OCTOBER 2019 VOL.3

POLICYPULSE

Thank You!

Thank you for taking the time to go through this latest edition of ***PolicyPulse****. We are so encouraged and enthused by the positive feedback received to date. Please do continue to write to us and let us know if you have any specific topic or industry you'd like us to cover or comment on. We have added in a few new sections based on feedback received. Trust you find these valuable.*

Our team at ***VeKommunicate*** *remains committed to providing information that's relevant, topical and based on verifiable industry research and data.*

PolicyPulse *is our monthly newsletter and is sent on a personal basis to key stakeholders like yourself. Hence we value your comments and look forward to hearing from you soon.*

Your continued support is highly regarded and appreciated.

Best wishes

Team VeKommunicate

IN THIS ISSUE

MACRO-ECONOMIC SNAPSHOT

Global Economy Outlook

World Economy

Through the first half of 2019, global growth has witnessed a slowdown, which has been harmonized around the globe, impacting major economies such as USA, Europe, China, India and large Latin American economies like Brazil and Mexico. As per the Fitch Rating's Global Economic Outlook (GEO) published in June 2019, the world Gross Domestic Product (GDP) is forecasted to be at 2.7 percent for 2020 and 2021 each, as compared to 2.8 percent in 2019. Failing prospects for business investment, weakness in consumer spending and a softer growth outlook in emerging markets have culminated in more bearish forecasts for the world economy.

Global Forecast Summary

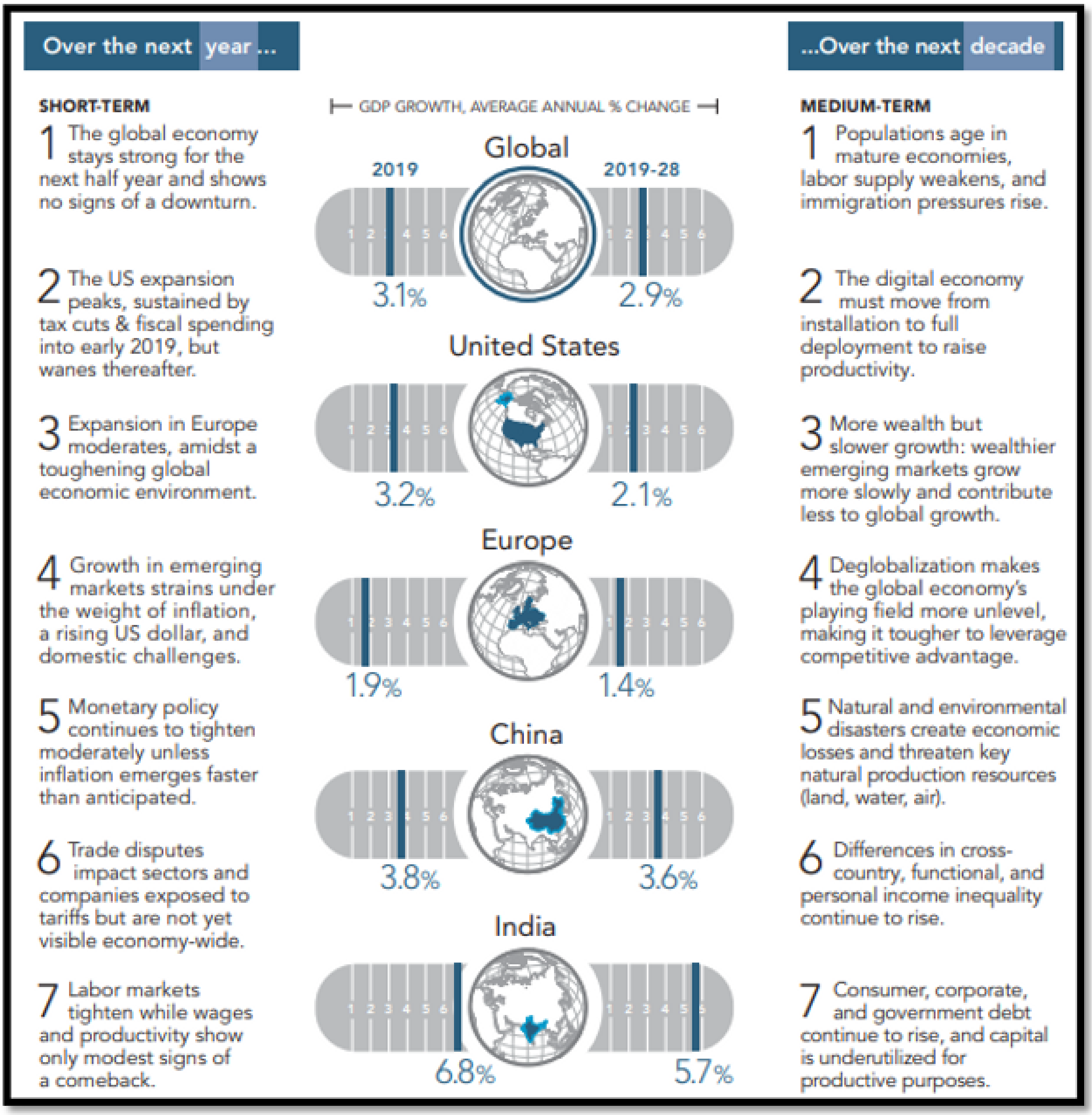
GDP Growth (%)	2018	2019 (F)	2020 (F)	2021 (F)
USA	2.9	2.4	1.8	1.7
EU	1.9	1.2	1.3	1.2
China	6.6	6.2	6	5.8
Japan	1.8	0.8	0.5	0.6
UK	1.4	1.4	1.5	1.8
Developed Economies	2.1	1.8	1.5	1.5
Emerging Economies	5.1	4.5	4.8	4.9
India	6.8	6.6	7.1	7
World	3.2	2.8	2.7	2.7

Source: FITCH Report and F denotes forecast figures

Multilateral and national policy actions seem more and more necessary to reset the global growth. There is a need to reduce trade and technology tensions between major economies around the world as also resolving uncertainty on time bound completion of trade agreements such as Regional Comprehensive Economic Partnership (RCEP) agreement, BREXIT, North American Free Trade Agreement (NAFTA) comprises of Canada, Mexico, and the United States, China-Japan-Korea (CJK) free trade agreement (FTA), etc. Specifically, countries are using tariffs to target bilateral trade balances or as a weapon for dialogue to pressure others for reforms.

As per IMF's (International Monetary Fund) World Economy Outlook 2019, "*with subdued final demand and muted inflation, accommodative monetary policy is appropriate in advanced economies, and in emerging market and developing economies where expectations are anchored. Fiscal policy should balance multiple objectives: smoothing demand as needed, protecting the vulnerable, bolstering growth potential with spending that supports structural reforms, and ensuring sustainable public finances over the medium term. If growth weakens relative to the baseline, macroeconomic policies will need to turn more accommodative, depending on country circumstances. Priorities across all economies are to enhance inclusion, strengthen resilience, and address constraints on potential output growth.*"

7 Short & 7 Medium-Term Shifts In The Global Economy



Source: Conference Board Global Economic Outlook 2019–2028

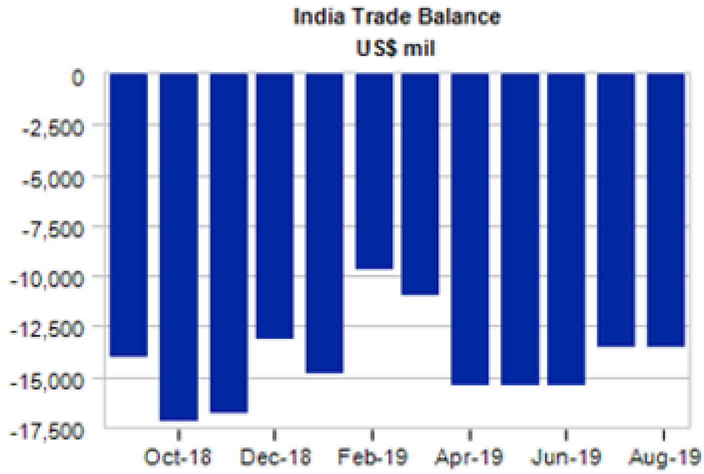
Focus On India

India's Gross Domestic Product (GDP) growth is forecasted at 6.6% for the current fiscal, from 6.8%projected earlier, citing persistent slowdown in manufacturing and agriculture sectors. However, GDP growth forecast for year 2021 and 2022 is at 7.1 percent and 7 percent, respectively.

India Forecast Summary

(%)FY starting April	FY18-19	FY19-20 (F)	FY20-21 (F)	FY21-22 (F)
GDP	6.8	6.6	7.1	7
Consumer Spending	8.1	7	7.9	7.3
Fixed Investment	10	3	7.3	7.4
Net Trade	(1.10)	0.00	(0.20)	(0.10)
CPI Inflation	2.1	3.8	4.1	3.8
Policy Interest Rate	6.5	5.5	5.75	6
Exchange Rate	69.82	70	71	72

Source: FITCH Report and F denotes forecast figures



Source: Ministry of Commerce and Industry

India's Eight Core Industry Performance Pointers

- India's eight core industries' output contracted 0.5 percent in August compared to 4 Percent in August 2018.
- Five sectors such coal, crude oil, natural gas, cement and electricity have recorded the first contraction in core industries data since April 2019, reflecting the weaker demand.
- For the April-August period, the core industries' output grew 2.4 percent compared to 5.7 percent in same period last year.
- Coal, crude oil, natural gas, cement, and electricity contracted 8.6 percent, 5.4 percent, 3.9 percent, 4.9 percent and 2.9 percent, respectively in August.
- However, refinery products, fertiliser and steel production grew 2.6 percent, 2.9 percent and 5 percent respectively during the month.
- During April-August, growth in the eight core industries grew by 2.4 percent from 5.7 percent in the year-ago period.

Source: Ministry of Commerce and Industry

INDUSTRY BULLETIN

Indian Cement Industry: The Path Ahead Towards Plastic Waste Management

The Indian cement industry is the second largest industry in the world after China. The major growth drivers of the cement industry are real estate and housing sector, with around 70 per cent demand coming from these sectors. During FY19, the cement industry achieved the highest double-digit volume growth led by improved realisations in FY19. Also, capacity utilisations have improved which contributed to the growth journey. As of FY18, the total installed capacity was 465 million ton. During this period, the industry had approximately 70 per cent utilisation, giving better scope for growth. Going ahead, looking at the cost rationalisation measures paying off, coupled with government's initiatives like reduce in corporate taxes, budget allocation in affordable housing and boost for infrastructure activities would drive the demand for cement.

Cement Industry Pledge Towards Plastic Waste Management

Rapid population growth, urbanization, and industrial growth have led to severe waste management problems in cities around the world. Development in economic prosperity and industrialization often conflict with environmental considerations. Globally, nearly 140 million tons of plastics are produced each year compared to 62 million tons in India. Out of which 15 percent o 17 percent are non-recyclable plastics. India recycled 57% of its total plastic waste in contrast to China (11%), the US (3.5%), South Africa (15%), and UK (7%). There are around 20,000 plastics recycling industries in India with a daily capacity of 1,500 tons.

Raw material substitution offers advantages for cement industry as well as for Municipal Authorities responsible for waste management. By co-processing of plastic waste with primary fuel, cement producers or power plants can save fossil fuel and raw material consumption, contributing to more energy-efficient production. A major advantage of this recovery method is by using an existing facility; the need to invest on other plastic waste processing or to secure land filling is eliminated.

Government of India has acknowledged the role of Indian cement industry in achieving the goal set by Prime Minister Mr. Modi of complete ban on single use plastics. Speaking at a session the Shri Parameswaran Iyer, Secretary, Department of Drinking Water and Sanitation said, *“CMA is playing an important role towards awareness of Swachhata hi Sewa plastics and putting it in front and centre of the agenda. The Cement Industry is a critical partner in our goal towards "SamuchitNiptaan" the total disposal of waste and plastics. I am thankful to CMA and its Member Companies for the support.”*

Shri Chandra Kishore Mishra, Secretary, Ministry of Environment, Forest and Climate Change said, "*The Indian Cement Industry found a place of prominence at the UN Climate Action Summit. Climate change threat is real and we have to work on it for real for the benefit of future generation. Technology and resource are two critical elements for transition. At the same time there is enough mettle in the Indian industry to find a way out and innovate new technology on our own*".

Shri Durga Shanker Mishra, Secretary, Ministry of Housing and Urban Affairs (MoHUA) said "*Single Use Plastics can be disposed in cement kilns and there will be no environmental issues as it uses high temperature where hazardous gases get absorbed. Very happy to hear about the plastic Ravana initiative on 8th October where CMA would showcase the process they are using to manage single use plastic waste.*"

The Cement Industry in collaboration with the Ministry created a huge RAVANA(s) made out of plastic waste across a few cities in India, which was disposed of coinciding with Dussehra. Ravana's effigy made of plastic waste was shown being disposed of mechanically in a cement plant. The intent is to personify Ravana in its plastic form as a demon bad for the society and environment and the role that the Cement Industry can play in helping overcome this menace in its plants in an environmentally friendly manner.

(CMA & MoHUA Initiative- Plastic Waste Ravana Effigy at Ramlila Ground, Delhi on October 8, 2019)

As of now, 46 cement plants in India are already using plastic waste within its 200 km radius. Cement industry is working actively to sum up all the 238 cement plants in India to utilise the plastic waste in their vicinity. However, there are roadblocks in reaching the ultimate goal as appropriate policies are needed to forefront the movement.

Government of India is looking at developing the following policies, which may become catalysts in achieving the goals:

a) Polluters to Pay: This principle is the commonly accepted practice that those who produce pollution should bear the costs of managing it to prevent damage to human health or the environment. For instance, a factory that produces plastics as a by-product of its activities is usually held responsible for its safe disposal. The polluter pays principle is part of a set of broader principles to guide sustainable development worldwide (formally known as the 1992 Rio Declaration).

b) Landfill Taxes: Waste taxes aim to promote waste recovery and reduce the amounts of waste ending up in landfills. Waste taxes are paid by the owner of the landfill, who passes on the cost through fees charged for the reception of waste. Many countries are looking to extend the tax base beyond municipal landfills and include all waste which could be reutilised on the basis of technical, economical or environmental premises. It is one of the discussed topics under the United Nations Sustainable Development Goals.

c) Tax incentives for companies who are engaged in waste management activities Government of India at a public forum clearly indicated its intention to work with Indian industry especially cement industry on the roadmap of plastic waste management.

POLICY BRIEF

Export Promotion Schemes 2.0

On 14th September 2019, Union Finance Minister Ms. Nirmala Sitharaman announced various schemes to promote and streamline exports from India. The major focus was about a new scheme Remission of Duties or Taxes on Export Products (RoDTEP), which is going to replace the existing Merchandise Exports from India scheme (MEIS) for all goods exported. The new scheme will allow reimbursement of duties on export inputs and indirect taxes through freely transferrable scrips. However, the rates are yet to be decided in the new RoDTEP scheme but it will be based on previous method. The RoDTEP may rebate the following embedded taxes and duties:

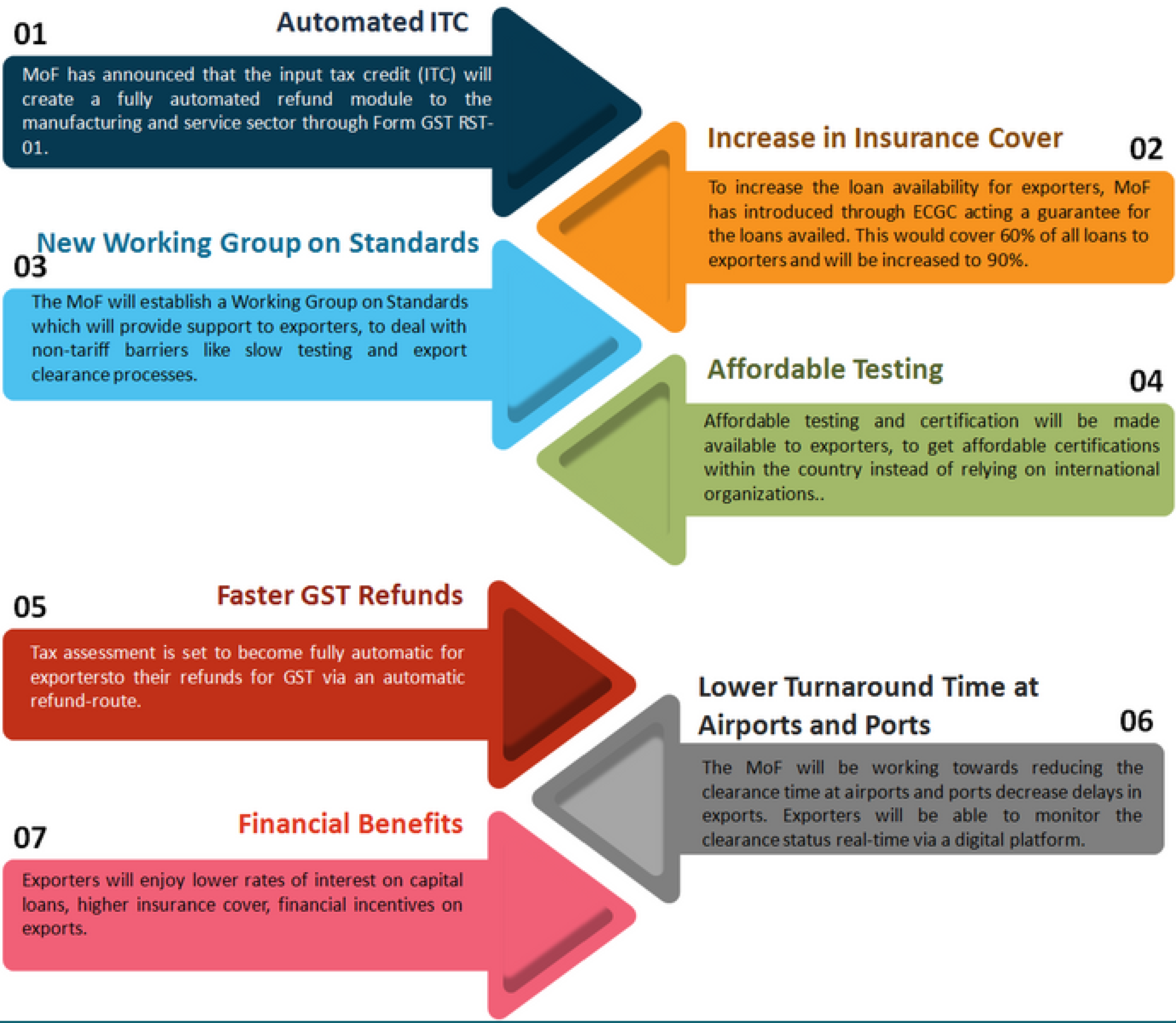
- State VAT on fuel used in transportation of inputs, generation of captive power and in the farm sector
- Mandi Tax
- Duty on electricity charges
- Stamp duty on export documents
- Embedded SGST/CGST paid on inputs such as pesticides, fertilizers etc. used in production of required raw materials, purchases from unregistered dealers, coal used in production of electricity, fuel used in transportation of finished goods, etc.

Such duties or taxes shall be remitted at an actual rate claimed by the exporter, subject to a notified ceiling rate and a value cap per unit of exported product. The rebate would be claimed as a percentage of the realized freight on board (FOB) value of exports. The ceiling rate and value cap for products (group of products) would be determined in consultation with related stakeholders. Sector, which will be covered by this new scheme will be export intensive sectors, labour intensive/ MSME sectors, sectors having high value-addition, engineering sector, agricultural exports etc.

The RoDTEP scheme will be monitored by the Ministry of Finance (MoF) and comes into effect from January 1, 2020. The scheme provides an additional export credit of up to Rs.68,000crores and the projected forgone revenue will be up to Rs.50,000 crores. The following were the other announcements covered on RoDTEP:

- The MEIS scheme will be applicable only until Procedure for December 31, 2019, replacing with RoDTEP
- Create a fully automated procedure for input tax credit (ITC) in goods and service tax (GST) to avoid double taxation
- Privileged Textile and other export sectors that are applicable for an incentive of up to 2% of MIES shall be replaced with RoDTEP scheme
- MoF has allocated a budget of Rs.1,700crore to provide higher insurance cover through Export Credit Guarantee Corporation (ECGC), to increase the lending opportunities from banks

Other Export Promotion Announcements:



FTA UPDATES

India-ASEAN Review On The Cart: Whether Industry Can Reap Benefits

India-ASEAN FTA came into effect in 2010 for goods and 2014 for services, was an important pillar in India's "Look East" Policy. Now India has rechristened its decade old policy into "Act East Policy", which kind of triggered the existing FTA to be reviewed by both sides to make it more user-friendly, simple and trade facilitative for businesses. Indian industry is of view that this agreement has not been fruitful for them, as the trade deficit with ASEAN nations has doubled from US$ 5 billion in 2011 to US$ 10 billion in 2018.

India's exports to ASEAN have increased by 57% between 2010 and 2018 while imports have increased by 93%.Between 2010 and 2018, among ASEAN countries, India's exports have increased most in case of Myanmar (US$ 0.27 bn to US$ 1.23 bn), Vietnam (US$ 2.47 bn to US$ 6.7 bn), Malaysia (US$ 3.5 bn to US$ 6.5 bn) and Thailand (US$ 2.1 bn to US$ 4.3 bn).

In case of India's imports from ASEAN, the growth has outpaced the growth in exports. Between 2010 and 2018, imports from Vietnam increased from US$ 0.99 bn to US$ 7.21 bn, Indonesia (US$ 9.69 bn to US$ 16.02 bn), Malaysia (US$ 5.99 bn to 10.41 bn), Thailand (US$ 3.94 bn to US$ 7.66 bn) and Singapore (US$ 7.26 bn to US$ 14.32 bn). However, it is to be noted that India has separate bilateral engagements with Singapore, Malaysia and Thailand and that increase in trade, especially imports, is a result of dual preferences.

What demands more concern is that these three countries along with others have been able to increase their exports to India utilizing the free trade agreements – AIFTA and bilateral – but Indian industries have not been able to penetrate these markets under the same preferences.

Trade Between India and ASEAN Members				
	2009 (before FTA)	2010 FTA came into force	2011 (after FTA)	2018 (Current Year)
India's exports to ASEAN	17.89	22.95	34.49	36.07
% share of India's total exports	13.56%	13.45%	13.38%	17.71%
India's imports from ASEAN	23.96	29.64	40.33	57.21
% share of India's total imports	9.00%	8.47%	8.72%	11.27%

Source: *ITC Trade Map; Values in US$ billion*

Top products of import by India from ASEAN			
Product Code	**Product label**	**India's Imports From ASEAN**	
		2010	**2018**
270119	Coal, whether or not pulverized, non-agglomerated	2897.52	6788.52
151110	Crude palm oil	3639.11	3986.73
270900	Petroleum oils and oils obtained from bituminous minerals, crude	1557.19	2868.27
851762	Machines for reception, conversion and transmission or regeneration of voice	115.77	2162.08
151190	Palm oil and its fractions, whether or not refined	838.70	1471.39
740819	Wire of refined copper, with a maximum cross-sectional dimension of <= 6 mm	9.377	1029.44
851770	Parts of telephone sets, telephones for cellular networks or for other wireless networks	288.26	854.61
271019	Medium oils and preparations, of petroleum or bituminous minerals	1795.76	800.34
847150	Processing units for automatic data-processing machines	210.92	678.61
400122	Technically specified natural rubber "TSNR"	263.715	672.145

Source: *ITC Trade Map, values in US$ million*

Top products Exported By India to ASEAN			
Product code	Product label	India's exports to ASEAN	
		2010	2018
271019	Medium oils and preparations, of petroleum or bituminous minerals	3147.86	7647.44
20230	Frozen, boneless meat of bovine animals	638.31	2481.20
271012	Light oils and preparations, of petroleum or bituminous minerals	0	1642.32
760110	Aluminum, not alloyed, unwrought	305.88	983.16
290243	P-Xylene	292.83	951.96
30617	Frozen shrimps and prawns, even smoked, whether in shell or not, incl. shrimps and prawns	0	856.28
710239	Diamonds, worked, but not mounted or set	518.63	663.74
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes	176.85	562.44
520100	Cotton, neither carded nor combed	313.87	534.74
711319	Articles of jewellery and parts thereof, of precious metal other than silver	281.85	423.92

Source: *ITC Trade Map, values in US$ million*

Top products of exports to ASEAN are petroleum oil, bovine meat, p-xylene, shrimps, diamonds (worked), medicaments, aluminum, cotton etc. while top products of imports include coal, palm oil, copper wires, crude petroleum, rubber, parts of telephone sets etc. Major beneficiaries in India's exports to ASEAN are shrimps, light oils and preparations of petroleum, cuttle fish and squid, cumin seeds, compression- ignition internal combustion piston engine, medium oils and preparations of petroleum, meat of bovine animals and many others.

Possible Reasons For Trade Deficit With ASEAN

a) Some of the key reasons behind India's increasing trade deficit with ASEAN have been higher import duties on essential goods like coal, petrol, edible oils, inadequate quality norms for processed foods in ASEAN nations, imposition safeguards and non-tariff barriers on textiles and pharmaceuticals, administrative complexities etc.

b) This FTA has witnessed the greatest reduction in Indian import tariffs. India offered around 9,000 products (at the HS 8-digit level) for tariff elimination (NT-1, NT-2) out of 12,000 tariff lines, 1,800 lines in sensitive track and almost 1,300 lines in exclusion. Whereas India kept around 10% of its tariff lines in exclusion, Thailand, Philippines, Myanmar, Brunei and Vietnam kept more number of tariff lines under exclusion.

c) Additionally, India was the late comer in the markets of ASEAN countries. The AIFTA came into effect in 2010 which was late compared to China (2005), South Korea (2007), and Japan (2008).

d) Domestic growers have expressed concerns at the time of negotiation of the FTA (goods chapter) that cheap imports from the ASEAN region would hurt domestic growers of tea, coffee, cashew, coconut, oil palm, rubber, spices and other plantation items because many of the ASEAN countries enjoy cost and quality advantages over India.

e) Stainless steel industry has been hurt in India because of the widespread mis-declarations by exporters ASEAN to avail preferential tariff under the FTA. Raw agarbatti imports from China and Vietnam rose by a massive 1641% after India reduced its imports duty to 5% under AIFTA in 2018. India has seen a surge in imports of copper wires (less than 6mm) from 4,000 MT in 2009 to 1.5 lakh MT in FY19 from ASEAN countries like Indonesia, Malaysia, Thailand, and Vietnam after India reduced import duty from 5% to 0% in 2017. Also, between FY 2017 AND FY 2018, value of import of televisions from Vietnam saw a 37-fold increase on account of zero custom duty.

Proposed Review: What Industry May Expect?

- The proposed review of ASEAN-India FTA is much needed in the view of difficulties that Indian industries have been facing since the FTA came into force. In fact, the domestic industry has been reluctant towards the ongoing RCEP negotiations as they fear the imports flooding the markets and impacting their competitiveness.
- The India-ASEAN FTA had the greatest impact on India’s trade and also saw the largest reduction in its import tariffs. While India offered around 9,000 products (at the HS 8-digit level) for tariff elimination (NT-1, NT-2) out of around 12,000 tariff lines, it kept 10% of tariff lines in exclusion. However Thailand, Philippines, Myanmar, Brunei and Vietnam kept more number of tariff lines under exclusion in comparison to India. Also, India offered higher margin of preference under the FTAs, leading to a much greater increase in the imports as compared to exports.
- The proposed review of the FTA should focus on addressing industry concerns but without taking protectionist measures. The attention should be on finding ways to enable the industries in ASEAN and India trade in a win-win manner rather than competing at each other’s’ loss. However, India should look to address the issues like administrative delays, margin of preference, circumvention of rules of origin and value addition norms, etc when it reviews this agreement.

EU Ready To Add Another Feather Into Its FTA Cap: What Does This Mean For India?

In 2017, European Commission President Jean-Claude Juncker reinforced that all current FTA negotiations within his mandate should be concluded by the end of 2019.As mentioned in our earlier “Policy Pulse” edition, EU is moving ahead from BREXIT and making "alternative arrangements" by expanding its trade agreement horizon. Since February 2019, it has signed three major trade agreements with MERCOSUR, Japan and Vietnam.

Recently, it has ignited discussions for a possible agreement with Thailand. The Thai Trade Negotiations Department has planned public hearings nationwide to hear out all stakeholders throughout October and November 2019. These FTAs are intended to do more than simply dismantle tariffs.

In addition, they are to improve market access by removing non-tariff trade barriers (for example, through regulatory cooperation), liberalizing trade in services, and opening markets for public procurement. These newer free trade agreements of the EU also go well beyond the regulatory scope of the WTO. They include competition rules, protection of foreign direct investment, and regulations to ensure sustainability (labor and environmental protection). The EU is also seeking to modernize older global agreements with Chile and Mexico, which contain only basic economic aspect.

EU-Thailand: Trade in goods			
Trade in goods 2016-2018, € billions			
Year	EU Imports	EU Exports	Balance
2016	20.7	13.6	-7.1
2017	22.3	15	-7.3
2018	22.9	15.1	-7.7

Source: EU

The EU is Thailand's fourth largest trading partner in the world and second largest investor here. Two-way trade between Thailand and the EU totalled US$ 47.3 billion in 2018, with Thai exports accounting for $25 billion and imports $22.2 billion. Under this agreement EU has agreed to help promote Thailand's 12 targeted industries that focus largely on high technology such as cars; smart electronics; affluent, medical and wellness tourism; agriculture and biotechnology; food; robotics for industry; logistics and aviation; bio-fuels and bio-chemicals; digital; medical services; defence; and education development.

EU is among India's major export destinations with exports worth of US$ 57 billion in 2018. Major exports from India were organic chemicals, machinery, textiles, iron & steel, electronic products, auto & auto components, pharmaceutical products, etc. Amid EU's initiative of moving ahead with trade agreements with South East Asian countries, there is a possible threat for Indian industry.

Trade Comparison In 2018

Product Code	Product label	India's Exports to EU	India's Exports to World	EU's Imports From World	Thailand's Exports to EU
'29	Organic chemicals	4.67	17.74	182.26	0.21
'84	Machinery & Parts	4.55	20.40	738.51	5.97
'27	Mineral fuels	3.80	48.29	721.85	0.01
'61	Articles of apparel and clothing accessories, knitted	3.61	7.56	96.73	0.37
'62	Articles of apparel and clothing accessories, not knitted	3.52	8.13	97.07	0.19
'71	Natural or cultured pearls,	3.41	40.10	107.11	1.69
'72	Iron and steel	3.25	9.98	169.96	0.13
'85	Electrical machinery	2.59	11.79	653.93	4.79
'87	Vehicles and parts	2.22	18.24	646.03	2.49
'30	Pharmaceutical products	2.15	14.28	283.05	0.05

Source: ITC Trade Map and Values in US$ Billion

Indian industry is of view that, the EU is now better prepared to engage strategically with global partners. While the EU is cautious about China's worldwide activities, the EU is optimistic about India as strategic partner and emerging global power.An impetuous for further strengthening EU-India relations came with the EU's Strategy on India adopted in December 2018. The strategy was well-received in India. It underlines that the EU prioritises a long-term engagement with India with joint efforts on issues such as cyber and maritime security, energy and climate, stable and smooth trade. The question, however, is on which issues the EU and India should develop their cooperation, how engagements should be rated internally, and through which mechanisms dialogue on the issues can be furthered.However, India needs to expedite the engagement process, if it wants to avoid the possible threat of losing out to South East Asian countries. As the EU-India strategic partnership is full of win-win solutions, Government of India and the EU may jointly map areas in which to scale up the cooperation.

PHARMA NEWS

No-Deal BREXIT: How Medicines & Devices Will Be Regulated In The UK

Although there may be another extension to BREXIT, the prospect for a no-deal BREXIT at the end of October 2019 still looms large. At this backdrop, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) have issued guidance on what will happen to drug and medical device regulations if such a no-deal path moves forward.

MHRA notes that the BREXIT transitional legislation will ensure that all currently granted Centrally Authorized Products (CAPs) will automatically get UK marketing authorizations (MAs) on exit day. Similarly on the device side, the UK will have a system in place that mirrors all the key elements contained in the EU medical devices regulation (MDR) and in vitro diagnostic regulation (IVDR). The UK will realign with the EU's new clinical trials regulation when it takes effect.

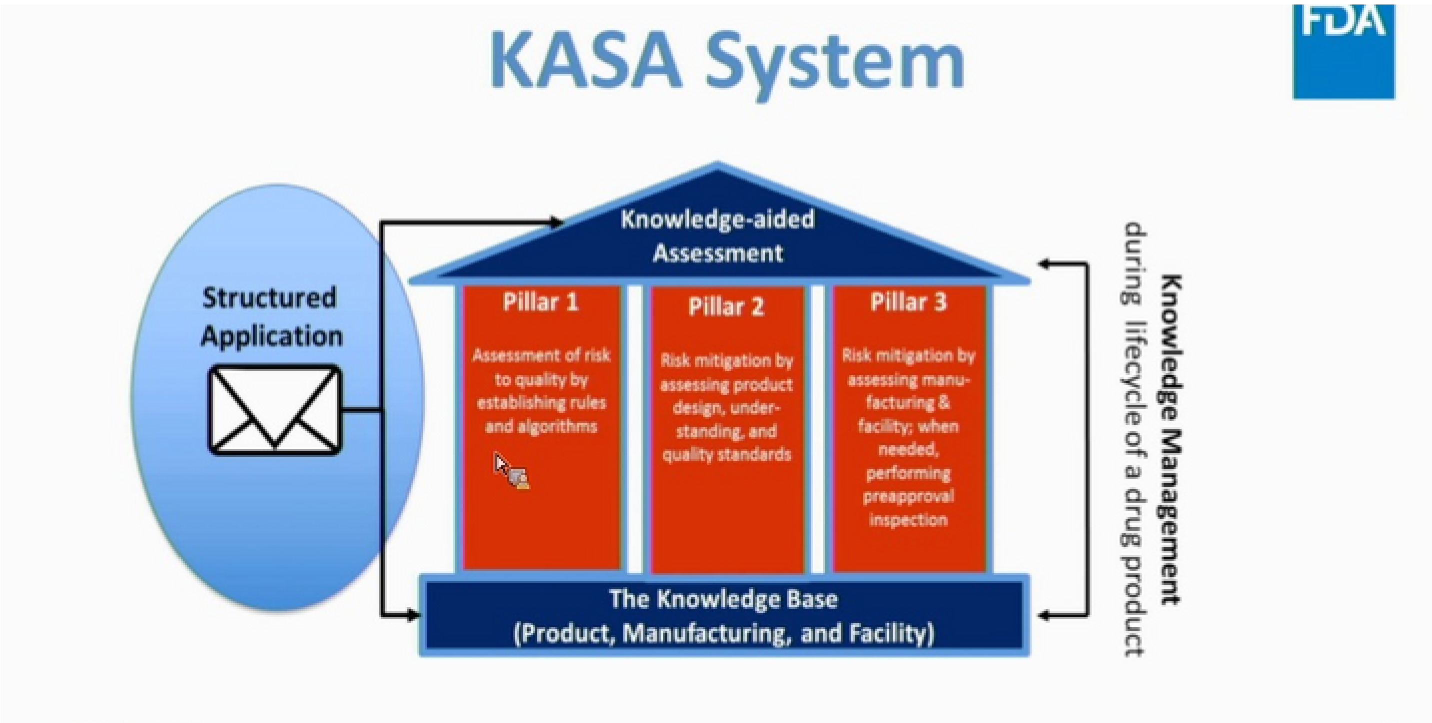
But MHRA will also have much more on its plate in a post-BREXIT world. For instance, currently, risk management plans, reports of suspected adverse drug reactions from the pharmaceutical industry, the majority of periodic safety update reports (PSURs) and post-authorization safety studies (PASS) are submitted and assessed at the EU level. But after BREXIT, these will need to be submitted to and assessed by MHRA. The regulator will also take over the system for pediatric investigation plans and control determining how orphan medicines are designated.

In some cases, drug and device firms will need to provide MHRA with more information and data to stay on the market in the UK. For instance, CAP Marketing Authorization Holders (MAHs) will have one year from exit day to provide MHRA with baseline data for CAPs that are converted into UK MAs. MAHs also will have a short period of time after exit day to opt out of having a UK MA. And by 31 July 2021, MAHs will need to establish a legal presence in the UK and have a qualified person for pharmacovigilance. MHRA also will give industry until the end of 2021 to amend certain administrative details on the packaging and in the package leaflets for a product already on the market.

On the device side, companies manufacturing devices, active implantable medical devices, in vitro diagnostics (IVDs) and custom-made devices will be allowed grace periods of between 4 and 12 months to allow time for compliance with the new registration process with MHRA. Sponsors will also have to submit all UK-relevant serious adverse events to MHRA. As far as clinical trials, many of the existing rules will remain, although the UK is also planning its own public database to provide UK patients and researchers a single reference point for all UK-based trials.

US FDA Plans For New Pharmaceutical Quality Assessment System

As part of its work to improve and modernize the quality assessment of drug applications, the US Food and Drug Administration (FDA) is developing a new, more standardized system, to be known as the Knowledge-aided Assessment & Structured Application (KASA), according to FDA's Center for Drug Evaluation and Research (CDER).



What Does It Offer?

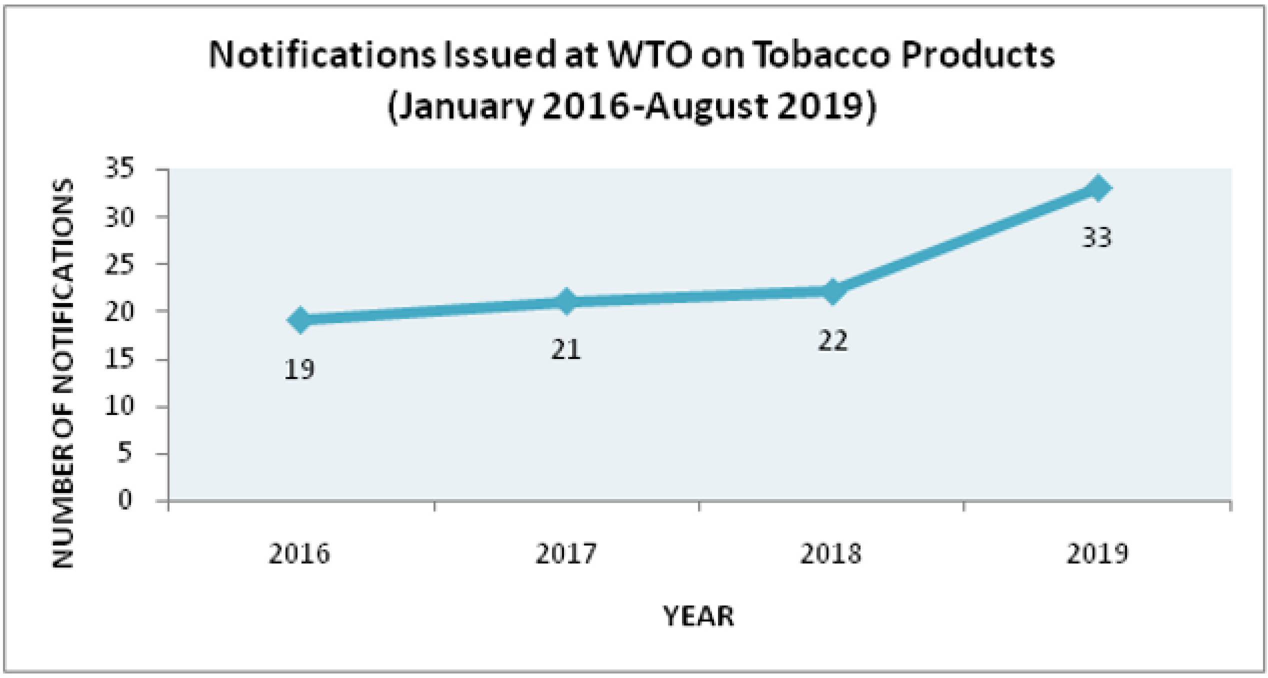
- KASA will capture and manage information in a structured format about the inherent risk and control approaches for product design, manufacturing and facilities. The system is meant to help FDA address challenges related to its quality assessments.
- Currently, when a quality assessor reviews a regulatory applicationit is not possible to easily locate historical data about similar products, processes, or the facilities. Such a practice has significantly reduced the efficiency of the regulatory assessment and increased the likelihood of inconsistencies.
- Further, in particularly urgent cases, the FDA may not have readily available up-to-date information to provide timely, thorough, and complete responses, hindering FDA's regulatory oversight. But with KASA, certain rules and algorithms will be able to estimate the initial inherent product and manufacturing risks.

- KASA will also help with risk controls related to product design and manufacturing. In addition, although KASA is being primarily developed as an assessment tool, it is capable of alleviating problems associated with the submission of drug applications via the electronic common technical document (eCTD) format.
- As far as the major benefits of this shift to a KASA system, it will move regulatory application assessment from the current unstructured text document to an issue-based regulatory and technical assessment using structured data and information with standard formatting, a common vocabulary, and a uniform output. In turn, this improves consistency, transparency, communication, and objectivity of regulatory actions, as well as knowledge management within the Agency.

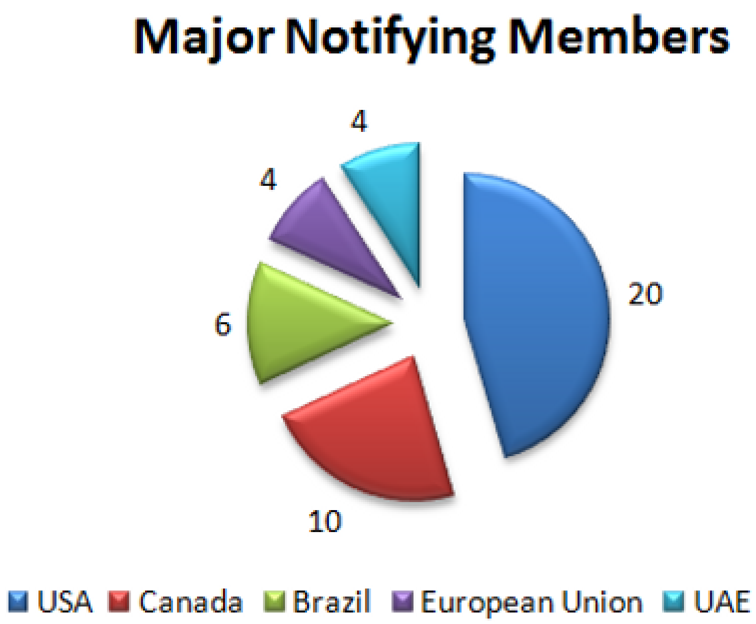
OFFBEAT

Tobacco Products – A Global Scenario

More than 30 countries ban e-cigarettes; India halts sales last month; Many European countries, including Austria, Belgium, Germany and Italy, classify e-cigarettes as tobacco products, subjecting them to strict controls. The landscape of tobacco use is changing swiftly. The number of notifications issued by WTO member nations has gradually increased in the last three years. A total of 95 notifications have been issued by 33 countries in the time period January 2016 to August 2019.



Out of the 33 notifying members, United States of America (USA), Canada, Brazil, European Union (EU) and United Arab Emirates (UAE) have been the major notifying members for tobacco products.



With more people dying from tobacco related illness, tobacco use is the single largest source of preventable deaths in the world. Tobacco comes in many forms, from cigars and cigarettes to smokeless tobacco and dissolvable nicotine products. Tobacco can also be fatal for non-smokers. Second hand tobacco smoke is a major contributor of diseases like cancer and heart diseases. In addition to the lethal impact on health, the total economic cost of smoking adds a substantial burden to the countries.

There have been many attempts at controlling the use of tobacco among the population and especially the youth. Countries have taken measures to bring the condition in control from changing the requirements of labeling, packaging, advertisement to bringing changes in the existing law.

Actions for controlling Tobacco use by various countries

- Control on advertisement of tobacco products
- Setting system of security features for tobacco products, to facilitate the verification on the authenticity of the tobacco products.
- Prohibition/Ban on e-Cigarettes
- Labeling requirements – Enlarging health warnings (text and picture) on front and back of cigarette packages
- Establishment and operation of a traceability system for tobacco products.

Tobacco Control Developments

FDA's Youth Tobacco Prevention Plan: It is a key component of Comprehensive Plan for Tobacco and Nicotine Regulation. It encompasses a series of actions aimed at stopping the use of tobacco products, especially e-cigarettes by the youth.

The Union

It draws from the best scientific evidence and expertise to advance solutions to public health challenges affecting people living in poverty: TUBERCULOSIS, TOBACCO USE, HIV AND AIDS, LUNG DISEASE and NON-COMMUNICABLE DISEASES.The Union currently supports tobacco control in 61 countries, and is part of an international network of organisations working to combat the tobacco epidemic.

(This offbeat article has been prepared by Anjali Chauhan, Research Analyst, RV-VeKommunicate)

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