

Good Risk Management Practice – the case for action

Poor Risk Management is worse than no Risk Management

'At least we tried' is a phrase unlikely to receive any sympathy when you are held to account for knowing about a risk, and not addressing it appropriately.

The minimum requirement is an explanation of the actions taken, or not, along with evidence to support the decisions made.

When implementing risk management then, it is imperative to put the mechanisms in place to manage the required actions before getting too excited about where the greatest risks exist in the business.

Recent events in the financial markets represent, only too well, the perils of inappropriate risk strategy, poor governance in respect of the strategy, and a lack of process to continually review and resolve risks. Much has been written and said about the limited understanding of financial products by those charged with managing the risks. Whilst the general public can do little about this, the regulatory bodies are there to protect us; but what happens when they too lack the risk management components essential to operate effectively?

There is little chance, post economic meltdown, that any regulatory body will be left so exposed again. Even less chance that it would be those that regulate our pharmaceutical industry. So, as the regulations continue to evolve into the 'prevention is better than cure' context, we had better make sure that we know what we are doing. This is only right. Lives may be ruined by poor financial risk management. Lives are lost through poor clinical risk management. So is no risk management better than poor risk management? That really depends on whether you are a patient, a shareholder or a litigator!

Good Risk Management is good business

Objectively informing risk/benefit decisions is very much the primary return on operating good risk management in business, but it is not just about being well prepared when things go wrong. We must remember that one of the primary aims of the pharmaceutical industry, and those who work within it, is to help people. Good risk management can, and will, give more people access to more products, and sooner.

Poor Risk Management in action!

High profile lawsuits are commonplace in the pharmaceutical world. No secret. The cost to individual patients and their families cannot be measured financially. The full commercial costs are also difficult to ascertain with accuracy. Awards to plaintiffs are typically well publicised, but represent only a fraction of the total commercial impact, when lost revenues, damaged reputation, share price impact, to name but three, are taken into account.

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Just some of the payouts in recent years¹:

Fenphen 2005	Wyeth \$21bn
Zyprexa 2007	Eli Lilly \$500m (in addition to \$700m in 2005)
Premarin 2007	Wyeth \$134m
Vioxx 2007	Merck \$4.85bn
Celebrex and Bextra 2008	Pfizer \$894m
Risperdal 2009	Johnson and Johnson \$3.95m
Phenegen 2009	Wyeth \$6.7m

Who knows what the total commercial cost was in each case. Likely, the impact is still being felt in many of these instances. So, how could risk management have made a difference in these, and other, cases?

Complete risk avoidance would be an unlikely scenario, but should be considered the ‘ultimate goal’ as we learn from our history as an industry. Better, in risk management terms, to consider how the following could have reduced the impact commercially, and for patients...

- Earlier identification and escalation of a potential problem
- Greater visibility of risk to a broader range of senior executives
- Ongoing integrated review of risk throughout the product lifecycle
- Faster implementation of actions to minimise and mitigate risk
- Assurance that risk minimisation was effective

Clearly, Risk Management Plans (RMPs) and Risk Evaluation Mitigation Strategies (REMS) go some of the way to reducing the likelihood and impact of product risks. But these can only operate to good effect in the right context. That is a context where risk management is well understood across the business and is an integral part of day-to-day practices. These examples, from a patient safety perspective, are an easy way to highlight the need and the opportunity in good risk management. The same approach also applies to the whole gamut of risks in the business, from research portfolio management, through supply interruption, to fulfilling regulatory compliance.

The signs of poor Risk Management

Whilst good risk management is common-sense, its application and operation in a business context require clarity, definition, discipline, management commitment, and engagement of a broad population. Even a business that believes this is all working well needs to take stock of how easy it would, or wouldn't, be to demonstrate to a third party. Good intent is a great starting point, but is just that, a starting point. Understanding the need and the approach is also a good starting point, but again, it is not enough.



Simplify what you do

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No surprise then, that most of the industry is not able to demonstrate Good Risk Management Practice. Good intent, yes. Good understanding, yes. Good practice, no.

The areas for improving risk management might be more familiar than you think. Take a look at some commonplace practices versus a GRMP approach:



Recognise the signs? Take stock, before someone else does!

GRMP – the low risk approach to risk management

If reading this far has got you worrying a little, good. The good news is that it is not so difficult to get Good Risk Management Practice (GRMP) operating in your function, or your business. It does, however, require commitment, and a level of effort to get going and maintain. Beware: it is easy to fall into the trap of creating a new and separate process and organisation – this is neither effective nor efficient. Far better to integrate risk management into existing business processes, functions and governance.

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The approach to implementing GRMP needs careful consideration. It is essential to avoid making a list of risks without having a robust process to identify root causes and execute effective actions to their conclusion, to ensure resolution. Think also about the sequence in which GRMP is implemented – it would be ironic to get it working in the lower risk areas first!

Think of GRMP not only as the management of risks, but also as the key to opportunity, through better informing the risk/benefit decisions that have become part of our daily business lives. GRMP not only protects the patient and the business, but also gives us the opportunity to focus our efforts where the patient and the business can benefit most.

For further information about GRMP and WCI's GRMP Assessment, please contact us at info@wcigroup.com or call +44 (0) 2392 268133.

ⁱ Information provided by Datamonitor