Role description

Job title	Medicines and Medical Devices Shortages Officer
Job family	Core
Job sub-family	Science & Regulation
Entry grade	FGIV
Role summary	Assist with providing scientific secretarial support to the MSG and/or MDSG, management and support of the EU SPOC and i-SPOC systems for medicines and/or medical devices, and case management of shortages of CAPs.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Facilitate the coordination of the implementation of the new legal mandate of EMA in the area of medicinal products and/or medical devices shortages; Provide scientific secretariat to the Executive Steering Group on Shortages and Safety of Medicinal Products and/or the Executive Steering Group on medical devices; Monitor any events which may lead to a major event or a public health emergency, and which may affect the supply of medicinal products and/or medical devices; Manage and support the EU network and industry network of single point of contacts (SPOC Network and i-SPOC), and monitor and analyse the data on shortages with view to identifying any potential or actual shortages of medicinal products and/or medical devices; Support the establishment and ongoing review of a list of critical medicinal products and/or medical devices, collect demand data for a specific list of medicines and/or medical devices from all National Competent Authorities (NCAs) through the EU network of single point of contacts; Coordinate collection of information on mitigation plans including production and supply capacity from industry; Review, analyse and aggregate the data submitted from NCA SPOCs to estimate demand in EU/EEA countries, match these data with aggregated supply capacity

	from industry, to support the Steering Group on the draft of recommendations on any measures to prevent or mitigate potential or actual shortages; Manage potential or actual shortages of CAPs; Provide scientific support to the activities of relevant group(s) on availability of medicines; Provide scientific secretariat to relevant group(s) on availability of medicines.
Role specific duties & responsibilities	The specific tasks of an individual job holder, linked to this 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 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 Medicines and Medical Devices Shortages Officer will: Liaise with relevant stakeholders.
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* Scientific (pharmacy, chemistry, biology or an equivalent) or technical (e.g. applied science) discipline. **Experience** Up to 3 years of full-time relevant professional experience;

	In supply chain and manufacturing of medicinal products for human use and/or medical devices obtained through previous work in academia, industry, notified body, EU competent authority; In interaction with stakeholders such as patients, healthcare professionals, academia, pharmaceutical and/or medical device industry. **Skills & Knowledge** Knowledge of the EU regulatory aspects related to the medicinal product and medical device lifecycle, from research and development, manufacturing to authorisation and post-marketing. **Certificates** n/a
Nice to have Education Experience Skills & knowledge Certificates	**Education** n/a **Experience** In working in a multicultural environment; Project management experience in leading, coordination, planning, implementation, evaluation and timely delivery of projects. **Skills & Knowledge** A clear understanding of the role of EMA within the legislative framework for the regulation of medicinal products and medical devices. **Certificates** n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	Shortage management & availability	Intermediate
Sub-family competencies	Regulatory frameworks & strategy	Basic
	Pharmaceutical quality	Basic
	Scientific product lifecycle and procedure management	Basic
	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