EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Pharmacovigilance Officer
Job family	Core
Job sub-family	Safety & Risk Management
Entry grade	FGIV
Role summary	Responsible for providing scientific input, advice, oversight and/or management relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) or any other Human or Veterinary medicine- related problem.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Responsible for the scientific coordination and regulatory and/or procedural support in relation to the any of the following areas; Manage the creation and implementation of the Agency signal management strategy; PRAC *(for PhV Officer in Human Medicines Division)* and CVMP/PhVWP *(for PhV Officer in Veterinary Medicines Division)* support for the relevant assigned type of procedures; Manage risk-management plans and oversight of post-authorisation studies; Manage activities relating to epidemiology on the basis of real-world data to study populations, diseases and the performance of medicines for the assessment of the safety and performance of medicines once placed on the market; *(not applicable to PhV Officer in Veterinary Medicines)* Liaise with Market Authorisation Holders (MAHs) with regards to the implementation of signal recommendations of the Pharmacovigilance Risk Assessment Committee PRAC *(for PhV Officer in Human Medicines Division)* and CVMP's Pharmacovigilance Working Party *(for PhV Officer in Veterinary Medicines Division)* including the monitoring of the compliance with PRAC signal recommendations, for the update of product information of Centrally Authorised medicinal Products (CAPs); Responsible for the coordination and scientific support relating to safety communications;

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	Cooperate with both National Competent Authorities (NCAs) in the management of safety signals for centrally authorised products, and Marketing Authorisation Holders (MAHs); Contribute to the coordination of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), which builds capacity in the delivery of post-authorisation studies; *(not applicable to PhV Officer in Veterinary Medicines)* Manage the development and maintenance of good pharmacovigilance practices (GVP) and standards for the system, as well as development and implementation of evidence-based process improvements and updates to GVP; Contributes to cross-functional initiatives aimed to improve pharmacovigilance capabilities related to signal detection; Drives policies, research and best practices for safety data mining, signal detection planning, management and tracking; Monitors safety of CAPs and prepares clear signal descriptions of issues identified.
Role specific duties & responsibilities	The specific tasks of an individual job holder linked to this general role description are further detailed and referenced in: activities of the organisational entity within which the job holder carries out those tasks; the set of annual performance and development objectives, which are established together with the line reporting officer; the requirement to comply with SOPs, WINs, confidentiality undertaking and other documentation relevant to the role and its scope. These will be agreed upon with the reporting officer upon assuming duties.
Managing resources	No management or supervision of resources.
Communication and professional contacts	Required to receive and convey information, orally and/or in writing, of a non-routine nature which needs careful explanation and interpretation e.g. explaining or interpreting policies, systems, processes; dealing with matters of a sensitive nature; formulating responses to more complex enquiries; drafting news items, letters, minutes, reports or presentations. Regular professional contacts with others inside and/or outside the Agency on functional matters. Solicits/gives information, provides advice/guidance and should use initiative. A likely requirement is to influence others' thinking and negotiate with various parties within own job responsibilities. Normally connected to the Agency's core business or a project. In particular, a Pharmacovigilance Officer will: Deal with requests related to access to information/documents; Support pharmacovigilance trainings to stakeholders (NCAs and/or MAHs); Respond to specific questions on procedures and guidelines;

	Liaise with the EU Medicines Network and MAHs, applicants, sponsors etc by providing clear communications to negotiate timelines, dossier contents etc.
Essential requirements Education Experience Skills & knowledge Certificates	**Education** A level of education which corresponds to completed university studies of at least three years attested by a diploma; *Field of Study* Life science (e.g. Medicine, Veterinary Medicine, Pharmacy, Biology). **Experience** Up to three years of full-time professional relevant experience; In a capacity of administrative support in procedure management or equivalent complex administrative procedures and/or experience in organising and supporting large meetings; In the regulatory, scientific or procedural aspects of the production and supervision of medicines on the market; In the science or processes of monitoring the safety of medicines. **Skills and Knowledge** In the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems; Pharmacovigilance EU law and regulation; Stakeholder management; Critical interpretation and analysis of safety data related to medicinal products use and their outcomes on patients; Knowledge of human pharmacology and physiology; Understanding of European PhV regulations (GVP) and signal detection theory and/or practice; Knowledge of epidemiology/pharmacoepidemiology. **Certificates** Biomedical/pharmacist/MD. *(not applicable to PhV Officer in Veterinary Medicines)*
Nice to have Education Experience Skills & knowledge Certificates	**Education** University degree of minimum 3 years in a biomedical or related discipline (medicine, pharmacy, biostatistics); *Field of Study* Physiology, Neurology, Epidemiology, Public health, pharmacoepidemiology, pharmacogenomics, biotechnology, toxicology, regulatory affairs, safety of medicines.

Experience

In information analysis and reporting on scientific/ regulatory matters;

In drafting scientific and/or technical documents (e.g. peer reviewed scientific publications, reports, scientific meeting minutes, project plans and reports, guidance documents, policies and procedures);

Medical practice (prescription/use of medicines) and pharmacy practice (e.g. dispensing medicines);

In the preparation or assessment of safety reviews and documents (e.g. signals, PSURs, RMPs, other regulatory procedures).

Skills & Knowledge

Understanding of scientific aspects of medicines development (such as quality, manufacturing non-clinical and clinical development, specific aspects of safety);

Understanding of clinical trial methodology;

Understanding of signal detection and pharmacoepidemiology;

Understanding of statistical aspects of signal detection and pharmacoepidemiology;

Certificates

Postgraduate certificate, diploma or MSc in a relevant discipline, e.g. epidemiology, public health, medical statistics.

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	Regulatory frameworks & strategy	Basic
Sub-family competencies	Pharmacovigilance	Intermediate
	Pharmaceutical quality	Intermediate
	Applied knowledge	Basic
Grade competencies	Adaptability and agility	Intermediate
	Coping with pressures and setbacks	Intermediate
	Analysing and problem solving	Intermediate
Core competencies	Ethics and integrity	Intermediate
	Team collaboration	Intermediate
	Customer centricity	Intermediate

	Results orientation	Intermediate
	Communication	Intermediate
	Cross-cultural sensitivity	Intermediate
	Continuous learning and self-development	Basic