Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 223 - 224 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.106
Short communication

Climate change and pharmacy: impact on drug stability, supply chains and public health with implications for pharmaceutical manufacturing

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Introduction

Climate change is increasingly recognized as an important factor influencing both environmental and public health systems, with direct implications for the pharmaceutical industry. For a manufacturer such as Alkaloid, these changes are not only environmental but also operational, affecting everyday processes such as Good Manufacturing Practice (GMP) compliance, Quality Management System (QMS), and supply chain management.

This review examines how climate-related factors can influence drug stability, logistics and production planning, with a particular focus on their practical impact on pharmaceutical operations.

Impact of temperature on drug stability

Changes in temperature, humidity and the growing frequency of extreme weather events (such as prolonged heat waves) present real challenges in maintaining product quality throughout the lifecycle of pharmaceutical products. Within a GMP environment, these parameters are treated as critical and must be strictly controlled during manufacturing, storage and distribution.

Higher temperatures and increased humidity can accelerate degradation processes, alter physical characteristics, and ultimately reduce the stability and shelf-life of finished products (ICH, 2003; WHO, 2018). These challenges become even more critical for temperature sensitive products, which require validated cold chain systems and continuous environmental monitoring - both of which are key elements within Alkaloid's quality management system (FDA, 2020).

From a Quality Assurance perspective, climate variability introduces additional complexity. Stability studies must increasingly reflect real-world conditions, while temperature excursions during storage or transport can result in deviations, out-of-specification (OOS) results, and potential product quality risks (FDA, 2020). In practice, this requires stronger risk assessment, more robust deviation handling and continuous improvement activities within the QA system.

Materials and Methods

This study is based on a qualitative review of scientific literature and regulatory guidelines (ICH, WHO, EMA, FDA), combined with practical consideration of pharmaceutical processes relevant to Alkaloid.

The analysis focuses on three key areas: manufacturing under GMP conditions, Quality

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Assurance systems and supply chain operations in line with Good Distribution Practice (GDP). A risk-based approach was applied to better understand how environmental changes, especially temperature and humidity, can impact product stability and process reliability across these areas.

Supply chain vulnerabilities

Climate change also affects pharmaceutical supply chains, particularly in transportation and distribution. Disruptions caused by extreme weather and increased risks of temperature deviations can directly impact product quality.

For a company like Alkaloid, which operates across multiple markets, maintaining controlled conditions throughout the supply chain is essential. This involves the use of qualified transport systems, temperature monitoring, and real-time tracking to ensure compliance with GDP standards (EMA, 2013; FDA, 2020). In such conditions, logistics is no longer only an operational function, but a critical part of product quality assurance.

Increased demand for medicines

Climate change is inevitably influencing public health trends. The increase in climate-sensitive conditions, including infectious diseases, leads to higher demand for pharmaceutical products (WHO, 2024). There is also a significant increase in heatstroke during hot weather periods, leading to increased cardiovascular disease, especially among vulnerable groups.

This places additional pressure on production planning, capacity management and raw material availability. As a result, manufacturing systems must become more flexible and resilient, with a stronger focus on risk management and long-term sustainability.

Overall interpretation

Climate change is becoming an increasingly important factor shaping pharmaceutical systems, influencing product quality, supply reliability as well as demand. Addressing these challenges requires not only technical solutions, but also awareness and coordination across different teams. In practice, the ability of employees to recognize risks and respond appropriately plays a key role. A balanced approach that combines pharmaceutical knowledge, environmental awareness and continuous improvement is essential for maintaining stable and reliable operations.

Conclusion

Climate change is no longer a theoretical concept—it is already influencing how pharmaceutical companies operate on a daily basis. For Alkaloid, it directly affects how medicines are produced, stored and distributed, as well as how their quality is maintained.

Awareness is therefore essential. Recognizing potential risks early allows for timely reactions and better protection of product quality. In everyday work, this means closer monitoring of environmental conditions, stronger control systems and more proactive decision-making.

Ultimately, climate awareness in pharmacy is not just about responsibility, it is about ensuring consistency, reliability and trust in every product that reaches the patient.

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