Pharma Trax SALES, MARKETING, AND R&D TRENDS AFFECTING THE HEALTHCARE INDUSTRY

By Carolyn Gretton

Pharma Faces Record
Patent Expirations

TREND: Pharmaceutical companies are facing an unprecedented period of patent expirations over the next few years, with industry executives warning of tough times ahead.

Thirteen blockbuster pharmaceuticals are expected to lose U.S. patent protection over the next two years, highlighting the challenges facing the pharmaceutical industry in the coming years. Data from EvaluatePharma show that drugs worth a total of $15.3 billion in sales will face generic competition in 2011, and that this number will double to $33.2 billion by 2012. EvaluatePharma also projects that in the next six years, an estimated $133 billion worth of branded drugs face patent expiry in the United States alone.

Pfizer is expected to suffer the biggest loss from this "patent cliff," with its $11 billion cholesterol-lowering medicine Lipitor going off patent later this year, and three other top-selling drugs facing generic erosion in 2012. As a result, EvaluatePharma projects Novartis will knock Pfizer from the No. 1 sales position by 2012.

For more information, visit evaluatepharma.com.

PROJECTED U.S. SALES OF TOP PRODUCTS GOING OFF PATENT IN 2011 ($ MILLIONS)

Rank	Product	Company	2010	2011	2012	2013	2014	2015	2016
1	Lipitor	Pfizer	$5,329	$4,528	$492	$146	$73	$45	$42
2	Zyprexa	Lilly	2,496	1,949	339	218	188	172	157
3	Levaquin	Johnson & Johnson	1,312	734	155	62	43	30	17
4	Concerta	Johnson & Johnson	929	587	306	221	189	150	111
5	Protonix	Pfizer	690	279	172	96	64	41	17

Source: EvaluatePharma. For more information, visit evaluatepharma.com.

PROJECTED U.S. SALES OF TOP PRODUCTS GOING OFF PATENT IN 2012 ($ MILLIONS)

Rank	Product	Company	2010	2011	2012	2013	2014	2015	2016
1	Plavix	Bristol-Myers Squibb	$6,154	$6,315	$3,014	$382	$113	$61	$28
2	Seroquel	AstraZeneca	3,747	3,771	1,669	985	861	792	732
3	Singulair	Merck	3,224	3,356	2,178	364	125	53	21
4	Actos	Takeda	3,351	3,275	1,360	582	511	462	413
5	Enbrel	Amgen	3,304	3,258	3,218	3,157	3,097	3,024	2,967
6	Lexapro	Forest	2,264	2,122	188	66	50	43	39
7	Diovan	Novartis	2,520	2,093	1,540	394	333	279	246
8	Viagra	Pfizer	992	1,007	328	75	59	54	46
9	Provigil	Cephalon	1,027	916	403	87	38	28	17
10	Geodon	Pfizer	864	907	539	120	35	28	22

Source: EvaluatePharma. For more information, visit evaluatepharma.com.

New Product Planning Team
KEY TO LAUNCH SUCCESS

The Best Practices benchmarking report, New Product Planning: Role and Activities for Medical Affairs, notes that in the preclinical through Phase II stages of development, NPP teams engage in a series of activities designed to determine the market fit and potential of identified drug candidates, and to prepare for key activities such as positioning and branding. After Phase II, NPP activities are more focused as more clinical data becomes available and outputs are refined to support critical commercial activities and maximize a product's launch and life-cycle success.

KOL MANAGEMENT TIPS

- Identify KOLs as early as possible, preferably in preclinical to gain a deeper understanding of the medical need and to provide insight into how the new drug can fit into the market and what it must accomplish to be considered effective. In Phase I, use input from KOLs to guide clinical trials and establish market-driven endpoints. In Phase II, set up advisory boards to help guide positioning and messaging to doctors and to provide insight for conducting Phase III trials. In Phase III, KOLs should be heavily influencing the clinical trial processes.
- Manage KOLs in two groups: one to guide the development process and provide insight as data comes back, the other to work more closely with publications and messaging.
- Branding of the science, like all marketing activities, must be updated regularly. As data come back about the drug at each phase, focus on positive effects. Carefully avoid messages that, with the benefit of new data, could cause a lack of trust among doctors or regulatory agencies.

Source: Best Practices report, New Product Planning: Role and Activities for Medical Affairs.
For more information, visit best-in-class.com.

Half of the small pharma segment companies included in the Best Practices study said their global NPP groups get involved with advisory boards in the preclinical research phase, while large pharma segment companies indicated their global NPP groups get involved more at the Phase I stage.

For more information, visit best-in-class.com.

Pharma Seeks HIGH-QUALITY, EXPERIENCED CLINICAL DEVELOPERS

The increase in volume, scope, and complexity of clinical trials is driving pharma companies to place more emphasis on high-quality clinical development teams and to keep a closer eye on third-party clinical service providers.

According to the Industry Standard Research (ISR) report, Clinical Development Staff Quality and Resourcing Models, both sponsor companies and clinical development service providers believe there is a shortage of high-quality, experienced, and well-trained clinical development personnel, with the impact affecting some positions more than others.

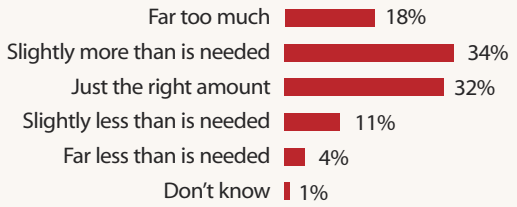
For example, sponsors expect a minimum of about seven years of experience from lead regulatory staff, the report notes.

The report also illustrates a perception gap as to how much oversight is conducted by the sponsor. About two-thirds of service providers surveyed by ISR said that sponsor companies either provided far too much or slightly more oversight than was necessary in managing projects outsourced to the service provider. By contrast, about one-third of sponsor companies surveyed indicated that their oversight of service providers was just the right amount.

For more information, visit isrreports.com.

SPONSOR ON LEVEL OF OVERSIGHT

What level of management oversight do you think your organization uses when managing a service provider?



Source: Industry Standard Research, Clinical Development Staff Quality and Resourcing Models. For more information, visit isrreports.com.

SERVICE PROVIDERS ON LEVEL OF OVERSIGHT

What level of oversight do you think sponsors use when managing a service provider?

Source: Industry Standard Research, Clinical Development Staff Quality and Resourcing Models. For more information, visit isrreports.com.

Emerging Nations Gain Strength IN MEDICAL TECHNOLOGY INNOVATION

During the last 50 years, the United States has provided an ideal innovation ecosystem that has fostered advances in medical technology. U.S.-based companies dominate the roughly $350 billion global medical device industry. But PricewaterhouseCoopers (PwC) notes U.S. performance is expected to decline in several areas.

Medical technology companies increasingly are going outside the United States to emerging nations such as China, India, and Brazil to seek clinical data, new-product registration, and first revenue.

But PwC researchers say factors related to intellectual property protection, difficulty of doing business in some emerging countries, and local supplier network concerns could make these markets less attractive despite their size and could hinder these nations' effort to assume innovation leadership.

PricewaterhouseCoopers' Medical Technology Innovation Scorecard: The race for global leadership assesses the capacity of nine countries to adapt to the changing nature of innovation: Brazil, China, France, Germany, India, Israel, Japan, the United Kingdom, and the United States.

On a scale of one to nine, the U.S. achieved the highest score, at 7.1; but the report predicts the country will lose ground over the next decade as emerging nations such as China, India, and Brazil continue to make strides in innovation capacity.

China, in particular, is expected to outpace other countries in innovation and reach near-parity with the developed nations of Europe by 2020.

For more information, visit pwc.com.

MED TECH'S NEW PILLARS OF INNOVATIONS

- System-oriented and value-based incentives. Fiscal and financial needs are compelling payers to press providers for greater value.
- Global networks of academic medical centers. Emerging markets are investing in their own academic medical centers, and U.S. and European institutions are seeking partnerships with these centers.
- Competing regulatory systems. Greater ease and cost-effectiveness of regulatory approvals are occurring in other nations.
- Individualized solutions and price sensitive customers. Personalized medicine and cost-shifting measures are driving individualization of healthcare.
- Global financial networks. U.S. venture capitalists are partnering with overseas counterparts and seeking co-investment opportunities.

Source: PricewaterhouseCoopers, Medical Technology Innovation Scorecard: The race for global leadership. For more information, visit pwc.com.

Data Masking Recommended for EHR SOFTWARE TESTING

The healthcare industry's shift from paper-based patient records to electronic health records (EHR) has spurred a need for new software and systems to process these records. Many companies working to create the next generation of healthcare systems and software have opted to use actual patient data to test these new products, potentially putting this data at risk of exposure to unauthorized parties, including identity thieves.

According to a Ponemon Institute whitepaper, Health Data at Risk in Development: A Call for Data Masking, slightly more than half of healthcare IT professionals surveyed said they do not protect patient data used in software development and testing, and 78% were either not confident or undecided as to whether their organization could even detect the theft or loss of real data. About 38% of respondents said they have had a breach involving data in a development and test environment, with 59% of those with breaches experienced disruption of operations, 56% facing regulatory action, and 36% suffering reputation loss.

For more information, visit ponemon.org. PV