

Brands move in on generics

Although generics makers and innovator firms have staked out fairly clear positions in the battle over follow-on protein products (FOPPs), industry consolidation may blur the lines a bit. Some small biotech firms are poised to take on larger competitors by pursuing development of FOPPs. And some leading innovator firms are moving forcefully into the generics business.

Novartis leads the trend with the planned addition of European generics firms Hexal AG and Eon Labs to its Sandoz unit. The deal would make Novartis the world's top generics drug maker, passing Teva and Mylan, while it also remains a leading innovator firm. Although some brand-name companies have been burned from the low-margin, high-volume generic drug business model, Novartis executives expect to gain from positioning the company as a prime source of both generic and branded products for major drug purchasers.

Novartis's move also reflects interest in developing FOPPs. In September 2004, Novartis senior vice-president Mathias Hukkelhoven said at the FDA public meeting on follow-on biologics that Novartis supported efforts by FDA and Congress to establish a robust and responsible policy for producing safe and efficacious new versions of protein products. FOPPs should have to meet high safety and efficacy standards, he said, but offer an opportunity to minimize duplication of preclinical and clinical testing to promote patient access to affordable medicines and to allow the "most innovative companies" to succeed.