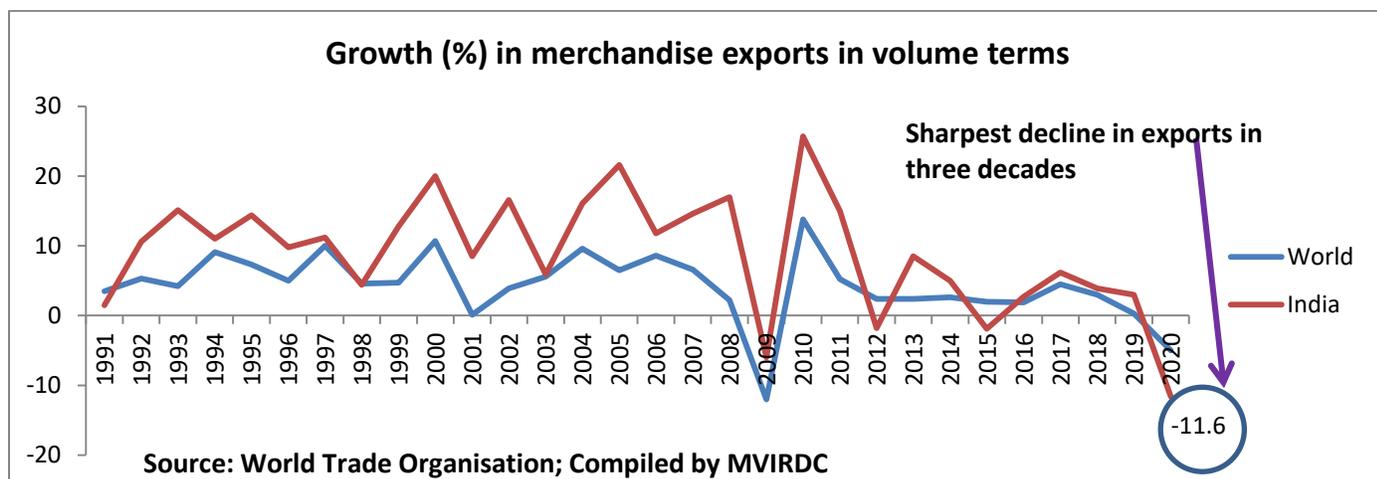


Memorandum for promoting India's Exports

Background

The COVID crisis has tested the resilience of Indian exporters like never before. India's merchandise exports declined a whopping 11.6% in volume terms in the calendar year 2020 and it is more than double the decline in world exports of 5% during this year. This suggests that India's export is more vulnerable to global shocks than the world exports, in general. As the following chart illustrates, India's export has been more volatile and vulnerable after 2009, as can be seen from sharper growth and declines as compared to the period before 2009. India's exports contracted (-6%) for the first time in 2009 (amidst the global financial crisis) in the last 30 years, since India's economic reforms of 1991. Since then, this negative growth repeated in three years, viz. in 2012 (-1.8%), 2015 (-1.9%) and 2020 which witnessed the sharpest ever decline of 11.6%.



On the other hand, India's exports of commercial services has not fallen as much as the world exports, which indicates its relatively less vulnerability compared to merchandise exports. India's commercial services exports declined 5% in 2020 compared to 20% fall in world commercial services exports.

Primary Survey

MVIRDC World Trade Center Mumbai conducted a primary survey with manufacturers, merchant exporters and export consultants to understand the challenges faced by the local industry in exporting

their products. The survey was conducted with around 70 participants, who include both existing and aspiring exporters, officials from MSME Development Institutes, EXIM consultants and academic researchers on foreign trade.

Based on our interaction with the survey participants, we could identify the following challenges faced by exporters.

Poor Demand: Since the outbreak of the COVID crisis, demand for handloom and handicraft products declined significantly. In the absence of brisk sales, both in the local and foreign market, manufacturers are holding excess inventories. The rising inventory has prevented manufacturers from starting new production cycle and this is threatening the livelihood of many labourers in tier II and tier III cities. For instance, many weavers in the Kinnauri district of Himachal Pradesh are struggling to sell their stole, muffler, salwar suit and other handmade woolen textile because of lack of demand in the market.

Virtual trade fairs: International trade fairs and exhibitions are not being held in the physical format amidst travel restriction in this pandemic circumstance. Therefore, exporters are unable to find new markets and buyers. Even though there are virtual trade fairs being held by different organizations, exhibitors are not receiving sufficient orders from visitors in these virtual trade fairs. As a result, export of handicrafts and handloom products has taken severe hit.

Challenge in accessing bank credit: On account of the uncertain economic environment, bankers are hesitant to extend unsecured loans to small scale manufacturers. On account of poor sales, weavers do not have sufficient funds to procure raw materials and maintain the production cycle. The government should provide interest-free loans to weavers so that they can continue their next production cycle. This will help save livelihood of these weavers.

Rising input cost: The cost of raw material has risen in the last few months. For instance, textile manufacturers informed that the cost of cotton has increased by Rs. 200 per kg in the last few months. A manufacturer-cum-exporter of furniture in Rajasthan raised concern about rising cost of logistics and raw materials. The manufacturer uses wood, stainless steel, rod and pipes as raw materials, the cost of which have risen in recent months. Also, the manufacturer faces shortage of labourers as migrant workers are heading to their hometown amidst COVID pandemic.

Promote tribal artists: There are many lesser known artists and designers who work directly with tribal weavers to promote the latter's arts in the local and global marketplace. The central and state governments should support these artists and designers who directly work with tribal weavers. These artists and designers need subsidy to participate in local and international fashion shows.

Need assistance in partnering with foreign distributors: Manufacturers of carpets, rugs and durries suggested that they need the support of India's trade mission abroad in tying up with distributors of their products in foreign countries. Often, Indian manufacturers find it difficult to identify reliable distributors of their products in foreign markets. Therefore, they seek the support of Indian trade mission abroad in getting in touch with the right distributors.

Need for awareness workshops: Many small scale manufacturers are not aware of the government schemes and initiatives to support MSMEs and exporters. Many survey participants were clueless about the Government e-Marketplace (GeM), which is a portal through which manufacturers can participate in government procurement. Awareness is also lacking on other initiatives such as the launch of Champions portal, to address challenges of MSMEs related to finance, raw materials, labour, regulations etc.

Provision of looms/workshed: In Assam, many women are skilled in handloom weaving. However, these weavers have to travel to faraway places and work for wages in large handloom units. If government provides looms or workshed to the household of every weaver, then these weavers need not travel faraway places and work for wages in others' handlooms. Instead, they can weave at their own homes and sell in the local and foreign market. The government should also support these weavers by facilitating access to cheap raw materials (such as cotton). Also, training programs must be conducted for these weavers to sell their products in the domestic and foreign market through e-commerce.

Lack of awareness about authentic handloom products: The cost of handloom product is far higher than the cost of powerloom products as the former is totally handmade and it takes more time to weave by hand. Manufacturers of powerloom textile are selling their products at low cost in the name of handloom products. Naïve buyers, who are not aware of the difference between handloom and powerloom products, buy powerloom products at low cost assuming that they are handloom products.

Need mentorship: Many aspiring exporters feel that they need training and handholding support from MSME Development Institutes and the District Industries Centers (DICs). One of the aspiring exporters in Mumbai said she got order from a West Asian country for supply of bio-compostable carry bags. However, she could not fulfill the order as she was not familiar with the procedures for exports. The government should create awareness in each and every district about the documentation procedures and regulations governing exports. The field offices of the Ministry of MSME and the District Industries Centers should collaborate with local trade associations to conduct training workshops on foreign trade and global quality standards. Aspiring exporters also need guidance on identifying potential foreign markets for their products.

Promising Destinations

India's overall merchandise exports declined 7.2% in value terms in the financial year 2020-21. At the same time, exports to around 32 countries witnessed remarkable growth during this period. This reflects the potential for diversification of India's exports to these 32 countries in the coming years. The most prominent among them is China, to which India's exports grew 16% to USD 16.8 billion in April-January 2020-21. Some of the new products exported by India to China are flat rolled steel products, vannamei Shrimp and naptha during this period.

Other prominent countries to which India's exports increased in April-January 2020-21 are: Australia (37%), Indonesia (9%), Switzerland (6%), Oman (5%), Bangladesh (1.4%) and New Zealand (24%). Exports to Australia grew because of rise in shipment of automotive diesel, pharmaceuticals, diamonds, textile furnishing materials, carpet, rice etc.

Similarly, Portugal (11%), Ghana (32%), Yemen (10%), Uganda (7%) and Venezuela (165%) are among the 32 countries where India's exports grew during the above mentioned period. The sharp increase in India's exports to Venezuela is led by growth in shipment of automotive diesel, pharmaceuticals, rice and cotton fabrics.

Africa is the region where India's exports saw growth to most number of countries. Some of them are: Benin (49%), Senegal (32%), Cote D'Ivoire (26%), Guinea (36%), Congo (5%), Malta (58%), Madagascar (10%), Djibouti (13%), Tunisia (3%), Cameroon (16%) and Burkina Faso (29%).

Among European countries, Greece (5%), Ireland (2%) and Hungary (12%) were major destinations to witness growth in India's exports besides Portugal and Switzerland as mentioned above. Exports to Hungary grew in double digit because of rise in shipment of radio navigational aid apparatus, air compressors and organic chemicals.

Sectoral Challenges and Suggestions

India exports around 30 principal commodities to various nations annually. Among them, India has witnessed double digit export growth in ceramic products, organic chemicals, agro-chemicals, accumulators & batteries and electrical machinery since 2015-16. Therefore, the new Foreign Trade policy may identify these champion export sectors and provide incentives to increase scale of production and strengthen our global competitiveness further.

At the same time, certain other manufacturing sectors need specific policy intervention to address the challenges unique to these sectors. India can promote export in these sectors if policymakers, industry associations and academia work together in addressing challenges faced by exporters of following goods, where there is substantial potential to grow exports.

Engineering goods

Engineering goods account for 26% of India's merchandise exports and India has competitive advantage in many sub-segments of this sector. Despite overall merchandise exports declining 7.2% in FY21, engineering exports managed to post just 2.6% contraction, which shows the resilience of this sector.

Engineering goods include a wide gamut of sectors, ranging from iron and steel, machine tools, industrial machineries, electrical machinery, automobiles, aircrafts, ships, boats and floating structures, among others.

Industrial machinery is one potential sector where exports can grow with focused policy intervention such as supply of raw material at reasonable cost, access to export credit and uninterrupted power

supply. India's export of heavy industrial machineries used in textile, paper, chemicals and cement manufacturing grew a whopping 82% since 2011-12. Export of these machineries grew from USD 447 million in 2011-12 to USD 816 million in 2019-20. Specifically, India witnessed sharp growth in export of water tube boilers, machinery for sealing bottles, machinery for heating, cooling and sterilization, injection moulding machines and parts used in textile machinery. Despite growth in exports, our share in world export of these machineries is hardly 2%, which reflects untapped export potential.

Suggestion: A major challenge faced by this industry is the sharp increase in price of raw materials such as steel, copper and aluminum. Government should ensure that these exporters are able to access raw materials at reasonable cost so that they remain competitive in the global market.

Man made textiles

Synthetic textile and readymade garments are potential sectors of export growth after cotton textiles. Synthetic textile and readymade garments account for 25% of total textile export of the country. Of these, synthetic yarn, fabric and made-ups contribute 15%, while synthetic readymade garments contribute the remaining 10%.

India ranks fourth in export of man-made staple fibres, filaments and yarns; but our share in world exports is paltry 4.5%, which signifies untapped export potential. Countries such as China, Indonesia, Taiwan, USA and South Korea are leading in export of these goods.

In the made-up sector, India ranks seventh in export of blankets and travelling rugs, printed bed linen, 13th in table linen and fifth in articles of interior furnishings. In some of these categories, India competes with Spain, Germany, Pakistan, Bangladesh, Mexico and Turkey, besides the export leader China.

India can export blankets, tarpaulin, curtains and shawls to USA, while it can export knitted or crocheted fabrics of dyed synthetic fibres to Vietnam. Bangladesh and Brazil hold market potential for pile fabrics and dyed woven fabrics of man-made fibres.

Suggestion: To realize this untapped export potential, government and industry associations should collaborate in providing marketing assistance, skill development, technology upgradation and enhancing economies of scale. There is also a need to correct the inverted duty structure in the man made textile sector by reducing GST on raw materials.

Wooden articles

It is noteworthy that India has become trade surplus in certain types of wooden furniture products as our exports has more than doubled since 2010-11 to USD 897 million in 2019-20. USA, Netherlands and Germany are the top markets for India's wooden furniture. France, UK, Australia and Canada are also

other major importers of India's wooden furniture. India is also a net exporter of value added goods such as marquetry, caskets, cases for jewellery and similar articles.

At the same time, industry sources feel that imports of wooden articles may grow in the coming years because of preference for global brands, entry of foreign players into the Indian market and lack of skill upgradation by the local wood processing units.

Suggestion: India needs to strengthen the global competitiveness of the local wood processing industry by modernizing local units, re-skilling workers and introducing stringent quality and certification norms.

Bicycle and parts

In the last decade, India became a net exporter of bicycle and components, from net importer. In 2011-12, India had a negative trade balance of USD 96 million, which gradually changed to a positive trade balance of USD 243 million by 2019-20.

Even though India is the second largest producer of cycles, after China, majority of the bicycles produced are of low-end varieties. Local manufacturers do not have the competitiveness to produce high-end light weight bicycles, which is demanded in Europe and USA.

The gap between India and China in terms of production volume is too high, with India clocking 1.72 crore annual production, compared to more than 22 crore by China. Thus, China has the scale economy to manufacture bicycles at globally competitive cost. Consequently, India is not a leading exporter of bicycles as it ranks 24th in world exports, although it ranks among the top 10 exporter of parts and components used in bicycles. World export market for bicycles is US\$ 8.7 billion, where China leads with a share of 33%, followed by Taiwan with a share of 16%. India's contribution to world exports is hardly 1% and this explains the untapped export potential for bicycle alone (excluding export market for parts and components).

Suggestion: Government should support the industry in technology upgradation for producing high-end light weight bicycles that is demanded in advanced countries. India is dependent on import for 15 critical parts used in manufacturing bicycles. There is a need to promote capacity building among local component manufacturers to produce these parts domestically and reduce reliance on imports.

Cotton linen

India exported USD 1 billion worth of toilet linen and kitchen linen, of terry toweling or similar terry fabrics of cotton in 2020. It had a share of 17 per cent in world exports of these products in 2019, second only to China whose share was 37 per cent, other major exporters being Pakistan (12 per cent), Turkey (9 per cent), Vietnam (4 per cent), Portugal (3 per cent) and Bangladesh (3 per cent).

Suggestion: Small and medium enterprises in this sector are unable to compete because of low scale of operation. Government should promote more cluster development, with common facility centers, uninterrupted power supply, effluent treatment plants and supply of cotton at reasonable cost. Small scale entrepreneurs also need guidance on export of these products through e-commerce.

Other Policy Recommendations – Merchandise Exports

India's export sector will have to compete in the global market in a challenging environment. Indian exporters no longer enjoy preferential tariff benefit under GSP from USA, globally countries are resorting to protectionist measures to discourage exports and India has received adverse ruling from WTO on certain export schemes.

In this scenario, we recommend the following measures to be considered for inclusion in the forthcoming Foreign Trade Policy of India:

1. **Design Studios:** Government should promote the setting up of design studios on a public private partnership model by collaborating with the industry. Such design studios should be set up in leather, textile, gems and jewellery sectors. India has the potential to be the global design hub in these three sectors by providing policy thrust on developing innovative designs through these studios.
2. **Establish auction mechanism for cut flowers in Northeast India:** Northeast states in India have great potential for export of cut flowers. Government should set up a facility for physical and online auction of these flowers so that domestic and global buyers can participate in these auctions. India needs to set up a facility for global auction of flowers, similar to the world's largest auction facility in Aalsmeer, Netherlands. The FloraHolland warehouse in Aalsmeer is the largest flower auction hub in the world with sophisticated facilities for cooling, sorting and transporting flowers.

Government of India should set up similar facility in the Northeastern region of India to unleash its untapped export potential.

3. **Organise international festival for Geographical Indications (GI):** India needs to promote export of its traditional goods which are assigned the GI tag in the global market. Government of India has so far assigned GI tag to around 400 products. GI tag certifies the unique properties of products grown in a particular geographical area. Government of India should promote these products by organising GI festival in New York, Paris, London and Tokyo, to start with. As we are about to celebrate the 75th anniversary of India's Independence, we can organise GI festival in these mega cities to create awareness about the traditional Indian products and thus promote their exports.

4. Government should publish foreign trade policy in simple language so that even small exporters can understand the same without having to depend on Customs House Agents or any other Agency.
5. Government should introduce Foreign Trade Policy after having consultation with the customs authority. This will avoid ambiguity or different interpretation of provisions in the policy between DGFT and the customs authority.
6. DGFT should institutionalize its trade education division and create awareness workshops and master classes on foreign trade. DGFT should rope in industry experts as faculty for these classes.
7. Government should expedite the clearance of the application of the brand duty rate so that exporters receive the excess dutydrawback over the prevailing industry rate on time.
8. Government should encourage export of value added goods as it will generate more foreign exchange by giving some additional benefit.
9. Government should set up more Inland Container Depots (ICDs) in districts where there is potential to enhance exports. These ICDs should have dedicated cargo rail connectivity.
10. Government should declare more air cargo terminals as authorised export terminals by introducing customs clearance facilities.
11. Government should develop inland waterways and coastal shipping which both have the potential to reduce logistics cost by 2-3%
12. India's next Foreign Trade Policy should articulate the vision of the government on trade, with more emphasis on trade facilitation, rather than providing trade subsidies.
13. The Foreign Trade Policy can provide WTO- compliant incentives in the following ways:
 - a) Incentivise for onboarding MSMEs into the e-commerce platform
 - b) Incentives for MSMEs to upgrade their technology, adopt Industry 4.0
 - c) Incentives for employees of SMEs to upgrade their skills and other capacity building activities
 - d) Incentives for SMEs to enhance their size of operation and become mid-sized firms
 - e) Incentives for SMEs to integrate into Global Value Chains
 - f) Subsidies against shipping and logistics cost for export by SMEs
 - d) Any other incentives that cannot be challenged in the WTO

e) Government can provide any subsidy against use of services that goes as input in the manufacturing sector. Subsidies given for services inputs cannot be challenged in the WTO

13. **Quality Standards:** Foreign Trade Policy should support agro producers in adhering to global quality standards. In many instances, India's export of agro products have been rejected or banned by foreign countries because of presence of pesticides or other harmful chemicals beyond the permissible limits. Countries such as Indonesia, UAE, Saudi Arabia, Canada, Australia and European Union have their standards for regulating imports of agro commodities. Often, exporters and aspiring exporters are not aware of the health certificates, sanitary and phytosanitary certifications required in the importing country. Government of India should create awareness about these standards among small growers and processors of agro commodities.

Promoting Services Exports

India, which was the 10th largest exporter of services in the world in 2008, has improved its ranking to 8th by 2019, with our share in the world exports growing from 2.7% to 3.5% during this period. The country made remarkable progress in the world service exports since 1997, when our rank was a poor 30th, with the world share of paltry 0.7%.

Today, India is behind seven countries in world export ranking for services and these are USA, UK, Germany, France, China, Netherland and Ireland. Many of these countries are ahead in export of travel, transport, financial, intellectual property and other business services.

Services sector is a critical sector of the economy, not only because it contributes more than 54% to India's economic activity, but also because it accounts for around 40% of India's overall exports. India's services exports declined 5.8% to USD 202 billion in FY21, compared to the de-growth of 7.3% in merchandise exports (to USD 290 billion) during the year. The country earned USD 85.8 billion in surplus through excess exports of services over imports and this is useful to meet most of the USD 98.5 billion deficit arising from trade in goods.

India has a vibrant service industry and it ranks second in terms of size of market for telecommunications, E-learning and legal & professional services. India is also the world's second largest exporter of computer and information services. Service sector contributes around 44% to India's total employment (ILO database). The tourism sector alone contributes 8% to the total employment in the country and it created 39 million jobs in 2019-20.

Challenges

Service sector in India, much like the manufacturing sector, suffers from common challenges such as poor access to credit at affordable interest cost, high cost of electricity, inadequate infrastructure facilities, lack of access to skilled workforce and general regulatory hurdles.

India can improve its position in world services exports from the current 8th rank if we address these challenges through effective policy intervention.

Services Exports - Policy Recommendations

Replace SEIS scheme: The current scheme, viz. Services Export Incentive Scheme (SEIS), does not fully refund taxes, duties and other incidental levies incurred by service exporters in the course of their normal business operations. This makes them uncompetitive in the global market. According to a study conducted by the Services Export Promotion Council (SEPC), service sector exporters incur 5-9% of their export value towards taxes and other levies that are not refunded. Therefore, the government should introduce a new scheme that reimburses all the incidental levies borne by exporters so that they become globally competitive. The government should bring all the 17 prominent sectors under this new scheme. According to SEPC, the new scheme will promote services exports to the extent of 370% of the fiscal cost of the scheme. The new scheme will also bring multiplier effect to GDP and employment creation.

Issue notification on SEIS for FY20: Services exporters are eagerly awaiting the government to disburse SEIS incentives for the year 2019-20. The undue delay in release of SEIS incentive has affected the financial position of exporters, who made investment in their business in anticipation of this benefit. At a time when exporters are reeling from the adverse impact of the pandemic, release of SEIS incentives for FY20 will provide much needed relief for the industry. Therefore, the DGFT should issue notification on release of SEIS incentives to service exporters.

Alignment of goals with other policies

Foreign trade policy, by itself cannot promote globally competitive firms. India should align its other economic policies, viz. industrial policy and government procurement policy to the overall objective of creating globally competitive firms. Our industrial and government procurement policies should encourage innovative product designs that reduces cost of production for manufacturers and brings more benefit for customers/consumers. Particularly, India should encourage innovation in emerging areas such as medical devices, drone vehicles, where the country is dependent on imports, to create local substitutes for the imported products.

In this regard, we suggest the following measures to promote enterprises that are engaged in design innovation and thereby promote India's overall export competitiveness. These measures have been compiled with inputs from FIRST, which is India's leading technology business incubator at IIT Kanpur.

- 1. Eliminate discretionary disqualification:** Design innovation is critical for India to become globally competitive in the manufacturing sector. India needs to support its start-up enterprises that are engaged in design and product innovation by providing them opportunity to bid for government procurement tenders. As per the current rules, a startup does not have to furnish Earnest Money Deposit (EMD) and must get preference in government tenders. However, citing concerns with Public safety, the decision is ultimately left at the discretion of the presiding public officer. This is sad when it happens even after the startup's product is certified by highest applicable Indian standard in the industry.

This public safety concern should rather be certification focused and application focused. In other words, if a start-up enterprise has the required certification, it should not be disqualified from the government tender based on the discretion of the procurement officer.

2. **Allow innovative products in government tender:** Further, new technologies being brought in by the startups allows a particular work, which was earlier done using a traditional process, to be done in a novel manner. However, tender conditions are set in a manner that innovative products – which by definition are not in use at present – are excluded and the startups are disqualified from competing despite having a better solution.

This needs to be looked into. It is not going to be easy but it can be done. May be floatation of a tender can be preceded by issuance of an invitation for Expression of Interest (EoIs) wherein no technical specifications are provided. Once the EoIs are received and there are innovative – unconventional – products, the presiding officer may ask for production of certification from regulatory bodies.

For this, India needs a robust testing and certification regime in every product category. Once such a regime is promulgated, subjectivity will be done away with.

3. **Need conducive policy regime to develop drone technology:** Government of India should address gaps in the regulatory regime that stifles innovation in drone technology by preventing players from operating at scale. The current regulatory regime discourages R&D, which will render domestic drone companies uncompetitive against foreign players five years down the line when the drone operations become normalized in India.

In March 2021, Government of India notified the Unmanned Aircraft System (UAS) Rules, 2021, to regulate research, testing, production, import and usage of drone vehicles.

We highlight the key issues related to these rules and propose necessary measures to address them suitably:

- A. Different Licenses are required at each step of business right from Prototyping/ R&D to Manufacturing of drone, trading of drone, ownership of drone, operating drone, manufacturing parts, importing drone parts etc. Such heavy license requirement does not promote ease of doing business and eventually growth of Industry within.
- B. Effectively, importing drone will require less number of licences when compared to developing and manufacturing drone in India. This kills the spirit of Atmanirbhar Bharat. More hurdles for already struggling drone start-up ecosystem in India.
- C. Licenses are required even for Prototyping and R&D activities. So there is going to be break on in-house innovation and IP generation.

- D. No timeline and procedures are mentioned for applying and granting such license. Digital sky portal as proposed in Dec 2018 is still not active to date and most of the industry is still operating in grey zone. Delay in implementation is promoting illegal use and loss of business for startups seeking compliance.
- E. Drone based deliveries are still banned plus more restriction on payload is imposed. Indian start-ups will again miss the bus for this upcoming largest market segment in drone Industry.
- F. According to the recent norms, licensing has to be done on some locations for establishment of drone ports thus chocking the ease of testing (commercial usage is strictly prohibited unless licensed exceptionally) of the existing UAS that are currently functioning within India. Hence, this puts a negative impact on the upcoming UAS projects which are on the verge of achieving heights.
- G. Even if a start-up comes across several hurdles to gather the respective parts and end up with the final functioning product, they find it difficult to enlist themselves according to the norms. This is so because the Digital Sky portal happens to be the sole portal for NPNT (No Permission, No Take off) functioning; but as mentioned in (Point D), it is a dead-end till date.

While it is understood that drones can pose serious national security risk, it is also true that it can deliver a lot of benefits to the society. The measures above will certainly kill the drone industry while won't be able to completely eliminate the security risks (illegal importation/development etc.). Thus, setting up a regulated industry is a much better option.

Proposal

Impose mandatory software and security features: Government should require all manufacturers of drones to embed software and security features in their drones for tracking and tracing them. This will ensure that the DGCA and the Ministry of Home Affairs can track any violation through this software once commercial operation has started. Operators found violating the set norms of DGCA and/or MHA should be imposed steep penalty and should be subject to cancellation of license. The manufacturer should not be held liable for violation by end users. On the other hand, strong legal action should be taken against the manufacturer if she sells drones without government mandated software or security features. Government can also think of making it mandatory to embed security software or hardware into components of a drone. Proposal along this line was made under DigitalSky NPNT (No permission No Takeoff) proposed in Civil Aviation Regulation (CAR) Dec 2018. According to this regulation, a manufacturer has to get her drone certified by DGCA/QCI for compliance. However, this is yet to be made operational while UAS Rules, 2021 has been promulgated.

In other words – the solution needs to be technological and not bureaucratic. Responsible implementation in timely manner is required from government's end to ensure smooth business for industry to grow. Drone industry is willing to support technology innovations to address the concerns of the government and also to fulfil the dream of India as Drone Capital of the world

- 4. Lack of local regulation for medical devices:** The medical devices regulatory framework has changed from April 1, 2020 wherein it was notified that from October 1, 2021, all medical devices developed in India have to be certified by CDSCO. As on 31st March, 2020, only around 25 medical devices were regulated in India. At present, CDSCO has offered the innovators of medical devices to voluntarily register their products. This makes the start-up firms wonder: “where they will go for a testing procedure? Even if they volunteer, how much of their precious time will it take?”

Further, this would mean that if the regulatory regime has to serve the medical devices industry there has to be a massive scale up of testing and certification infrastructure else. In the absence of adequate testing infrastructure, there will be enormous wait for a device to be cleared for commercial sale which will certainly discourage innovators.

Regulatory landscape for medical devices in India:-

As most would agree, India is not a hotbed of high-end manufacturing companies. We are enamoured by Siemens, GE, Philips, Samsung, Toshiba, Nikon and other international brands. There are very few global Indian brands in this class. This is particularly true for medical devices.

A growing start-up like NOCCA Robotics in their recent “ventilator project” has gone through such hurdles which is an eye-opener for every start-up out there in the Indian market. It stemmed from the fact that there is no regulatory framework for medical devices.

For start-ups of medical devices in India, clearing the regulatory phase is a huge deal. It is seen most of the times that start-ups are unable to commercialize their product within their projected plan. Consequently, a set-back is created within the mindsets of the entrepreneurs who have worked enough and are standing just near to the door of success.

The main issue which they face in India is the lack of access to a proper regulatory framework. We know for certain that in early April last year, the PM issued a directive to the bureaucracies that – to remove all obstacles for manufacturing of critical medical equipments in India. But practically, the challenge strikes for any novice medical device manufacturer in the market -when it comes to the installation of their new product in any of the hospitals whether private or government regulated. This is so because doctors won't allow any non-certified product on their unit (as they are relying on the European (CE) and US (FDA) based certified medical equipment for ages and obviously it is a matter of life and death of any individual). We know that for a start-up to get a global certification it will take at least one year and it is massively expensive, hence they mostly walk through a “regulatory haze” and their project plan gets delayed for a long period of time.

Start-up enterprises from the medical devices sector complain that they need FDA or CE certification to register on GeM platform. Insisting on regulatory certification is a reasonable demand for registration on the GeM portal. But in the absence of an Indian regulatory or certification framework, local entrepreneurs have to rely on foreign certification, which is expensive and time consuming.

Proposal

Let us not re-invent the wheel rather prescribe regulatory norms in keeping with the international standards. We already have internationally recognized organizations such as NABCB, NABL to coordinate roll out of such a regime. However, we must create a lot of testing centres. It will be a success if we utilize our reputed technical education institutions which already have most of the infrastructure needed for the purpose to get accredited quickly and roll out the service. Unless we have a lot of test centres, the start-ups will have to wait for a frustratingly long time to get their products tested and certified which will erode their financial viability.

It is also to be emphasized that all measures must be taken to ensure that any entity, start-up or otherwise, does not adopt short-cut for quality which will hurt brand-India and our products will never become global brands.