

JOB DESCRIPTION

Position Title: Assistant General Counsel

Department: Legal

Report To: Senior Vice President and General Counsel

Job Summary: Reporting to the Senior Vice President and General Counsel, the Assistant General Counsel will be responsible for providing legal advice and advocacy to Association for Accessible Medicines (AAM) staff and member company representatives on issues relating to generic and biosimilar medicines in the U.S. The position will collaborate with the General Counsel and other AAM staff to determine advocacy strategy and engagement. Working with the General Counsel and outside counsel as necessary, the Assistant General Counsel will provide advice on Hatch-Waxman and pharmaceutical patent issues, and the Association's FDA advocacy. The Assistant General Counsel will also help manage amicus briefs on behalf of AAM with outside counsel and help review Association advocacy materials and contracts with outside counsel as necessary.

Essential Duties and Responsibilities:

- Provide legal assistance to General Counsel on legal, regulatory and policy issues relating to generic and biosimilar medicines
- Serve as primary legal counsel on certain issues related to regulation of generic and biosimilar medicines and intellectual property, assuring coordination between General Counsel and all AAM activity
- Prepare analysis of proposed regulations and legislative proposals
- Provide counsel to member company staff or related stakeholders and work with AAM staff to form advocacy positions on relevant issues
- Identify and recommend appropriate action to address issues related to legislation and regulatory issues to generic pharmaceutical industry priorities
- Prepare briefing materials for AAM staff and member companies on issues and implications of regulatory and intellectual property issues of relevance to AAM priorities
- Manage certain litigation projects including preparation of amicus briefs with outside counsel
- Provide legal review of association advocacy materials and contracts
- Assist with association compliance with lobbying, antitrust, and other requirements

- May be asked to lead advocacy activity related to legislative or regulatory priorities
- May be asked to represent AAM in meetings with government agencies or other stakeholders
- Perform other duties as assigned consistent with the goals of AAM.

Qualifications: To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Possess a working knowledge of relevant statutes, regulations, guidances, and policies including the Abbreviated New Drug Application (ANDA) and Hatch-Waxman provisions of the Federal Food, Drug, and Cosmetic Act, Generic Drug User Fee Amendment (GDUFA), biosimilar approval provisions of the Public Health Service Act, and intellectual property protection for new drugs and biologics. Knowledge of drug pricing, coverage, and reimbursement law is preferred but not required.
- Competent in analyzing legislative and regulatory proposals and their impact on generic and biosimilar drug manufacturers
- Be able to interact with a wide range of stakeholders within the association, member companies, legislative staff, and regulatory staff, including at the FDA and HHS
- Possess strong written and oral communication skills, including the ability to summarize and assess the impact of policy proposals on the generic and biosimilar medicines industry and to deliver advocacy positions in public forums
- Ability to work independently as well as collaboratively on a team
- Be able to manage multiple projects at once and manage outside counsel

Education and Experience Requirements:

- J.D degree, required
- 5+ years legal practice in relevant areas at a law firm, Federal government, Congress, or in a pharmaceutical company, required
- Member of the DC bar, or able to waive in, required
- Experience in trade association or as counsel for association clients, preferred



Your Generics and Biosimilars Industry

Physical Demands: The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- None

Work Environment: The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Standard office environment

Travel: minimal

This job description does not imply that the stated requirements are the only expectations for the position. Incumbents are expected to perform any other duties that may be assigned. AAM has the right to revise this job description at any time. AAM is an “at will” employer and as such, neither this job description nor your signature constitutes any form of contractual agreement between you and AAM.

Acknowledgement:

Name: _____ Date: _____

