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WILL WE SEE A RETURN TO GROWTH FOR THE GENERICS INDUSTRY?

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Will we see a return to growth for the generics industry?

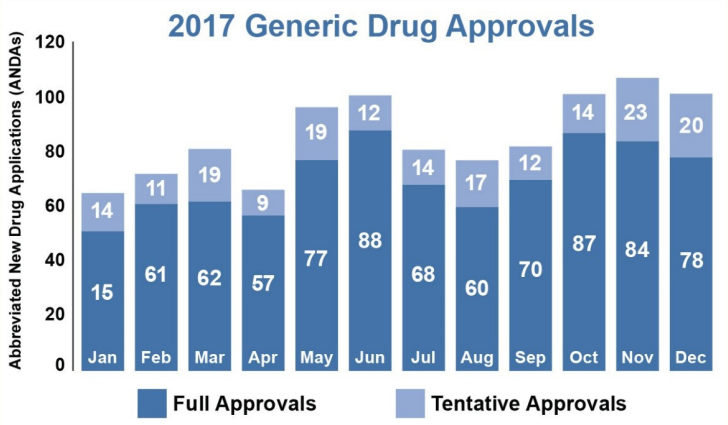
With Shire losing a case against Zydus, Mylan's launches of generics Copaxone, Estrace and Sustiva and Teva following suit with its generic products for Estrace, Viagra and Minastrin 24 Fe - analysists (1) keep giving positive forecasts for the industry post-2017.

Will 2018-19 be a year of growth for generics Pharma?

Branded products going generics. In 2018 at least 77 branded products above 100$ M (1) expect to go generics, which could potentially drive 5$B of new generics product sales making 2018 the first year of growth since 2015. There are notable opportunities in both big brand products going generics such as Cialis, Humalog, Restasis, Advair, Latuda, Gilenya, Lyrica and the smaller ones like Delzicol. Nuvaring, Ampyra among others.

The number of approvals is also expected to grow year on year. At the beginning of 2018, FDA reported that the number of approvals in 2017 exceeded 1,000 with 80 of the products being "first generics".

Since lowering the cost of drugs is a public health priority, the first generic drugs approvals allow to stimulate a competitive environment that ultimately leads to the further price erosion of the generic medicines. According to FDA the high approval rates are expected to continue.



SOURCE: IMS- HEALTH

What about the rest of the world?

Part of the success for generic companies comes from the ability to expand into the global markets. However, with the local governments also looking to achieve lower prices and the stronger local production, the cost containment policies, especially those aimed at older API's, make regulatory approvals and the market entries a complex process for both branded and generics drugs.

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Examples of Global Drug Cost Containment Policies

Policy Class	Specific Type of Action	Representative Countries Adopting Policy
Pricing Controls and Cuts	One-off cut in prices of patented medicines	Austria, Belgium, Germany, Italy, Portugal, Spain, UK
	Implementation of reference pricing	Brazil, Canada, France, Germany, Italy, Mexico, N. Zealand, Spain
	Change in reference price system by cluster	Greece, Ireland, Portugal, Spain
	Reduction of Mark-Up for Distributors	Austria, Canada, Greece, Ireland, Italy, Portugal, Spain
	Implementation of Essential Drug List with Low Prices	Argentina, China, India, Russia, Vietnam
	Mandatory Annual Price Cuts	Japan, Philippines
	Increase of government rebates / most favored nation approach	Germany, United States
	Extraordinary Price Reviews	Greece, Ireland, Portugal, Slovakia, Spain
	Group purchasing approach / negotiation for lower prices	Canada
Reimbursement Policies	Delisting of products on reimbursement lists	Czech Republic, Greece, Portugal, Spain
	Increase in patient co-pays	Austria, France, Greece, Ireland, Sweden
	Health Technology Assessment / Cost-Benefit for price decisions	Germany, United Kingdom
	Entry management agreement	Belgium, Italy, United Kingdom
Policies to promote generic medicines	Implementation of INN name prescribing (can't use brand name)	France, Italy, Portugal, Slovakia, Spain
	Incentives for physicians to prescribe generics	Belgium, France, Hungary, Japan
	Incentives for pharmacists to prescribe generics	Belgium, France, Ireland, Japan
	Incentives for patients to receive generics	France, Iceland, Ireland, Portugal, Spain
	Generic price cuts and tendering approach	Canada, China, Italy, Vietnam

Sources: Torreya research and Belloni, A., et.al., "Pharmaceutical Expenditure and Policies," OECD Working Papers No. 87, April 19, 2016.

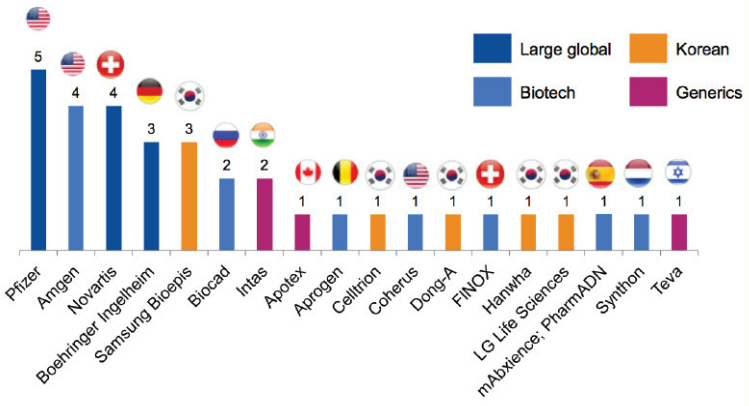
Opportunities in the biosimilar market

Despite biosimilar market being in a development phase, the expectations from the next wave of biosimilars that include trastuzumab, rituximab, adalimumab and bevacizumab, etanercept

These new opportunities for brand value development would most certainly be utilised by such large generics players as Teva, Mylan and Sandoz that will be competing for a share of the market alongside Pfizer, Amgen and Merck.

New biosimilars are being developed by diverse companies

Number of products in registration, pre-registration, and phase III



SOURCE: IMS- HEALTH

What could be holding back the trend?

Not only the industry has strong launches that grant certain exclusivity periods, the companies are well adept in the product life-cycle strategies and possess very strong litigation handling capabilities – all of which delay timeline for new value-creating launches.

Another bottleneck is unclear regulatory pathways for some of the products.

Sometimes the problem could be attributed to the uncertain timing of the regulatory approval, however, sometimes the bottleneck is just the type of the product that the company is trying to get approved.

One of the examples would be underutilised opportunities in the respiratory field where the combination of drug and device raise questions in both development and IP.

Nevertheless, despite regulatory, competitive and pricing pressures, the outlook for the generic industry for the next 1-3 years remains positive