EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Hajar Youssoufi

Work experience

Stock Shortage Evaluator – DQRS Unit – Inspection Directorate – ANSM *June 2023 – Present*

- Analyze reports of potential or actual shortages of major therapeutic interest medicines (MITM) to assess the criticality of the situation.
- Evaluate risks to patient health and public health, in coordination with other ANSM departments.
- Prioritize reports based on their criticality and risk to patients.
- Review, complete, and correct—when necessary—the solutions proposed by pharmaceutical laboratories.
- Develop and implement tailored action plans to prevent or mitigate shortages.
- **Evaluation of Authorization Requests for Importation and Supply**
- Inform and engage stakeholders (healthcare professionals and patients) in collaboration with the relevant Medical Drug Directorates.
- Prepare, disseminate, and update information on the availability of major therapeutic interest medicines (MITM) on the ANSM website.
- Draft summary documents for ANSM committees.
- Prepare response projects to internal and external inquiries regarding supply difficulties of MITM (Ministry of Health and Prevention, inquiries from healthcare professionals, patients or their representatives, questions from parliamentarians, media, etc.).
- Participate in coordination meetings organized by CASAR for high-risk situations.
- Contribute to decisions on sanctions against non-compliant operators in the context of managing supply tensions or stock shortages.

Regulatory Affairs Manager – Pharmaceutical Affairs Pharmacist Hikma France (manufacturing site) – *January 2022 to May 2023*

- Management of Hikma France's Product Portfolio (exclusively injectable medicines)
- Management of Packaging Components
- Coordination of New Product Launches
- Drafting of Shortage Management Plans (PGP)
- Management of National Supply Tensions with ANSM
- Participation in audits (audits on local Pharmacovigilance activities)
- Handling of product quality complaints
- Drafting, reviewing, approving, and updating Quality documents: SOPs, forms, quality manuals, etc.
- Management and follow-up of CAPAs (Corrective and Preventive Actions) for anomalies, complaints, and audits
- Delivery of pharmaceutical training (GMP, GDP, PV)
- Management of Change Controls
- Management of temperature excursions
- Processing of medical information requests
- Pharmaceutical reconciliation with the Pharmacovigilance department
- Review of PQRs (Product Quality Reviews) for the manufacturing site

Regulatory Affairs Pharmacist Organon France (MAH and manufacturer) – *February 2021 to October 2021*

- Management of Product Portfolio (biosimilars, hormone therapy, and women's health)
- Initiation and validation of packaging components
- Management of stock shortages:
- Updating Shortage Management Plans (PGP)
- Management of European and local Additional Risk Minimization Measures (aRMMs):
- Updating internal regulatory procedures

Regulatory Affairs Pharmacist Sandoz France (MAH and manufacturer) – *October 2019 to January 2020* and *May 2020 to November 2020*

- Management of product portfolio (cardiology, men's health, gynecology, urology, nephrology, pulmonology, OTC)

Regulatory Affairs Pharmacist Les Laboratoires Servier (MAH and manufacturer) – *January 2019 to September 2019*

- Management of product portfolio (cardiology and metabolism)
- Regulatory, competitive, and cross-functional regulatory intelligence
- Updating regulatory databases
- Coordination of submission planning and preparation of the MA (Marketing Authorization) budget
- Updating regulatory procedures and standard operating procedures (SOPs)

Regulatory Affairs Pharmacist (via a consulting firm) AstraZeneca (MAH and manufacturer) – *September 2017 to April 2018*

- Manufacturing site transfer project (production, packaging, and batch release): Leadership, coordination, and monitoring of regulatory activities implementation.
- Serialization: Regulatory coordination (61.3 notification, implementation tracking, internal communication, updating packaging components).
- Product portfolio management: Submission and tracking of variations, validation of HandicapZero patient

information leaflets, approval of Vidal monographs.
- Initiation and validation of changes to packaging components.
- Management of parallel import requests.
- Drafting of Shortage Management Plans (PGP).
- Drafting the regulatory section of Product Quality Reviews (PQR).

Regulatory Affairs Apprentice Mylan Medical SAS (MAH and manufacturer) – *September 2016 to September 2017*

- Preparation, submission, and tracking of Marketing Authorization (MA) variation dossiers according to national, MRP, and DCP procedures.
- "Stock recovery" project launched by ANSM in May 2017.
- Requesting modifications and validation of packaging components.
- Implementation of pregnancy pictograms on secondary packaging following the decree of May 5, 2017, regarding the display of pictograms on the outer packaging of certain medicines or products.
- Assessment of the regulatory impact of new laws and decrees in the French Public Health Code (CSP), and requesting modifications to affected packaging components.
- Review and approval of Vidal monographs in accordance with approved SmPCs.
- Validation of HandicapZero patient information leaflets.
- Updating internal regulatory procedures.

Intern in Pharmaceutical and Chemical Quality Compliance Evaluation ANSM – Solid Oncology and Hematology Products Directorate (Health Authority) – *June 2015 to October 2015* (5th-year pharmacy internship, "Industry" track)

- Technical and regulatory acceptability review, evaluation of Marketing Authorization (MA) variations, updating product information, and notifications to laboratories.
- Non-Medicinal Clinical Trials: Technical and regulatory acceptability review, evaluation, notifications to sponsors, and management of extension requests.

Education and training

State Doctorate in Pharmacy (Diplôme de Docteur d'État en Pharmacie) University of Picardie Jules Verne, Faculty of Pharmacy – 2010 to 2018 – **Grade: Highest Honors - Thesis Topic:** *"Brexit and Its Impact on the Pharmaceutical Industry"* Publicly defended on **July 13, 2018**.

Master 2 in Regulatory Affairs – "Pharmaceutical Regulation and Law" University of Strasbourg, Faculty of Pharmacy – 2016 to 2017 – **Grade: Highest Honors**

Master 2 in Business Administration and Management Institute of Business Administration (IAE) – Amiens – 2015 to 2017 – **Grade: Very Good**

Additional information

Publications

Not applicable

Projects

Not applicable

Memberships

Not applicable

Other Relevant Information

Not applicable