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Generics poised for further consolidation

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WITH A number of blockbuster drugs recently off patent and others soon to lose their exclusivity, generics companies are experiencing both the benefits and the risks of going up against branded pharmaceuticals.

The push toward less-expensive but quality-grade prescription drugs is intensifying, and pressures on the pharmaceutical industry are shaping a new course. In particular, political advocacy for the containment of health care costs is generating more-favorable legislation and policies in support of generic drug development and increased use.

"Top generic companies are now huge, global players themselves driving demand and inspiring confidence in generic drugs as high quality, therapeutic equivalents. Today generics are outperforming big pharma," says Jean Hoffman, president of Q Street Advisors, a Portland, Me.-based strategic advisory firm.

Today's top generics companies are consolidating their leadership and establishing a firmer foothold in the top ranks, Hoffman pointed out at a meeting held by the Generic Pharmaceutical Association during the Drug, Chemical & Associated Technologies (DCAT) annual meeting held in New York earlier this month.

"There continues to be consolidation among global and regional US and EU generic companies as well as major customers in the US," she notes. "EU customers remain fragmented and mostly national, with differing packs, rules and brands, thereby making them less attractive to active pharmaceutical ingredient [API] manufacturers, but not forever."

Generics leaders

Top 1999		Top 2004	
1 Novartis/Sandoz	8%	Teva	8%
2 Mylan	7%	Novartis/Sandoz	6%
3 Teva	7%	Mylan	6%
4 Merckle/ ratiopharm	5%	Merckle/ ratiopharm	5%
5 Watson	4%	Hexal (now Sandoz)	4%
Next 5	14%	Next 5	16%
Top 10	45%	Top 10	45%

Source: IMS Health

Novartis's move in February 2005 to acquire both Eon Labs Inc. and Hexal AG, based in the US and Germany, respectively, for $8.5 billion, signals growing consolidation in the generics arena. The acquisition catapults Sandoz, the generics arm of Novartis, into the global leading position, toppling Israel-based Teva Pharmceuticals Inc., which was ranked the number-one generic drug company last year by IMS Health.

In 2004, Teva held an 8 percent market share, followed closely by Sandoz and Mylan Laboratories Inc., each with a 6 percent market share, according to IMS. Hexal held a 4 percent market share in 2004.

In what is becoming an increasingly competitive market, API manufacturers must distinguish themselves as well as comply with stronger regulatory guidelines for pharmaceutical-grade APIs. Western API producers must also deal with the issue of growing competition from highly competent Asian manufacturers with low-cost product.

Not only do Western players face competition from well-established and technically competent companies in India, they are also seeing the fragmented base of Chinese API producers solidify. Although China lags behind India's capabilities in high-quality API production, much investment is being made to move domestic companies forward. "China is already a key part of the supply chain for pipelines in supplying lower-cost intermediates," says Hoffman.

Hoffman notes that China is still years behind India and not yet a significant factor in new drug products. China's strength instead is in supplying older products. However, select Chinese plants are making progress toward replacing older products with higher-value, newer products.

Going forward, many API manufacturers will also contend with issues revolving dose-form drugs. ■