

DCAT

# TOP Industry NEWS

*BUSY WEEK? Here are the  
TOP INDUSTRY NEWS stories  
you might have missed, as  
selected by DCAT Editorial  
Director Patricia Van Arnum.*



**More successful NDA approvals than any other. Delivered.**

**1. Fresenius Kabi to Acquire Akorn and Merck KGaA's Biosimilars Business for \$5.5 Billion**

Fresenius Kabi has agreed to acquire Akorn, a specialty generics company, for \$4.75 billion and Merck KGaA's biosimilars business for up to approximately \$730 million. [Read More](#)

**2. FDA OKs Samsung Bioepis' Biosimilar to J&J's Top-Selling Remicade**

Samsung Bioepis has received approval from the FDA for Renflexis (infliximab-abda), a biosimilar referencing Johnson & Johnson's (J&J) anti-inflammatory drug, Remicade (infliximab), which had 2016 sales of \$6.97 billion. [Read More](#)

**3. US Supreme Court Hears Biosimilar Dispute Between Sandoz and Amgen**

In a case with implications for biosimilar launches in the US, the US Supreme Court heard oral arguments from Sandoz, the generic drug arm of Novartis, and Amgen regarding the interpretation of notification requirements by a biosimilar developer to an innovator drug company. [Read More](#)

**4. Teva Launches Competitors to GSK's Top-Selling Asthma Drug**

Teva has simultaneously launched AirDuo RespiClick (fluticasone propionate and salmeterol inhalation powder) and an authorized generic to that product, which are potential competitors to GlaxoSmithKline's Advair, a top-selling product with 2016 sales of £3.5 billion (\$4.5 billion). [Read More](#)

**5. Japan's Sawai to Acquire Upsher-Smith's US Generics Business for \$1 Billion**

Sawai Pharmaceutical, a Japanese generic pharmaceuticals manufacturer, has agreed to acquire the US generics business of Upsher-Smith Laboratories, a generics manufacturer, for approximately \$1 billion. [Read More](#)

**6. Novartis On Track in Productivity Initiatives**

Novartis reports that it is on track with productivity initiatives created with the formation of Novartis Technical Operations (NTO) and its Global Drug Development (GDD) organization, two enterprise-wide entities formed in 2016. The company has the goal of achieving more than \$1 billion in annual cost savings by 2020 through NTO and GDD. [Read More](#)

**7. US Senate Committee Approves Nomination for FDA Commissioner**

The US Senate Committee on Health, Education, Labor & Pensions has voted to advance the nomination of Scott Gottlieb, MD, as the next FDA Commissioner. The nomination now goes to the full Senate for consideration. [Read More](#)

**8. Sun Pharma Cited by FDA in Inspection of Formulation Plant**

Sun Pharmaceutical Industries has received a Form 483 from the FDA following an April 2017 inspection of its solid dosage manufacturing facility in Dadra, India. [Read More](#)

## 9. [Pharma Execs, EFPIA Call for Move of EMA HQ Post Brexit](#)

Major pharmaceutical companies and the European Federation of Pharmaceutical Industries and Associations are calling on the European Council to decide on the new headquarters for the now London-based European Medicines Agency in the wake of the UK's pending separation from the European Union. [Read More](#)

## 10. [UK Regulatory Agency Outlines Plan Post Brexit](#)

The UK's Medicines and Healthcare products Regulatory Agency released a report to highlight its priorities post Brexit, including a proposed model for the future regulation of medicines in the UK. [Read More](#)

***The DCAT organization is happy to provide this service to its members each Friday. Have a great weekend!***

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### About Top Industry News

The DCAT organization recognizes its members have minimal time to keep up with the continuous flow of news covering this dynamic industry. To help ensure our members never miss the most important stories impacting the global pharmaceutical manufacturing industry, we will deliver each Friday, the week's Top Industry News, as selected by DCAT Editorial Director Patricia Van Arnum.



The Drug, Chemical & Associated Technologies Association (DCAT) is a not-for-profit, global business development association whose unique membership model integrates both innovator and generic drug manufacturers and suppliers of ingredients, development and manufacturing services, and related technologies. We are committed to provide programs, events and services that help our members meet their business objectives, expand their network of customers and suppliers, and gain insight into industry trends, markets, and those issues impacting pharmaceutical development and manufacturing.



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