SECTOR WATCH
PHARMACEUTICAL

## USFDA warns Emcure Pharma for 'failing' to 'adequately investigate' injection sterility issues

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NEW DELHI, AUGUST 16

**Batches of amikacin sulfate injection and prochlorperazine edsylate injection were recalled from the US market in May this year "due to microbial growth" in one of their sub-lots**

SAMPLES OF certain injections manufactured by Emcure Pharmaceuticals between 2017 and 2018 were found contaminated with specific disease-causing bacteria, according to a warning letter sent by the US Food and Drug Administration (USFDA) the firm earlier this month.

The regulator has pointed out that Emcure "failed" to "adequately investigate" these sterility failures, adding that this is not the first time it uncovered such findings at the firm's facility.

Warning letters are issued when the US drug regulator finds a manufacturer has "significantly" violated FDA regulations. According to the letter issued to Emcure on August 2, the firm failed to thoroughly investigate the presence of 'bacillus cereus' growth found in one of its injectable drugs during sterility testing performed on June 4, 2018.

Emcure also failed to adequately investigate sterility failures in another injectible medicine found to contain growth of another type of bacteria, 'lysinbacillus fusiformis', during tests performed on November 24, 2017, the FDA said. Batches of amikacin sulfate injection and prochlorperazine edsylate injection manufactured by Emcure were recalled from the US market in May this year "due to microbial growth" detected in one of their sub-lots. According to the USFDA's latest letter, Emcure's investigations "substantially" addressed the potential of the batches contaminated during the process of sterility testing (done to check whether the products are free from bacteria and safe for use). However, while the firm pegged "laboratory error" as the most probable root cause for the contamination, it "de-emphasised" the role of potential manufacturing causes.

The microorganisms found during the failing sterility tests were also recovered in the production area "in a six-month time-frame prior to the sterility failures," according to the USFDA. For instance, the bacillus cereus recovered in June 2018 from the sterility testing of the batch of one of the injections in question had also been recovered in the firm's vial filling room in December 2017, according to the letter. "Your review of environmental data was insufficient in that it relied too heavily on findings in the laboratory. You concluded that data indicated potential contamination control risks in the testing facility, but did not sufficiently address production failure modes," stated the USFDA in its letter.

"Your written response provided a table with a retrospective review of container closure integrity test (CCIT) results, but it lacked a comprehensive evaluation of discrepancies, deviations, complaints, and investigations related to a potential container-closure integrity failure mode," it stated. "Notably, your film has recalled products in the past due to container-closure integrity failures in batches of products that originally passed CCIT studies. Integrity of container-closure systems is critical to ensure product sterility," it added. Similar observations of "inadequately performed microbiological investigations" were made following a previous inspection of an Emcure facility in August 2017, the USFDA mentioned.

"Repeated failures demonstrate that executive management oversight and control over the manufacture of drugs is inadequate. Your executive management remains responsible for fully resolving all deficiencies, and ensuring ongoing CGMP (current good manufacturing practice) compliance," it stated. Emailed queries to Emcure's official email identified on the Ministry of Corporate Affairs website remained unanswered by press time Friday.

FY19 GROWTH SLOWER THAN THAT IN FY18: CARE RATINGS STUDY

# 'Top 969 companies added 5.84L jobs over last 2 years'

ENS ECONOMIC BUREAU
NEW DELHI, AUGUST 16

A GROUP of 969 companies across 33 sectors in the country reported a 5.2 per cent annual growth in jobs over the last two years as these companies saw their employee strength rise from 54.45 lakh in the year ended March 2017 to 60.29 lakh in March 2019.

The growth, however, is not uniform over the two years as FY18 witnessed a faster 6.2 per cent growth against a growth of 4.3 per cent in FY19, thereby reflecting a slowdown in the pace of job creation in the organised sector last year.

According to a Care Ratings study which compiled data reported by 969 companies in their annual reports over the last three years shows that these companies added 5.84 lakh individuals in the job cycle.

While 53 companies in the IT sector added 1.4 lakh people over the last two years, 37 banks in the list added 1.02 lakh jobs during the period. While finance sector that includes the troubled NBFC sector also added 88,684 jobs, the auto and ancillary sector which is currently under stress and is staring at big job loss, also reported addition of 58,131 employees over the last two years.

On the other hand, companies in the mining sector reported the highest number of job losses.

According to the report, 5 mining sector companies reported a decline of 24,388 employees from a headcount of 3.23 lakh in March 2017 to 2.98 lakh in March 2019. Also 20 companies in the iron and steel sector reported a decline in their aggregate employee strength by 11,869.

Even as the data shows net addition of jobs across these 969 companies in the organised sector, the report points that the data sourced from annual report has some shortcomings as it does not include outsourced human resources and often when there is merger and acquisitions (M&A) activity, the acquiring company witnesses an increase in labour force while the entity that is bought would not get included in the sample due to the absence of continuous data as the company ceases to exist. "Therefore some of the increases may not necessarily be due to new jobs being created but existing personnel moving across companies," said Care Ratings report.

It further pointed that the companies in the sample are relatively larger ones and "excludes the SME segment which has tended to more vulnerable to the external environment."

Against this data of relatively larger companies, the CMIE database on "Unemployment Rate in India" shows that the total number of those employed across the country has seen a decline over the last two years.

The data shows that while the total number of employed in June 2017 stood at 40.85 crore, it stood at 40.5 crore in July 2019 thereby witnessing a decline of 35 lakh jobs in the period.

According to the data, the unemployment rate has jumped from 4.12 per cent in June 2017 to 7.51 in July 2019. The CMIE database provides estimates of the unemployment rate based on a panel size of over 178,000 households.

EXPLAINED

### Organised sector: Pace of job creation slowed in last 2 yrs

PACE OF job creation has slowed in the last two years even in the organised sector, reflecting the slowdown pressures in the broader economy. What is of greater concern is the contraction in employment levels in unorganised sector.

Against data of relatively larger companies, the CMIE database on "Unemployment Rate in India" shows that total number of those employed across the country has seen a decline over last two years and unemployment rate has risen from 4.2 per cent in June 2017 to 7.5 per cent in July 2019.

## Norms eased for shares with differential voting rights; to boost startups

ENS ECONOMIC BUREAU
NEW DELHI, AUGUST 16

**Ministry said its objective was to enable promoters of Indian firms to retain control of their companies**

THE CORPORATE Affairs Ministry on Friday relaxed norms relating to the issue of shares with differential voting rights. The move is expected to make it easier for startup promoters to retain control of their companies while raising capital from foreign investors.

Indian companies, including startups, will now have up to 74 per cent of the total voting power in respect of shares with its differential voting rights (DVRs), according to amendments to the Companies (Share Capital and Debentures) Rules. This was previously capped at 26 per cent.

The government has further done away with an earlier requirement that mandated a company to have distributable profits for three years in order to be eligible to issue shares with DVRs. Startups recognised by the Department for Promotion of Industry & Internal Trade can now issue Employee Stock Options (ESOPs) to promoters or directors holding more than 10 per cent of equity shares within 10 years from the date of their incorporation from five years earlier, according to the ministry.

The amendments were made following requests from innovative tech companies and startups, said the ministry in a release. This is also aimed at strengthening "the hands of Indian companies and their promoters who have lately been identified by deep pocketed investors worldwide for acquisition of controlling stake...to gain access to the cutting edge innovation and technology development being undertaken by them," it added. "The government had noted that such Indian promoters have had to cede control of companies which have prospects of becoming unicorns, due to the requirements of raising capital through issue of equity to foreign investors," the ministry stated.

The ministry said its objective was to enable promoters of Indian firms to retain control of their companies "in their pursuit for growth and creation of long-term value for shareholders, even as they raise equity capital from global investors".

## 'RBI likely to cut rates by 40 bps before this fiscal-end'

As monetary easing till now appears to be insufficient in boosting economic growth, the Reserve Bank of India (RBI) is expected to cut interest rates by 40 basis points before the end of the current financial year, according to a Fitch Solutions report

### RECENT 35 BPS CUT

RBI, on August 7, had cut benchmark repurchase and reverse repurchase rates by an unconventional 35 basis points, slightly higher than market expectations of a 25 bps cut

### 110 BPS THIS YEAR

RBI has cut interest rates four times this year but the transmission of the same by banks to borrowers has lagged. In all, the central bank has cut interest rates by 110 bps this year

■ But this has not yet led to a boost in economic activity. While the growth rate has slowed to a five-year low, consumer confidence is waning and foreign direct investment has plateaued, according to the report

■ The auto sector is also facing its worst crisis in two decades and reports suggest thousands of job losses in the automobile and ancillary industry

■ In the real estate sector, the number of unsold homes has increased while fast-moving consumer goods (FMCG) companies have reported a decline in volume growth in the first quarter. Moreover, lending to job-creating MSME sector has slipped.

■ A poor monetary policy transmission mechanism in India could necessitate steeper interest rate cuts than we currently expect, the report said

**THE REPORT** forecasts real GDP growth in the current 2019-20 at 6.8 per cent, slightly below the RBI's downwardly revised 6.9 per cent projection

**A REBOUND** in private consumption and investment following the RBI's monetary easing inform our view for growth to pick up over the coming quarters from the 5.8 per cent in January-March, it said

**HOWEVER, INDIA'S** growth rebound would be capped due to a deteriorating external outlook as well as borrowing constraints due to collapse of several NBFCs, which would limit prospects for consumption growth

## Over 3K temporary jobs cut due to low demand: Maruti Suzuki chairman

ENS ECONOMIC BUREAU
NEW DELHI, AUGUST 16

**Sundaram-Clayton, Hero MotoCorp announce temporary production shut downs**

OVER 3,000 temporary employees have lost jobs with the country's largest carmaker Maruti Suzuki India Ltd (MSIL) due to the ongoing slump in the automobile industry.

According to a PTI report, MSIL chairman R C Bhargava said contracts of the temporary workers were not renewed while asserting that permanent workers have not been impacted. "This is a part of the business, when demand soars, more contract workers are hired and reduced in case of low demand," he said while speaking to some TV channels.

Bhargava was responding to a query on whether the current slump and production cuts have led to job cuts in Maruti. "Around 3,000 temporary workers have lost jobs with Maruti Suzuki," he added. Reiterating that automobile sector creates job in the economy — from sales, service, insurance, licensing, financing, accessories, drivers, petrol pumps, transportation — he cautioned, "fewer automobiles (sales) will impact jobs on a larger scale."

These are not even visualised. The impact is much higher, he added. When asked if the industry has hit the rock bottom in terms of sales in July, he said revival in the sense of positive growth will start from third or fourth quarter of this fiscal, partly because of the lower base effect. "Hopeful to see strong revival in FY 2021. By then transition to BS VI will be over," he added. Commenting on expectations from the upcoming festival season, he said due to the good monsoon, rural sales may pick up.

"If government makes an announcement and takes positive actions it should help improve the situation," he said, however, it was up to the government to decide on GST rate cut and take the corrective action.

"Personally we would like to see GST benefits linked to greener/cleaner cars...The government gave tax cut on EVs but hybrid should be given duty cut. There should be tax cut on CNG vehicles," he added.

Meanwhile, TVS group auto component maker Sundaram-Clayton Ltd (SCL) on Friday said it will be shutting its Padi factory in Tamil Nadu for two days owing to slowdown in the automotive industry, joining two-wheeler major Hero MotoCorp which also announced closure of its plants for four days. SCL, a manufacturer and supplier of aluminium die cast products to domestic and global automotive OEMS, said it has declared August 16 and 17, 2019, as non-working days for its Padi factory. "This is due to business slowdown across sectors," Sundaram-Clayton Ltd said in a statement.

Two-wheeler maker Hero MotoCorp also said its manufacturing plants have been shut for four days from August 15-18 as part of annual routine and also to adjust production in line with current market demand, according to a PTI report. "While this has been part of the holiday calendar on account of Independence Day, Raksha Bandhan and the weekend, it also partly reflects the prevailing market demand scenario," Hero MotoCorp added. **WITH PTI**

## 'Non acceptance' of coins by several banks, states; FinMin reviews issue

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NEW DELHI, AUGUST 16

**Demand deficit and non-acceptance of coins by several banks and thereon, in several states was taken up by a high-level meeting chaired by then Finance Secretary Subhash Chandra Garg on May 22**

DESPITE THE Reserve Bank of India (RBI) issuing advisories and even threatening penal action if banks did not accept coins for public distribution, the Finance Ministry has reviewed complaints that many banks as well as several states have persisted with such "non acceptance".

The subject of demand deficit and non-acceptance of coins by several banks and thereon, in several states was taken up by a high-level meeting chaired by then Finance Secretary Subhash Chandra Garg on May 22, 2019. Minutes of the meeting, accessed by *The Indian Express*, reveal that shortage of storage space and the circulation of fake coins, especially Rs 10 coins, have been cited as the main reasons for the problem.

The banks named by officials as being the ones which are not accepting coins are ICICI, HDFC, SBI and PNB. The minutes note, "It has been reported that even banks such as SBI, HDFC, PNB and ICICI are not accepting coins. The reason cited by these banks are space constraint and branch limit issue. Some banks have also mentioned shortage of staff for not taking coins..." The states which were specifically mentioned for being the ones from where grievances have been received for non-acceptance of coins are Uttar Pradesh, Odisha, Karnataka and West Bengal. There are detailed notes about how in Delhi, traders, shopkeepers and common people have been rejecting variants of Rs 10, mostly thinking the coins were fake. The situation, the Finance Ministry has stated, is the same in most of the North-Eastern states, with this logic being recorded, "the reason people generally mentioned is no one is accepting it, so we are also not accepting it..."

At the high-level meeting, the previous attempts of the RBI which directed all banks to immediately instruct their branches to accept coins of all denominations tendered at their branches were also taken up. The minutes read, "the RBI has been receiving complaints about non-acceptance of coins by bank branches. Such denial of service has further induced refusal on part of shopkeepers and small traders, etc to accept coins as payment for goods sold and services rendered causing inconvenience to the public at large..."

Almost identical instructions had been issued by the RBI to the top brass of all banks on February 15 last year wherein they were asked to tell all their branches to accept all coins and that any non-compliance could call for action against the banks, including penal measures. As reported earlier, (*The Indian Express*, April 14, 2019), at an earlier meeting in the Finance Ministry on the same subject, the RBI had reported that there was a "reverse flow" of coins and that the buildings holding the coins for the central bank were now "on the verge of collapse due to weight."

At this meeting privatisation of distribution methods and exports were discussed as options to end the coin glut.

NO WORD FROM FIRM DURING THE RELEASE OF ESTIMATE-BEATING EARNINGS ON THURSDAY

# Alibaba and the $15 bn question: Amid Hong Kong's protests, when to list?

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HONG KONG, AUGUST 16

### LAUNCH WAS LIKELY BY THE THIRD QUARTER

**THE COMPANY was most likely to launch the offer — potentially the world's biggest of the year — as early as the third quarter, after its first-quarter earnings, was widely viewed as the most likely window**

HONG KONG'S political unrest is posing a dilemma for Alibaba Group Holding Ltd on the timing of its planned $15 billion listing in the city, with sources saying China's biggest e-commerce company is now considering several timetables.

New York-listed Alibaba was most likely to launch the offer — potentially the world's biggest of the year — as early as the third quarter, sources have said, and late August, after its first-quarter earnings, was widely viewed as the most likely window. In preparation for the giant offer, bankers advising other large listings in Hong Kong have been careful to avoid planning their launches around that period.

But not a word was mentioned by Alibaba on the Hong Kong listing when it released estimate-beating earnings on Thursday. Two sources involved in the deal and one other briefed on Alibaba's discussions described the company's thinking on the deal as "fluid" and said Alibaba was considering several timetables. Alibaba declined to comment.

The Hong Kong listing deal was estimated at up to $20 billion, but is more likely, according to sources close to the deal, to raise between $10-$15 billion. The listing was always expected to be a complex affair because of China's tight control of cross-border share trading, but Hong Kong's unrest has taken the complexity several notches higher.

More than 10 weeks of confrontations between police and pro-democracy protesters have plunged Hong Kong into its worst crisis since it returned to Chinese rule in 1997 and presented President Xi Jinping with his biggest popular challenge since taking power in 2012.

This week protesters effectively closed the city's airport on two successive days, disrupting tens of thousands of travellers and posing a practical problem to any company considering launching a deal roadshow in Hong Kong.

Under the circumstances, when Alibaba lists becomes crucial as it sends a signal to the rest of the world on the state of Hong Kong as a business and financial centre and provides a window into China's reading of the situation. "How do you think Beijing feels about giving Hong Kong a $15 billion gift like this, right now?" asked one capital markets professional not involved in the Alibaba deal. A listing by Alibaba is a big deal for Hong Kong, which loosened its rules last year specifically to lure overseas-listed Chinese tech giants to list closer to home.

Alibaba would be the first to test the new system.

Asked this week whether Hong Kong's turmoil would affect its listing, Hong Kong stock exchange chief executive Charles Li avoided directly acknowledging the company's application, which is still technically confidential.

But Li added: "I am confident that companies like that ultimately will find a home here, because this is home and I think they will come. I don't know when though." Alibaba's Hong Kong listing is also sensitive for China, which has been working to give mainland investors a bigger role in funding the country's fast-growing tech sector.

Officials are conscious that capital controls and the US listing preference of most of China's first-generation tech giants mean that international shareholders have profited far more from their success than local investors. Mainland investors can buy Hong Kong shares through the so-called Stock Connect, which allows investors in Shanghai, Shenzhen and Hong Kong to trade shares listed on each others' exchanges.

But the inclusion of Alibaba's Hong Kong in the Stock Connect is not guaranteed because the scheme does not yet allow mainland buying of companies which have weighted their voting rights in favour of founders, such as smartphone maker Xiaomi and Meituan Dianping, the online food delivery-to-ticketing firm. Both took advantage last year of another Hong Kong rule change to float in Hong Kong with weighted voting rights structures. **REUTERS**