GOLD	RUPEE	OIL	SILVER
₹39,210	₹71.02	$58.27	₹46,390

*Indian basket as on October 4, 2019

SENSEX: 37,531.98 ▼ 141.33 **NIFTY:** 11,126.40 ▼ 48.35 **NIKKEI:** 21,587.78 ▲ 212.53 **HANG SENG:** 25,893.40 ▲ 72.37 **FTSE:** 7,177.37 ▼ 20.51 **DAX:** 11,970.35 ▼ 127.08

Indian equities, currency and commodity markets were closed on account of Dussehra; International market data till 1900 GMT

PARLIAMENTARY PANEL HAD FLAGGED ITS TRIAL APPROVALS AS 'OUTRAGEOUS'

Conduct post-marketing surveillance on abdominal painkiller: CDSCO to states

PRABHA RAGHAVAN
NEW DELHI, OCTOBER 8

INDIA'S TOP drug regulator has asked companies manufacturing an abdominal painkiller combination, which it approved nearly a decade ago, to submit post-marketing data to prove its safety and effectiveness for a specific indication in the Indian population.

The move comes nearly seven years after a Parliamentary committee flagged the drug's clinical trial approvals as "outrageous" case of a potential nexus between pharmaceutical companies and experts important to the regulator's approval process. It further follows a decision by the manufacturer that first received the approval to surrender its licence for the product. Its approval is also a topic of contention in an ongoing case at the Delhi High Court by public health activist and Ranbaxy whistleblower Dinesh Thakur.

The medication, a fixed dose combination (FDC) of aceclofenac and drotaverine, was initially approved by the Central Drugs Standard Control Organisation (CDSCO) on September 15, 2008, stated a letter to all state drug controllers last month, which *The Indian Express* has reviewed.

However, the Parliamentary Standing Committee on Health in 2012 flagged the drug for "shortcomings" in its approval process.

According to the panel, the FDC "did not have permission for sale in any of the major developed countries" and no "special or specific relevance to the medical needs of India".

Following this, the government referred the combination to a new drug or subject expert committee (NDAC/SEC) "for examination and review."

"Based on the recommendations of the Subject Expert Committee, it was decided that the FDC of Aceclofenac 100 mg + Drotaverine Hydrochloride 80 mg tablet shall be indicated for treatment of 'colicky pain due to smooth muscle spasm' for its continued marketing," stated Drug Controller General of India (DCGI) V G Somani in his September 19 letter. However, its manufacturers were directed to conduct trials, and SEC asked the company that first received the licence for the product "to revise the indication and submit the clinical trial protocol for conducting the study."

"However, after a series of communications, M/s Themis Medicare finally surrendered the product licence," stated the DCGI.

Yet, the proposal was "again re-deliberated" in the reproductive and urology SEC's meeting, he added. "After detailed deliberation, the committee recommended that the firm(s) may be directed to conduct Active Post Marketing Surveillance in minimum 200 patients and the study should include patients of primary dysmenorrhea, biliary colic and ureteric colic. The study should be completed within one year and results...should be placed before the committee for further review," he stated. Somani directed states to conduct this surveillance "for the treatment of colicky pain due to smooth muscle spasm".

The Parliamentary panel that scrutinised the combination's approval had taken issue with the fact that its trials were conducted "only in Maharashtra". Among the cases it listed "to prove the apparent nexus that exists between drug manufacturers and many experts whose opinion matters so much in the decision making process at the CDSCO", the committee said that "nothing can be more outrageous" than the clinical trial approval granted for this FDC.

EXPLAINED

Move to ensure safety of drug for Indian populace

THE MOVE may help ensure that this combination is a safe and effective painkiller for the Indian population, considering that serious questions were raised earlier about its approval process.

The Parliamentary panel on approval noted "... an official of the CDSCO advised the manufacturer ... to not only select experts but also get their opinions and deliver them to the office of the DCGI. No wonder that many experts gave letters of recommendation in identical language apparently drafted by the interested drug manufacturer."

INTERVIEW WITH LORD MAYOR OF CITY OF LONDON

'London is not immune from Brexit, but largely prepared for various outcomes'

EVEN AS the United Kingdom heads towards an imminent no-deal Brexit, the City of London has witnessed an increase in jobs and growth in capital since the referendum on the UK leaving the European Union. In an interview with PRANAV MUKUL and ANIL SASI, Lord Mayor of the City of London PETER ESTLIN told *The Indian Express* that Brexit provides the UK with an opportunity to start a global dialogue by itself on how financial technology companies are regulated across the world. Edited excerpts:

"India itself is exploring the issues around data localisation. We've been doing the same through GDPR. And we've been as a government, the UK government imposed a Digital Services Tax"

PETER ESTLIN
LORD MAYOR OF LONDON

How much of a concern is it that you are headed into a pretty much no-deal Brexit? Is there a concern raised by corporates in the UK and also by Indian companies there?

So, in terms of all my travels, if we look at the UK first and then look at some of the local international partners, I mean, fundamentally, the City (of London) is not immune from Brexit, but is largely prepared for various outcomes.

So I'm very optimistic that we're going to carry on seeing the growth rate that we've seen in the last three years. Since the referendum, we've actually seen an increase in job flow, we've seen an increase in capital, which may seem perverse, but actually people are almost more attracted to ensuring that they've got a foothold in what is the world's greatest financial market.

So as I travel around the world, and you know, India is no different, actually, and businesses are keen to continue looking at that trading focus, and they like the fact that we're really trying to reach out and to do deals around the world.

So I'm pretty optimistic. I believe that actually, you know, we're well positioned. That's not to say that, you know, things couldn't go wrong, but I think we're going to we're pretty well positioned.

The EU competition regulator has hauled up technology companies and has been more consumer centric. Does Brexit provide the UK with an opportunity to give a free hand to innovation in tech?

Well, I think they are different issues. India, like the UK, is a very much incubator innovation centre. We're seeing huge levels of that innovation. What that innovation is doing — whether it's in health and life sciences or financial technology and energy — is doing two things.

One, it's creating economic growth. Second, it's also pushing the boundaries of business. And so how we look at data going forward, how we look at intellectual property, how we look at international taxation, these are issues that we need to dialogue on to say, how is that framework going to work in the 21st century?

And so one of the benefits to the UK of leaving the EU is it can actually get on and have those negotiations.

And we have a great network in the financial services space called G-fin. And so I'm keen to ensure that we get the Indian regulators as part of G-Fin, which is the global network of financial regulators that are really keen to develop this next wave of regulation, not adding layers on that, what do we take out, but what do we reflect on that needs to promote the digital economy.

One concern, especially from the Indian side, is that Brexit could lead to requirement of fresh regulatory clearances to do business in the EU and go through the entire process of that. Do you think that's a genuine concern and is there a solution for that?

It depends on what services one is providing. But yes, If there is some sort of a hard border, as it will be between the UK and Europe, then there will be a need for the larger institutions, if they are selling services into the EU and are based in the UK to have a footprint there. And we've seen a number of businesses do that and have a few people on the ground in the EU.

But equally, you know, I think that what we are seeing here is just the sheer scale of innovation is looking at the way business is changing and how businesses are getting done. We don't have regulation in place today to deal with that.

India itself is exploring the issues around data localisation. We've been doing the same through GDPR. And we've been as a government, the UK government, imposed a Digital Services Tax. Discussions around these areas need to take place and certainly that's part and parcel of my objective during this visit ... through a dialogue with the regulators and how we can continue that conversation to benefit both the UK and India.

BRIEFLY

Boeing gets first 737 MAX order since crash

Bengaluru: Boeing Co secured the first new order in months for one of its grounded 737 MAX planes in September, the company said on Tuesday, as it reported total deliveries for the first nine months of 2019 that were just half of those a year ago. Aviation regulators grounded the 737 MAX worldwide, following a second fatal crash in March that killed all 157 people on board an Ethiopian Airlines plane.

EU pledges to regulate digital currencies

Brussels: The European Union's finance commissioner pledged on Tuesday to propose new rules to regulate virtual currencies, in a reaction to Facebook's plans to introduce Libra, which the EU considers a risk to financial stability. **REUTERS**

No Tata Nano production in 2019 so far

New Delhi: Tata Motors has not produced a single unit of Nano in the first nine months of 2019 and sold one unit in February. The firm has been maintaining that no decision has been made yet on the Nano's future. **PTI**

Shubh Loans gets NBFC licence

New Delhi: Fintech start-up Shubh Loans on Tuesday said it has received a licence from the Reserve Bank of India to set up a non-banking financial company. **PTI**

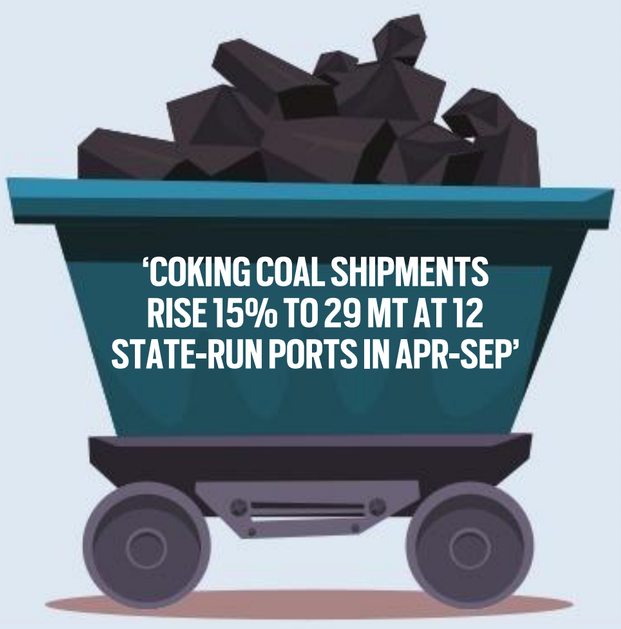
Coal shipments handled by India's 12 major state-run ports during April-September rose by 15.25 per cent to 29.29 million tonne (MT), according to the Indian Ports Association

25.41 MT
The amount of coking coal cargo state-run ports had handled in the corresponding period of the previous fiscal

13.20%
The percentage by which shipment of thermal or steam coal declined, reaching 44.87 million tonne

70%
Dependency of power generation on dry fuel, making thermal coal the mainstay of the country's energy programme

200 MT
The mark which the country's overall thermal coal import is likely to cross in 2019-20



660 MT
The 2019-20 target that Coal India likely to miss by 55-75 MT

80%
The country's domestic coal requirement which Coal India accounts for

1.48%
Slight upswing in cargo handling at 12 major ports; 348.4 MT in April-Sept this fiscal against 343.3 MT in the year-ago period

60%
The amount of country's cargo handled by 12 ports, which include Deendayal (erstwhile Kandla), Mumbai, JNPT, and Mormugao

No festive cheer for Maruti as output slashed for eighth straight month

ENS ECONOMIC BUREAU
NEW DELHI, OCTOBER 8

MARUTI SUZUKI India cut its production by 17.48 per cent in September, making it the eighth straight month when the country's largest carmaker lowered its output, in line with the slowdown in the automobile sector. A series of growth-promoting measures taken by the government have failed to lift car sales growth even in the festive season.

The company produced a total of 1,32,199 units in September, as against 1,60,219 units in the year-ago month, Maruti Suzuki India said in a filing with the NSE. Last month, passenger vehicles' production stood at 1,30,264 units, as against 1,57,659 units in September 2018 — a decline of 17.37 per cent, the company said.

Maruti's production of mini and compact segment cars, including the Alto, the S-Presso, the New WagonR, the Celerio, the Ignis, the Swift, the Baleno and the Dzire, stood at 98,337 units, as against 1,15,576 units last September, down 14.91 per cent. Similarly, production of utility vehicles such as the Gypsy, the Vitara the Brezza, the Ertiga, the XL-6 and the S-Cross declined 17.05 per cent to 18,435 units, compared to 22,226 units a year ago.

The company produced a total of 1,32,199 units in September as against 1,60,219 units in the year-ago month

Mid-sized sedan Ciaz saw its production reduced to 2,350 units in September from 4,739 units in the same month last year. Light commercial vehicle Super Carry's production was also trimmed to 1,935 units last month, from 2,560 units in September 2018, the filing said. In August, the automaker cut its production by 33.99 per cent at 1,11,370 units.

All the major automobile makers, including Maruti, Hyundai, Mahindra & Mahindra, Tata Motors, Toyota and Honda, have reported double-digit decline in domestic passenger vehicle sales in September, as the onset of the festive season failed to lift the slump in the auto industry.

During the month, Bajaj Auto witnessed a 35 per cent drop in domestic sale of motorcycles at 1.77 lakh units. Ashok Leyland announced the sale of 4,035 units of medium and heavy commercial vehicles in September, which is a 69 per cent decline over its sale of 13,056 units in September 2018.

With GDP growth rate falling to 5 per cent for the first quarter ended June 2019 and wage growth not keeping pace with expectations, economists and market experts say that people are generally looking to reduce their expenditures and the sentiment has turned negative. The government last month announced drastic cuts in corporate tax rates, a step that will aid profitability of companies and encourage them to reinvest profits.

Nissan names Uchida next CEO, Gupta COO

MAKI SHIRAKI & KEVIN BUCKLAND
TOKYO, OCTOBER 8

NISSAN MOTOR Co named Senior Vice President Makoto Uchida as its next chief executive on Tuesday, picking a relative outsider who joined the automaker mid-career and is known for his rigorous work ethic and relentless focus on cost control.

In picking Uchida, the board of Japan's second-largest automaker selected an executive who was not seen as a top contender in recent weeks.

He will be joined by Mitsubishi Motors executive Ashwani Gupta, who was named as chief operating officer. Former China chief Jun Seki, who was widely seen as one of the top contenders for the CEO job, will be vice COO, the company said.

The three will take the helm of a company that has been shaken by turmoil following the downfall of former Chairman Carlos Ghosn last year and the departure of former CEO Hiroto Saikawwa

Nissan Motor's newly appointed CEO Makoto Uchida. *Reuters File Photo*

"Strong leadership is required," Yasushi Kimura, Nissan's chairman, told a news conference. "Group leadership, where they all support each other, will be more transparent." Directors at Nissan, including those from top shareholder Renault SA, voted unanimously in favour of the two executives, a source said.

Ghosn is awaiting trial in Tokyo on financial misconduct charges that he denies. **REUTERS**

New IMF chief Georgieva warns of 'synchronised slowdown' in global growth

REUTERS
WASHINGTON, OCTOBER 8

NEW INTERNATIONAL Monetary Fund Managing Director Kristalina Georgieva issued a stark warning about the state of the global growth on Tuesday, saying trade conflicts had thrown it into a "synchronised slowdown" and must be resolved.

In her inaugural speech after taking over the global crisis lender on October 1, Georgieva unveiled new IMF research showing that the cumulative effect of trade conflicts could mean a $700 billion reduction in global GDP output by 2020, or around 0.8 per cent .

The research takes into account U.S. President Donald Trump's announced and planned tariff increases on remaining Chinese imports, or around $300 billion worth of goods. Much of the GDP losses will come from a decline of business confidence and negative market reactions, she said.

"In 2019, we expect slower growth in nearly 90 per cent of the world. The global economy is now in a synchronised slowdown. This means that growth this year will fall to its lowest rate since the beginning of the decade," Georgieva said.

The Bulgarian economist, a former European Union official who previously held the number two job at the World Bank Group, said that trade had "come to a near standstill."

She warned that fractures in trade could lead to changes that last a generation, including "broken supply chains, siloed trade sectors, a 'digital Berlin Wall' that forces countries to choose between technology systems.'"

In calling for countries to work together to revise global trade rules to make them sustainable, she referenced frequent complaints about China's trade practices, without specifically naming the country.

DECISION AIMED AT 'PUNISHING BEIJING FOR ITS TREATMENT OF MUSLIM MINORITIES'; HIKVISION TO BE AMONG TARGETED FIRMS

US expands blacklist to include China's top AI startups ahead of trade talks

DAVID SHEPARDSON & JOSH HORWITZ
WASHINGTON/SHANGHAI, OCTOBER 8

THE US government widened its trade blacklist to include some of China's top artificial intelligence startups, punishing Beijing for its treatment of Muslim minorities and ratcheting up tensions ahead of high-level trade talks in Washington this week.

The decision, which drew a sharp rebuke from Beijing, targets 20 Chinese public security bureaus and eight companies including video surveillance firm Hikvision, as well as leaders in facial recognition technology SenseTime Group Ltd and Megvii Technology Ltd.

The action bars the firms from buying components from US companies without US government approval - a potentially crippling move for some of them. It follows the same blueprint used by Washington in its attempt to limit the influence of Huawei Technologies Co Ltd for what it says are national security reasons.

US officials said the action was not tied to this week's resumption of trade talks with China, but it signals no let-up in US President Donald Trump's hard-line stance as the world's two biggest economies seek to end their 15-month trade war.

The Commerce Department said in a filing the "entities have been implicated in human rights violations and abuses in the implementation of China's campaign of repression, mass arbitrary detention, and high-technology surveillance against Uighurs, Kazakhs, and other members of Muslim minority groups."

"The US government and Department of Commerce cannot and will not tolerate the brutal suppression of ethnic minorities within China," said Secretary of Commerce Wilbur Ross.

China said the United States should stop interfering in its affairs. It will continue to take firm and resolute measures to protect its sovereign security, foreign ministry spokesman Geng Shuang told a regular media briefing without elaborating.

Hikvision, with a market value of about $42 billion, calls itself the world's largest maker of video surveillance gear. SenseTime, valued at around $4.5 billion in a May 2018 fundraising, is one of the world's most valuable AI unicorns while Megvii, backed by e-commerce giant Alibaba, is valued at around $4 billion and is preparing an IPO to raise at least $500 million in Hong Kong.

The other firms on the list are speech recognition firm iFlytek Co, surveillance equipment maker Zhejiang Dahua Technology, data recovery firm Xiamen Meiya Pico Information Co, facial recognition firm Yitu Technology and Yixin Science and Technology Co.

A US Hikvision spokesman said the company "strongly opposes" the decision and noted that in January it retained a human rights expert and former US ambassador to advise the company on human rights compliance.

"Punishing Hikvision, despite these engagements, will deter global companies from communicating with the US government, hurt Hikvision's US businesses partners and negatively impact the US economy," the company added. Hikvision also said that it was assessing the potential impact of the blacklisting and was working on contingency plans.

John Honovich, founder of IPVM, said Hikvision and Dahua both use Intel Corp , Nvidia Corp, Ambarella Inc, Western Digital and Seagate Technology as suppliers and that the impact on the Chinese companies would be "devastating". **REUTERS**

Beijing urges US to remove sanctions on Chinese firms

Hong Kong: China strongly urges the United States to remove sanctions on Chinese firms and will take any necessary measures to firmly protect its own interests, China's Commerce Ministry said in a statement late on Tuesday.

The US government on Monday expanded its trade blacklist to include some of China's top artificial intelligence startups, saying it was in reaction to Beijing's treatment of Muslim minorities.

The move ratcheted up tensions ahead of high-level trade talks in Washington this week. **REUTERS**