AFRiSUMMIT

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Exclusive Interview with **Gold Sponsor**

Mr. Jerome Cabannes

The CEO of

الدوائية SPIMACO

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- Can you provide an overview of SPIMACO's regulatory strategy and how it aligns with evolving pharmaceutical regulations in the region?

SPIMACO, as a leading Saudi pharmaceutical company in the Middle East & North Africa, is focused on expanding its global footprint by delivering high-quality generics and biosimilars, particularly in rare diseases and oncology, alongside our established portfolio in chronic diseases and OTC products. Our regulatory and market access strategy involves over 150 new registrations, in the Middle East and Africa by 2025. This approach ensures that we remain aligned with evolving regional regulations, enabling us to deliver innovative therapies that meet local market demands while upholding the highest standards of quality and compliance.

- What are the key regulatory challenges SPIMACO faces in different markets, and how do you address them to ensure compliance and timely market access?

One of the major challenges in many markets, particularly in the Middle East and Africa, is addressing drug shortages. SPIMACO's near-shoring strategy, through our own manufacturing plants or partnerships with local CMOs, positions us as a reliable partner for health authorities in ensuring a sustainable drug supply for a wide range of therapeutic areas. To achieve this, we work closely with regulators to expedite product registrations through regulatory reliance frameworks, regional harmonization, and "green corridors" for generics and biosimilars—especially those addressing critical supply gaps or being first to market. Additionally, we engage in constructive discussions to ensure fair pricing and smooth market access, despite challenges such as inflation and rising transportation costs.

- With the increasing focus on harmonization in the pharmaceutical industry, how is SPIMACO adapting to international standards?

Operating across diverse regulatory and economic environments presents SPIMACO with a unique opportunity to contribute to global public health while building our capabilities to meet the highest international standards. We are a multicultural team with expertise across various regions, and we work closely with HR to implement continuous training programs that ensure we stay aligned with the latest global guidelines. Externally, we collaborate with health authorities to meet local requirements while actively engaging in discussions aimed at harmonizing regulatory frameworks at the regional level. This not only facilitates market

access but also helps ease the regulatory burden on authorities, ultimately improving patient access to essential medicines.

- How does SPIMACO collaborate with health authorities and industry stakeholders to streamline regulatory processes and accelerate approvals?

In today's environment of supply constraints, SPIMACO prioritizes near-shoring and local manufacturing to ensure a stable and reliable supply of medicines. As we expand our portfolio into areas such as biosimilars, rare diseases, and oncology, we actively collaborate with health authorities and regulatory agencies to develop frameworks that support these strategic initiatives. This includes working on regulatory and pricing models that encourage innovation within the regional generics and biotechnology sectors. Soon, we aim to lead cross-industry collaborations, working alongside trade associations and health authorities to further streamline regulatory processes and accelerate approvals.