

February 2009

A quarterly newsletter for the
pharmaceutical industry

Life sciences insights

Changing times

Life sciences insights: changing times

Welcome to the premiere issue of Life sciences insights, the Ernst & Young Global Pharmaceutical Center's quarterly publication offering insights on current and emerging topics. From the uncertainty of the global market day to day, to the strategic immediacy of regulatory mandates, to the transformation in the way consumers acquire medicine, the life sciences industry must understand the changing business environment and adapt its strategies. This issue of Life sciences insights focuses on the current dynamics of the global financial crisis and its impact on the life sciences industry, the emergence of risk evaluation mitigation strategies (REMSs) mandated by the Food and Drug Administration (FDA) and the deregulation of pharmacies and over-the-counter (OTC) medications in Europe. We hope you find these insights helpful in navigating the evolving landscape of the life sciences industry.



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Transforming crisis into opportunity: the pharmaceutical sector in 2009

The unprecedented financial events of 2008 have caused turbulent times, impacting nearly all industries and geographies with a credit freeze and significant stock market volatility. It has created extraordinary challenges and choices for all companies.

Impact on the sector

The pharmaceutical sector, while not unscathed, has shown resilience to the economic downturn due to its low levels of debt and its access to large cash flows. The current challenge of raising capital faced by so many others has had less impact on this cash-rich sector. The top 20 pharmaceutical companies have access to an average US\$7.5 billion in cash, cash equivalents and short-term investments, with some of the largest companies having in excess of \$20 billion. According to Datamonitor, the average net debt as a proportion of capital employed for these top 20 companies is just 6%, while the average net debt carried by financial institutions is 95%.

Considering that the long-term pressures on the pharmaceutical industry have already been priced into company valuations, the pharmaceutical sector's stock has outperformed the general indices during the financial crisis. For the full-year 2008, the S&P Pharmaceuticals Index was down 21.2%, versus a 38.5% drop in the S&P 500, a 31.3% drop in the FTSE 100 and a 33.8% drop in the Dow Jones Industrial Average.

However, the financial crisis of 2008 is creating another dark cloud over an industry already facing significant market challenges. Among these are massive revenue declines expected from expiring patents, lackluster pipelines and regulatory setbacks. There is also heightened competition from generics, particularly as the rising costs of healthcare force governments, payors and consumers to seek lower prices.

"BIO estimates that 138 public companies, or 40 percent of U.S. public biotechs, have less than a year's operating cash left. Of those, 96 have less than six months of cash."¹

- *The San Francisco Chronicle*, 16 November 2008

¹ Bernadette Tansey, "Darwinian scene for smaller fry in biotech sector," *The San Francisco Chronicle*, 16 November 2008, via Dow Jones Factiva.

Accelerating change

Pharmaceutical companies have been responding to these market pressures by reducing costs, streamlining processes and striving to maintain innovation. But the global economic downturn is acting as an accelerant, fanning the flames of change, in the effort to build leaner, more innovative companies.

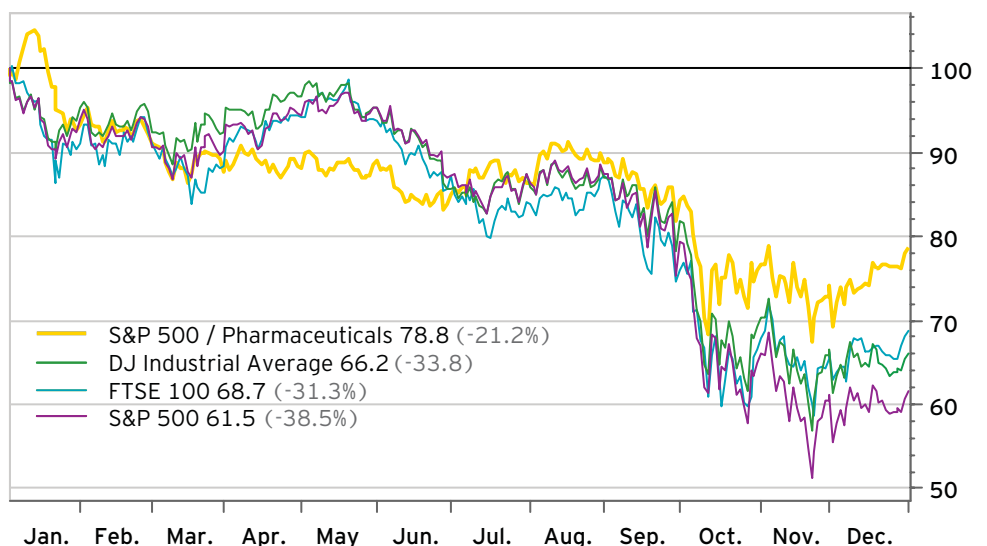
Companies are also hoping to take advantage of the opportunities that are presenting themselves during these challenging economic times. Although the current market situation is ripe for consolidation, there has been little merger and acquisition (M&A) activity by pharmaceutical companies until January 2009 when Pfizer announced plans to acquire Wyeth for \$68 billion. In recent years, most of Big Pharma has been more focused on smaller, strategic

Stock market decline (1 January 2008-31 December 2008)

Pharmaceutical stocks have outperformed other major indices as the market has declined during the current economic slowdown.

Indexed price

(1 January 2008 equals 100 in the local currency for each index)



Data source: Prices / Exshare

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Share of US public biotech companies by market cap size

Market capitalization	1 Jan. 08	15 Oct. 08
Less than US\$50 million	35%	52%
US\$50-100 million	15%	12%
US\$100-250 million	21%	12%
US\$250-500 million	10%	9%
Over US\$500 million	18%	16%

Source: Ernst & Young

acquisitions than on mega-mergers. Before the economic downturn, competition for the right licensing and acquisition candidates was intense, and valuations were climbing. It's clear that the dynamics are changing and, for the first time in years, we are entering a buyer's market and pharma is poised to take advantage of the best possible biotech deals. As the market continued downward, as of 15 October 2008, 52% of US public biotech companies had less than US\$50 million in market capitalization, down from 35% at the beginning of January 2008. The time for increased consolidation could be just around the corner, with more mega pharma mergers possible as well as more pharma-biotech combinations.

Healthy networks

The pharma sector is not independent and, in fact, relies on a variety of businesses and organizations in its ecosystem. These companies are not insulated in the way that cash-rich pharmaceuticals are. The current economic environment may have a negative impact on the financial health of such suppliers and partners, affecting their ability to obtain the necessary capital to deliver on their commitments to pharma. For instance, the loss of a critical supplier could disrupt manufacturing and/or distribution and destroy value.

Supplier health is important from several perspectives: business continuity, quality and reputation. More and more of the value life sciences enterprises deliver is dependent on a growing "extraprise" that includes:

- ▶ Active pharmaceutical ingredients and other essential materials and equipment for manufacturing

- ▶ Third-party vendors that touch customers or patients (e.g., contract sales organizations, speaker program administrators and call centers)
- ▶ Business process outsourcers (e.g., contract research organizations, clinical testing facilities and financial processing outsourcers)
- ▶ Contract manufacturers
- ▶ Logistics brokers
- ▶ Insurance brokers and other financial services providers
- ▶ Key data and information providers
- ▶ Wholesalers
- ▶ Critical consultants

The range of suppliers that make up a pharma company's ecosystem is extensive. Risks and vulnerabilities could be prevented by performing detailed financial analysis and due diligence upfront and as part of the ongoing relationship. Often companies only understand counterparty risk at a high level and overlook the importance of knowing the lesser factors that contribute to risk situations. Early identification of potential issues could allow for alternative scenario planning, reengineering of the supply chain to minimize exposure to risky suppliers and the ability to preemptively renegotiate supplier terms and conditions to mitigate interruption and protect capital. Through this process of risk identification and intervention, companies can preserve value and improve working capital. This also helps to avoid unexpected costs that arise from a disruption in the supply chain.

What are the long-term implications for pharmaceutical firms faced with the hurricane effect of healthcare market

pressures and the aftermath of the credit crisis? Long-term strategies are an important factor in a company's future success. Up until now, many of the actions undertaken by pharma companies have focused on short-term tactics, such as cost-cutting to shore up the bottom line. Now is the time to execute transformational strategies in a transformational way. In troubled times, companies with capital can really pull ahead of the competition by acting boldly to execute their strategies.

For additional information on how pharmaceutical companies need to transform their businesses to achieve success, see Ernst & Young's latest issue of *Progressions*, *Executing for success: powering new business models*.

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Identifying and managing supplier risk



An ideal supplier risk-management system generates just enough information to drive action – often requiring a tiered approach

Risk evaluation mitigation strategy: the next decision-maker for the industry?

One year after the Food and Drug Administration's Amendments Act (FDAAA) was signed into law, the impact of the FDA's new authority is beginning to be understood. One of the new powers given to the FDA under the law was to mandate the establishment and implementation of REMS programs. The inclusion of the REMS provision created concern that such programs may affect:

- ▶ Drug development costs
- ▶ Rates of drug approval
- ▶ Market penetration of a drug

Now that a year has passed since the law was signed, it is possible to assess these concerns by reviewing the FDA's actions with regard to its new power.

But first, what is REMS?

REMS is the new legal framework for risk management plans, specifying timelines and procedures for submission and review. The FDA may require a REMS at the time a New Drug Application is approved to ensure that the benefits of a medicine outweigh its risks. The FDA may also require a REMS after approval, based on reports of adverse

Requirements for risk evaluation mitigation strategies (REMS) since FDA authority went into effect (15 April 2008 through 23 October 2008)

Manufacturer	Drug name	REMS requirement
GlaxoSmithKline	Advair Diskus	Medication guide
GlaxoSmithKline	Advair HFA	Medication guide
Pozen-GlaxoSmithKline	Treximet	Post-marketing study, medication guide, patient survey, compliance report
UCB	Cimzia	Medication guide
Adolor-GlaxoSmithKline	Entereg	Post-marketing study, restricted patient use, hospital registration, communication plan, other
GlaxoSmithKline	Ziagen	Post-marketing study, restricted patient use, communication plan
Biovail	Aplenzin	Medication guide
Immunex	Enbrel	Medication guide
Schering-Plough	PegIntron Rebetol Combopack	Medication guide
Schering-Plough	Intron A	Medication guide
Wyeth-Ayerst Laboratories	Venlafaxine hydrochloride extended release tablets	Medication guide
Boehringer Ingelheim	Viramune tablets and oral suspension	Medication guide, communication plan
Prestwick Pharma	Xenazine tablets	Medication guide

REMS – A document prepared by a pharmaceutical company and submitted to the FDA. It outlines the steps and timetable that the pharmaceutical company will follow to ensure the safe use of a drug

Patient medication guide – A package insert containing safety information that a patient receives with the medication. The pharmaceutical company prepares the guide and includes the FDA's comment. The FDA must approve the final content.

Communication plan for healthcare practitioners – If required, this plan will outline for healthcare practitioners the information they must provide their patients regarding

the drug and could range from education programs for nurse practitioners who will administer the drug to a certification program for the healthcare facility.

Timetable for assessment – Post-approval assessments of the commitments initially outlined in the REMS must be performed at a minimum of three points in time: 18 months, 3 years and during the seventh year after its approval. The FDA may waive the requirement for the seventh year.

Post-approval studies – Pharmaceutical companies must collect and analyze safety and efficacy data from ongoing clinical trials and from the drug's use in public once it has been approved.

incidents. Each REMS is tailored to fit the safety profile of each new drug. For example, the REMS could include special requirements for a patient medication guide, a communication plan for healthcare practitioners, labeling, post-approval studies or a timetable for assessment and limitations on direct-to-consumer marketing. A REMS can also restrict distribution of a product to specific hospitals, provider groups or patient subpopulations. Failure to comply with the REMS program can be very costly to a company: penalties are as high as US\$250,000 per violation with a cap of US\$10 million per proceeding.

As of 23 October 2008, 13 REMS programs had been approved. Eleven of these required only medication guides and a timetable for assessment. Two required the certification of prescribers and pharmacies and the enrollment of patients in programs designed to ensure full understanding of the risks involved. According to Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research, "REMS has led the FDA to approve drugs that otherwise would have been rejected."² REMS pioneers include CV Therapeutics, UCB, GlaxoSmithKline, Biovail and Pozen – companies whose products may have received more rapid approval under the REMS program.³ The payoffs were immediate:

- ▶ GlaxoSmithKline PLC forecast £4 billion in sales for 2009 due to new approval to expand the labeling to treat chronic obstructive pulmonary disease. This is up 14% in sales from 2008.
- ▶ UCB's market cap gained US\$1 billion overnight following the approval of Cimzia.
- ▶ CV Therapeutics received US\$175 million after selling off half its future royalties to TPG-Axon Capital.
- ▶ Pozen received a US\$20 million milestone payment from GlaxoSmithKline after the approval of Treximet.

One notable trend has emerged: REMS programs that limit a drug's penetration into the market. Companies have been pursuing personalized medicine strategies with the use of biomarkers or other diagnostics to target for effective treatment. The FDA, however, has already used the REMS program to restrict drugs to specific patient subpopulations. GlaxoSmithKline's Ziagen, for example, is used for the treatment of HIV-1 infection. Through the use of this medication, it was discovered that patients who test positive for a specific gene variation are at a significantly increased risk for a potentially fatal reaction to the drug. Therefore, the FDA required a REMS that called for patients to be given a genetic test prior to treatment. This is the first case of FDA-mandated genotyping, which ultimately restricts the market penetration of a drug.

Another market-limiting example is the REMS associated with the approval of Entereg. Entereg's application was originally submitted to the FDA for approval in 2004. After two approvable letters and a clinical hold, Entereg has finally received approval with a REMS attached. The REMS required limiting distribution of the drug to registered hospitals. It also required an educational program, provided by the pharmaceutical company, to ensure that the drug was not prescribed for more than a 15-day period. As seen in the Ziagen and Entereg examples, the REMS process has the potential to lead inadvertently toward personalized medicines by making the industry develop products for more defined, smaller patient populations.

In light of these experiences, companies should consider the following points and determine if they are applicable to their new drug application submission:

- ▶ Develop a REMS to increase the FDA reviewer's comfort level in making a decision during the drug approval process. In contrast with the previous voluntary risk management plans, the FDAAA legally requires that a REMS is associated with required monitoring and penalties for noncompliance. While it may not alter a decision, it may provide a reviewer with greater reassurance.

- ▶ Increase the likelihood of timely approval by utilizing a REMS to demonstrate to the FDA that the sponsor company has taken the necessary steps to ensure that the drug is restricted to use in a defined situation where the benefits exceed the risks. This could be defined as a restricted population, a method of drug administration or the setting of the drug administration.

Pharmaceutical companies have increased their interest in managing risk as a result of compliance and product safety issues, the global financial crisis and new challenges to revenue growth and product pipeline. Pharmaceutical companies' strategic decisions and transformational choices will create new risk areas to manage and monitor. As part of a comprehensive and connected risk management approach, REMS can be a positive force that drives change and leads innovation.

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³ Michael McCaughan, "FDAAA Pays Off: Drug Safety Controls Bring Immediate Returns to Sponsors," *The RPM Report*, May 2008.

Pharmacy and OTC deregulation in Europe

A French traveler visiting the US for the first time is often struck by the wide availability of prescribed and/or OTC drugs in places ranging from gas stations, mass-merchants, hypermarkets, pharmacy chains or through the internet. In many cases, the seller will have no qualification in the field of healthcare.

The situation couldn't be more different in the traveler's home country, where any type of drug, prescription and OTC alike, must be dispensed in a pharmacy lawfully owned by a qualified pharmacist who can own only one pharmacy.

A look beyond French borders reveals a multitude of different models across Europe, ranging from a state-owned pharmacy monopoly in Sweden to a very US-like pharmacy chain-dominated model in Norway.

The nature of the European drug market, with its diverse healthcare systems, its fragmented regulatory and cultural environments and its differing rules for pharmacy ownership, has resulted in the development of a "patchwork landscape" in terms of business models for the pharmacy business.

This situation is changing, and the pharmaceutical distribution environment in Europe is undergoing major alterations resulting in a certain degree of convergence. The transformation, which will have profound impact on market dynamics, is happening on two fronts:

- ▶ As markets deregulate, new pharmacy chains, retail and internet pharmacies are emerging.
- ▶ OTC-drug dispensing is expanding beyond the pharmacy to new channels such as drugstores and supermarkets.

Pharmacies

In the US pharmacy market, this transformation started much earlier and is still evolving at a very fast pace. As of 2007, there were 60,500 pharmacies and nearly 500 retail pharmacy chains in the US. These chains include: traditional retail pharmacy chains, the largest being CVS/Caremark;

mass merchants, the largest being Wal-Mart; and supermarkets, the largest being Albertson's. In addition to the chains, there are 33,394 independent retail pharmacies in the US.

In contrast with the US market, the European pharmacy landscape is composed of about 150,000 pharmacies with only 15,000 belonging to a chain of more than 10 stores. Every pharmacy in Europe requires a license issued by a ministry, a health board or a local authority. Some countries (e.g., the UK, Spain, Italy and France) have dispersion rules regulating the number of inhabitants per pharmacy, and in certain cases, there are rules about the minimum distance between pharmacies.

Differing pharmacy ownership rules among the EU member states have shaped models that reach to the extremes. In Sweden, the pharmacy business is a state-owned monopoly that was created in a wave of nationalization in the early 1970s, leading to the creation of Apoteket AB, a public sector company owned by the Swedish state and awarded the exclusive right to operate community and hospital pharmacies.

At the other end of the spectrum are the large areas of the pharmacy landscape already in the hands of corporate entities in the liberalized markets. Pharmacies in chains account for 80% of the pharmacies in Norway, 50% in the UK, 40% in the Netherlands and 35% in Ireland. Still, the pharmacies in most countries, including the largest pharmaceutical markets – such as Germany, France, Spain and Italy – are independently owned, and ownership is restricted both in terms of the number of pharmacies and the qualifications of the owner.

OTC drugs

In the US, OTC drugs are sold in pharmacies and supermarkets and by mass merchants. In most European markets, OTC drugs are still sold almost exclusively through pharmacies; for the sale of OTC drugs outside pharmacies, the line is blurred. Besides pharmacies, many countries have drugstores selling healthcare

products and deriving most of their revenue from toiletries, baby products and cosmetics. In France and Spain, these outlets are not allowed to sell any form of registered drug, but in Germany and the UK, they can sell a restricted range of low-potency, everyday OTC products. In these countries, the drugstore market has changed through the development of powerful chains. These chains sometimes belong to supermarkets, which are controlling most of the domestic market and are expanding across Europe.

Deregulation drivers

In Europe, a shift is underway with deregulation expected to occur within the next year both in pharmacy ownership and in the sale of OTC drugs outside pharmacies.

The rationale behind deregulating pharmacy ownership is the expectation that liberalization will increase competition. This, in turn, is expected to lower drug expenditure while improving, or at least maintaining the current state of, the accessibility and the quality of pharmacy services.

The tension is between the member states' national laws and European law. Healthcare, including the dispensing of drugs, is under the remit of the individual states, which thus can decide what type of pharmacy market, regulated or deregulated, best suits their national health policies and economic imperatives. On the other side, competition, in terms of "ensuring efficient and least restrictive competition to spur European economic growth, and deliver better services and value for consumers,"⁴ is under the remit of the European Commission. The Commission's work focuses on six professions – lawyers, notaries, accountants, architects, engineers and pharmacists – which the Commission considers potentially overregulated.

On the OTC sales side, drivers of deregulation include moving drug costs from governments to consumers, as OTC drugs often are not reimbursed, empowering the public by encouraging responsibility for self-medication

⁴ http://ec.europa.eu/competition/sectors/professional_services/overview_en.html

In the last few years, enforcement of the provisions of the European Commission (EC) treaty has prompted deregulation of public services in several EU member states. One of the targeted sectors is healthcare and, within healthcare, the pharmacy business.

In February 2008, the EC initiated infringement proceedings with a letter of formal notice against Germany over its restrictions on the ownership of pharmacies. Several other member states (including Italy, Spain, Austria, France and Germany) are also being investigated with regard to the compatibility of their national pharmacy rules with the provisions of the EC treaty.

In Germany in the first quarter of 2009, the European Court of Justice is due to rule on the right of corporate entities to own and operate pharmacies and on the restriction on multiple pharmacy ownership. Previously, in December 2008, the Advocate General of the European Commission gave a preliminary legal opinion that the national regulations on the pharmacy market “are justified by the objective of seeking to guarantee an appropriate supply of medicinal products to the public.” Although this is a legal opinion and not the final ruling, the European Court of Justice has followed such opinions in most cases.

and widening access to medication. For the pharmaceutical companies, OTC drugs represent a lucrative segment, not subject to pricing controls. Lobbying against deregulation are the pharmacists, who are protecting their livelihoods and advocating for the need to associate drug dispensing with consultation.

Sweden has already decided to deregulate its market. The state-owned Apoteket AB will lose its monopoly on 1 July 2009. Nonprescription drugs will be made available in grocery stores and supermarkets three months later. The government will sell 50% of its pharmacies, opening the door to the creation of pharmacy chains.

Gains from deregulation

What would be the consequences of pharmacy deregulation? Those who would potentially gain are pharmacy chains, mail order and internet pharmacies, drugstore chains and supermarkets.

Pharmacy chains

There are lessons to be learned from recently deregulated markets. After market deregulation in Norway in 2001, the number of pharmacies grew from 399 to 559 by 2006. The three largest pharmacy chains now control 78% (437) of the 559 pharmacies and represent 97% of the total pharmacy revenue in Norway. Five years after deregulation, only 15 pharmacies are still independent, evidence of the dramatic effect deregulation can have on the market.

Mail order and the internet

Mail-order and internet pharmacies are allowed to sell OTC and physician-prescribed drugs in the US, where the penetration rate has been steadily growing at about twice the market growth rate. In Europe, due to the greater concentration of pharmacies, the different reimbursement structures and the extremely prohibitive legislation, the growth of the virtual distribution channel has been hampered. The countries in which internet pharmacies have developed include the UK, the Netherlands and Switzerland. In

Germany, DocMorris has been the first mover in that space, initially sparking controversy and legal disputes. DocMorris is a successful business today, with German wholesaler Celesio as majority shareholder. This market is attracting interest overseas from Medco, the leading US pharmacy benefit manager. It has also recently acquired Europa Apotheek, one of Europe’s leading mail-order pharmacies, serving the Dutch and German healthcare markets from its operations in the Netherlands.

Drugstores and supermarkets

Drugstores and supermarkets have been using the internet pharmacy model as a way into the pharmacy business. With pharmacy deregulation bound to occur, many large players have initiated pilot projects, teaming up with internet pharmacies and allowing customers to order online and collect their orders in the stores. The large supermarket chains are lobbying for a further deregulation of the OTC markets, which are still in the hands of the pharmacists. In France, E. Leclerc recently led a public campaign to demand a change in the law to allow nonpharmacy sales of OTC drugs, claiming it would offer a 25% discount off the pharmacy prices currently in effect.

The verge of change

The pharmaceutical distribution environment in Europe is on the verge of a major transition toward more liberalized and open markets. Increasingly, OTC drugs will start to appear outside of pharmacies, in drugstores and supermarkets, driven by governmental pressure to reduce cost, empower patients and widen access.

In the pharmacy business, the change agents will most likely be the pharmaceutical wholesalers. These wholesalers have lately been squeezed between the cost-containment initiatives of their suppliers, who are the drug manufacturers, and their customers, who are the payors.

These imminent changes represent major challenges for drug manufacturers, who see their distribution channels morphing rapidly and will have to adapt their business models accordingly.

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EYG No. CW0061
0811-1006386

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