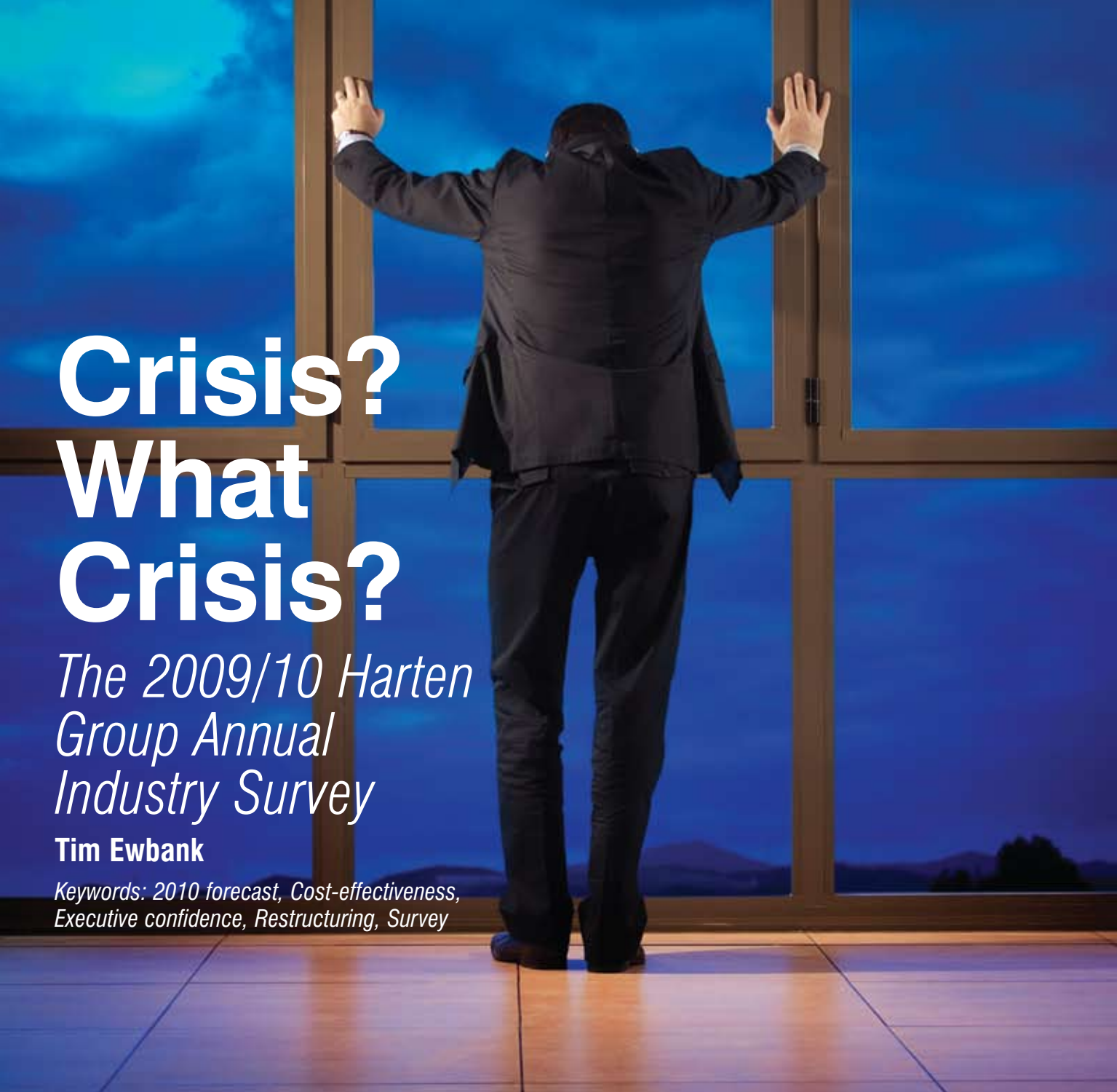


Crisis? What Crisis?

The 2009/10 Harten Group Annual Industry Survey

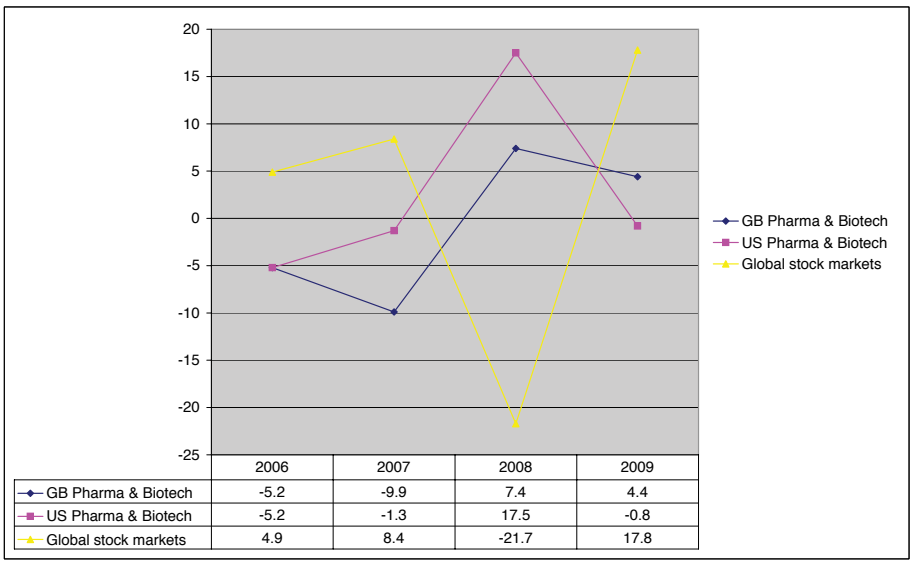
Tim Ewbank

Keywords: 2010 forecast, Cost-effectiveness, Executive confidence, Restructuring, Survey

HARTEN GROUP'S 2008/9 survey[1] was written in the immediate aftermath of the financial meltdown and the start of the global recession, so participants were understandably pessimistic about the coming year. This year, our eighth annual industry survey looks back at how events turned out compared to their gloomy outlook. Was it as bad as they feared or were there any unexpected highlights? It will also take a cautious look at what 2010 might hold. With a General Election looming in the UK and much political posturing about impending cuts in public spending, we will see what our participants predict.

"The overall picture confirms the industry's reputation as a counter-cyclical, defensive stock…"

IN TERMS OF overall financial performance, Fig 1 shows the stock market performance of the US and UK pharmaceutical companies, biotech companies and all stocks. The overall picture confirms the industry's reputation as a counter-cyclical, defensive stock with 2008 performing considerably better than the market as a whole, but significantly underperforming on the rebound in 2009. The difference from the total market was 28% and 13% for 2008 and 2009 respectively, while UK and US life sciences indices tracked each other more closely.



	2006	2007	2008	2009
GB Pharma & Biotech	-5.2	-9.9	7.4	4.4
US Pharma & Biotech	-5.2	-1.3	17.5	-0.8
Global stock markets	4.9	8.4	-21.7	17.8

Figure 1 Comparison of US and GB pharmaceutical and biotechnology companies' performance, 2006-2009.

Survey demographics & method

HARTEN GROUP'S EIGHTH annual survey canvassed executives' views on the issues facing the industry in 2010. It compares their forecast for 2009 with how the year played out in retrospect. We surveyed over 600 executives in pharma and biotech companies (divided roughly three to one respectively) in December 2009. The respondents fell into four generic job categories:

- CEOs, MDs and General Managers: 13%
- Medical, clinical research, regulatory: 55%
- Commercial, business development & licensing: 11%
- Operations, HR & project directors: 21%

The composition by role mirrored the previous year's survey, making the cohorts' opinions directly comparable. The survey invited participants to identify their top five issues facing the industry in 2010 from a list of 20. Also, they were asked to list the most important issues in 2009 retrospectively, which provided an opportunity to compare the previous year's predictions with reality. Finally, a comparative question attempts to understand how respondents think 2009 compared with 2008, and will compare with 2010.

How did 2009 compare to expectations?

TO BEGIN WITH, here's an example of how fickle a business prediction is, even in our mature and stable industry. The Swine Flu pandemic was not even mentioned in last year's survey. Fortunately, it did not spread to the extent predicted, but nonetheless resulted in large quantities of unused vaccines, which demonstrates the difficulty of epidemiological risk management.

At the level of the year as a whole, Figure 2 shows that 2009 turned out much as last year's cohort expected, with roughly 50% predicting and experiencing 2009 to be a worse year than 2008. Perhaps surprisingly, over 40% felt 2009 had actually proved to be a better year than expected.

The remorseless downward pressure on the cost of medicines in the UK continued with the renegotiation of the PPRS (Pharmaceutical Price Regulation System). At the same time, a recent Department of Health report into the comparative cost of medicines across 13 global markets, revealed the UK to be 12th in the table, making UK prices lower than any comparable European country. Yet periodic media stories of patients being denied new medicines as a result of NICE assessments creates the impression that unit prices are unrealistically high.

As major products reach the end of their patent protection and quickly see their market share being reduced by generic substitution, companies need to adjust to the reality. Nor is this trend anywhere near over; the analysis organisation Evaluate Pharma (*www.evaluatepharma.com*) estimates that half of over $380 billion worth of patented medicines will lose patent protection within five years.

The consequence of these trends is both predictable and recurrent: another bout of corporate cost-cutting through acquisitions and restructuring. The year started with Pfizer's acquisition of Wyeth, then Merck & Co's tie-up with Schering Plough and in September, Abbot acquiring Solvay. All of these have or will result in restructuring

"The consequence of these trends is both predictable and recurrent: another bout of corporate cost-cutting through acquisitions and restructuring."

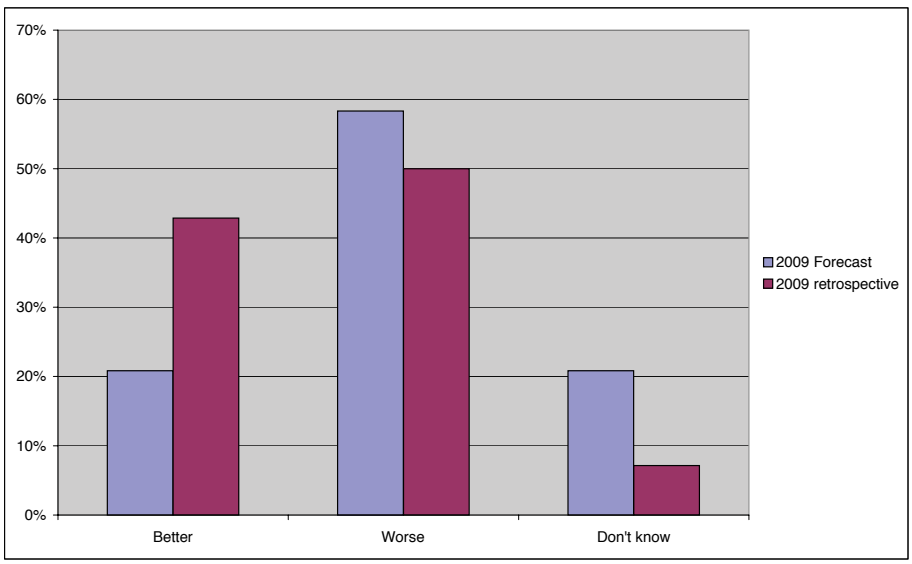


Figure 2 Perceptions of 2009 performance compared with predictions.

programmes. Locally, the immediate effect of this trend will also be felt in AstraZeneca's recently-announced restructuring plan.

Two new strategies are discernible to counteract these downward pressures, both unthinkable even a few years ago. In a reversal of the pattern of the previous decade, the combined effect of downward pressure on drug prices in the UK and the relative weakness of the pound against the euro has made the UK a net exporter of medicines to Europe. Attendees of a recent IMS conference heard that the current estimate of pharmacy-level parallel export exceed £350 million per annum. Conversely, parallel imports have fallen by half.

The second trend is that generics companies are no longer regarded as vilified copycats, but accepted as allies, who can offer expanded access in emerging markets. A new class of *"branded generics"* has emerged, which sell at a premium over unbranded equivalents. In emerging markets, this premium can be seen as *"the price of reassurance"* against dubious or fake local products. As a result of this new reality, there have been a string of deals between major pharma companies and generics manufacturers, such as GSK and Dr. Reddy's Laboratories in India, and Sanofi-Aventis with both Medley in Brazil and Zentiva in eastern Europe.

What will 2010 hold?

IN TERMS OF the respondents' views of 2010, over half (54%) expect it to be a better year than the one just ended (up from 21%); whereas only 30% are expecting it to be worse (down from 59%).

The most striking aspect of Figure 3 is the extent to which pharma and biotech's issues are now closely aligned. Of the top ten issues listed by frequency of citation, only one (time and cost of regulatory approvals) has a variance of greater than 5%. This convergence is probably a reflection of the growing maturity of the biotech sector, with more companies having products on the market. There is a group of shared issues that all broadly point in the same direction: cost-effectiveness (in rank order: cost containment, maximising R&D returns, maintaining growth targets and the cost of regulatory approvals and generic competition)

Future directions

THE OVERALL IMPRESSION from this year's survey is that while there is a considerable degree of change ongoing within the industry, little of it can be attributed directly to the credit crunch, but rather it is the continuation of the structural forces that are reshaping the industry. The rate of change may have accelerated slightly, but on the scale of a glacier rather than a tsunami.

Looking forward to next year's survey, there are several themes to watch. A possible change of government will inevitably mean that the NHS will be a high priority campaigning topic with all parties making vague, unsubstantiated promises of reduced costs and improved patient care. On past experience, it is unlikely that any changes promised will have had measurable effects by this time next year.

How President Obama's healthcare reforms affect both patients in the US and consequently our industry is more difficult to discern, as the loss of the Democrats' Senate majority may lead to a different outcome from the current, published proposals.

There are two long-term issues that are of potentially profound importance. Firstly, the ominous first uses of UK's draconian libel law or the threat of libel against investigators or publication in peer-reviewed journals. For example, a Danish radiologist is being pursued for libel over remarks he made two years previously about one of GE Healthcare's investigational medicines. Another current example is the decision by the journal, Archives of Diseases of Childhood to withhold from publication the results of a massive study of infant hospital Accident and Emergency department attendances following legal advice.

Secondly, the bigger question of the viability of the UK for clinical research and development is still unresolved. The continued restructuring of the industry and increasingly onerous regulatory requirements for approval are eroding the UK's attractiveness as a location for clinical research. The Times reported that the pharmaceutical industry now recruits only one third of the patients to clinical trials in the UK compared with the period before the EU clinical trials directive, and the number of studies seeking ethical approval has fallen by 30%. Countries with expanding markets in other parts of the world, however, have a growing research capability. IMS predicts that by 2012, nine of the top 20 research locations will be countries currently considered to be emerging markets.

"The most striking aspect of Figure 3 is the extent to which pharma and biotech's issues are now closely aligned."

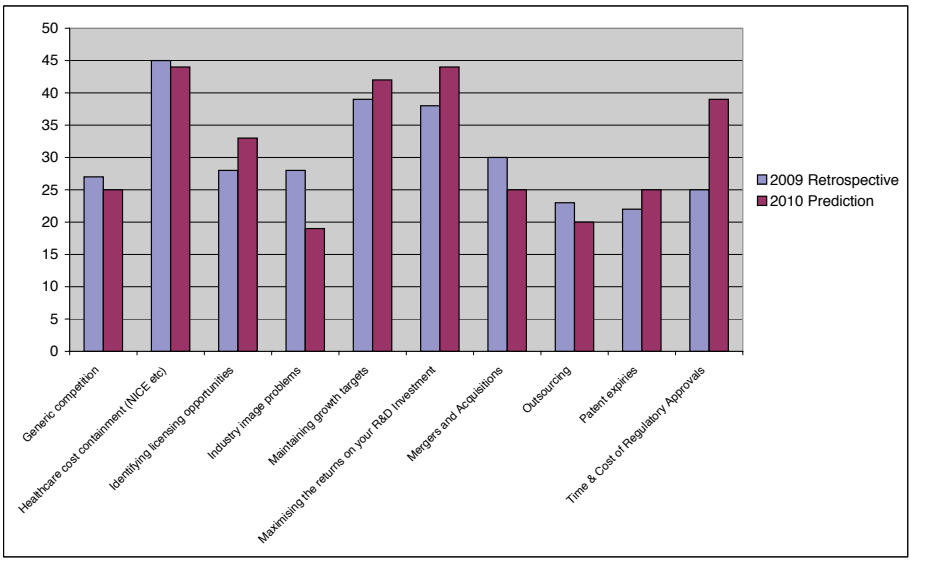


Figure 3 Comparison of important issues in 2009 (in retrospect) and 2010 (predicted).

However, given that only one of four of the issues flagged last year proved to be of any significance, suggests that clinical research staff need not enrol on Mandarin or Urdu courses just yet…

"… the bigger question of the viability of the UK for clinical research and development is still unresolved."

*Tim Ewbank is Chief Operating Officer of Harten Group (**www.hartengroup.co.uk**), a specialist provider of interim management, consulting and high value search services to the pharmaceutical and biotech industries.*

References

1. Ewbank T (2009): "*What a Difference a Year Makes! The 2008/9 Harten Group Survey*", CRfocus 20(4), p7

*To comment on this article, email **comment@crfocus.org**. Comments might be published on the Clinical Research focus web pages, with author's name/affiliation, unless notified otherwise.*