

Third Party Due Diligence in the Pharmaceutical and Medical Device Sectors

REGIONAL CASE STUDIES

MENA

When a standard pre-renewal due diligence exposed allegations of corruption against an existing agent, PSA quickly transitioned ongoing inquiries into an active investigation under privilege. Following additional inquiries and media research in Arabic, PSA identified and recovered supporting documentation that verified the allegation. We then traveled to a 3rd country to obtain statements and to receive copies of receipts from those involved. Our action led to the debarment of the agent and supported effective disclosure to US regulators of our findings.

European Union (EU)

PSA conducted investigative due diligence in Southern Europe on a high-risk but essential counterparty with a history of corruption concerns. PSA was able to explore all available reporting in English and local languages, discreetly interview previous employees, and speak directly with those involved in previous enforcement proceedings. Armed with this detailed understanding, PSA began mapping the current organization, its management, incentives, processes, and controls. As a result, we were able to demonstrate the company had taken effective steps to amend its management and culture and had put in place sufficient controls to permit our client to engage with them under certain conditions.

Africa

PSA's research in West Africa established a potential distribution partner that was well-placed to support an expansion of the Client's products into the region. The research established the bona fides of the distributor, confirmed their access and capability, and confirmed a commendable track record of working for other similar companies in the region.

TOPICAL CASE STUDIES

HCP Vetting

PSA was approached by a pharmaceutical company with 2,000+ HCPs in East Asia, some of which had PEP concerns. PSA was able to develop and apply a robust, cost and time-appropriate scope of work to sufficiently vet HCPs and remediate false positives.

Agent and Distributor Vetting

PSA assisted in the ground-up establishment of a purpose-built due diligence program for a medical device company under pressure to demonstrate effectiveness and in the early stages of a deferred prosecution agreement (DPA).

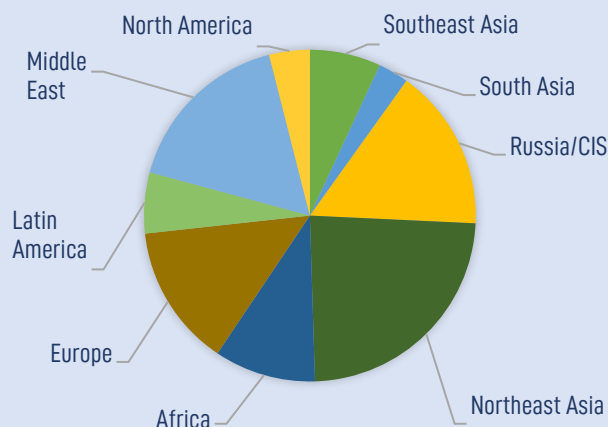
Working with the Client's legal and compliance leaders, PSA brought in an appropriate platform partner and then developed and applied a risk assessment methodology to the Client's 3rd parties. PSA was able to identify and then immediately initiate appropriate due diligence on the highest-risk counterparties first, thereby enabling the application of a robust and defensible risk-based approach to due diligence.

Whistleblower Response

PSA responded to allegations of fraud and bribery in the Chinese distribution networks of a global medical device company. Responding from PSA's Shanghai office, we were able to swiftly engage in discreet human source inquiries and records-based research to assess the veracity of the claims, and then to expand our search to quickly identify the mechanism and parties responsible.

Global distribution of pharmaceutical and medical device investigations and due diligence reports

Pharmaceutical and medical device companies make up 20% of PSA clientele. They order reports in every region of the world. In 2023 PSA provided services in 151 countries on six continents.





Pacific Strategies & Assessments

Established in 2000, PSA is a specialist risk consultancy delivering critical information to our clients through our Due Diligence, Investigations, and Advisory services. We operate where our clients do business, with regional offices staffed by investigators and responders who have extensive in-region experience gained from professional

backgrounds in corporate investigations, government intelligence and law enforcement. With a disciplined focus on information collection, we have a 23-year track record of supporting businesses in conducting assessments of complex operating environments.



Due Diligence

Our DD products are tailored to our clients' needs and based in deep understanding of best practices and regulatory guidelines. We scale from desktop research to on-the-ground investigations with multiple process-based due diligence options.



Investigations

PSA has a proven record in supporting companies in complex, international investigations. Our investigative abilities can be scoped to accommodate a variety of engagements, including whistleblower response, fraud investigations, and asset tracing.



Advisory

PSA provides strategic guidance to firms to address specific concerns. We tailor services to support clients on a variety of complex issues, including complex disputes, country-specific operational risks, emerging regulatory issues, and point-specific human risks.