

POLICY PULSE

A Monthly Newsletter



**“WISHING NEW
BEGINNINGS,
NEW HOPE AND
A HAPPY NEW
YEAR!”**

FIRST TAKE

Moving Forward

The vaccine has arrived, and countries are hoping to move forward in 2021 with renewed hope and confidence. The unprecedented Covid pandemic that hit mankind across the globe during the beginning of last year, taught us to unify and face one of the greatest health emergency situation collectively, find solutions to manage the pandemic and changed our normal way of living. Truly a humbling experience!

While, concerns remain as some countries are still battling huge rise in numbers, 2021 promises to help the global economy overcome the challenges faced in 2020.

This New Year edition of Policy Pulse looks at the various issues that are likely to impact business in India and the world. The economic outlook looks stronger and the WTO is gearing up for a new push with Joe Biden taking charge in the US. This year is expected to see the exact impact of Brexit for businesses in the EU, UK and the globe. 2021 may see the new normal setting the stage for a brighter economic outlook around the world!

IN THIS ISSUE

MACROECONOMIC SNAPSHOT

- Global Economy-----03
- Indian Economy Outlook-----04

WTO UPDATES

- Global Merchandise Trade Registers Growth In Q3-2020- WTO Reports-----06
- Towards WTO's 12th Ministerial Conference (MC12)-----06
- WTO Members Discuss Market Access Issues Related To Logistics And Financial Services----07

FTA & OTHER UPDATES

- UK – EU Signs Trade Deal-----08
- UK Signs FTA With Turkey-----08
- African Free Trade Bloc Commences-----08
- Bangladesh And Bhutan Agreed Towards Signing A PTA-----09

POLICY/REGULATORY BRIEF

- Environment Ministry Sets Up National Authority To Regulate Carbon Markets-----10
- India – USA Signs MoU On IP Cooperation-----10
- Ports Sector May Get Overhaul As The Ministry Proposes Indian Ports Bill 2020-----10
- Authority To Oversee International Bullion Exchanges-----11
- Transport Ministry Considers E20 Fuel As Automotive Fuel And Co-driver Airbags-----11
- India- Vietnam Summit-----11
- Power Ministry Establishes Electricity Rules For Ease Of Doing Business-----12
- Ethanol Distillation Receives A Boost-----12
- NITI Aayog Launches Vision On Public Health -2035-----12
- Ministry of Ports, Shipping And Waterways To Develop Specialized Warehouses-----13
- Australia Proposes Amendments To The Designs Act-----14
- China: Traceability Of Medical Devices Commences-----14
- China Notifies Measures On Security Review Of Foreign Investments-----14
- EU Upgrades Digital Services Rules-----15

OPINION COLUMNS

- Cybersecurity: EU Strategy To Secure Future/Digital Economy-----16
- COVID-19 Medicine And Vaccine Development: Regulatory Support-----18
- Single Use Plastics: A Global Concern-----20
- Medical Tourism In India-----23

MACROECONOMIC SNAPSHOT

Global Economy

A Brighter Outlook But Revival Will Be Slow

The global economy is slowly gaining strength compared to the second and third quarter of 2020, despite rising cases in some parts of the globe. Following a steep decline in early 2020, the world economy rode a rebound that began in May 2020 and remained on track to surpass pre-pandemic GDP levels by the end of 2020, setting the stage for strong post-recovery growth in 2021. Please find below some global economy projections made in end of December 2020:

- Wall Street's biggest banks are predicting the coronavirus-hit world economy will crawl through the early days of 2021 before bouncing back as vaccines and more fiscal stimulus flow into it. After the unanticipated shock and recession in 2020, economists are bracing for a shaky start to the new year as 2020 ended with a spike in infections and further rounds of restrictions.
- Morgan Stanley predicts an expansion of 6.4% in 2021 and maintains their call for a V-shaped recovery. Economists at the Citigroup Inc are less confident, who predict growth of 5%.
- OECD, in its recent projections cited that vaccination campaigns, concerted health policies and government financial support are expected to lift global GDP by 4.2% in 2021 after a fall of 4.2% this year.
- Fitch expects world GDP growth will be 5.3% in 2021. It reflects a stronger-than-expected recovery in 2021.
- Goldman Sachs Group Inc. expects the global growth forecast will be at 6% in 2021. It adds that, just as the global economy rebounded quickly from the lockdowns in the 3rd quarter 2020, it expects the current weakness to give way to much stronger growth when the worldwide lockdowns end and a vaccine becomes available.
- JPMorgan Chase & Co. expects the global growth forecast will be at 5.8% in 2021. It says that the global growth momentum is expected to slow sharply, with the US and the European GDP started contracting in the new year. But the outlook in 2021 has brightened as the successful vaccine trials bolster confidence that the link between virus containment and mobility will soon be broken.
- Bank of America Global Research expects the global growth forecast will be at 5.4% in 2021. It bats for a rocky start in 2021. However, a combination of fiscal stimulus and wide vaccine distribution should boost growth by mid-year. Despite the recovery, global inflation likely will remain low and many policy rates likely will remain stuck near zero.

The bounce-back, analysts aver, will be strongest in the Asian countries that have brought the virus under control. The consensus is that even with a rebound, employment and inflation will stay under pressure in most parts of the world, requiring central banks to keep their easy money stances through the year.

The coronavirus is once again taking its toll on economic activity as the second wave prompts new restrictions, but the vaccine news is a game-changer for the outlook over the next two years."

Brian Coulton, Chief Economist, Fitch Ratings

GDP Growth and Inflation								
	Share of 2019 world GDP		Real GDP growth			Inflation		
	PPP	MER	2020p	2021p	2022-2026p	2020p	2021p	2022-2026p
Global (Market Exchange Rate (MER))	-	100.0%	-4.0	4.7	2.8	1.9	1.9	2.6
Global (Purchasing Power Parity (PPP) rate)	100.0%	-	-4.1	5.1	3.3	2.4	2.4	2.9
G7	31.7%	45.3%	-5.4	3.7	1.5	0.9	1.3	2.0
E7	36.2%	27.7%	-1.3	6.8	5.1	0.0	0.0	3.4
USA	15.9%	24.5%	-3.7	3.5	1.8	1.3	1.7	2.3
China	17.4%	16.8%	1.9	8.0	5.7	2.8	2.3	2.9
Japan	4.1%	5.8%	-5.4	2.4	0.6	0.1	0.0	1.2
UK	2.4%	3.2%	-11.3	4.5	1.8	0.8	1.4	2.0
Eurozone	10.7%	13.1%	-7.7	4.2	1.4	0.3	0.9	1.9
Australia	1.0%	1.6%	-3.8	3.1	2.5	0.9	1.4	2.5
India	7.1%	3.3%	-9.6	9.0	7.5	5.4	4.1	4.0
Brazil	2.4%	2.1%	-5.5	2.9	2.2	3.0	3.2	3.5
Canada	1.4%	2.0%	-5.5	4.1	1.7	0.8	1.0	1.9
South Africa	0.6%	0.4%	-8.6	3.3	1.8	3.2	3.8	5.1
Saudi Arabia	1.2%	0.9%	-5.4	3.2	2.4	3.5	3.1	2.1

Source: PwC UK analysis, National statistical authorities, IMF, Consensus Economics, OECD

Indian Economy

Economists predict that India's economy could rebound may range 7.6% to 9.2% growth in the new calendar year, with COVID vaccinations helping boost business activity, increased capital expenditure on infrastructure and an improvement in consumption. The improvement in business sentiment could remain uneven over the next several quarters.

Barclays has pegged a 9.2% year-on-year growth in India's GDP for calendar year 2021. Nomura expects the Indian economy to grow at 9.9% in 2021, eclipsing China (2021 GDP growth pegged at 9%) and Singapore (at 7.5%) during this period. It has turned positive on India's cyclical outlook for 2021, and believes the country is on the point of a cyclical recovery. It also expects the Reserve Bank of India (RBI) to maintain an accommodative stance in the first half of 2021 and a gradual withdrawal of liquidity in the first/second quarter of 2021,

shift to a neutral stance in Q2/Q3 of 2021, followed by higher policy rates in early 2022. It expects inflation to average at around 5.5% in first half of 2021, before easing to 4.1% in the second half.

S&P Global Ratings has raised India's growth projection for the current financial year to (-)7.7% from (-)9% estimated earlier on rising demand and falling COVID-19 rates. For the next financial year 2021-22, S&P projected growth to rebound to 10%. According to a report by India Ratings, Indian economy, though projected to grow 9.6% in the 2021-22 in year-on-year growth term, may grow just 1% in real terms to Rs 147.17 lakh crore as against Rs 145.66 lakh crore in 2019-20, at the 2011-12 prices. According to the rating agency, the country's GDP is expected to contract 7.8% to Rs 134.33 lakh crore in 2020-21, but may grow 9.6% to Rs 147.17 lakh crore in 2021-22. "These growth numbers suggest a strong V-shaped

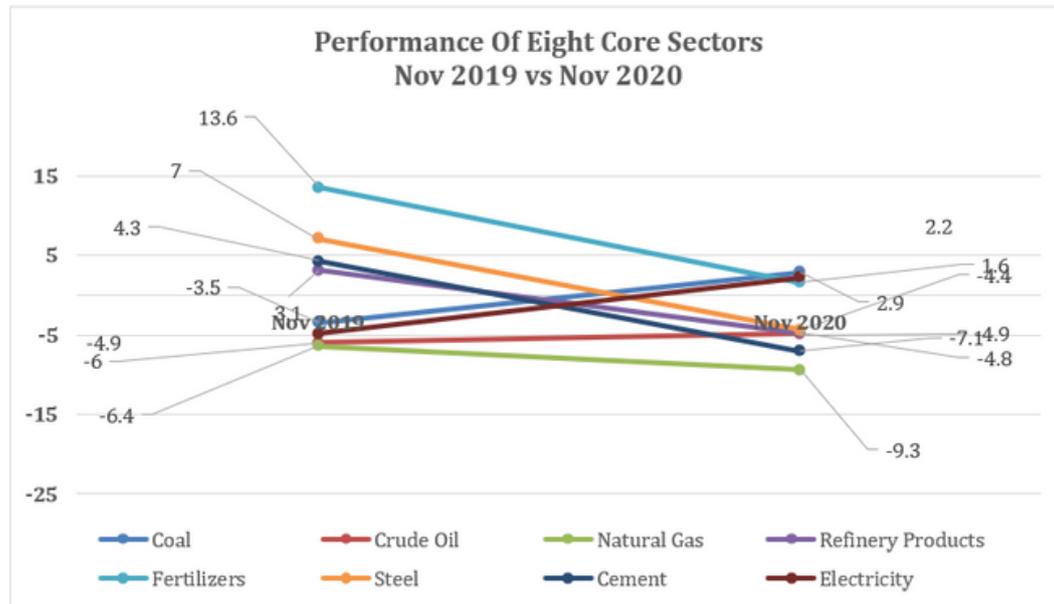
recovery, leading to the belief that the economy is out of the woods and on the path of a strong recovery. Even a moderate improvement in 1Q and Q2 of FY22 reflects a decent annualised GDP and IIP growth due to the low base," India Ratings said in the report. This suggests that the economy will be able to just recover the lost ground in 2021-22 and surpass the 2019-20 GDP level in a meaningful way only in 2022-23.

Manufacturing output was about 3.5% higher in October 2020 when compared to the year-ago period, while the output of consumer durables rose by almost 18%. The demand for goods drives India's recovery, and the household savings have risen due to the uncertain outlook and constraints of social distancing. Vehicle sales, both two-wheelers and cars, have rebounded recently. The RBI has also been careful about cutting its policy rate, especially as higher inflation has pushed real rates to exceptionally low levels. Rolling out vaccines to India's huge population will be challenging.

However, the aim to immunize 300 million people by August 2021, combined with an existing high infection rate in some parts of the country, could result in a pronounced decline in reported cases in later 2021.

Performance of Eight Core Industries

The combined Index of Eight Core Industries stood at 125.9 in November, 2020, which declined by 2.6% as compared to the Index of November, 2019. Its cumulative growth during April to November, 2020-21 has been (-) 11.4%. Out of the eight core industries, except coal, crude oil and electricity, all other sectors such as natural gas, refinery products, fertilizers, steel and cement sectors have witnessed a negative growth in November 2020 in comparison to the rate of growth in November 2019. However, only the performance refinery products sector has witnessed a growth in November 2020, in comparison to October 2020, other sectors have witnessed a negative growth in November 2020 in comparison to October 2020.



Source: Ministry of Finance

"We project GDP growth to remain in negative territory in Q1-2021 (- 1.2%), pick up to 32.4% in Q2 on base effects, before easing to 10.2% in Q3 and 4.6% in Q4. Overall, we expect GDP growth to average 9.9% in 2021 versus -7.1% in 2020, and 11.9% in FY22 (year ending March 2022) versus -8.2% in FY21,"

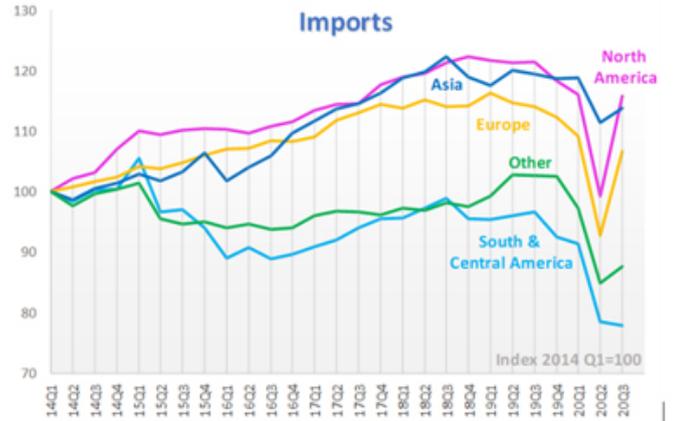
Sonal Varma, Managing Director and Chief India economist, Nomura

WTO UPDATES

Global Merchandise Trade Registers Growth In Q3-2020- WTO Reports



The trade statistics of the third quarter (Q3) of 2020 indicate that the merchandise exports trade volume from the industrialized regions grew and registered a growth higher than Q2 of 2020. This growth trend is led by the products of electronics, textiles and automotive sectors. Following which the toys, games, sporting equipments and travel/luxury goods are identified to register a growth. In terms of region wise growth, Asia posed 10.1%, EU at 19.3% and North America at 20.1% growth. However, on comparing with the previous year growth rate, only Asia has registered a 0.4% increase in exports. However, in terms of trade volumes of merchandise imports, the regions of North America and EU registered 16.6% and 15% respectively. Asian region saw 2.1% rise in its merchandise imports for Q3.

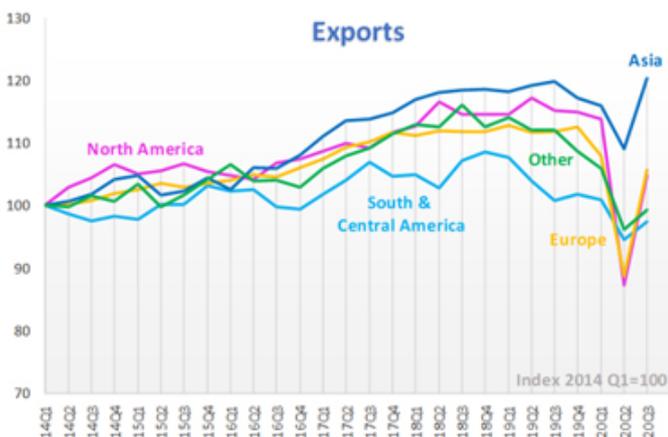


Source: WTO

Such growth rate is attributed to the fiscal and monetary policy introduced in the major economies, performance of online retail businesses and service providers. However, whether this momentum of increase in trade volume of Q3 would get reflected in Q4 of 2020 depends on the Covid-19 disease situation in the countries.

Towards WTO's 12th Ministerial Conference (MC12)

The Joint Statement Initiatives (JSIs) which was launched at the MC11 in Buenos Aires to negotiate on e-commerce, investment facilitation for development, services domestic regulation and MSMEs. In December 2020, the coordinators of JSIs stated that substantial progress has been made on various aspects and as a result, there is a possibility of delivering concrete results at forthcoming MC12. They noted that these aspects would provide solid grounds for 'building a more responsive, relevant and modern WTO'. They also added that negotiating members are reaching a consensus on various themes in the negotiating texts. Further, they are of the view that it would accelerate economic



Source: WTO



The other discussion was led by the communication from Australia, Canada, Switzerland and UK on financial services. It covered topics from insurance, banking, asset management, and financial advisory services. Members also continued discussion on agriculture related services including commission agents' services, wholesale trading and retailing. Such services are integral to agriculture, hunting and forestry, veterinary and distribution services of agricultural and food products. This discussion was based on communication from Australia, Canada, Chile, New Zealand and Uruguay.

growth and investments which has been hit by the global pandemic situation. It is to be noted that e-commerce has 86 members, services domestic regulation has 63 members, investment facilitation has 106 members and MSMEs working group has 91 members who are presently participating in the negotiations at the WTO.

WTO Members Discuss Market Access Issues Related To Logistics And Financial Services



In December 2020, during the informal meeting of the Special Session of the Council for Trade in Services, the WTO members discussed on two communications pertaining to logistics and financial services. One from China brought out the importance of logistics services and its evolution over the years. It also highlighted its relevance to trade in goods, supply chains, and e-commerce.

FTA & OTHER UPDATES

UK – EU Signs Trade Deal



As the Brexit period was nearing the transition deadline, the UK signed a trade pact with the European Union after several rounds of negotiations. With this deal- Trade and Cooperation Agreement (TCA), the movement of persons, goods, services and capitals needs to adhere to rules of both sides. The deal contains provisions for tariffs and quota free trade in goods, however in compliance with the rules of origin. Also, the deal has sector specific annexes covering automotive, chemical, pharmaceutical, organic products and wine sectors. However, both sides agreed to negotiate on market access for financial services outside the deal and hoping to achieve a MoU on regulatory cooperation in financial services by March 2021. It is to be noted that UK establishes its own emission trading system from 1 January 2021.

While the UK prepared to formally leave the EU, it signed a free trade agreement with Turkey to continue free flow of goods and protect its existing business with it. It is set to benefit the automotive, machineries, iron and steel sector of UK whereas the Turkey side focus is on precious metals, vehicles, textiles and electrical equipment. Further, the two countries agreed to expand the scope of this agreement to include services and agriculture in two years. It is to be noted that UK has negotiated deals with Japan, Canada, Switzerland and Norway earlier.

UK Signs FTA With Turkey



African Free Trade Bloc Commences



Creating One African Market

Due to Covid-19 pandemic situation, the African countries delayed the trading in the region under the African Continental Free Trade Agreement (AfCFTA). However, 1 January 2021 marks the beginning of African trade under AfCFTA. Currently, 54 of the 55 African Union member states except Eritrea have signed and 34 countries have ratified the agreement. Such countries are Angola, Burkina Faso, Cameroon, Central African Republic, Chad, Côte d'Ivoire, Congo, Djibouti, Egypt, Eswatini, Ethiopia, Niger,

Equatorial Guinea, Gabon, The Gambia, Ghana, Guinea, Kenya, Lesotho, Mali, Mauritania, Mauritius, Namibia, Nigeria, Rwanda, Saharawi Arab Democratic Republic, Sao Tome and Principe, Senegal, Sierra Leone, South Africa, Togo, Tunisia, Uganda, and Zimbabwe. Experts say that it may take decades to reap the full benefits of such agreement, however the start of the process would boost intra-African trade. Also, it will enable integration of regional value chains in the African region.

Bangladesh And Bhutan Agreed Towards Signing A PTA



Both the neighbours of India has finalised terms for signing a preferential trade agreement. After signing the deal, Bhutan would get duty free access to 34 products including fruits whereas Bangladesh would get such benefit for 100 different goods including garments, processed agricultural goods and electronics. Further, Bangladesh is looking to sign a FTA with countries like Sri Lanka, Thailand, Turkey and others as it getting close to graduating from the least developed countries status.

POLICY/REGULATORY BRIEF

INDIA

Environment Ministry Sets Up National Authority To Regulate Carbon Markets



In order to coordinate India's response on climate change matters, the Ministry of Environment, Forest and Climate Change (MoEFCC) has announced the setting up of high-level inter-ministerial Apex Committee for Implementation of Paris Agreement (AIPA). AIPA is entrusted to function as the national authority to regulate carbon market in the country. It would be headed by the Secretary of MoEFCC as the chair and its membership includes various ministries like finance, agriculture, science and technology, energy, commerce, power, health, water, rural development, housing and urban affairs, external affairs along with Niti Aayog. AIPAs main function is to coordinate and report on Nationally Determined Contribution (NDCs) to the respective forums. It would develop policies, and programmes and monitor and report on India's initiatives on climate action in terms of its international obligations. As the national regulator, AIPA would provide guidelines on carbon pricing, market mechanisms and other related mechanisms in relation to climate change and NDCs. It would also take into account on private sector's contribution in addressing climate change and may provide guidance to the sector in accordance with nation's climate goals. The setting up of AIPA comes at a crucial juncture as the year 2021 marks the beginning of implementation of the Paris Agreement.

India - USA Signs MoU On IP Cooperation

The Department of Promotion of Industry and Internal Trade (DPIIT) of the Ministry of Commerce and Industry have signed a MoU with the United States Patent and Trademark Office (USPTO), Department of Commerce of the USA on intellectual property cooperation. This MoU would facilitate the two parties to exchange information on best practices and new developments on processes of registration and examination of applications for patents, trademarks, copyrights, GI, and industrial designs. Also, it is to exchange information and extend cooperation on matters like IP systems and related developments, protection of traditional knowledge and implementation of IP rights. It is to enable the parties to exchange experts, conduct training programs.



Ports Sector May Get Overhaul As The Ministry Proposes Indian Ports Bill 2020

To enable and facilitate investments in the port sector, the Ministry of Ports, Shipping and Waterways has issued a draft Indian Ports Bill 2020 for consultations. It is proposed to repeal the Indian Ports Act of 1908. This bill considers providing a conducive environment for the development of ports to augment the lengthy coastline of India. Further, it proposes establishing a regulatory

framework and authority – Maritime Port Regulatory Authority to facilitate the sector. Also, it proposes formulation of National Port policy and plan in consultation with stakeholders. Besides, this bill has taken into account of India's international obligations while it seeks to promote structured growth for the sector.

Authority To Oversee International Bullion Exchanges

Earlier, the Indian government had notified the financial products and services related to bullion under the International Financial Services Centres Authority (IFSCA) Act, 2019. Further, the IFSCA had been given the mandate to operationalise the International Bullion Exchange at the International Financial Services Centre in GIFT City, Gandhinagar, Gujarat. Following which, the IFSCA has issued the International Financial Services Centres Authority (Bullion Exchange) Regulations 2020 in the Gazette. This regulation covers the bullion exchange, clearing corporation, depository and vaults. It also contains details like fit and proper requirements, registration of intermediaries and other persons, maintenance of records and books, etc. It is to be noted that recently, IFSCA has obtained membership of the International Association of Insurance Supervisors (IAIS) which is headquartered in Switzerland.

Transport Ministry Considers E20 Fuel As Automotive Fuel And Co-driver Airbags

The Ministry of Road Transport and Highways is considering the E20 fuel as automotive fuel. The ministry is seeking comments for this fuel which is a blend of 20% ethanol with gasoline for the automobiles and also on the mass emission standards for this fuel. This consideration is intended to facilitate ways to reduce emissions of carbon dioxide, hydrocarbons and also to reduce the oil import bill, thus saving foreign exchange.



In case of airbags, the ministry is proposing to mandate an airbag for passenger seated on the front seat next to the driver. Currently, comments are being sought as the timelines for implementation is scheduled for 1 April 2021 for new model vehicles and 1 June 2021 for existing models.



India- Vietnam Summit

In the third week of December, a virtual summit was held between India and Vietnam wherein the 'Joint Vision for Peace, Prosperity and People' was adopted to guide the Comprehensive Strategic Partnership between the countries. Both sides vowed to work towards human centric globalization while focusing on building reliable, efficient and resilient supply chains. Along with harnessing the 'digital' space, both sides intend to deepen cooperation in nuclear and space technologies, ICT, agriculture, water, healthcare, vaccines and pharmaceuticals, smart cities and start-ups. India would further increase its assistance in Mekong-Ganga Quick Impact Project, ITEC and e-ITEC programmes in diverse sectors. Both sides signed the Plan of Action for period 2021-2023. In total, seven MoUs/Agreements were signed.

Power Ministry Establishes Electricity Rules For Ease Of Doing Business



The Ministry of Power has notified the 'Electricity (Rights of Consumers) Rules, 2020'. This marks a significant step towards ease of doing business as it is the first time such rules on rights to the electricity consumers have been laid down. This rule prescribes time limit for availing a connection depending on the location – metro, other cities, and rural areas. This rule gives clear indication on billing and payment methods, supply, compensation, and grievance redressal mechanism.

assistance granted to sugar exports is set to expire by 2023 as per WTO obligations. Hence, the government is looking at ways to increase the production of fuel grade ethanol. As relying only on sugarcane is not a sustainable option, the government is encouraging the production from cereals – rice, wheat, barley, corn, sorghum and other products like sugar beet for ethanol. It is also seen as a way to increase farmers' income in the country. Hence, the modified scheme contains various provisions which facilitate setting up distilleries.

NITI Aayog launches Vision On Public Health -2035

Ethanol Distillation Receives A Boost



The existing scheme to facilitate ethanol distillation in the country has been modified. Initially, the 20% blending of fuel grade ethanol was fixed to achieve by 2030. However, the government has proposed the target by 2025. Besides, the production of excess sugarcane and sugar needs to be diversified as surplus stocks requires adequate storage spaces and also, there is a need to find an alternate way as the financial



The NITI Aayog has released a white paper on strengthening health systems in the country titled as 'Vision for Public Health Surveillance in India by 2035'. Importantly, this vision has been formulated by recognizing the threats to public health from re-emerging and new communicable diseases, increasing rates of non-communicable diseases and acute and chronic conditions, and growing anti-microbial resistance. Besides, experiences of India in tackling small pox, polio, TB, HIV and outbreak of vector borne diseases have also been considered for creating this vision. Also, it considered global best practices and experiences of countries like Thailand, Taiwan, Germany, UK, USA and Canada.

It clearly recommends the individual digital health records as the basis for enhancing surveillance. It intends to leverage the Ayushman Bharat scheme particularly focusing on non-communicable diseases and also reducing out of pocket expenses of the public for treatments. This paper maps out India's position in 2035 on public health surveillance as follows:

- India's Public Health Surveillance will be a predictive, responsive, integrated, and tiered system of disease and health surveillance that is inclusive of prioritized, emerging, and re-emerging communicable and non-communicable diseases and conditions.
- Surveillance will be primarily based on de-identified (anonymised) individual-level patient information that emanates from health care facilities, laboratories, and other sources.
- Public Health Surveillance will be governed by an adequately resourced effective administrative and technical structure and will ensure that it serves the public good.
- India will provide regional and global leadership in managing events that constitute a Public Health Emergency of International Concern.

By acknowledging the role of digital platform in surveillance, the vision document envisages the creation of an independent Institute of Health Informatics. This vision document gives a holistic perspective to public health surveillance by emphasizing on inclusion of plant, animal and environmental surveillance. That is, it proposes to develop 'One-Health Approach' inclusive of the focus on anti-microbial resistance. It advises to strengthen the capacity of laboratory with new diagnostic technologies of molecular diagnostics, genotyping and phenotyping. It highlights the importance of Electronic Health Records (EHR) with unique health identifier (UHID) role in public health surveillance. It proposes a Surveillance Information Platform which would store, analyse and generate reports for action. That is, 'information for action' would become available for relevant departments and related stakeholders to address the issue.

In addition, this document suggests seven steps for India to augment public health surveillance with a focus on non-communicable, occupational diseases including mental health problems, approach towards elimination of target diseases, capacity building on epidemic intelligence with citizens being the centre of such action plans. It also suggests strengthening human resource capacity, laboratory infrastructure, referral networks and community-based surveillance. To reach the vision as laid out in this document, it categorically states that execution of public health surveillance policies requires a federated system of governance mechanism between the Centre and States integrated with political, technical, digital and managerial leadership. Thus, this vision would bring the existing health related initiatives, schemes, and policies operating in vertical silos at different levels under the broad framework and facilitate the flow of information between relevant stakeholders in identifying and addressing public health related problems in the country with citizens being at the core.

Ministry of Ports, Shipping And Waterways To Develop Specialized Warehouses

The ministry is intending to create product specific warehousing facilities near ports and multi modal logistical parks. Such warehousing spaces would reduce the cost of storage, and other logistical difficulties faced by the manufacturers and supply chain handlers. The chosen products for specific warehousing near ports and alongside Inland Waterways are cement silos, liquid tanker, chemical tankers, cold/refrigerated storage, electronics product storage, pharmaceutical storage, auto spares parts & components storage and lastly, any other suggested format of warehousing space. In order to facilitate such creations, the ministry intends to handhold the industry as required to undertake and build such infrastructures. The ministry is executing this initiative under its Sagarmala Programme to increase infrastructure capacity which would further enhance 'ease of doing business'.

GLOBAL POLICY UPDATES

Australia Proposes Amendments To The Designs Act



An amendment has been proposed to the Designs Act 2003 in the Australian Senate titled as 'Designs Amendment (Advisory Council on Intellectual Property Response) Bill 2020'. The bill has been proposed based on recommendations from the Advisory Council on Intellectual Property. The key features are identified to be introduction of grace period, prior use infringement exemption, provisions for an exclusive licensee to undertake infringement proceedings as such proceedings so far could only be initiated by the registered owner of the designs, definition of familiar person, deferred publication and other changes. It is likely to be adopted by the end of 2021.

China: Traceability Of Medical Devices Commences

In 2019, the Chinese regulator for medical products, NMPA (National Medical Products Administration) had mandated the requirement of UDI in medical devices by October 2020. The regulator had identified 69 types of devices for compulsory listing of UDI.



UDIs make it easier to carry out recalls in an increasingly challenging operational environment.

These devices are 'high risk' category which have been classified as class III medical devices as per the Medical Device Classification Catalogue. However, the NMPA announced an extension of its implementation date to 1 January 2021 due to disruptions caused by Covid-19 pandemic situation. As of date, these 69 devices that are manufactured from 1 January 2021 require to carry a UDI. Thus, long awaited traceability system for medical devices has begun in China. (UDI stands for Unique Device Identification for medical devices which are a part of harmonization process in the field of medical devices by the International Medical Device Regulators Forum (IMDRF)).

China Notifies Measures On Security Review Of Foreign Investments

China has notified the regulatory guidance related to foreign investments in December 2020 titled as 'Measures on Security Review of Foreign Investments'. This has been issued by the National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM). This measure is scheduled to take effect on 18 January 2021. Through this measure, the regulatory authority would be established under the NDRC.



The following industries are identified to fall under the ambit of this measure including defence, agricultural products, energy and resources, equipments, infrastructure, transport, cultural products and services, IT, internet products and services, financial services, key technologies, etc. Experts say that the list of industries have been expanded and suggests investors to pay attention to the inclusion of terminologies like 'other means, directly or indirectly' in People's Republic of China.

EU Upgrades Digital Services Rules



As a part of shaping its digital future and economy, the EU has announced updates to the rules governing the digital services rules. The European Commission has proposed two legislations at the European Parliament – Digital Services Act (DSA) and Digital Markets Act (DMA).

DSA concerns online intermediaries and platforms like online market places, social networks, content sharing platforms, app stores, online travel and accommodation platforms. According to the EU, the main concern is to address issues of trade of illegal goods, services and content online, spreading of disinformation, etc. DMA is set to address the large platforms that have emerged between business and consumers, thus acting as gate keepers. The EU finds them as private rule-makers with an ability to influence the internal market. Hence, to ensure safety and open online platform availability to everyone, the EU has proposed these legislations for consultations.

OPINION COLUMNS

Cybersecurity: EU Strategy To Secure Future/Digital Economy

Policy Matrix
Manonithya



As the world is witnessing exponential growth in data systems, AI, electronic systems, IoT, and other cross-cutting technologies and their penetration in every sphere of economic and social life of human beings, cybersecurity has become integral part of daily life. It may range from protection of personal data, operation of industrial systems or house hold articles. With Covid-19 pandemic, the digital industrial landscape of EU like other countries has got intensified. It also widened the IT related objects falling under vulnerability scale of cyber threat. Further, such threats have the potential to disrupt international stability and order.

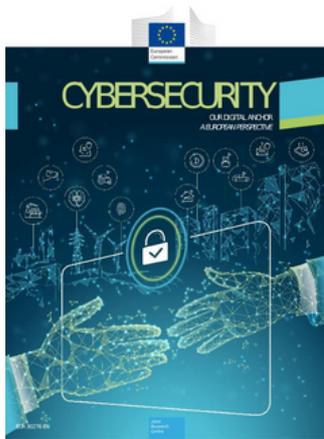
The EU recognizes the cyber threats to personal freedom, business, and nation states and any hit on critical digital infrastructure world have a direct negative impact on economy, disruption of daily life, block on government functions, thus leading to distrust and weaker societal ethos. Given this situation, the EU identifies the lack of

human resources with cybersecurity skills, inability of MSMEs to handle such threats, and also recognizes lack of information sharing on cyber attacks among the EU member states and its institutions. Hence, it considers that improving Cybersecurity mechanisms is essential to benefit from IT related innovation, connectivity and automation business.

As a result, in December 2020, the EU proposed a new 'The EU Cybersecurity Strategy for the Digital Decade' to the European Parliament and the Council. It is regarded as a critical component of shaping EU's Digital Future, Recovery Plan for Europe and the EU Security Union Strategy. This aims to ensure trustworthy and secured digital services and products to conduct business. It considers this strategy to facilitate its leadership at the global space on cybersecurity aspects to promote an open, stable, and secure cyberspace echoing the EU principles of law, human rights, fundamental freedom and democratic values. This strategy includes a framework for regulatory, investment and policy initiatives to be taken by the EU over the course of this decade.

The EU proposes to revise its Network and Information System (NIS) Directive to strengthen sectors like energy, transport and health as it plans to increase its investment in key areas like AI, encryption and quantum computing. The European Commission (EC) is considering horizontal rules which would be applicable on all products and services placed in the internal market. Such a move would have an impact on connected device manufacturers and users as Cybersecurity rules for all vehicle types would be fully implemented by July 2022.

To avoid market concentration of DNS service provided by non-EU entities and to diversify, the EC is looking at developing a public 'European DNS Resolves Service - DNS4EU'. It is to be noted that the EU advocates for an open and global internet space. Further, to reduce dependency on non-EU countries for critical technologies, it intends to pay attention to developing proposed Cybersecurity Industrial Technology and Research Competence Centre and Network of Coordination Centres (CCCN).



The EU would establish 'Joint Cyber Unit' as it seen as an instrument to complete the European Cybersecurity crisis management framework. This unit is considered to address the lack of platform wherein public agencies can collaborate with private sector to forge an operational cooperation and assist mutually in tackling cyber threats and incidents. It is also looking at strengthening the existing Cyber Diplomacy Tool Box so that it may have the provisions of restrictive measures for listings under the horizontal sanctions regime against cyber attacks.

In addition, the EU realizes the importance of international standardization in the rapidly advancing technologies and also notices that such standardization is being used by other countries to cater their political and ideological agenda. Hence, it intends to focus on its leadership role and it intends to achieve through proposal of its 'Programme of Action to Advance Responsible State Behaviour in Cyberspace (PoA)' in the UN

Implications: Firstly, on digital products and services level, it is to be noted that the EU intends to step up its role in international standardization process on digital services and products.

The other countries may want to keep a close watch on standardization process as it may lead to internalization of such international standards in their domain. As a result, the focus may extend to conformity assessment procedures, and related activities. Also, the EU plans to revise its NIS Directive and may notify related measures and hence, manufacturers and exporters of IT related products and services may face an increase in certification requirements. Further, the EU favours open and global internet and hence, slight variations may emerge in the preferred digital products and services in the EU internal market. Hence, the trading partners of EU may engage with their domestic industry to develop or update their strategy on cybersecurity related aspects as it would enhance their participation in international standardization process. Simply put, any measures to strengthen cybersecurity may require businesses to adapt and hence, resulting in increase in cost in supply chains.

Secondly, as the EU may seek greater cooperation at the UN level or regional level, the other countries may want to formulate or update its position on matters of cybersecurity. Also, the EU may increase its engagement with regard to Budapest Convention on Cybercrime. India is not a party, however countries other than EU members like Australia, US, Canada, Argentina, Japan, Philippines, Sri Lanka, Peru, Chile, UK, Turkey and Ukraine are party to this Convention. Hence, any EU suggestion at the Convention may have a ripple effect. Given the nature of technologies, along with the nation states, it is imperative for business to keep a tab on such developments.

(The writer is a Senior Research Analyst)

Global cybersecurity market is predicted to grow from 167.1 billion USD in 2019 to 248.26 billion USD by 2023, with CAGR at 10.4% - Statista

COVID-19 Medicine And Vaccine Development: Regulatory Support

Anatomy of a Regulation

Aishwarya



The global scientific community and the pharmaceutical industry were asked to respond urgently to the COVID-19 pandemic. As a result, the worldwide endeavour to create a safe and effective COVID-19 vaccine is finally beginning to bear fruit. As on 30 December, eight vaccines have now been authorized around the globe, while more than 50 remain in development. This article focuses on the third pillar involved in this task- the regulators.

Regulatory Support: Manufacturers of vaccines, medicines, diagnostic tests and medical devices have to obtain approval from regulatory authorities before these can be used on the general public. The unprecedented experience of the COVID-19 pandemic has demonstrated that countries' ability to ensure availability of medicines and facilitate their development is currently limited. Many countries had to resort to ad hoc measures to manage the crises. Nevertheless, regulatory authorities around the world have taken steps to create a supportive and conducive environment for the development and approval of medicines and vaccines.

Considering the urgency of the situation, 'Emergency Use Authorisation' has emerged as the tool to ensure access to vital medicines and vaccines.

European Union: For COVID-19 medicines, the European Medicines Agency (EMA) is employing an expedited procedure, called 'rolling review', a regulatory tool that speeds up the assessment of a promising medicine or vaccine during a public health emergency. Normally, all data on a medicine's effectiveness, safety and quality and all required documents must be submitted at the start of the evaluation in a formal application for marketing authorisation. In the case of a rolling review, the EMA reviews data as they become available from ongoing studies.

EMA has also put in place a dedicated expert task force- COVID-19 Task Force (ETF) which offers informal consultation and rapid scientific advice. COVID-19 vaccine developers may receive from them, prompt guidance and direction on the best methods and study designs to generate robust data. On 21 December 2020, the EMA announced its recommendation to grant a conditional marketing authorisation for the vaccine Comirnaty, developed by BioNTech and Pfizer. Based on this recommendation, the European Commission then granted a conditional marketing authorisation for Comirnaty, making it the first COVID-19 vaccine authorised in the EU. This authorisation is legally binding across all Member States.

Brazil: Brazilian Health Regulatory Agency (ANVISA) issued a Normative Instruction^[1] that establishes the procedure for the continuous submission of technical data for the registration of vaccines for Covid-19. This is a differentiated procedure to allow the analysis of the data on Covid-19 vaccines as they are generated and presented to the Agency, aiming at a later submission of registration when filling out the necessary regulatory requirements.

[1] Normative Instruction number 77, 17 November 2020

Thus, Brazil has ensured that the regulatory resources are directed towards applications for COVID-19 vaccines and fast-tracked the approval process without compromising on the usual quality and safety requirements.

India: The drug regulations (Drugs and Cosmetics Act and Rules) do not have provisions for emergency use approval. However, the pandemic led authorities to issue such approvals over the last few months. The CDSCO granted emergency or restricted emergency approvals to Remdesivir and Favipiravir for COVID-19 treatment in June and Itolizumab in July. So far, applications for emergency authorisation have been submitted for three different vaccines. A panel of experts is reviewing the applications and pending its clearance, the Drugs Controller General of India (DCGI) is expected to grant final approval for emergency use.

What Next? Once vaccines are approved, ensuring the right people get the vaccine at the right time is one of the upcoming challenges. This is where the presence of robust and comprehensive health information systems will aid the government in identifying the critical-need population in a timely manner. According to the COVID-operational guidelines released by the Ministry of Health and Family Welfare, the COVID Vaccine Intelligence Network (Co-WIN) system, a digitised platform, will be used to track the enlisted beneficiaries and the COVID-19 vaccines on a real-time basis. It specifies that the latest electoral roll for Lok Sabha and Legislative Assembly elections will be used to identify the priority population over the age of 50. Transparency in the formal distribution systems and keen regulatory oversight shall be key to offset the less spoken-about challenges: skepticism, distrust, theft and corruption. As the world steps into the second year of this pandemic, countries' logistical and administrative capabilities will continue to be tested. One hopes that India proves up to the task.

(The writer is a Research Associate)

Single Use Plastics: A Global Concern

Between The Lines

Anjali Chauhan



A wrapper on a candy bar, a plastic bag to carry takeaway, a straw in iced coffee seem harmless when taken individually. These modern conveniences are so omnipresent and used so widely that we hardly register them in our minds. It is impossible to visualize today's world without plastic. Due to its versatility, affordability and durability, plastic is found in a number of applications including clothing, machinery, construction, electronics, transportation, agriculture and packaging contributing most of the demand for plastics. Although, badly managed waste plastics are significant sources of plastic entering the environment, whether from littering, illegal dumping or escaping from waste management systems.

Single Use Plastics (SUPs) are particularly problematic as they are designed for one use. These are often used for convenience or 'on the go', where there is a high risk of not being disposed properly, and entering the environment having a detrimental impact on our oceans, wildlife and our health. Examples of SUPs include straws, cotton buds, drink stirrers, tableware

(plates, trays, bowls) and cutlery, produce bags, plastic cups and lids etc.

In the recent years, increasing public awareness on the concern of plastics pollution has led to the implementation of numerous waste prevention policies across the world. As per United Nations Environment Programme (UNEP) 2018, 127 out of 192 countries (about 66%) have adopted some form of legislation to regulate plastic bags as of July 2018. Plastic bags regulations include restrictions on the manufacture, distribution, use, and trade of plastic bags, taxation and levies, and post-use disposal. 27 countries have instituted taxes on the manufacture and production of plastic bags while 30 charge consumers fees for plastic bags at the national level. 43 countries have included elements or characteristics of extended producer responsibility for plastic bags within legislation. 63 countries have mandates for extended producer responsibility for single-use plastics, including deposit-refunds, product take-back, and recycling targets.

According to UNEP, as of July 2018, eight out of 192 countries worldwide (4%) have established bans of microbeads (solid plastic particles) through national laws or regulations. These countries include Canada, France, Italy, Republic of Korea, New Zealand, Sweden, United Kingdom of Great Britain and Northern Ireland, and the United States of America. An additional four countries including Belgium, Brazil, India, and Ireland - have proposed new laws or regulations banning microbeads at the national level. The Ministry of Environment, Forest and Climate Change (MoEFCC), India is currently working on the definition and the list of products to be covered under SUPs.

Acknowledging the global concern of increased use of plastics, countries across the globe have become very active in this area. Addressing the issue of SUPs was seen as one of the major highlights at the World Trade Organisation (WTO). A number of notifications were issued in the last few months of 2020 which concerned various aspects for controlling the plastics in the environment. Some of the steps taken globally towards a SUP free environment are described below.

New Zealand: In November 2020, New Zealand issued a consultation document to seek feedback on two proposals related to plastic design, use and disposal. The report sets out recommendations to reduce the impact of plastics on the environment, yet retain some of the benefits that plastic offers to modern society. Through Proposal 1, the Government is looking to move away from hard-to-recycle plastics, starting with a phase-out of some polyvinyl chloride (PVC) and polystyrene packaging and all oxo-degradable plastic products. This is part of a long-term shift toward a more circular economy for plastics where packaging materials are made of higher value materials that are easier to recycle. This proposal aims to meet its objective in two phases by 2023 and 2025. Through Proposal 2, the Government also seeks feedback on a phase-out of some single-use plastic items. This includes controlling or prohibiting the manufacture or sale of products that contain specified materials for up to seven single-use plastic items. The products proposed are Plastic straws, Plastic cotton buds, Plastic drink stirrers, Single-use plastic tableware (plates/trays, bowls) and cutlery, Single-use plastic produce bags, Single-use plastic cups and lids (not including disposable coffee cups) and Non-compostable produce stickers. This proposal aims to help to encourage reuse, reduce waste to landfill, and minimise harm to the environment from plastic litter. The government proposes to meet its objectives to phase out all these items by 2025 at the latest.

Mauritius: In November 2020, Mauritius notified two regulations concerning control of single use plastic products and banning of plastic bags. According to the regulation on control of single use plastics, no person shall import for home consumption, manufacture, possess, sell, supply or use any non-biodegradable single use plastic product. Such products include Cutlery (forks, knives, spoons, chopsticks), Plate, Cup, Bowl, Tray, Straw, Beverage stirrer, Hinged container, plastic lid for single use plastic product and plastic receptacles of any shape, with or without lid, used to contain food which is intended for immediate consumption, either on the spot or take away and supplied by a food service business.

As of 15 January 2021, the above mentioned single use plastic products will be banned. However, three single use plastic products, namely, plastic tray, plastic hinged container and sealed plastic straws forming an integral part of the packaging of another product will be banned as from 15 April 2021.

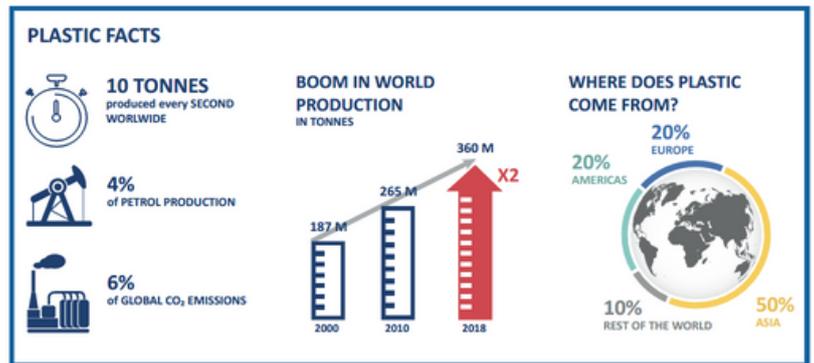
According to the regulation on banning of plastic bags, as of 1 March 2021, the possession, use, distribution, selling, exportation, importation, manufacture or supply of plastic bags will be banned with certain exemptions. The importation or manufacture of an exempt plastic bag or a biodegradable plastic bag or a compostable plastic bag will be subject to registration with the Director of Environment. A Certificate of Registration will be issued which will be valid for a period of three years and will be renewed. Furthermore, the importation or manufacture of a biodegradable plastic bag or a compostable plastic bag will be subject to a clearance from the Director of Environment.

Trinidad and Tobago: In November 2020, it issued a draft standard concerning imported and locally manufactured compostable and biodegradable food-contact, single-use tableware, packaging, products and materials, inclusive of cutlery, plates, straws, cups, and other disposable food and beverage containers and associated lids. The standard outlines the compulsory requirements for the aforementioned products and packaging as well as the mechanisms to demonstrate compliance to these requirements and also includes measures to be taken in the event of non-compliance.

China: In November 2020, China issued requirements for restricting excessive package in case of foods and cosmetics. The standard majorly specified the terms and definitions, requirements, detection, and rules for restricting excessive packaging of food and cosmetics. It is applicable to the sales packaging of food and cosmetics, and it is not applicable to gifts or products not for sale. As per the standard, the number of packaging layers for grains and its processed products should not exceed three layers and should not exceed four layers for other commodities.

Way Forward: Globally, there are multiple ongoing efforts on the reducing and recycling of plastic products but not all countries have specific legislation in place to ensure control on producers or manufactures to address waste minimization, adopt recycling targets or charge enough to restraint the purchase of plastic products. Adopting determined legislations regulating plastics, would allow achieving a sustainable environment. However, individual choices and the collective shifts add up quickly. Making just one simple swap, like purchasing a reusable water bottle, can spare the environment hundreds of plastic bottles each year.

(The writer is a Research Associate)



Countries that have banned or are in the process of banning single-use plastics



“Transitioning to more eco-friendly alternatives can be a lengthy process. In the meantime, strengthening circular thinking and waste management systems can successfully help in reducing plastics pollution.” – United Nations Environment Programme (UNEP)

Medical Tourism In India

Policy Dimension

Himani



The world has witnessed people travelling across the globe for treatment. The term 'Medical tourism' is usually defined as the act of travelling to foreign country for receiving medical treatment. The Organization for Economic Co-operation and Development (OECD) defines the medical tourism as when "consumers elect to travel across international borders with the intention of receiving some form of medical treatment". Originally, this was referred to the movement of patients from less developed countries to developed nations for getting treatments not available in their own country. But, now this movement is also affected by the relative low cost treatment availability in less developed nations, availability of cheap flights and increased availability of online information related to availability of medical services.

The Medical tourism is among the sectors experiencing the fastest growth in recent years. Patients across the globe are looking for better treatment across countries which can be combined with a nice vacation.

Some of the leading destinations for medical tourism include Canada, Singapore, Japan, United Kingdom, Dubai and India.[1] The medical tourism concept has been boosted with the constant growth of globalisation. This has also been uplifted by international trade in health services. Other impacting factors include unavailability of certain specialists or state of the art treatments or the long waiting list.[2] The factors that can affect the growth of this sector negatively may include communication barrier, counterfeit or poor quality medication of some countries, antibiotic resistance and risk of blood clotting due to flying after surgery.

As per the reports, the global market size for medical tourism was accounted for USD 44.8 billion in 2019 and is expected to grow with a 21.1% compound annual growth rate (CAGR) between 2020 to 2027.[3] However, a flattened growth curve has been observed due to the imposed lockdown and ban on international flights during the COVID-19 pandemic. However, with suspension of these bans slowly, the medical tourism sector will soon sustain its growth.[4]

Scope of Medical Tourism in India: Over the past few years, India has become the favoured destination for medical tourism. With this, the growth of medical tourism was expected to worth 9 billion by 2020, but the COVID-19 pandemic changed the scenario. Nevertheless, India Tourism Development Corp. (ITDC) claims that India will sustain the growth of this sector faster than some of the developed nations of Europe as well as USA due to better handling of the situation.

India has been experiencing rise in medical tourism not only due to the modern medical practices but also includes traditional practices like Yoga, Ayurveda, Panchakarma, Rejuvenation Therapy, etc. which helps in providing overall wellbeing and health. Further, this growth has been supported by the low cost treatment availability in India, cheap tourism, less waiting time, availability of qualified doctor, easy medical visa processing and English speaking doctors, thus reducing the language barrier. It is clearly

[1]<https://www.magazine.medicaltourism.com/article/top-10-medical-tourism-destinations-world>

[2]<https://thedope.news/why-medical-tourism-is-booming-in-india/>

[3]<https://www.grandviewresearch.com/industry-analysis/medical-tourism-market>

[4]<https://www.medgadget.com/2020/11/global-medical-tourism-market-size-to-worth-usd-65-79-billion-by-2025.html>

Medical Treatment	Cost required to be invested for procedures (\$)					
	USA	India	Thailand	Poland	Mexico	UK
Heart bypass	113,000	10,000	7,140	13,000	3,250	13,021
Hip replacement	47,000	9,000	12,000	6,120	17,300	12,000
Breast implants	6,000	2,200	2,600	2,200	2,500	4,350
Knee replacement	48,000	8,500	10,000	6,375	14,650	10,162
Heart valve replacement	150,000	9,500	11,000	9,520	18,000	-

Source: Research Article: Medical Tourism: An Emerging Terrain with Covid-19[5]

evident from the above Table that India is among the countries providing low cost treatments together with Mexico. The OECD has also stated that a patient in USA can save approximately 30-50% of treatment cost from common ailments by traveling to Asia or Latin America. Above all this, the policy outlook of India for medical tourism is also boosting the sector like a visa- on arrival system from few countries has been facilitated by the Indian government.

The sector comes under category of niche tourism in India. The Government of India has constituted a 'National Medical and Wellness Tourism Board' which provides a framework for promotion of the medical and wellness tourism which also includes Ayurveda and other medicinal system of India covered by Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH). Further, a healthcare portal[6] is also functional which was launched

by the Department of Commerce and Services Export Promotion Council (SEPC) to provide a single source platform for all the relevant information to medical travelers on the top healthcare institutions in the country in English, Arabic, Russian and French. Despite this, India has to build a strong regulatory framework for this sector and requires more government initiatives supporting traditional medical system of India for becoming the leader in the medical tourism sector. As the vaccination drive for Covid-19 has already started in many countries including India, the sector may revive in the later part of 2021.

(The writer is a Research Analyst)

[5]<https://www.longdom.org/open-access/medical-tourism-an-emerging-terrain-with-covid19.pdf>

[6]www.indiahealthcaretourism.com



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