



PHARMACEUTICALS

# The Tablet

Risk and Disclosures in the Pharmaceuticals, Medical Devices and Diagnostics, and Biotechnology Industries 2008–2009

KPMG INTERNATIONAL

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This special edition of The Tablet presents the executive summaries of KPMG's Risk and Disclosure Handbook 2008-2009 – Volume I: Pharmaceutical Industry, Volume II: Medical Devices and Diagnostics Industries and Volume III: Biotechnology Industry.

**The Handbook cover each of the following industries:**

- Pharmaceutical
- Medical Devices and Diagnostics
- Biotechnology

**Major topics covered:**

- Industries Overview
- Operating and Financial Review
- Financial Statement Disclosures and Risk Factors
- Comparative Financial Performance Data

Since our last review of the disclosures made by Pharmaceutical Companies in their annual reports, it has been an amazing year. Lehman Brothers had just collapsed – since then the financial markets have been on a roller coaster ride as economic instability spread around the world in a way not experienced since the Second World War. One year on and the uncertainty is no longer surrounding whether we are in a recession, but how deep will it be and how long will it last.

Very few industries have been immune from the effects of the economic downturn of the last year. Some commentators note that Pharmaceuticals is one of those industries. Although it is certainly true that medical need follows its own set of drivers, the industry is particularly

dependent on government expenditure, which may well mean that the true impact of the downturn may continue to hit the industry for several years as governments focus on reducing spend, with Healthcare being a potential target.

The economic downturn is impacting governments who are wrestling with ever increasing deficits as they try to stimulate their economies. In the US, this is also leading to increased attention on the rising cost of healthcare, with various healthcare reform initiatives being debated. There is also concern that the economic climate may trigger other countries to adopt similar reforms to those in the US, such as increased focus on pricing or encouraged use of generics.



# Pharmaceutical Industry

What is more certain as far as the Pharmaceutical industry is concerned is that current world events are likely to trigger reform, with those announced in the US starting to gain momentum and other countries following, whether in respect to pricing pressure or encouraging use of generics.

It is also true that the challenges faced by the Pharmaceutical industry, for example in respect to product innovation, productivity and output in the Research and Development (R&D) process, were evident well before the onset of the global economic crisis. If the platform for change was smoldering before last autumn, it is certainly burning brightly now for board members.

It is clear from the annual reports and accounts, of those selected for review, in the Pharmaceutical Disclosures Handbook, that many boards are taking a knife to their cost base, as they address structural and operational challenges. These are often resulting from reducing pipelines and constraints on existing products, while grappling with the question of where future growth will be found and how much to invest in R&D.

On a more positive note, the global economic slowdown has created a potentially beneficial environment for those with strong balance sheets wanting to expand and build on their R&D base. We have seen a number of strategic acquisitions – Roche took full ownership of Genentech in March 2009, Lilly acquired ImClone in November 2008 and Pfizer announced in January 2009 plans to acquire Wyeth.

Further merger activity looks likely, with companies using their healthy cash balances and strong cash flow generation to fund acquisitions and finance growth. Opportunities should exist due to keener prices amongst the small to medium companies who are struggling for funding.

Many of those staring down the barrel of billions worth of drug-patent expirations – Bristol-Myers Squibb (BMS) and GlaxoSmithKline (GSK) for example – have already started this process. The environment continues, as it has for the past number of years, to be focused on risk over benefit. It is risk that will be a driver of reform as well as pricing issues.

Governments will demand that companies be more proactive in getting adverse event information and that new products offer specific benefits when compared to existing treatments. In addition, approval times are going to continue to lag, thereby lengthening the approval process, with less market time and less patent time in the market to recoup costs.



# Medical Devices and Diagnostics Industries

The analysis in the Medical Devices and Diagnostics Disclosures handbook highlights the industries continue to exhibit very acceptable growth levels especially considering the current economic climate. This results from greater health awareness, the aging population and continued technological developments which are key to the success of the industries.

Growth is not without its challenges as competitor activity means products are brought to market quicker with new advances often without significant price increases. Government focus on rising healthcare spend also means suppliers have to continually address their costs and associated pricing strategies.

Continued innovation is also vital to these industries with increased pressure for companies to generate new products with a clear advantage over competition. In the current climate this is even more imperative as governments and other customers seek justification for the premium prices which are often charged.

The pressure for innovation is also reflected in that, while demand is escalating for the products of these industries, price increases have been slowing over the last few years, as hospitals and other healthcare providers postpone investment decisions. The current climate is unlikely to see an improvement in this area and the continued growth of the industries is unlikely to be driven by price increases of existing products but by growth in volume and the introduction of new technologies which can command higher prices.

One of the key differences in the industries (and with that of the overall pharmaceutical sector) is the customer base. Medical devices suppliers tend to be more reliant on institutions and government organizations, which may have longer term consequences resulting from regulatory reform and funding pressures. Whereas in medical diagnostics, the client/customer focus

is moving towards the delivery of over the counter (OTC) self diagnosis kits. There have been concerns regarding the accuracy of such technology which combined with the exposure to a larger market brings increased risks.

An analysis of risks shows that for Medical Devices, the risk that has clearly become more prominent in 2008 is the consolidation of the Healthcare industry. This increases the pressure on sales and pricing of products.

In Diagnostics, the risk that clearly became more important in 2008 and mirrors that seen in the pharmaceutical industry, that was occurring from a reliance on Information Technology (IT). As IT becomes more complex and there is an increased dependence on IT systems in the day to day running of a diagnostics company, the potential downside of any IT failure becomes more catastrophic.

A major impact on these industries may be greater consolidation with the major pharmaceutical players. The last year saw high profile pharmaceutical company activity in the M&A arena often to improve drug pipelines and deliver synergistic benefits. However a parallel strategy could see a broadening of company portfolios and a move to embrace more of the pharmaceutical value chain. An ever increasing key part of this chain is diagnostics, which are increasingly involved in therapeutic decision making. The potential convergence of the pharmaceutical and diagnostic technological platforms is likely to be a major driver which could result in greater consolidation.



# Biotechnology Industry

Biotech companies have struggled for funding in the current environment; the IPO market is almost completely dormant and secondary offerings are currently limited.

Generic biologics are on the verge of regulatory approval in the US. The US is trying to develop a pathway for generic or follow-on biologics. Recent proposals look to limit patent exclusivity to between five and twelve years. In addition to the patent exclusivity period, the Food and Drug Administration (FDA) will need to determine what clinical data/trials will be needed for approval of a follow-on or generic biologic. Given the complexities of a biotech product, the clinical path could be more complex and costly than the generic path for small molecules. In addition, the FDA could require certain clinical data. These factors could lessen the number of generic entrants and/or lessen the pricing differential as compared to a pharmaceutical generic.

In Europe a regulatory pathway for follow-on biologics has been in place since 2006. The European Medicines Agency (EMA) has issued the first guidelines for regulatory pathways for certain biologic product groups. The first such approval for a follow-on biologic was for *Omnitrope* which was launched at a 20 percent discount to the branded drug. Recently, the EMA also approved biosimilar forms of two Amgen drugs, *Epogen* and *Neupogen*.

Challenges faced by the Pharmaceutical industry, for example in respect to product innovation, productivity and output in the Research and Development (R&D) process, represent opportunity for the biotech industry.



Opportunity can take the form of an alliance with a large pharmaceutical company, through to being acquired. In the last four years, 13 of the 25 biggest biotech companies (by revenue) were acquired, four by larger biotech companies. The acquisition trend is likely to continue as cash rich pharmaceutical companies seek new developmental compounds.

Maintaining the biotech company's entrepreneurial spirit is critical to the success of a biotech acquisition. This is particularly challenging when a large pharmaceutical company is the acquirer. Nevertheless, in several of these acquisitions the biotech entity was allowed to maintain its separate identity and operate largely autonomously.

The funding environment continues to be difficult in 2009 and therefore biotech companies will continue to be willing to partner development candidates early in the process to lessen their development risk. Biotech companies will benefit from the pool of experienced scientists and professionals due to restructuring within the Pharmaceutical industry, resulting from acquisitions and downsizing.





# Future of GAAP to IFRS Conversion in the Pharmaceutical Industry

2009 will be another challenging year for the wider Pharmaceuticals industry.

The external environment is difficult and therefore pharmaceutical companies must ensure internally they have a current and clear strategy and move towards the right structure to enhance agility and secure long term growth. Laying the groundwork for the potential future conversion from US Generally Accepted Accounting Principles (US GAAP) to International Financial Reporting Standards (IFRS), the Securities and Exchange Commission (SEC) proposed a potential “roadmap” for the phasing in of mandatory IFRS filings by US public companies.

The roadmap is conditional on progress toward “milestones” that will be monitored by the SEC between now and 2011. At that time, the SEC will decide whether to proceed with rule making requiring US issuers to use IFRS as issued by the International Accounting Standards Board (IASB) beginning in 2014 for large accelerated filers. The proposal had a comment period which ended on 20 April 2009.

IFRS conversions are likely to impact many facets of the enterprise, including internal controls, accounting policy, tax provisioning, shared services, financial reporting processes, IT systems, treasury, legal, internal audit, and others. The transition from US GAAP to IFRS will require a coordinated effort that should be led by top management to help ensure the development of comprehensive accounting policies and company-wide consistency in the application of those policies.

Additionally, it will be important for companies to develop a communication plan that will keep key internal and

external stakeholders informed of the company’s plans, progress against those plans, and consequences to the company’s financial reporting.

The promise of improved performance in the finance function, reduced cost, and use of a single accounting “platform” will require planning, program management, and resources with deep knowledge of IFRS and how IFRS applies to the company’s industry. The roadmap guidelines and proposed timeline provides public companies and their boards with an important opportunity to plan for the potential adoption of IFRS and thus avoid a “fire drill” exercise and the need to use topside and workaround solutions in the future. It is critical that board members gain fluency in IFRS and consider a suitable course of action for a potential transition to global standards.

Today more than 100 countries around the world, including European Union (EU) member countries, require or permit IFRS or a variant of IFRS for reporting by listed companies. As a result, US companies with international components may be more motivated to move quickly to develop additional in-house IFRS knowledge and begin plans for conversion. Even in advance of US adoption of IFRS, many companies may have to deal with IFRS financial statements in a variety of situations, such as foreign subsidiaries, merger or acquisition targets, and joint-venture investments.

# Recent Publications



## KPMG Disclosures Handbook 2008 – 2009: Pharmaceuticals, Medical Devices and Diagnostics, and Biotechnology Industries

In this seventh edition, KPMG has analyzed and compared some of the largest companies in the Pharmaceutical, Medical Devices and Diagnostics, and Biotechnology industries for the 2008–2009 reporting season. This year we have produced three standalone volumes;



- Volume I – Risk and Disclosure in the Pharmaceutical Industry
- Volume II – Risk and Disclosure in the Medical Devices and Diagnostics Industries
- Volume III – Risk and Disclosure in the Biotechnology Industry



This research has focused on the disclosure of business risk and critical accounting policies. Also summarized are the selected 2008 comparative financial performance data of the largest pharmaceutical, medical devices and diagnostics and biotechnology manufacturing companies around the world.



## The Tablet

Previous issues of The Tablet have covered:

- Risk Mitigation
- Transfer Pricing
- Centers of Excellence
- Back Office Optimization
- Regulating Sales and Promotional Compliance
- Supply Chain Management and Tax Efficiency
- EU Competition Authorities' focus on the Pharmaceutical Industry
- New US Public Policy Environment
- M&A

For copies of these publications, please contact your local KPMG representative.

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This edition of The Tablet is part of a series focusing on issues in the pharmaceuticals industry. For more information, visit <http://www.kpmg.com/Industries/IM/CP/>

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