

Role Profile

Pharmaceutical Assessor, Pharmaceutical Assessment – Veterinary Sciences

ROLE SUMMARY

The Pharmaceutical Assessor will work as part of the Pharmaceutical Assessment section in the Veterinary Sciences (VS) department and will assist in the evaluation of the pharmaceutical aspects of new applications for veterinary medicinal products and variations of existing authorisations for pharmaceutical products containing new chemical entities or established active ingredients.

The Pharmaceutical Assessor will work closely and maintain effective working relationships with the other members of the Pharmaceutical Assessment section, and with members of the Veterinary Sciences department as a whole, to ensure effective co-ordination and co-operation across all areas of assessment and to ensure that the objectives of the VS department are met.

The Pharmaceutical Assessor will maintain effective working relationships with colleagues in other sections and departments of the HPRA, and with stakeholder sections, to ensure that Pharmaceutical Assessment issues requiring cross-functional input are effectively investigated and followed up on.

KEY RESPONSIBILITIES

- Technical Objectives
 - Conducting scientific evaluation of pharmaceutical data submitted in support of applications for marketing authorisation for veterinary medicinal products containing new chemical entities or established active ingredients. Analysis of their risk/benefit profiles; reporting and forming conclusions in respect of their suitability for use as veterinary medicinal products as well as consideration of the public health consequences of their use.
 - Conducting scientific evaluation of pharmaceutical data submitted in support of:
 - National applications for marketing authorisations, including Parallel Products
 - Centralised applications to the EMA for marketing authorisations when the HPRA is acting as rapporteur, co-rapporteur or peer reviewer on behalf of the EMA
 - Centralised scientific advice applications where the HPRA is acting as rapporteur or co-rapporteur on behalf of the EMA
 - EU applications when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure
 - Preparation of assessment reports on applications for marketing authorisation for veterinary medicinal products and submission of reports to other EU member states when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure
 - Analysis in the context of public health, of risk-benefit profiles in respect of applications for marketing authorisation; making recommendations and preparation and presentation of reports to the Board, Advisory Committees and Sub-Committees or the Management

- Committee of the HPRA, and/or the CVMP or their representative working parties, regarding the suitability of veterinary medicinal products for marketing approval
 - Assisting the Pharmaceutical Assessment Manager in ensuring the accuracy of relevant data inputted in the computer databases and information systems of the HPRA
 - Participation in the HPRA sampling and quality defect post-marketing surveillance programme.
- Operational Objectives
 - Assisting and working with the Pharmaceutical Assessment Manager to:
 - Meet the goals and objectives of the section
 - Upkeep and further develop the Quality Management System (QMS) procedures for the section in line with the operational goals of the VS department
 - Plan and organise their work tasks that ensure efficient delivery of work
 - Providing support to other colleagues within the VS department, where required
 - Promoting a positive, open, friendly and professional working environment
 - Assisting in the compilation of data and preparation of reports as required
 - Attending meetings of the HPRA Advisory Committees as required
 - Attending Working Groups/Committees/meetings at the European Medicine Agency (EMA), as required
 - Attending meetings with other Irish Agencies, as required
 - Maintaining appropriate records of meetings and activities
 - Attending and contributing to meetings of the Pharmaceutical Assessment section and VS department
- Strategic Objectives
 - Supporting the Pharmaceutical Assessment Manager in the:
 - Running and on-going development of the section
 - Preparation of work objectives for the section
 - Prioritisation of work objectives and ensuring that the operational goals of the section are achieved and
 - Providing support and direction to colleagues and others within the section and the VS department
- Quality and Knowledge Management
 - Assist the managers of the Pharmaceutical Assessment section to ensure:
 - The effective implementation of the HPRA Quality Management System within the section
 - That there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge gained by the section
 - That available information and knowledge across the HPRA is effectively used by the section
 - That procedures remain up to date with relevant developments in National, European and International regulations, legislation and guidelines
- Performance Management
 - Participating in the performance development programme within the Pharmaceutical Assessment section to maximise efficiency gains for the Veterinary Medicines Department
 - Working with the Pharmaceutical Assessment Manager to promote effective performance within the section

- Taking measures to identify and resolve issues impacting performance in the Pharmaceutical Assessment section
- Reporting regularly on progress against specified goals/targets and objectives
- Communications/Customer Service
 - Conducting technical liaison with applicants, regulatory authorities, healthcare professionals and other relevant stakeholder
 - Provision of technical information, advice and guidance to regulatory authorities, healthcare professionals and other relevant stakeholder
 - Liaising with officers of the State, other bodies and industry sections, as appropriate, on Pharmaceutical Assessment issues
 - Provide timely input to the HPRA's newsletter and website as necessary
 - Participate in regular team/section meetings
 - Ensure that HPRA policies and procedures are communicated in a consistent way to stakeholders
- Team Development
 - Working with the Pharmaceutical Assessment Manager:
 - To ensure the provision of adequate technical, non-technical and continuous professional development for colleagues in the section and within VS
 - To ensure the provision of high-quality induction and ongoing training for colleagues in the section
 - In co-ordinating the planning and delivery of training for colleagues in the section
- General
 - Represent the HPRA at both national and international meetings and/or conferences as required
 - Perform such other duties as the HPRA may reasonably required

QUALIFICATIONS AND EXPERIENCE

- To be considered for this post, candidates must have:
 - A degree in pharmacy, chemistry or other relevant scientific discipline
 - A minimum of 2 years relevant industrial, regulatory and/or research experience in the pharmaceutical industry, a regulatory authority or in a related field
The necessary breadth of knowledge to review the pharmaceutical sections of a marketing authorisation application
 - A proven track record of working within multidisciplinary teams
 - Direct experience working with stakeholders/customers
 - Proven ability of demonstrating excellent interpersonal, communication and presentation skills
 - Proven ability to meet deadlines
 - Demonstrated initiative and team working capabilities
 - A demonstrated ability to think critically and independently
- In addition, the following would be considered an advantage:
 - A postgraduate qualification in a relevant scientific discipline
 - Experience in the manufacture, pharmaceutical assessment or quality assurance of sterile products
 - Experience in dealing with EMA

REMUNERATION

Salary: €73,313-85,017 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 (or 40% of available working days) 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 remote 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 three-year contract post.

Note: The issuing of a three-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 **19/11/2024**.

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 **27th November 2024**. 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 (Networx).

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 during the interview correspondence.

