In Vivo
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A Year Of Surprises Shakes Up Off-Patent Industry

Sandoz, Mylan And Teva Switch Places At The Top

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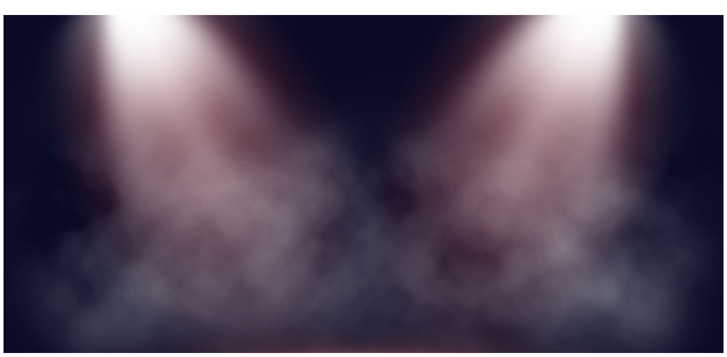
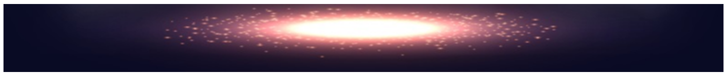
Executive Summary

After an eventful year for the off-patent industry, the world's leading generics and biosimilars players have switched places in *Generics Bulletin*'s newly compiled global sales ranking.





SPOTLIGHTING THE TOP GENERICS AND BIOSIMILARS PLAYERS *Source: Shutterstock*

After a year that has seen major changes for some of the biggest players in the global off-patent industry, it is perhaps no surprise that annual rankings of the world's top 50 generics and biosimilars companies reflect this upheaval.

This year, annual rankings produced by *In Vivo's* sister publication *Generics Bulletin* paint a picture that looks quite different to predictions made by industry onlookers just 12 months ago, particularly when it comes to the top of the table.

Last year, Mylan topped the list, followed by Sandoz Inc. and Teva Pharmaceutical Industries Ltd.. At the time, *Generics Bulletin* predicted that Sandoz would slip down the table in future due to its deal to divest a large chunk of its business – in the form of its US solid-dose and dermatology units – to India's Aurobindo.

However, while that deal had been expected to close by the end of 2019, it eventually fell apart altogether. As a result, Sandoz has not only maintained its position in the top three but has vaulted to the top of sales rankings, with its $9.37bn total for the combined generics, biosimilars, active pharmaceutical ingredients and OTC category narrowly exceeding that of Mylan, despite the Novartis unit seeing a 1% drop in turnover in 2019.

Mylan Prepares For Viatris Merger

While Mylan's total company sales in 2019 grew by 1% to $11.5bn, the latest ranking excludes from the key category around $1.8bn of Mylan's turnover from respiratory and allergy brands such as EpiPen (epinephrine), Perforomist (formoterol) and Tobi (tobramycin).

Mylan was also a firm with very different expectations hanging over it midway through last year, with investors keenly anticipating the firm's long-trailed management announcement of restructuring plans expected to revitalize the company. But eventually the firm revealed significantly more far-reaching change, in the form of a merger with Pfizer's Upjohn off-patent unit to become Viatris. (Also see "Pfizer To Merge Off-Patent Business With Mylan" - Generics Bulletin, 29 Jul, 2019.)

Although the close of this merger has been pushed and had no effect on Mylan's 2019 figures, the expected successful completion of the deal promises to leave the company in a very different position 2021's industry rankings.

Sandoz and Mylan's leading positions this year come at the expense of Teva, which remains in third place after seeing its group sales drop by 8% to $16.89bn with its generics, biosimilars, APIs and OTC figure making up $9.33bn.

Teva president and CEO Kåre Schultz had been clear that the firm expected 2019 to represent "the bottom of the trough" for the company's sales and earnings, as it emerges from a years-long period of upheaval in the form of a restructuring program that has seen it shed thousands of staff, shutter more than 20 manufacturing sites and prune its product portfolio, especially in the US. The firm is also focusing on brands such as Ajovy (fremanezumab) and Austedo (deutetrabenazine) as major growth drivers, especially as Copaxone (glatiramer) sales continue to atrophy in the face of global generic competition.

Working down our top 10 list, we see Pfizer no longer listed under the banner of Pfizer Essential Health – after the company reorganized its reporting structure in 2019, eliminating this grouping – but instead ranked according to its combined sterile injectables and biosimilars business, much of which was inherited from the legacy Hospira unit. The figure of just under $6bn includes a significant portion of biosimilars sales that are likely to top $1bn in 2020 after reaching $911m in 2019.

As major firms like Sandoz, Mylan and Teva do not typically split out sales of OTC products separately from their generics offerings, the ranking includes OTC products alongside prescription generics and biosimilars.

This means that Perrigo's extensive range of consumer health care products – many of which are approved through the generic abbreviated new drug application pathway in the US – puts it squarely in the top 10 when combined with the Prescription Pharma unit that it is considering selling or spinning off. The firm is taking its time to secure adequate value for the Prescription unit but says the recent sale of its UK-based Rosemont Pharmaceuticals liquid generics business proves that attractive multiples are still out there in the generics space.

Sun Pharma's business enjoyed double-digit growth in 2019, although the Indian company has been weighed down recently by a costly settlement connected to the US price-fixing investigations relating to its Taro subsidiary. And Fresenius Kabi AG ranked in seventh position this year thanks to its large intravenous portfolio, even as it recently conceded that its biosimilars business had been slower off the mark than it had expected.

Aurobindo, meanwhile, has climbed up the rankings from 10th to eighth position despite the collapse of its deal with Sandoz that would have likely propelled it even higher.

Rounding out the top 10 are China's Shanghai Fosun Pharmaceutical (Group) Co., Ltd. – that saw 15% growth to more than $3bn for its pharmaceuticals unit – and Germany's STADA, which saw a group increase of 12% to $2.92bn in the wake of an acquisition spree in 2019. The firm's generics, biosimilars, APIs and OTC figure of $2.75bn excludes its branded products Apo-Go (apomorphine) and value-added bortezomib that together accounted for $171m in 2019.

Generics Bulletin's Top 50 Company Rankings

Company	Generics / Biosimilars / APIs / OTC ($m)	Prescription Brands ($m)	Other ($m)	Total turnover ($m)	Change %	Notes
Sandoz	9,731	-	-	9731	-1	Total includes $534m from sales of anti-infective parties
Mylan	9,566	1,805	130	11,501	+1	Prescription Brands is Respiratory and Allergy the category
Teva	9,326	3,389	4,172	16,887	-8	
Pfizer Sterile Injectables and Biosimilars	5,946	-	-	5,946	-1	
Perrigo	4,837	-	-	4,837	+2	Comprises $967m from Prescription Pharma, $2, Consumer Self-Care Americas and $1,382m from Healthcare International

Sun Pharma	4,539	-	19	4,558	+13	Financial year ended 31 March 2020; converted fı rupees
Fresenius Kabi	3,292	-	4,457	7,749	+4	Generics / Biosimilars / OTC / APIs figure is Intra Drugs unit; converted from euros
Aurobindo	3,257	-	-	3,257	+18	Financial year ended 31 March 2020; converted fı rupees
Shanghai Fosun	3,066	-	962	4,028	+15	Converted from Chinese yuan
Stada	2,750	171	-	2,921	+12	Converted from euros; branded products includes sales of €74.5m and value-added bortezomib sal €78.5m
Cipla	2,360	-	56	2,416	+5	Financial year ended 31 March 2020; converted fı rupees
Dr Reddy's	2,311	151	-	2,462	+13	Financial year ended 31 March 2020; converted fı rupees
Lupin	2,135	-	33	2,168	+5	Financial year ended 31 March 2020; converted fı rupees
Intas	2,108	-	-	2,108	+14	Financial year ended 31 March 2020
Hikma	1,973	219	11	2,203	+6	Figures based on approximate 90:10 revenue spli generics and brands
Zydus Cadila	1,692	-	318	2,010	+8	Other sales are Consumer Wellness & Animal Hea segments; Financial year ended 31 March 2020; c from Indian rupees
Sawai	1,679	-	-	1,679	-1	Financial year ended 31 March 2020; converted fı Japanese yen
Nichi-Iko	1,655	65	29	1,749	+14	Financial year ended 31 March 2020; converted fı Japanese yen
Servier Generics -incl. Biogaran, Egis and others	1,549	-	-	1,549	+8	Financial year ended 30 September 2019; convert euros
Krka	1,546	-	122	1,668	+12	Converted from euros
Glenmark	1,471	-	29	1,500	+8	Financial year ended 31 March 2020; converted fı rupees
Aspen	1,373	888	-	2,261	+1	Generics/Biosimilars/OTC/APIs comprises $103 Regional Brands (now including High Potency & C and $336m from APIs and FDFs; financial year en June 2019; converted from South African rand
Amneal	1,309	318	-	1,626	-2	
Sanofi Generics	1,204	-	-	1,204	-28	Converted from euros
Alkem	1,177	-	-	1,177	+13	Financial year ended 31 March 2020; converted fı rupees
Gedeon Richter	1,172	230	382	1,748	+12	Prescription Brands is Vraylar (cariprazine), Reagi (cariprazine) and Esmya (ulipristal acetate); conv euros
Torrent Pharma	1,052	-	67	1,119	+3	Financial year ended 31 March 2020; converted fı rupees
Towa	1,016	-	-	1,016	+5	Financial year ended 31 March 2020; converted fı Japanese yen
Endo	985	1,929	-	2,914	-1	Generics/Biosimilars/APIs/OTC figure is Generics

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Celltrion	928	-	-	928	+54	Converted from South Korean won
Ache	848	-	-	848	+5	Converted from Brazilian reals
Hypera	834	-	-	834	-12	Converted from Brazilian reals
Jubilant	806	-	485	1,291	0	Generics/Biosimilars/APIs/OTC figure is Pharma segment; Financial year ended 31 March 2020; Co from Indian rupees
Sopharma	777	-	-	777	+9	Converted from Bulgarian lev
Mallinckrodt	739	2,424	-	3,163	-2	
Akorn	682	-	-	682	-2	
Ipca Labs	665	-	-	665	+23	Financial year ended 31 March 2020; converted fr rupees
Lannett	655	-	-	655	-4	Financial year ended 30 June 2019
Alembic Pharma	649	-	1	650	+17	Financial year ended 31 March 2020; converted fr rupees
Biocon	646	-	275	921	+15	Financial year ended 31 March 2020; converted fr rupees
Orion	605	455	117	1,177	+8	Converted from euros
Wockhardt	586	-	-	586	+6	Financial year ended 31 March 2020; converted fr rupees
Kalbe Farma	585	-	947	1,532	+7	Converted from Indonesian rupiah
Advanz Pharma	508	-	-	508	-5	
Bausch Health Generics	459	-	-	459	+11	
Adcock Ingram	408	-	4	412	+11	Financial year ended 30 June 2019; converted fro African rand
Strides Pharma Science	390	-	-	390	+26	Financial year ended 31 March 2020; converted fr rupees
Coherus Biosciences	356	-	-	356	-	
Natco Pharma	285	-	-	285	-9	Financial year ended 31 March 2020; converted fr rupees
Beximco	278	-	-	278	+29	Financial Year Ended 30 June 2019; converted fro Bangladeshi taka

Source: In Vivo, Generics Bulletin

Mid-Table Also Sees Movement

However, significant movements were not limited to the industry's largest handful of players, with a group of major Indian companies also jostling for position just outside the top 10.

Dr. Reddy's Laboratories Ltd. climbed above rivals Lupin Limited, Intas Pharmaceuticals Ltd. – including its Accord business – as well as UK-based Hikma Pharmaceuticals plc, from 15th place last year to 12th this year, thanks in part to Dr Reddy's substantial active pharmaceutical ingredients business now being included in our key category.

While our top 50 ranking compiles sales data for 2019 or the closest available reported year, many Indian companies report on the basis of financial years that ended 31 March 2020, meaning that some of these firms may have seen some effect from coronavirus-related stocking towards the very end of this period.

Meanwhile, the disaggregation of Hikma's reported sales total is based on an estimated 90%-10% turnover split for generics and brands communicated to *Generics Bulletin* by the company.

Japanese firms Sawai and Nichi-Iko also featured highly in our rankings – again based on financial years ending in March 2020 – while Slovenia's Krka rounded out the top 20 with double-digit growth in 2019 after several years of reliable increases.

Slightly further down the table is Amneal, which has seen mixed fortunes since its merger with Impax and which reported its 2019 results after Chirag Patel and Chintu Patel returned as co-CEOs of the firm they co-founded midway through last year.

Other significant movements include Sanofi's generics business falling from 16th position to 24th, in the firm's first full year of reported sales following the divestment of its Zentiva generics business in Europe.

Meanwhile Korea's Celltrion Healthcare Co., Ltd. scraped into the top 30 – with growth of more than half in 2019 thanks to its expanding portfolio of biosimilars, marketed worldwide through various partnerships as well as its own burgeoning front-end operations – and Japan's Towa also moved up the list slightly, from 30th to 28th position, with its recent purchase of the Pensa Investments generics business from Spain's Esteve promising to potentially propel it even further up the ranking next year.

Lower down the table, Aché and Hypera both registered sales of just under $850m in 2019. And a little behind these two Brazilian firms, troubled Mallinckrodt and Akorn featured, despite both experiencing difficulties and grappling with bankruptcy proceedings.

Meanwhile, Biocon rose up the rankings from 43rd position last year to 40th position this year, as its successful biosimilars business closed in on a sales target of $1bn by the end of its financial year ending in March 2022.

The ranking puts Biocon close to fellow Indian firms Ipca and Alembic, as well as Wockhardt which earlier this year closed a deal worth around $260m to divest a chunk of its branded generics business in India and certain international territories to Dr Reddy's. Meanwhile, Strides was smaller in 2019 following earlier divestments.

Rounding off our top 50 are a pair of new entrants this year. US biosimilars specialist Coherus BioSciences, Inc. reported 2019 turnover of $356m from almost a full first year of sales from its Udenyca (pegfilgrastim-cbqv) rival to Neulasta that launched in January 2019. And Bangladesh's Beximco enjoyed 29% growth to around $278m, having made headlines recently with the launch of the world's first generic version of remdesivir.

With major deals still in the works, biosimilars continuing to grow in significance and the COVID-19 pandemic promising to reshape the industry landscape at the same time as it exerts short-term pressures on supply and demand, the global off-patent industry continues to operate in a shifting environment that makes predicting the future a difficult task. As the industry continues to work its way through the turbulence of 2020, it is possible that next year's ranking will once again look very different.