How the Business Manages Risk

Risk Agenda

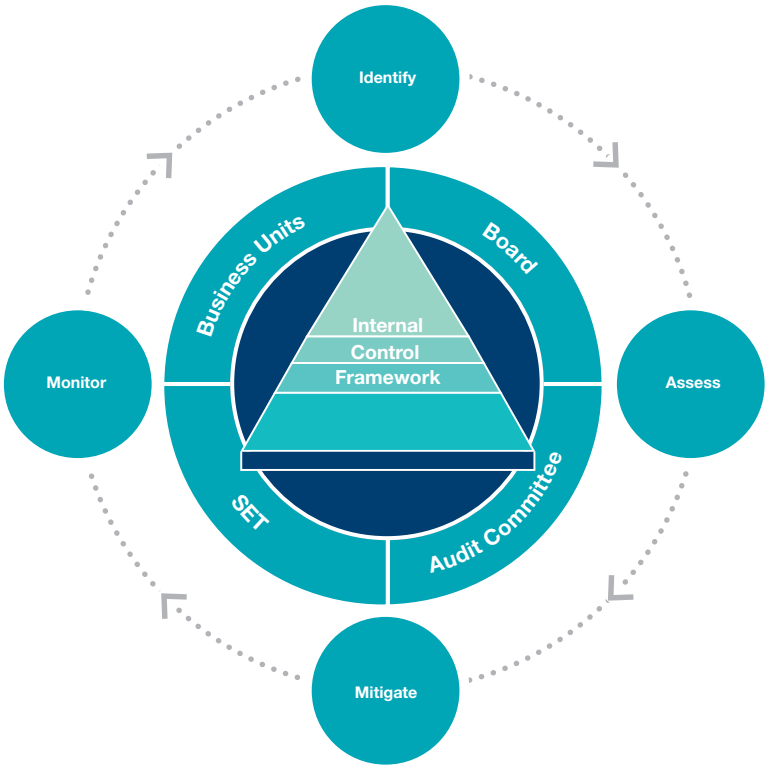
Effective risk management is key to the achievement of our business strategy. In October 2013 the Board commenced a review of the Group's risk management process in order to assess whether there was scope for improvement. Deloitte LLP were retained to assist with the review, which formed part of their wider remit to assist in the review of the Group's internal financial controls. More detail in relation to this review can be found on pages 81 to 82 of the Audit Committee Report.

The review confirmed that, overall, the risk management process was appropriate for the size of the Group and provided validation of the existing risks. However, the following areas of improvement were suggested:

- ownership of the risks should be created at SET level;
- amendments to both the process and documentation, including the introduction of half-yearly risk interviews with the SET; and
- the proposed appointment of the Internal Audit Function should encompass a risk assurance remit.

It is considered by the Board that these changes to the current risk system and framework will ensure that:

- the SET provides a platform for reviewing and assessing risk from both a bottom up and top down level, and acts as a link between the Board and the business units ensuring that risk management is embedded within the business;
- any risks identified in relation to the achievement of the Group strategy are correctly captured and monitored;
- the risk appetite is correctly assessed and understood; and
- there is a strong governance framework clearly linking our risk management and internal controls framework. For information on the Internal Control Framework see pages 76 to 77.



Risk Framework

The SET is now a pivotal platform responsible for the overall risk framework. It drives the identification of risks, establishes the owners of each of those risks and ensures that they are correctly mitigated and monitored. The SET reports the risks to the Board. Each SET member owns one or more of the risks and is scheduled to attend Board meetings during the course of the financial year to conduct a detailed review of their risks. For the purpose of the year end disclosure each SET member has met with the Chief Financial Officer and Company Secretary to discuss their risks and controls.

The discussions have focused on a number of areas including:

- understanding the possible root causes of the risk;
- reviewing what controls are currently in place; and
- assessing whether additional controls should be added in order to ensure that the risk is appropriately mitigated.

The SET will also ensure that ongoing monitoring is embedded in their business units or function.

The SET has identified and agreed key risks with the Board. Of these, a number are deemed to be generic risks facing every business including failure to comply with financial reporting regulation, IT failure and non-compliance with legislation. The table below therefore details the eight principal risks which are bespoke to our business and provides information on:

- how they link to the Group strategy;
- how they could potentially impact the business; and
- what controls have been put in place to mitigate them.

Key of trend compared to prior year: No Change | Increased Risk | Reduced Risk

Link to Strategy	Risk	Potential Impact	Mitigation	Trend
	Competitor Risk: Competitor products launched against one of our leading brands (e.g. generics or superior product profile). We depend on data exclusivity periods or patents to have exclusive marketing rights for some of our products. Although we maintain a broad portfolio of products, we recognise that our unique products, like *Vetoryl* and *Felimazole*, have built a market which may be attractive to competitors. We need to ensure that, should competitors enter the market, we create additional unique selling points which allow us to maintain our market share.	Revenues and margins may be materially adversely affected upon the expiry or early loss of patents, or by generic entrants/competitors into the market for one of our leading brands. Costs may increase due to defensive marketing activity.	We focus on lifecycle management strategies of our key products to ensure that our products fulfil evolving customer requirements. Product patents are monitored and consideration is given to the formulation of a defensive strategy towards the end of the patent life or the data exclusivity period. We monitor market activity so that prior to competitor products being launched, a response strategy can be established and executed by our marketing team. This defence plan is intended to minimise competitor impact.	
	Product Development Risk: Failure to deliver major products either due to pipeline delays or newly launched products not meeting revenue expectations. Delivery of our pipeline is key to the achievement of our strategy and our future success. We commit substantial resources to development. However, we may be unable to develop or get new products approved. It may also be difficult to predict whether newly launched products will meet commercial expectations.	A succession of clinical trial failures could adversely affect our ability to deliver shareholder expectations. Our reputation and relationship, not only with our shareholders, but also with veterinarians, could be damaged. Our positioning in the market may be affected and could reduce our leading position in key therapeutic areas. Reduced revenue and profitability may mean we are unable to recoup the costs incurred in developing and launching the product, resulting in impairment of intangible assets.	Potential new development candidates are assessed from a commercial, financial and scientific perspective by a multi-functional team to allow senior management to make go/no go decisions. The pipeline is discussed regularly by senior management, including the Chief Executive Officer and Chief Financial Officer. Regular updates are also provided to the Board. Each development project is managed by a dedicated clinical project manager who chairs a monthly project team meeting. Before major costly efficacy studies are initiated, smaller proof of concept studies are conducted to assess the effects of the drug on the target species and for the target indication. In respect of all new product launches a detailed marketing plan is established and progress against that plan is regularly monitored. The Group ensures that it has a detailed market knowledge and retains close contact with customers through its management and sales teams which are consistently trained to a high standard.	

How the Business Manages Risk continued

Link to Strategy	Risk	Potential Impact	Mitigation	Trend
	**Regulatory Risk:** Failure to meet regulatory requirements. We perform our business in a highly regulated environment, not only from a manufacturing perspective but also in respect of product approvals. Failure to adhere to, or maintain, regulatory standards could ultimately affect our manufacturing capability and our ability to deliver products to market on time.	Delays in regulatory reviews and approvals could impact the timing of a product launch and have a material effect on sales and margins. Any changes made to the manufacturing, distribution, marketing and safety surveillance processes of our products may require additional regulatory approvals, resulting in additional costs and/or disruption. Failure to achieve regulatory requirements may result in operational closures which in turn increases expenditure and delays to production.	The Group strives to exceed regulatory requirements and ensures that its employees have detailed experience and knowledge of the regulations. Manufacturing and PDRA have established quality systems and standard operating procedures in place. Regular contact is maintained with all relevant regulatory bodies in order to build and strengthen relationships and ensure good communication lines. The regulatory and legal teams remain updated in respect of changes with a view to ensuring that the business is equipped to deal with and adhere to such changes. Where changes are identified which could affect our ability to market and sell any of our products, a response team is created in order to mitigate the risk. External consultants are utilised to audit our manufacturing quality systems.	
	**Regulatory Risk:** Continuing pressure on reducing antibiotic use. The issue of the potential transfer of increased antibacterial resistance from food producing animals to humans is subject to regulatory discussions. In some countries this has led to government recommendations on reducing the use of antibiotics in food producing animals.	Reduction in sales of our antimicrobial product range. Our reputation could be adversely impacted if we do not respond appropriately to government pressure.	Regular contact is made with all relevant veterinary authorities to ensure that we have a comprehensive understanding of regulatory changes. We strive to develop new products that minimise antimicrobial resistance concerns.	
	**Reliance On Third Parties Risk:** Failure of a major supplier resulting in loss of raw materials or product supply or delay in clinical trials. We rely on third parties for the supply of all our raw materials. Failure to supply these raw materials will affect our manufacturing and development capabilities. It is important that we manage our stock levels of key raw materials and are able quickly to identify and obtain materials from a second source.	This may lead to significant delays and/or difficulties in obtaining goods and services on commercially acceptable terms potentially increasing the cost of production. Disruption in production may result in product shortages and significant delays, which may lead to lost sales.	The performance of our suppliers is monitored. As a result, if we identify a potential issue, we source promptly from either an identified alternative supplier or a new supplier. Where a manufacturing transfer is required, stock is built up in order to avoid/mitigate an out of stock situation. In respect of DPM, a 'second sourcing' project for key materials has established our approach for all components. In addition the top ten Group products are continually risk assessed in order to identify the key suppliers of materials or finished products. All contracts with suppliers are reviewed from both a commercial and legal perspective to ensure that assignment of the contract is allowed should there be a change of control of either of the contracting parties. Risk mitigation strategies are in place such as maintenance of buffer stocks and dual sourcing.	

Link to Strategy	Risk	Potential Impact	Mitigation	Trend
	**Reliance On Third Parties Risk:** Loss of key third party customers from DPM. Contract manufacturing represents approximately 9% of Group revenues and 46% of our manufacturing volume. Contract manufacturing is a significant part of our revenue.	Loss of a key customer can impact manufacturing revenues and lead to an increase in the cost of goods of the remaining portfolio.	Robust supply agreements are in place with each of our key customers and are regularly reviewed. Close, regular contact is maintained through the sales director with key customers Monthly service level monitoring and reporting is in place. We have an experienced sales team which focuses on bringing in new customers.	
	**People Risk:** Failure to have robust succession plans in place leading to gaps in knowledge and experience in key roles in the business. We pride ourselves on the low turnover of staff in senior and other key positions. However we must ensure that we have plans in place should we lose key personnel on whose capabilities we depend.	Loss of knowledge, skills and experience could erode our competitive advantage. Inability to attract and retain key personnel may weaken succession planning and could have an adverse impact on results.	Succession planning is driven by the Nomination Committee and the Group HR Director. Where deemed necessary Key Man Insurance is in place. A new HR plan is being implemented to strengthen our talent management and succession planning. Remuneration packages are reviewed on an annual basis in order to ensure that the Group can continue to retain, incentivise and motivate its employees.	
	**People Risk:** Risk of failure to adequately resource the business to meet strategic ambitions (e.g. knowledge and investment). We have a clear focus on our four strategic growth drivers. As Dechra expands we need to ensure that we have the necessary skills to execute our strategy and that we allocate sufficient resources where required.	Implementation of our strategy may be delayed and we may not meet shareholders' expectations We have failed to identify potential capability gaps. We may be unable successfully to integrate acquisitions. Resources are too stretched, leading to potential personnel issues.	The Group HR Director is in the process of commencing a capability study in order to ensure that we have the correct level of skill, knowledge and experience internally to deliver our strategic goals, and to identify where to attract and recruit skills if they are not already present in the Group.