Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional (SpringerBriefs in Pharmaceutical Science & Drug Development)

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This Brief defines competitive intelligence (CI) as a tool for making investment decisions within the pharmaceutical industry. It provides an overview of processes that the regulatory affairs professional must take into account when evaluating data impacting product-based risk evaluations. These apply particularly to evaluations that focus on outputs such as regulatory approval, or the commercial impact of product labeling on the sales forecast over a limited timeframe. The Brief also provides an overview of intellectual property assessment that can impact a product’s lifespan on the market due to patent protection itself (or loss of patent protection) or via regulatory exclusivity. Case examples are discussed to illustrate the importance of keeping up with the ever-changing regulations, and how to interpret them in the context of CI. In addition, there is a section on virtual data rooms (VDRs) which currently function as the cornerstone of due diligence investigations. While aimed primarily at regulatory affairs professionals in the United States, this publication provides a useful adjunct for other pharmaceutical executives, especially those new to product-based investments, and regulatory affairs professionals in other regions. ?

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