HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile

Graduate Programme, Regulation of Veterinary Medicines

Stream 3

ROLE SUMMARY

The Regulation of Veterinary Medicines Stream runs for a duration of 12 months, consisting of two 6 month rotations. This Stream is structured to ensure graduates gain an insight and exposure to different sections within the Veterinary Sciences department, encouraging them to develop and enhance multiple competencies and offers the graduate a comprehensive understanding of the veterinary medicines on our market.

Graduates will gain a unique insight into how veterinary medicinal products are authorised in Ireland. They will understand the different regulatory structures and activities in place and how pharmacovigilance issues are reported, effectively investigated and followed up.

In this stream, the graduate will be exposed to two key work programmes at the HPRA that focus on the veterinary medicines on our market:

1. Pharmaceutical Assessment of veterinary medicinal products

The first six-month placement will involve pharmaceutical related assessment activities as well as regulatory and policy in the area of veterinary medicines.

The pharmaceutical assessment team is responsible for the evaluation of the data submitted in marketing authorisation applications relating to product development, manufacturing processes, quality control testing and evaluation of data to support the stability of products over their shelf life. Following authorisation, products undergo many changes over the course of their life cycle and the team is also responsible for evaluation of those changes.

The graduate role will focus on post-authorisation quality related assessment activities, primarily variations. The types of changes typically applied for relate to formulation changes, change to methods and sites of manufacture, new active substances, changes to specifications, test methods and stability related changes.

The graduate will gain an understanding of how a marketing authorisation (MA) is changed and maintained throughout its life cycle, the data provided and the assessment procedures and processes involved in its approval.

The graduate will be exposed to the legal requirements for veterinary medicinal products and gain insight into recent changes in legislation, the legislative and regulatory processes involved in implementing new legislation and the impact of the changes for marketing authorisation holders and regulatory authorities. The graduate will also gain exposure on how the HPRA designs efficient work flow systems and processes in accordance with lean six sigma principles and the role of quality management systems in ensuring the effectiveness of those processes.

There will be an opportunity to become involved in a business project as the regulatory procedures laid down in the new legislation are introduced into the department.

- *Regulatory and Policy*

The HPRA plays an important role in the elaboration of national and European regulatory policy on veterinary medicines.

Working in the area of regulatory and policy will provide the graduate with a platform to gain practical experience and build knowledge around the legislation underpinning the regulation of veterinary medicines and the challenges around availability of these products in Ireland. The graduate will develop skills in handling multiple priorities and a range of different competencies that cultivates a solutions-focussed perspective to reduce the impact of availability of veterinary medicinal products.

The graduate will also gain an insight into the latest national and international strategies by gaining awareness of how the Irish regulatory environment is developed and the drivers involved, and the role of Ireland in the EU and international regulation of veterinary medicines.

At the end of their six month rotation, the graduate will have developed a tangible appreciation for the national and global impacts of veterinary medicines authorisation and the variety of stakeholders involved.

2. Safety and Efficacy Assessment of veterinary medicinal products

In the second six-month rotation, the graduate will build upon their knowledge of assessment activities by understanding the role of safety and efficacy assessment in veterinary medicines. In this section, they will gain an understanding of how applications are evaluated from a safety and efficacy perspective, as well as the monitoring of post-marketing safety data using pharmacovigilance and how this relates to veterinary medicinal products in Ireland.

The graduate will be exposed to a broad range of regulatory activities while learning about the applicable processes. They will have an opportunity to develop competency in these areas, and will also gain knowledge of the broader framework of safety and efficacy assessment in relation to overall regulatory activities and benefit/risk assessment.

The graduate will also gain an understanding of how the HPRA assesses a marketing authorisation (MA), including how it is approved and maintained throughout its life cycle. They will understand the regulatory requirements for safety evaluation of veterinary medicines as it relates to the user of veterinary medicines, the consumer of products derived from animals treated with veterinary medicines and the environment. In addition, knowledge and understanding will be gained of the pre-clinical and clinical requirements needed to demonstrate the efficacy of veterinary medicines and the trials that may be conducted in support of efficacy and how the findings from such studies are reflected in the Summary of Product Characteristics. An understanding will also be gained of how changes to the safety and/or efficacy profile of a product are monitored and assessed and the regulatory options available to address any changes that arise.

The graduate will also understand the role of quality management systems and the sharing of regulatory information relevant for the Safety & Efficacy team and the Veterinary Sciences Department.

➢ *Pharmacovigilance of veterinary medicinal products*

The continuing safety and efficacy of veterinary medicinal products is monitored through pharmacovigilance of veterinary medicinal products which also forms part of the work of the Safety & Efficacy section of the VSD. The HPRA is moving towards a new method of oversight (signal management), through participation in the EU pharmacovigilance network, and the graduate will learn how the new system works in practice. The graduate may also be introduced to colleagues in the Compliance Department, who have responsibility for market surveillance and recalls.

The graduate will also be exposed to the regulations that underpin pharmacovigilance and how it operates for veterinary medicinal products. They will gain an understanding of how signals are evaluated and how these may affect the product information. The graduate will have an opportunity to develop their competencies in understanding how product shortages are managed and the role played by the HPRA in communicating and providing input into it's elaboration. They will understand how the HPRA produces its annual report on antimicrobial consumption.

This is achieved via interaction with multidisciplinary teams with other departments in the organisation and with external stakeholders (including marketing authorisation holders, wholesalers, manufacturers, the HSE, healthcare professionals and patients).

Working in the safety and efficacy assessment of veterinary medicinal products will provide the graduate with a platform to gain practical experience and build knowledge around safety and efficacy activities, including individual case report processing and evaluation, follow-up of reports, cumulative review, regulatory impact, and interaction/communication across the various stakeholder groups.

KEY RESPONSIBILITIES

Operational Objectives

- Assessment of veterinary medicinal products
    - Supporting the Quality, Safety and Efficacy assessment teams in their work and participation in team meetings.
    - Support evolving business needs and requirements of the section in undertaking new areas of technical responsibilities in line with needs.
    - Preparing and compiling data for review and assisting with the preparation of reports.
    - Liaising with and providing information and guidance on vigilance related matters to assist with internal/external responses to queries, as necessary.
    - Identifying opportunities for continuous improvement by highlighting quality management issues for review and consideration.
    - Participating in the formulation and preparation of regulatory policies, guidelines and procedures.

- Regulatory and Policy
    - Supporting the Regulatory and Policy team in the operation of the programme.
    - Understanding the interplay between the HPRA and the Department of Agriculture, Food and the Marine, in relation to the regulatory oversight of veterinary medicinal products.

- Pharmacovigilance and monitoring of veterinary medicinal products
    - Understanding of how pharmacovigilance operates for veterinary medicinal products
    - Understanding product literature insofar as post-marketing experiences is concerned.
    - Develop critical thinking and solution-focussed competencies.
    - Helping to develop the shortages function in the HPRA.
    - Contributing to the preparation of Pharmacovigilance (PV) related publications.
    - Contributing to the collection and review of data on antimicrobial consumption.

- Quality & Knowledge Management
    - Ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge.
    - Assisting the teams in remaining up to date with relevant developments in national, European and International regulations and legislation.
    - Contributing to the effective implementation of the HPRA quality management system within the Veterinary Sciences Department.

- Performance Management
    - Working with colleagues in the relevant Veterinary Sciences sections to promote effective performance.
    - Taking measures to identify and resolve issues impacting performance in the Sampling & Analysis programme.
    - Reporting regularly on progress against specified goals/targets and objectives.
    - Highlighting issues identified (e.g. with reporting, procedures, compliance monitoring) and contributing to the development of measures to resolve them.

- Communication/Customer Service
    - Attending and contributing to HPRA internal meetings, as appropriate.
    - Attend external meetings as deemed appropriate by section manager in current rotation.
    - Assisting in the development and implementation of communication and awareness raising strategies and activities relating to topics of public importance for stakeholders.
    - Participating at regular internal team, section and department/organisational meetings.

- Team Development
    - Participating in technical and skills training and continuous professional development.
    - Participating in induction and ongoing training, including comprehensive on the job training.
    - Attending technical quality system training.

- General
    - Liaising with and providing support to other areas of other sections in the rotation as required.
    - Performing such other duties as the HPRA may reasonably require.

QUALIFICATIONS AND EXPERIENCE

To be considered for this post, candidates must:

- Be on track for or have achieved a minimum 2:1 honours Bachelor's Degree (NFQ level 8) or equivalent in any of the following disciplines, or other relevant disciplines:

Pharmacy	Toxicology
Pharmaceutical Analysis	Pharmaceutical QA
Pharmaceutical Medicine	Regulatory Affairs
Pharmacology	Science
Immunology & Global Health	Or related discipline (Veterinary Medicine or Veterinary Nursing)

- Excellent communication, teamwork and organisational skills.
- Interest in contributing to the protection and enhancement of public and animal health through the regulation of medicines, medical devices and other health products.
- Excellent data analysis skills.
- Demonstrate initiative and team working capabilities.
- Highly motivated with the ability to manage deadlines.

REMUNERATION

Salary: €24,601 per annum (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.

DURATION OF POST

12 months.

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).

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.

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.

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 the **31st October 2021**.

HOW TO APPLY

Applications should be submitted via the HPRA Recruitment Portal.

INTERVIEWS

It is anticipated that interviews for this post will take place in **November 2021**. The HPRA will make reasonable accommodations for a person with a disability during the recruitment process.

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

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.