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2012 Industry Outlook

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Poised for a new year of challenges and opportunities, we ask what distinguishes 2012 from its preceding year? The word that comes to mind is clarity. Not in the sense of stock market predictability, nor the emergence of clear industry direction, but the clarity that comes from a better understanding of the relationship between government regulation, market demand and industry thinking.

Last year we grappled with consequent U.S. market consolidation amongst the pharmaceutical giants. Coupled with meager venture capital investment, we wondered what would become of the innovation engine in the U.S. that has fostered a market worth between $170-$180B.* Would the drive for low-cost manufacturing ship facilities offshore or would industry circle its wagons on home terrain and find a way to become competitive again? Last year we saw several significant developments that are central to 2012. First, China's response to the issuance of their new GMP 10 guidance has been measured and deliberate. In 2011 we began to see companies in China - cash rich but experience poor - recognize that changes were needed to be able to compete in the worldwide markets. We see Chinese manufacturers looking to the West for equipment and expertise in an effort to shrink the learning curve, putting cost as secondary. Recognizing that China is in the game to stay, the FDA opened two offices in Beijing and Shanghai to gain a foothold in over 5,000 API manufacturers and serve the burgeoning growth of new pharma and biotech companies.

Second the agency issued their new guidance for Process Validation. This guidance, more than any other issued since the Critical Path initiative was first conceived, stated that the agency would demand change in terms of how drugs were developed and quality was defined.

So what can we expect to see in 2012? We will see sustained market development in emerging markets as India and China continue to move to their next level of maturity and the newly anointed Next 11 (Bangladesh, Egypt, Indonesia, Iran, South Korea, Mexico, Nigeria, Pakistan, the Philippines, Turkey and Vietnam) jostle for position in the global pharma marketplace. Given these realities the industry can expect the following:

1. The FDA will strive to become a global organization. The agency has clearly stated that protecting public safety is its number one goal. To do this it must balance three potentially contradictory initiatives. First, bring more innovative and efficacious drugs to the market faster. Second, ensure that approved marketed drugs are safe and efficacious and, third, protect the public by ensuring the safe use of approved marketed products. Some could argue this is the reason the FDA exists, but the complexity of achieving these three goals has never been greater.

Bringing new drugs to market faster depends on wholesale adoption by the agency and industry of the key principles of ICH Q7a, 8, 9 and 10. Short of this we are left with the same systems of checks and balances which have bloated the current product development cost and timeline for a new drug. Reconciling inconsistent regulatory standards is a very real issue to companies employing a global supply chain. International collaboration will cease to be an adjunct activity for the agency and will become the central issue for handling new product submissions. As industry struggles with inconsistent global regulatory requirements, the agency will need to escalate its post-market surveillance as the key method for evaluating what new and better safety indicators should be applied to new drug development to ensure public safety.

The agency must also look inward to address the disparate philosophies that manage quality among its different divisions. One need only look at the failure of the 510K process for medical devices to recognize new thinking is required. With the FDA experiencing a three-fold increase in the number of products to inspect over the past decade, the agency will continually need to rely on their international partners to ensure safe and efficacious products are allowed to be sold and consumed by the American market.

2. Payer cost containment pressure will continue to challenge the industry. With the 2012 election year as a backdrop, the Affordable Health Care Act will once again take center stage as Washington tackles the issue of rising health care costs. Whatever the solution, it is likely that pressures on cost control will only intensify. With so many blockbuster drugs coming off patent, competition in the marketplace will be fierce. Generic companies are not known for their rigorous development programs: they focus on achieving bioequivalence rather than process understanding. In a market where generic drugs fill the overall marketplace, can the agency move the industry forward, or will short-term economic drivers beat out the benefits of long-term gains from a change in thinking?

3. The new Process Validation guidance will put some distance between overseas manufacturers and U.S. and European innovator companies. Many overseas manufacturers use U.S. and Europe as templates for the standard of how they should steer their manufacturing and quality practices. With the new PV guidance issued in January 2011, the FDA raised the bar in terms of understanding process capability and predictability. Overseas manufacturers, much like the generic companies, will need to change their strategy toward process understanding to compete in the marketplace. They too face the scrutiny of the FDA and its equivalent regulatory agencies in the EU. As overseas manufacturing continues to grow, the agency will need to respond accordingly to ensure that regulations are strictly enforced to maintain product quality and efficacy for safe consumption.

4. PAT adoption will continue to struggle. Over the last decade we have seen significant maturation in both the approach and application of PAT within the industry. The next challenge facing a broad base adoption of PAT is the escalating complexity of the overall supply chain. Establishing a control strategy for raw materials and API suppliers that spans cultures, business practices and technology is a daunting proposition. Additionally, given the dominant market share of generic drugs in which product portfolio lifecycles are short, PAT will be hard pressed to demonstrate its business value. No doubt PAT will have its place but wholesale adoption similar to that of the chemical industry is not likely anytime soon.

5. FDA enforcement will escalate. The challenges of a global supply chain will apply constant pressure on the agency to avoid high profile missteps. The recent Avastin decision has cast more doubt on the effectiveness of the current drug approval process. The current commissioner has vowed to provide unprecedented transparency within the agency to demonstrate that accountability will be the cornerstone of the new FDA. The hope was that the agency's new TRACK program would reinforce and foster this concept, but the program has become a disappointment with performance metrics that place too much emphasis on meeting goals rather than driving performance and enforcing accountability. Without a core foundation for accountability and resolution in the drug approval process, the best way to demonstrate that the agency is emphasizing public safety will be to step up enforcement.

6. M&As will continue. Consolidation and alliances will transform the market as companies adapt to changing conditions within the industry. With M&A gaining quick access to new areas of growth, it is likely there will be a significant increase in in-licensing activities and collaborations for the development of pipeline candidates. Instead of developing a product from scratch, which involves a lot of capital, pharma companies will increasingly shop for mid-to late-stage pipeline candidates. In addition to portofolio considerations, the emerging markets themselves represent growing market opportunities.

Conclusion

The coming year will be one where we will get a glimpse of whether the agency will effectively begin the transition to a role of global regulatory authority. To do this effectively it will have to manage its own divisional inconsistencies while dealing with harmonization issues through collaboration with other regulatory bodies. As an industry we can expect stepped-up enforcement as the FDA moves to implement its new process validation guidance. The cost of healthcare will figure prominently in the media as we move into an election year and payer pressure will remain great. The big consolidations will begin to stabilize and hopefully will put their considerable muscle behind change and transformation in the industry. The principles and practices laid out over the past decade will begin to yield dividends as organizations capable of embracing the new principles of how we develop drug products and define product quality come center stage. The agency's ability to effectively reinforce these new principles and requirements will soon describe what the new global marketplace will look like and whether the emerging markets will become larger participants in the U.S. market. The clarity we are striving for is key to a better understanding of the relationship between government regulation, market demand and industry thinking.

Reference:

*Source : IMAP's Pharma & Biotech Industry Global Report — 2011