



# Pharmaceutical Risks 2018

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.

Global

2018



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

- **Macroeconomic uncertainty** in key markets from factors such as the UK's vote to leave the EU (Brexit), economic recession in Brazil and Russia, slowdown in China and change of administration in the US
  - **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
- **Rising pressures from environmental activists** due to increasing speculations of pharmaceutical residues leading to contamination of water and soil

- **Competition from non traditional players** providing services on digital health technology i.e. telehealth, mhealth, wearables and social media
- **Failure to complete or integrate acquisitions** and JVs into existing operations as pharma companies increase focus on in-licensing mid-to-late stage pipeline drugs
- **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

- Growing **need to adopt digital technologies** across the value chain including drug development and commercialization, and use of data analytics
- **IT risks** relating to increased dependence on information technologies and networks in research and development, production and sales, as well as cyber-security breaches

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

