

ASSOCIATION FOR ACCESSIBLE MEDICINES

Commitment to Quality Excellence

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aam
Association for Accessible Medicines



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Improving patient access to affordable high-quality medicines is a core value of companies that develop and manufacture generic and biosimilar medicines. Our companies produce and distribute the medicines that make up approximately 90% of all prescriptions filled in the United States – but at just 22% of total prescription drug spending. We serve as a key pillar in our national healthcare system. Our work includes promoting marketplace competition and supporting strategic enhancements to the Food and Drug Administration's (FDA) generic drug and biosimilar approval process. We do this for one purpose: to put affordable quality medicines within the reach of patients who need them, in order to improve health outcomes and lower health care costs.

High prescription drug costs impact a patient's ability to fill their prescription(s) and to adhere to the doctor-prescribed regimen. Every dollar saved at the pharmacy counter is a dollar that patients can spend on life's essentials and other pursuits – or put away for future use. We help patients live better lives, and we do so in a way that saves precious resources for patients, taxpayers, and our economy.

Today we introduce **AAM's Commitment to Quality Excellence** which has been fully endorsed by the AAM Board of Directors. While AAM's member companies have demonstrated a commitment to quality excellence for many years, it is incumbent upon us to declare to our patients and customers the values upon which our industry is based, and the ethical and business standards upon which we remain committed to operating.

Our commitment to quality excellence has been evidenced externally over the years not only through the quality of our products, but also through the work of AAM and our member companies on our internal and external endeavors such as; continuous learning and improvement, engagement in public policy, scientific and educational forums with regulators, academia and industry colleagues, and ongoing input into regulatory and technical dialogues and processes with regulators and other segments of industry – i.e., active pharmaceutical ingredient manufacturers, packaging and labeling companies, etc. We urge industry associations from the brand and biotech pharmaceutical sectors to follow our lead by joining this commitment to quality excellence by developing and publishing their own position paper. Our patients count on all of us to promote and protect their health, and we must take all necessary steps to document and effectuate this responsibility.

AAM and our member companies hold our obligations to patients and to public health to be paramount, as such, our members have embraced and continue to drive a commitment to quality excellence. A commitment to quality excellence is essential for pharmaceutical manufacturers to ensure patient safety and satisfaction, which results in business success. By sustaining a patient-and quality-focused environment, we assure that patients are well-served by the generic and biosimilar pharmaceutical industry.

Over the last 100 years the pharmaceutical industry, in concert with regulators, has evolved its scientific discipline practices and level of maturity with respect to assuring product quality from Quality Control through Quality Assurance to Continuous Quality Improvement, and the development of robust Quality Systems; thereby, declaring a **Commitment to Quality Excellence** in the consistent delivery of product quality and safety. While the Good Manufacturing Practice regulations (GMPs) of the Food and Drug Administration (FDA) define the minimum standards that are required to meet and maintain a state of control in the manufacture and distribution of drug products, an exclusive focus on GMPs is not enough. Pharmaceutical manufacturers must also focus on patient needs for high quality, available products. The expectation is that we continue to achieve high quality through the implementation of comprehensive, modern quality systems and risk management approaches in our pursuit and commitment to quality excellence.

AAM and its member companies acknowledge the commitment to quality excellence and our intention to continually invest in the tools and infrastructure necessary to support quality, continuous improvement, and excellence. To accomplish this critical role, we must continually stay keenly focused on quality improvement. This requires knowledge, diligence, vigilance, and senior management commitment. It also requires ongoing dedication of energy and resources to robust programs on such key issues as:

Education and Training Program

These programs should be implemented across the entire company for ALL levels of employees to foster behaviors which build toward quality excellence;

Leadership Program

Educate on the roles and responsibility of Senior Leadership that would then be cascaded down through the entire organization;

Empowerment Program

ALL employees are actively engaged in the pursuit of quality excellence;

- Employee Engagement Initiatives
- Absence of Fear Initiatives
- Raise-the-Bar Initiatives

Communication Program

Data and information are consistent across the entire organization, including appropriate channels to escalate issues up the chain of command;

- Transparency Initiatives
- Dissemination Initiatives
- Escalation Protocol
- Listening Systems

Rewards & Recognition Program

Incentivize the right behavior, which in turn drives quality excellence;

- Incentivizing the Right Behavior
- Disciplining the Wrong Behavior
- Balanced Performance Reviews

Continuous Improvement Program

Acknowledge and learn from mistakes, which will lead to a continuous learning environment. We continue to actively participate in creating and learning from industry best practices;

- Celebrate and Learn from Mistakes
- Foster Ownership/Accountability
- Quality Planning
- Establishment of Goals and measures that matter

AAM and its full members never take the ethics of healthcare access for granted. We believe wholeheartedly in our ethical mission; and as such, we will embrace the six programs above to ensure continuous quality improvement of our products and systems – our commitment to quality excellence. AAM looks forward to working with all stakeholders to expand access to generic and biosimilar medicines – the proven, reliable way to drive down the cost of medicine, which helps patients, strengthens our economy, and benefits our society.