



Pharmaceutical Risks 2016

KPMG presents our view of the top risk by value driver faced by corporates in the Pharmaceutical sector

Global

October 2016



2016 Risks for Pharmaceutical

Emergence of fast evolving digital technologies, increased regulatory pressure and global economic uncertainty are key factors in the current risks landscape. KPMG Risk Consulting assists clients to develop robust risk mitigation methods by interpreting the underlying drivers of global risks.



Strategy

- **Macroeconomic uncertainty in key markets from factors such as the UK's vote to leave the EU (Brexit), economic recession in Brazil and Russia and slowdown in China affecting sales and profitability due to tightened healthcare budget by government.**
- Delay in commercialization of product due to challenges including technological innovation, clinical trials, regulatory approvals, encountering infringement claims and feasibility.
- Biotech drugs are gaining traction and increasing competitive pressure on traditional business model based on chemical drug.



Growth

- **Competition arising from non traditional players providing services on digital health technology i.e. telehealth, mhealth, wearables and social media and creating a significant changes in the industry model.**
- Risk of exclusive investments in research and development (R&D) for new products or extension on existing product , beyond the growth of sales.
- Expanding international operations leading to risks due to non-compliance with various regulations, economical and political developments, discriminatory fiscal policies etc.



People

- Inability to attract and retain qualified personnel while appropriately managing costs related to employee benefits.



Operational Excellence

- Outsourcing risk with increasing reliance on third parties for key business functions such as clinical trials, manufacturing, sales and R&D..
- Risks associated with product liability, and recalls, resulting in legal proceeding and tarnishing brand name.
- **Inability to recover and sustain critical operations following a disruption in the production and manufacturing facility.**



Technology

- IT risks relating to increased dependence on information technologies and networks in research and development, production and sales,.



Profitability and liquidity

- Heavy reliance on the performance of certain flagship products.
- The risk of adverse movements in interest rates, exchange rates and stock prices..



Reputation and Ethics

- Failure to protect patient's interests and maintain the integrity of human clinical trial research..
- Risk to reputation/brand as a result of negative assessment or comments from stakeholders.



Compliance

- Claims and investigations relating to competition law, marketing practices, pricing, compliance, antitrust, environmental, employment and tax litigations.
- Risk of securing and protecting intellectual property rights from third parties who can launch generic versions of company's products or impose infringement allegations.
- Increasing pressure on prices due to government price controls.
- Increasing healthcare regulatory requirements for clinical trials and launch of products.
- Fraud, violations of the laws tariff/policies and cross-border legislations.



Health, Safety and Environment

- Rising pressures from environmental activists due to increasing speculations of pharmaceutical residues leading to contamination of water and soil.

Legend

Emerging Risk

Existing Risk

Retiring Risk

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