HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Role Profile
Graduate Programme, Medicines on our Market
(Stream 2)

ROLE SUMMARY

The Medicines on our Market Stream (Stream 2) runs for 18 months, consisting of three 6 month rotations and is structured to ensure graduates gain an insight and exposure to different departments, encouraging them to develop and enhance multiple competencies and offer the graduate a comprehensive understanding of the Medicines on our Market.

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

1. Authorising Medicines

The authorisation of a medicine requires the evaluation of the safety, efficacy and quality of the medicine. This evaluation requires the assessment of the preclinical, clinical and pharmaceutical parts of a dossier that is submitted in order to gain the authorisation. Specific sections within the authorisation department assess each section to assure that the technical work completed and submitted to the HPRA meet the rigorous requirements that are set in order to prove the benefit and reliability of the medicine.

The graduate will learn about the national and international frameworks that define the preclinical, clinical and quality requirements that a medicine must meet before being authorised. An understanding will be gained of the processes by which the HPRA assesses the medicine and how the HPRA ensures that the medicine is suitable for use by patients and healthcare professionals.

The graduate will also gain an understanding of what the HPRA does after the authorisation of a medicine to ensure that it continues to be manufactured according to the most up-to-date technology and that the information available to patients and healthcare professionals is kept relevant based on the continual monitoring of its usage.

The department also oversees the authorisation process for conducting clinical trials in Ireland, the data from which may be used in verifying the safety and benefit of medicines. The graduate will gain an understanding of the regulatory and technical requirements for conducting a clinical trial in Ireland.

Practical experience in assessment activities for medicines will be gained through a supervised work programme that provides the graduate with a valuable breadth and depth of experience in medicine authorisation assessment.

2. Market Compliance

The Sampling and Analysis programme functions to support the HPRA in monitoring the quality and safety of medicinal products both on the Irish market and produced for export. It allows us to identify medicinal products on the Irish marketplace and / or produced in Ireland which may not be compliant with their marketing authorisations or other expected standards.

We achieve this through a risk-based approach to surveillance testing and product examination. This programme contributes to the HPRA's role in protecting public and animal health by checking the quality of the medicines via laboratory testing and ensuring that any non-compliance issues are followed up on and addressed. It also allows us to identify deficient analytical test methods that may be in use at pharmaceutical company laboratories. The programme also allows us to check that the product information supplied in packs of medicines is correct and up-to-date. The graduate will gain a detailed understanding of how the sampling and the independent testing of medicines contributes to the protection of public and animal health.

The graduate will be exposed to the regulations that underpin the surveillance testing activities that the HPRA oversees and coordinates, as well as the type of product testing and examination work that the HPRA coordinates or carries out. The graduate will apply quality risk management principles in the design of annual surveillance. The programme will provide the graduate with a platform to learn about medicinal product specifications, test methods, marketing authorisations, and contract laboratory operations. It will also address how the HPRA's sampling and analysis programme supports pharmacovigilance investigations. The graduate will also gain an understanding of how the HPRA's surveillance activities fit in with European initiatives and programmes in this area.

The graduate will have an opportunity to develop competencies in dealing with the test results that come from the laboratory testing of medicines, as well as in dealing with the results from packaging and labelling examinations carried out on medicinal products.

3. Shortages in Medicines

Medicine shortages are increasingly prevalent globally, and Ireland, like all European countries, has the potential to be affected. The HPRA has created a new function internally to co-ordinate the management of medicine shortages and it works closely with various key players in the health sector with the aims of preventing a shortage and reducing the impact of a shortages when they do occur.

The shortages function in the HPRA interacts 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).

The graduate will gain insight into the activities undertaken by the shortages team in co-ordinating the reaction to an actual or potential shortage of a medicine. This will involve the application of knowledge gained at undergraduate level as well as aspects the graduate will be exposed to in the HPRA graduate programme. Often shortages are unpredictable and the shortages team has to react to emergent situations. Therefore, 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 a shortage on patients. Given the diverse nature of the causes of shortages and the variety of stakeholders involved, the graduate will gain a tangible

appreciation for the national and global impacts of medicines authorisation and supply chain, up to and including the patient.

The graduate will therefore have an opportunity to develop competencies in understanding the complexities of the medicine supply chain, develop analytical and investigational skills whilst working with stakeholders to understand the root cause of shortages and develop appropriate responses to ensure the impact on patients is reduced as much as possible. The graduate will also gain insight into the latest national and international strategies aimed at long term prevention of shortages.

KEY RESPONSIBILITIES

Operational Objectives

- Authorising Medicines
  - Learn how a medicine becomes authorised and available for use in Ireland.
  - Learn how the quality and benefit of a medicine is maintained.
  - Understand the different regulatory processes by which an authorisation for a medicine is obtained and maintained throughout its lifecycle.
  - Understand the regulatory and technical requirements for conducting clinical trials in Ireland.
  - Gain practical experience in assessment activities for medicines.

- Market Compliance
  - Supporting the Sampling & Analysis group in the operation of the programme.
  - Assisting in identifying future risk-based sampling and analysis projects in relation to medicines on the market in Ireland as well as those manufactured in Ireland for export.
  - Working to prioritise Sampling & Analysis work on a case-by-case basis in accordance with risk-based principles.
  - Helping to further develop and improve the risk-assessment methods in use for Sampling & Analysis work.
  - Working within the Sampling & Analysis team to ensure that the goals and objectives of the programme are met.
  - Assisting in the accurate logging, tracking, maintenance and compilation of data.
  - Assisting in the generation and issuance of Sampling & Analysis reports
  - Assisting in the review laboratory reports and certificates of analysis.

- Shortages in Medicines
  - Learn about the complex causes and impacts of medicine shortages.
  - Understand the activities undertaken by the team at HPRA working to prevent shortages and reduce their impact on patients.
  - Assisting in handling shortage cases.
  - Develop critical thinking and solution-focussed competencies.
  - Helping to develop the shortages function in the HPRA.
  - Gain insight into the latest international strategies to deal with medicines shortages.

- Quality & Knowledge Management
  - Ensuring that there are effective mechanisms in place to capture, store and communicate key information, experience and knowledge.

- Assisting the Sampling & Analysis team in ensuring that the Sampling & Analysis programme remains up to date with relevant developments in national, European and International regulations and legislation.
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- Contributing to the effective implementation of the HPRA quality management system within the Compliance and HPM departments.

- Performance Management
  - Working with colleagues in the Authorising Medicines, Market Compliance and Shortages in Medicines 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
  - Assisting in the development and implementation of communication and awareness raising strategies activities for the Sampling & Analysis Programme.
  - 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 & Regulatory Affairs
Pharmaceutical Analysis	Pharmaceutical QA & Regulatory Affairs
Pharmaceutical Medicine	Science
Immunology & Global Health	

- 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: €23,999 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

18 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 2019**.

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 2019**.

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

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.*