharmacovigilance databases and extracting and analysing data from pharmacovigilance databases.
  - Safety issues/signals.
  - Preparation of assessment reports on pharmacovigilance data relating to veterinary medicinal products.
  - Preparation of assessment reports on pharmacovigilance systems operated by marketing authorisation holders.
  - Technical liaison with colleagues in order to facilitate the auditing of pharmacovigilance systems operated by marketing authorisation holders.
  - Assisting with the assessment of certain types of safety and efficacy related variations.
  - Communicating with marketing authorisation holders and other regulatory agencies in relation to certain safety and efficacy related variation applications.
  - Monitoring and reviewing the adequacy of product literature of authorised veterinary medicinal products.
  - Assessing proposed changes to product literature of authorised veterinary medicinal products.
  - Contributing to the maintenance of the HPRA website on veterinary pharmacovigilance-related issues/communications.
  - Participation in meetings of the European Regulatory Network, as required.
  - Providing written and/or oral advice to colleagues, applicants, regulatory authorities and other relevant bodies and healthcare professionals on veterinary pharmacovigilance activities, requirements and best practices.
  - Development of new and maintenance of existing initiatives and activities to promote veterinary pharmacovigilance in Ireland.
  - Providing support to other colleagues within the department.
  - Promoting a positive, open, friendly and professional working environment.
  - Assisting in the compilation of data and preparation of reports as required.
  - Maintaining appropriate records of meetings and activities.

- Quality and Knowledge Management:
  - Assisting the Veterinary Assessment Manager to ensure the effective implementation and management of the HPRA Quality Management System within the Veterinary Sciences department.
  - Assisting the Veterinary Assessment Manager with knowledge management in relation to developments in national, European and international regulations and relevant legislation relating to pharmacovigilance of veterinary medicines.
  - Ensure that processes and procedures remain up to date with relevant developments in national, European and international regulations, legislation and guidelines.

- Assisting the Veterinary Assessment Manager to ensure that available information and knowledge across the HPRA is effectively used by the Safety and Efficacy Assessment team.
- Participating in internal audits including the identification and implementation of any required corrective actions.
- Contributing to the recording, management and sharing of regulatory information relevant for the Safety & Efficacy team and the Veterinary Sciences Department.
- Drafting and revising Quality Management System-related documentation concerning pharmacovigilance.

- Performance Management/Team Development:
  - Reporting regularly to the Veterinary Assessment Manager against specified goals/targets and objectives.
  - Participating in the performance management programme within the Safety and Efficacy Assessment team to maximise efficiency within the department.
  - Working with the Veterinary Assessment Manager to prioritise work objectives and to ensure that the strategic and operation goals of the department are met.
  - Taking measures to identify and resolve issues impacting performance.

- Communication/Customer Service:
  - Provide timely communication with Applicants, other regulatory authorities, healthcare professionals and relevant stakeholders, including the provision of technical advice, information and presentations.
  - Participating in and contributing to regular Safety and Efficacy Assessment team and departmental meetings.
  - Liaising with officers of the State, other bodies, and industry sections, as appropriate, on matters relating to pharmacovigilance of veterinary medicinal products.
  - Providing timely input to the HPRA's newsletter and HPRA website as necessary.
  - Working with the Veterinary Assessment Manager to ensure the provision of high quality induction and ongoing training for colleagues in the Safety and Efficacy Assessment team.
  - Ensuring delivery of customer service levels according to agreed requirements.
  - Representing the HPRA at national, European and international meetings, as requested.

- General
  - Perform such other duties as the HPRA may reasonably require

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
  - A third level qualification in a scientific discipline that is relevant to veterinary science and the safety monitoring of veterinary medicinal products.
  - A minimum of one year's experience working in a veterinary practice or a research or regulatory environment relevant to the safety monitoring of veterinary medicinal products.
  - An awareness of the EU pharmacovigilance requirements and/or the regulation of veterinary medicines.
  - Familiarity with farming and/or the husbandry of animals.
  - Experience in writing and/or reviewing scientific publications or reports.

- Have excellent organisational, administrative, computer and communication skills along with demonstrable attention to detail.

- In addition, the following would be considered an advantage:
  - Knowledge of medical or veterinary technical terms.
  - Highly motivated with proven ability to manage multiple deadlines and tasks effectively.
  - Experience in the development or implementation of quality management systems.
  - Demonstrable ability to work both on own initiative and as part of a team.

REMUNERATION

Salary: €34,759 per annum (*new entrants - incremental scale).

DURATION OF POST

This is a three-year contract post.

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).

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.

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.

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.

CLOSING DATE

The closing date for applications for this post is **Sunday 3rd October 2021.**

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

INTERVIEWS

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

It is anticipated that the first round interviews for this post will take place via Microsoft Teams on **Friday 15th October 2021.**

The HPRA will make reasonable accommodations for a person with a disability during the recruitment process.

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.

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.

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.