



Compliance with Regulations Policy

Introduction

At Prism Industries Pvt Ltd, we recognize that compliance with local, national, and international regulations is a critical component of our operations. As a global leader in the pharmaceutical and nicotine product industries, including nicotine-based formulations, quinine, hyoscine, lumefantrine, and artemether, we are committed to adhering to all applicable laws and regulations that govern the production, sale, and distribution of our products.

Ensuring compliance is not only essential for maintaining our industry reputation, but it is also a key element in safeguarding public health, maintaining ethical business practices, and operating within the legal frameworks that protect consumers and the environment. As regulations evolve globally, particularly around products like nicotine and e-liquids, we proactively work to ensure that our operations stay ahead of regulatory changes and meet or exceed the required standards.

This Compliance with Regulations Policy sets forth the framework by which Prism Industries will ensure full compliance with the relevant laws and regulations regarding our products. These include, but are not limited to, regulations concerning nicotine products, quinine, hyoscine, lumefantrine, artemether, packaging, labeling, health warnings, and age restrictions. We are committed to integrating these compliance requirements into our daily operations and ensuring that all stakeholders involved with our products adhere to the highest standards of legal and regulatory adherence.

Scope and Applicability

This policy applies to all employees, contractors, suppliers, distributors, and third-party business partners who are involved in the production, distribution, marketing, or sale of Prism Industries' products. These include:

- **Nicotine-based products** such as nicotine salts, e-liquids, and related vaping products.
- **Pharmaceutical products** such as quinine, hyoscine, lumefantrine, and artemether, which are critical in the treatment of various diseases including malaria.

The policy covers all stages of production and distribution, including the sourcing of raw materials, manufacturing, packaging, labeling, marketing, distribution, and sales of these products.

CIN: U24231GJ1992PTC017501

Office: 208, Trivia Complex, Nr. Natubhai Circle,
Race Course, Gujarat, INDIA, Pin-390007

Phone: 0265-3504649/50 **Mob:** +91 98250-51262, +91 92274-06992

E-mail: marketing@prisminltd.com

PAN: AABCP7162Q

Factory: Survey No. 637/23/A1, Khambhat Dhuvaran Road, At: Kalamsar,
Ta.: Khambhat, Dist. Anand, Gujarat, INDIA, Pin-388640

Mob: +91 98250-50731, +91 97277-01668

E-mail: info@prisminltd.com

GSTIN: 24AABCP7162Q1ZY



Objectives of the Compliance with Regulations Policy

1. **Ensure Adherence to Legal and Regulatory Requirements**

The core objective of this policy is to ensure that Prism Industries complies with all relevant local, national, and international regulations governing the production, distribution, and sale of nicotine products, pharmaceutical products (quinine, hyoscine, lumefantrine, and artemether), and any other related goods. This includes staying up-to-date with evolving regulations, particularly in markets where regulatory environments are in flux.

2. **Maintain Public Health and Consumer Safety**

Compliance with regulations is vital to protecting public health and consumer safety. For products like nicotine, quinine, and other pharmaceuticals, it is critical that all health warnings, age restrictions, packaging laws, and marketing regulations are followed to ensure that these products are used safely and responsibly.

3. **Promote Ethical Business Practices**

By adhering to legal and regulatory requirements, we promote ethical business practices throughout our operations, ensuring that our products are manufactured, marketed, and distributed in a manner that meets both legal obligations and social responsibility standards.

4. **Minimize Legal and Financial Risks**

Non-compliance with regulations can lead to significant legal and financial risks, including fines, lawsuits, and damage to our company's reputation. This policy ensures that all operations comply with the law, thereby minimizing the risk of regulatory violations and maintaining the integrity of the business.

5. **Create Transparency and Accountability**

We aim to foster a transparent, accountable culture where compliance with regulatory requirements is embedded in every level of the company's operations. This includes regular monitoring, reporting, and auditing of compliance activities to ensure continued adherence to relevant laws.

Key Principles of the Compliance with Regulations Policy

1. **Adherence to Industry-Specific Regulations**

Prism Industries is committed to adhering to all industry-specific regulations, particularly those that govern the production and sale of nicotine products and pharmaceutical products. This includes compliance with:

- **Nicotine and E-Liquid Regulations:** Compliance with laws and regulations governing the sale, distribution, and marketing of nicotine-based products and e-liquids, including age restrictions, packaging laws, health warnings, and public health considerations.



- **Pharmaceutical Regulations:** Adherence to regulations surrounding the production and distribution of quinine, hyoscine, lumefantrine, and artemether, ensuring that these products meet international pharmaceutical standards and local health and safety requirements.
2. **Age Restrictions**
For nicotine-based products, Prism Industries strictly adheres to age restriction laws in every region we operate. These laws are designed to prevent the sale of nicotine products to minors and ensure that our products are marketed and distributed only to legal adult consumers. We enforce stringent age-verification procedures at all points of sale, whether in physical locations, online platforms, or through third-party vendors.
3. **Packaging, Labeling, and Health Warnings**
In compliance with regulatory requirements, all of our products, including nicotine-based formulations and pharmaceutical products, are properly packaged and labeled according to legal standards. This includes:
- **Health Warnings:** All packaging for nicotine products, quinine, hyoscine, lumefantrine, and artemether must contain appropriate health warnings, in line with the regulations of each jurisdiction. For nicotine products, this may include warnings about the risks of addiction and other health effects.
 - **Labeling Requirements:** Our products are labeled with necessary details such as ingredients, recommended usage instructions, storage guidelines, and batch numbers to ensure traceability and consumer safety. Pharmaceutical products, such as quinine and artemether, also carry required information on dosage, side effects, contraindications, and storage conditions.
4. **Advertising and Marketing Compliance**
We ensure that all marketing and advertising campaigns comply with relevant regulations governing the promotion of our products. This includes advertising restrictions, particularly for nicotine-based products, which are often subject to stringent rules regarding where and how they can be advertised (e.g., no marketing to minors, restrictions on certain platforms or media).
5. **Environmental Compliance**
Prism Industries is committed to adhering to environmental regulations that govern the manufacturing and disposal of products, including nicotine-based formulations and pharmaceuticals. This includes compliance with environmental impact assessments, waste disposal regulations, and sustainable sourcing practices to minimize our ecological footprint.

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6. Quality Control and Manufacturing Standards

Our manufacturing processes must adhere to Good Manufacturing Practices (GMP) to ensure that products are consistently produced and controlled to meet the highest quality standards. This applies to nicotine products, quinine, hyoscine, lumefantrine, and artemether, ensuring product integrity, safety, and efficacy.

7. Ongoing Monitoring and Auditing

To ensure continued compliance with evolving regulations, Prism Industries conducts regular internal audits and reviews. These assessments are designed to identify any areas of non-compliance, gaps in knowledge, or new regulatory requirements that need to be addressed.

Compliance Procedures

1. Regulatory Awareness and Training

Employees at all levels of Prism Industries, particularly those involved in product development, manufacturing, marketing, and compliance, will receive regular training on current and emerging regulations that affect the production and sale of nicotine, quinine, hyoscine, lumefantrine, and artemether. This includes training on labeling requirements, packaging laws, health warnings, and age verification procedures.

2. Regulatory Monitoring and Updates

We maintain a system for monitoring and reviewing changes in relevant laws and regulations across all markets where our products are sold. This ensures that Prism Industries is proactive in responding to new or updated regulatory requirements. A designated compliance team is responsible for tracking regulatory changes and ensuring that the organization adheres to them.

3. Supplier and Vendor Compliance

Prism Industries holds its suppliers and vendors to the same high standards. We require that all suppliers and vendors of raw materials and components, such as those for nicotine, quinine, hyoscine, lumefantrine, and artemether, provide certifications demonstrating compliance with applicable legal and regulatory requirements.

4. Reporting Non-Compliance

Any instance of non-compliance, whether identified internally or externally, must be reported immediately to the Compliance Officer or relevant department. Prism Industries ensures that there are clear channels for reporting violations or concerns, with guarantees that reports are handled confidentially and without fear of retaliation.

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5. **Corrective Action and Enforcement**

Prism Industries takes swift corrective action when instances of non-compliance are identified. This may involve revising processes, retraining employees, adjusting marketing strategies, or engaging with regulatory authorities to resolve the issue. Any violations are taken seriously and may result in legal or disciplinary action.

Roles and Responsibilities

1. **Compliance Officer**

The Compliance Officer is responsible for overseeing the implementation of this policy, ensuring that Prism Industries stays compliant with all relevant regulations. The Compliance Officer will regularly monitor industry regulations, coordinate training programs, and ensure that all departments follow appropriate compliance procedures.

2. **Management**

Management at all levels is responsible for ensuring that their teams adhere to regulatory requirements and follow this Compliance with Regulations Policy. Management should promote a culture of compliance, provide resources for training, and support the implementation of compliance strategies.

3. **Employees**

All employees are expected to understand and follow the regulatory requirements relevant to their roles. Employees must participate in compliance training, adhere to the procedures established by this policy, and report any instances of non-compliance promptly.

4. **Suppliers and Vendors**

Suppliers and vendors are expected to comply with all applicable legal and regulatory standards, particularly in relation to the products they supply to Prism Industries. This includes providing relevant certifications, adhering to quality control standards, and ensuring compliance with environmental and safety regulations.

Conclusion

Prism Industries Pvt Ltd is committed to complying with all local, national, and international regulations governing the production, marketing, and distribution of our products, including nicotine-based formulations, quinine, hyoscine, lumefantrine, and artemether. By adhering to this Compliance with Regulations Policy, we aim to maintain the highest standards of product safety, regulatory adherence, and business integrity. Through ongoing training, monitoring, and audits, we ensure that our operations remain compliant with current and evolving laws and regulations.

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PRISM INDUSTRIES PVT. LTD.

A WHO-GMP Certified Company
(Formerly known as Prism Industries Ltd.)

This commitment to compliance safeguards public health, protects our business interests, and upholds the trust of our customers, employees, and stakeholders.

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