



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Medicines and Medical Devices Shortages Specialist
Job family	Core
Job sub-family	Science & Regulation
Entry grade	AD06
Role summary	Provide 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	Perform duties reserved only for the Temporary Agent contractual category. 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;

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	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	Plan most daily work details within given priorities. May have a direct supervision of one or more people performing related work. Work may include a degree of planning and coordination, including small projects.
Communication and professional contacts	Required to regularly communicate (verbally and in writing) information, which requires careful explanation and interpretation, taking into account what to communicate and how best to convey the information. Writing and creating information that is specialist, sensitive, confidential, legal and/or regulatory in nature. 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 Specialist will: Liaise with relevant stakeholders, including international partners, ECDC, WHO and learned societies (e.g. ESICM).
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 3 years from the time when a university degree was awarded on completion of a minimum of three years of study;

	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	Intermediate
	Pharmaceutical quality	Basic
	Scientific product lifecycle and procedure management	Intermediate
	Applied knowledge	Intermediate
Grade competencies	Adaptability and agility	Intermediate
	Analysing and problem solving	Intermediate

	Prioritising and organising	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	Intermediate