



USFDA Drug Approvals at All-time High; Indian Firms Get 35-40% of Nods

The US Food and Drug Administration (USFDA) has granted the highest number of drug approvals in its history this year. The regulator has bettered last year's numbers with 971 approval actions this year. This includes 781 final nods and 190 tentative go-aheads.

Generic drug approvals

	Approvals	Tentative approvals	Total
FY13	440	95	535
FY14	409	91	500
FY15	492	120	612
FY16	651	184	835
FY17	763	174	937
FY18	781	190	971

Source: USFDA

Indian firms account for 35-40 per cent of the global nods. Analysts feel that rising rate of approvals would on one hand increase competition in the US generic market, and on the other allow new players to enter. However, analysts expect the growth in approvals to flatten as the number of filings has seen a dip in FY18. This is not expected to rise substantially in the coming years.

The USFDA follows an October-September calendar. Of the total approvals in FY18, around 12 per cent were for complex generics and 95 for first time generics. In FY17, the number of products approved were 937, of which 763 were final approvals.

The approval rate by USFDA has been rising for the past few years. This is primarily because in 2012, the Generic Drug User Fee Amendments (GDUFAs) were implemented to expedite the process of approvals. In 2016, the GDUFA entered its cohort-five phase, in which the FDA has to act on 90 per cent of the abbreviated new drug applications (ANDAs) submissions within 10 months. Compared to this, in the cohort-four phase, it had to act on 75 per cent of ANDAs submitted within 15 months.

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The number of final ANDA approvals had increased from 651 in FY16, to 763 in FY17, and the trend was expected to continue. "However, this just saw a marginal increase and stood at 781 for FY18. We believe that the ANDA approval rate is likely to flatten," said Amey Chalke, analyst with HDFC Securities. He added that ANDA filing rate saw a significant jump from 539 in FY15 and 852 in FY16, to 1,306 in FY17.

However, this was down to 1,044 in FY18 and should now normalise. "We do not expect the number to rise substantially in the coming years," Chalke said. Interestingly, the ANDA withdrawal count of 548 saw a major spike in FY18, more than double its FY17 number of 214.

Chalke said, "Evident from this data, competitive intensity in the US generics market is reducing. We believe this will also lead to easing of pricing pressure." This can be a good sign for established drug firms who have significant exposure to the US market like Aurobindo, Sun Pharma and Cadila Healthcare, among others. "With rising approvals, the competition ate into our margins in the last couple of years. There was price erosion in the base business," said a senior executive of a leading pharma firm.

More approvals would mean entry of new players and this would intensify the competition. "However, with ANDA withdrawals on the rise, it may ease the pricing pressure to some extent," he added.

Of the Indian firms, Aurobindo and Cadila Healthcare received the maximum number of approvals in FY18 at 63 and 59, respectively (including tentative approvals). Of the global firms, Mylan received nod for 62 products in the US market. (Source Business Standard)

"Live as if you died tomorrow. Learn as if you were to live forever"
- Mahatma Gandhi

GHIT Fund Partners with Ono Pharmaceutical

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The Global Health Innovative Technology (GHIT) Fund has welcomed Ono Pharmaceutical Co., Ltd. (Ono) to join GHIT as a new affiliate partner. Ono, headquartered in Osaka, Japan, is a research and development (R&D)-oriented pharmaceutical company and a pioneer in the field of immuno-oncology. With the addition of Ono, GHIT now counts 21 public and private organizations as funding partners.

"Ono's partnership with GHIT underscores the strong



commitment of industry to global health R&D. GHIT's inception was led by industry and now 16 life science companies are GHIT funding partners together with the Government of Japan, the United Nations Development Programme, the Bill and Melinda Gates Foundation, and the Wellcome Trust. Ono's engagement increases GHIT's momentum toward accelerated product development for patients worldwide afflicted with infectious diseases," said Dr. BT Slingsby, CEO of the GHIT Fund.

Gyo Sagara, Ono's President, Representative Director, and CEO, said, "We sincerely support GHIT's efforts to combat infectious diseases in low- and middle-income countries. Ono's corporate philosophy is 'Dedicated to Man's Fight against Disease and Pain' and our key business pillars are 1. R&D for innovative products, 2. Creating a technology platform, and 3. Building partnerships. Based on the concept, we aim to improve access to healthcare around the world. We are confident that our engagement with GHIT can help accelerate R&D for patients in low- and middle-income countries."

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The GHIT Fund invests and manages a portfolio of development partnerships aimed at neglected diseases, such as HIV/AIDS, malaria, tuberculosis and neglected tropical diseases that afflict the world's poorest people. The GHIT Fund mobilizes Japanese pharmaceutical companies, academic and research organizations to engage in the effort to create new drugs, vaccines, and diagnostics. (Source: BioSpectrum)

Novartis to Buy Cancer Drugmaker Endocyte for \$2.1 Billion in Cash

Novartis AG has agreed to buy U.S. drug maker Endocyte Inc for \$2.1 billion in cash as the Swiss drug maker expands its radiopharmaceuticals business. The \$24-per-share offer represents a premium of 54 percent to Endocyte's closing price on that day.

The approach is one of three key areas, along with cell and gene therapies, where Novartis is keen to expand, and Chief Executive Officer Vas Narasimhan signalled that he still hasn't finished raising the drugmaker's profile in those fields. The company remains interested in bolt-on-acquisitions, he said.

"We believe we need to move into advanced-therapy platforms," Narasimhan said in an interview on Bloomberg Television. The Endocyte transaction "will give us the global footprint, capability and portfolio to really own" the so-called radioligand sector, he said.

Endocyte's experimental prostate cancer therapy, known as Lu-PSMA-617, has progressed to final-stage testing in men who have limited options for treatment and may reach the market in 2021, Novartis said. It uses a small molecule to aim a radioactive cancer drug, at a target, called PSMA, that's found in high numbers on the surface of diseased cells, according to Endocyte.

Novartis said in September that it will cut 2,550 jobs in Switzerland and Britain over four years, as the it strives to boost profits and focus on new medicines. (Source: Business Standard/Reuters)

Zydus to Buy Kraft's India Biz for \$638 Million

Zydus Wellness, a subsidiary of Ahmedabad-based pharma major Cadila Healthcare, announced a definitive agreement to acquire the India business of US-based Kraft Heinz in a deal valued at US\$ 638.19 Mn. The buyout will give Zydus Wellness ownership of health and energy drink brands Complian and Glucon-D, among others. The transaction also catapults Zydus Wellness into the top-five health food and nutrition companies in India.

"This acquisition is an ideal addition, supporting our aspirations to grow in the consumer wellness space by providing multiple choices to the health-conscious consumers," said Sharvil Patel, chairman of Zydus Wellness.

Zydus Wellness will receive a US\$ 138.88 Mn infusion from parent Cadila to clinch the deal. It is also likely to raise equity worth US\$ 138.88 Mn - US\$ 208.33 Mn from private equity investors True North and Multiples, as reported by Times of India, a national newspaper reported earlier. "Select private equity companies have also committed to partnering the transaction by way of equity support," Patel said.

The India portfolio of Kraft Heinz, the world's fifth-largest food and beverages company.

Zydus Wellness will have consolidated revenues of US\$ 236.11 Mn. The four brands of Kraft Heinz clocked revenues of US\$ 159.72 for the 12 months ending June 30, 2018. The deal gives Zydus Wellness global rights for Glucon-D and Nycil. For Complian, it has received rights for India and other substantial markets such as Southeast Asia, Middle East and SAARC countries, among others.

Zydus Wellness and Coca-Cola were the top contenders for the Kraft Heinz brands, for which other conglomerates such as the Tata group and Dabur India were also in the fray at some point of time. Zydus managed to snap up the deal with Coca-Cola chasing the bigger acquisition of GSK's market-leading health food drinks portfolio consisting Horlicks and Boost.

"The acquisition will create enhanced infrastructure and distribution reach, which will have a combined strength of five manufacturing facilities, 1,800 distributors and nearly 2 million customer touchpoints," added Pankaj Patel, chairman of Zydus group. (Source: Times of India)

The UK's Medicines Regulator has Launched New Hard Brexit Consultations

Regulation

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has launched a public consultation on how its regulatory processes should change in the event of a “no-deal” Brexit.

In an announcement in early October, the agency said it was seeking feedback on changes to four key statutory instruments that underpin the UK's pharma law framework to help make processes for medicines, clinical trials and medical devices are “legally coherent” on exit day.

The consultation focuses on the Medicines for Human Use (Clinical Trials) Regulations 2004; the Medical Devices Regulations 2002; the Human Medicines Regulations 2012 (HMRs); and the Medicines (Products for Human Use) (Fees) Regulations 2016.

Should the UK fail to reach an agreement with the EU, the government's preferred option is for the MHRA to act as a stand-alone medicine regulator, taking on the functions and decisions currently exercised by the European Medicines Agency.

General approaches to the change in legislation include maintaining the UK legislative vehicles that implement EU directives, transposing EU regulations into UK law and then revoking the EU regulations themselves and making provision to prosecute offences which occurred before the UK is officially due to leave the EU on 29 March 2019.

The consultation also proposes a notional “UK mark” to replace or run alongside the European CE mark.

The management board of the European Medicines Agency (EMA) has discussed revisions to its “access to documents” policy, following a public consultation in 2017, as part of its mid-year report.

The policy is linked to Regulation (EC) No 1049/2001, which allows EU citizens to access EU documents.

The amendments to the policy increase its scope to include EMA documents not related to medicinal products. The board was also updated on the ongoing development of the EU clinical trial portal and database.

The EMA states that the portal and database are in an intensive phase of pre-testing before formal user acceptance testing can begin in early 2019.

This comes after a study published by the British Medical Journal revealed that almost half of European institutions running clinical trials do not report their results.

(Source: Getting The Deal Through)

India & Korea Ink MoU to Promote Medical Devices Sector

The objective of the MoU signed between the two Countries is to promote the development of business relation between India and Republic of Korea, promoting bilateral trade, investment in both countries and the development and exchange of technology.

In a bid to further provide an impetus and boost Indian & Korean Medical Device Industry, The Association of Indian Medical Device Industry (AiMeD) has inked a memorandum of understanding (MoU) with BUSAN TECHNOPARK from Republic of Korea to jointly work to promote medical devices industry in both the countries.



The agreement was signed by Rajiv Nath, Forum Coordinator, AiMeD and Soo-Hoo Shin Chief of Healthcare Technique Division from BUSAN TECHNOPARK.

The objective of the MoU signed between the two Countries is to promote the development of business relation between India and Republic of Korea, promoting bilateral trade, investment in both countries and the development and exchange of technology. Additionally, to encourage and promote participation from both the countries at various business platforms created by Indian Medical Devices Industry Association and BUSAN TECHNOPARK.

Through this cooperation AiMeD and Busan Technopark will provide assistance for visiting delegations, comprising of officials and businessman, on both side with a view to promote their business missions and facilitate business collaborations. AiMeD will also offer business-to-business match making with regard to promotion of technology and investment tie-ups to companies based in Republic of Korea. Similarly, Busan Technopark will assist AiMeD Members in their business endeavours.

“The medical devices sector is being seen as the next big thing after IT and Defence sectors and India has the potential to emerge as a major manufacturer and exporter on the lines of pharma products. The government has undertaken several measures to promote its ambitious ‘Make in India’ mission in Medical Devices. The MoU between AiMeD and BUSAN TECHNOPARK is in line with realising these national objectives,” Nath said. (Source: BioSpectrum)

Private Equity Firm EQT Launches \$654 Million Cash Bid for Sweden's Karo Pharma

STOCKHOLM — Private equity firm EQT made a recommended 5.97 billion Swedish crown (509.52 million pounds) cash bid to buy Swedish speciality pharma group Karo Pharma.

The offer, made by the EQT VIII fund and unanimously recommended by Karo Pharma's board, represents a 25.3 percent premium to Karo's closing price on Friday (27th October)

"We are delighted that the Board of Directors has decided to recommend EQT VIII's offer," EQT partner Per Franzen said in a statement.

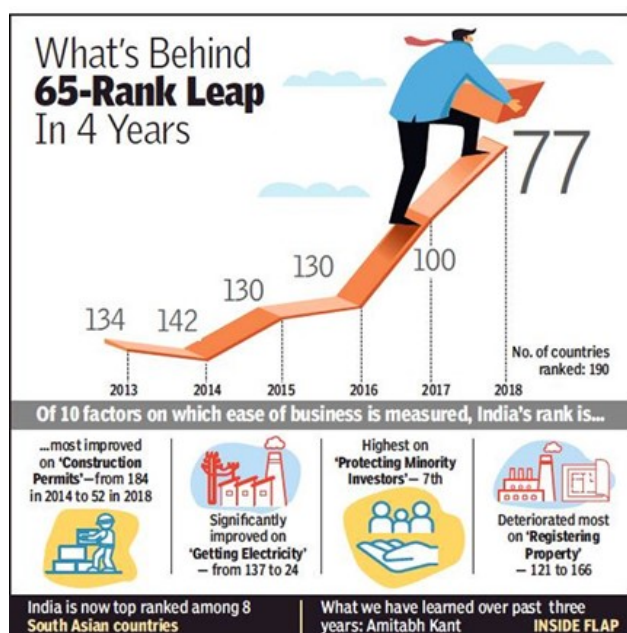
"We are impressed by Karo Pharma's development and successful strategic transformation from an early stage research and development company into a leading speciality pharmaceutical company with a strong product portfolio and European reach."

EQT said that Karo Pharma Chairman Anders Lonner and board member Per-Anders Johansson, together representing in total 13.6 percent of shares and votes in the company, had declared they intended to accept the bid.

The acceptance period is expected to run between Nov. 13 and Dec. 10 and requires EQT to take ownership of 90 percent of the shares. It said it does not currently own or control any shares in Karo Pharma. (Source: The New York Times)

India Jumps 23 places in World Bank Rankings

India jumped 23 places to 77 in the World Bank's ease of doing business global rankings for 2019, becoming the top-ranked country in South Asia for the first time. The country has moved 53 places up the rankings in the last two years.



The World Bank on 31st October, released its 'Doing Business 2019: Training, for Reform' report, which ranked economies on their ease of doing business, from 1 to 190. A higher ranking means the regulatory environment is more conducive to the starting and operation of a local firm.

While India's overall ranking improved significantly, it took a beating in two categories where the government's landmark reforms were expected to lead to better results. In 'Paying Taxes', the country slipped two notches to 121, despite the implementation of the goods and services taxes' regime.

The World Bank praised India for merging taxes and revising the tax code, but it did not result in a higher ranking in the category. Also, the Insolvency and Bankruptcy Code (IBC) coming into effect could not save India from falling five positions to 108 in the 'Resolving Insolvency' category. Estimates by the Department of Industrial Policy and Promotion (DIPP) suggest that claimants working through the IBC have realised almost 59% of the claims.

"Delighted at yet another rise in India's ease of doing business rank, we are unwavering in our commitment towards economic reforms, which will ensure an environment that fosters industry, investment and opportunities," the Prime Minister of India tweeted.

In 'Trading Across Borders', India jumped 66 places to come in at the 80th position. DIPP officials attributed this to the implementation of a risk management system at ports that waives inspection requirement for 80 percent of the products.

The latest report by the Washington DC based multilateral agency is based on 128 economies implementing 314 specific business reforms over the past year. This surpassed the previous all time high of 290 reforms two years ago. India is among 11 major economies for which the World Bank took into account two specific metropolitan areas, Delhi and Mumbai (Source: Business Standard)

India's Drug Industry Divided Over Licence Fee Hike

Indian Government is expected to raise the fee for site registration and product approvals by over five times, the pharmaceutical industry seems to be divided on the matter. While the multi-national corporations' lobby feels that imports of niche and speciality medicines would be affected, the domestic lobby of major pharma manufacturers say the overall impact would not be much as it is a one-time cost.

Analysts, however, are of the opinion that if the fee increase goes through, irrational combinations and products that do not have the potential to do well in the market will weel out. "If this happens, companies will only register those products which will give them good returns," said Ranjit Kapadia, Pharma analyst.

The government charges fee for grant of registration certificates, licences for import of drugs and medical devices. In India, the fee for regulatory licenses is very nominal as compared to countries such as the US and China and has not been revised for over 10 years. The government has been mulling a fee hike to boost domestic drug manufacturing. This would essentially mean that the site registration fee for importing medicines and product approval would increase significantly.

At present the government charges around US\$675 for applications for new drugs as against around US\$58700 charged by the US regulator. For imported pharmaceutical products, the fee is expected to go up from US\$ 1000 per product to around US\$ 5000 once the new regulations are notified. According to the Organisation of Pharmaceutical Producers of India (OPPI) that represents the multinational pharma firms in the country, importers of speciality medicines and niche products are likely to be most impacted by this increase in fee.

The proposed escalation is not only five times as it seems but is many fold because of two additional practices that the Central Drugs Standard Control Organisation (CDSCO) has initiated in the registration process, it said. In 2013, the CDSCO started registering all facilities with same registration fee instead of the prior practice of registration of final dispatch facility. Further the recent 2018 CDSCO practice of registering all stock keeping units for a brand, which was done on a molecule basis earlier, has added to the burden, OPPI said.

"This escalating effect will make launch of products and vaccines particularly for low disease burden unviable in India," said OPPI President A Vaidheesh, who is also the managing director of GlaxoSmithKline Pharmaceuticals. However, supporting the increase in fee, the Indian Pharmaceutical Alliance (IPA), which represents the leading domestic pharmaceutical companies, said it would be a fair play if it happens because when Indian firms go abroad they are charged heavy fee for new drug implications and active pharmaceutical ingredients.

"It won't affect the industry as it is a one-time cost and will have a very insignificant effect on the volumes," said D.G. Shah, secretary general, IPA. (Source: Business Standard)

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For feedback and query

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