RV VeKommunicate

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POLICYPULSE

IN THIS ISSUE

FOREWORD

The world has been responding to the pandemic -COVID-19- that has plagued nearly all countries across continents. Economies have stalled and lives have been lost. This issue of Policy Pulse takes a look at various issues that have arisen because of COVID-19. Besides these, it has also looked at a couple of other issues which are of interest to businesses.

WTO Director General, Mr. Roberto Azevêdo Step Down Early

World Trade Organization (WTO) Director-General Mr. Roberto Azevêdo announced to step down (one year before his term's expiration) effective August 31, 2020 after seven years at the helm of the global trade body. His departure comes at a difficult time for the WTO, when the whole world is struggling with the pandemic.

Experts believe the next leader will need to spearhead effective reforms to become relevant again." *The next leader of the WTO must command respect in the corridors of power of the major players,"* said Simon Evenett, professor of international trade and economic development at the University of St. Gall in Switzerland. *"This is not the time to promote another ambassador. Someone with very senior government experience or global status is needed"*, he said.

MACRO-ECONOMIC SNAPSHOT

Global Economy Forecast

As per IMF's World Economic Outlook issued in April 2020, the global economy is projected to contract sharply by -3 percent in 2020-21, much worse than during the 2008–09 financial crisis, as a result of the pandemic. The global economy is projected to grow by 5.8 percent in 2021 as economic activity normalizes, helped by policy support. These projections assume that the pandemic fades in the second half of 2020 and containment efforts can be gradually unwound.

As per "World Economic Situation and Prospects" report issued by United Nations dated 13th May 2020, the world economy is projected to shrink by 3.2 per cent in 2020. GDP growth in developed countries will plunge to –5.0 per cent in 2020, while output of developing countries will shrink by 0.7 per cent. Main projections of this report are:

- The projected cumulative output losses during 2020 and 2021 is nearly $8.5 trillion, which will wipe out nearly all output gains of the previous four years.
- Lockdowns and the closing of national borders enforced by governments have paralyzed economic activities across the board, laying off millions of workers worldwide.
- Governments across the world are rolling out fiscal stimulus measures equivalent overall to roughly 10 per cent of the world GDP to fight the pandemic and minimize the impact of a catastrophic economic downturn.
- While both new infections and COVID-19-related death have slowed down in recent weeks, uncertainties persist about the future course of the pandemic and its economic and social consequences.
- Uncertain between saving lives and saving the economy, some governments are already beginning to cautiously lift restrictions with a view to jump start their economies.
- The pace and sequence of recovery from the crisis will largely depend on the efficacy of public health and fiscal measures, containing the spread of the virus, minimizing risks of reinfection, protecting jobs and income and restoring consumer confidence.

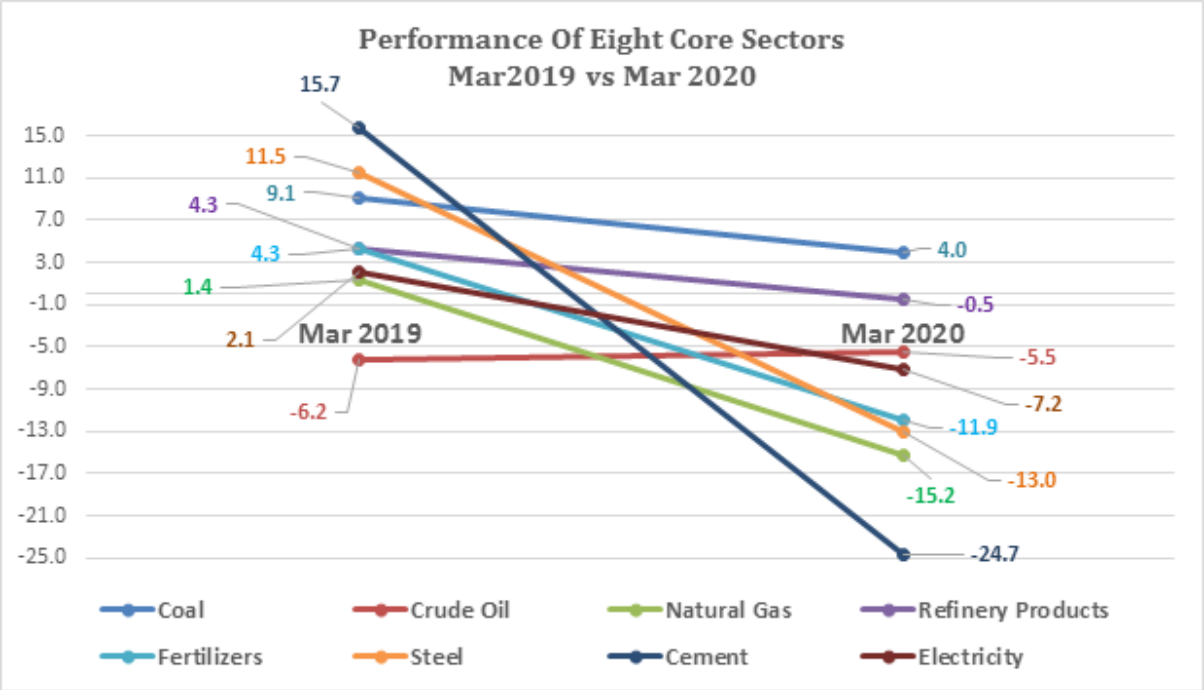
IMF Forecast: Indian Economy

Parameters	2019-20	2020-21 (Forecast)	2021-22 (Forecast)
GDP- Constant Prices (%)	4.23	1.87	7.43
GDP- Current Prices (Billions US$)	11043.18	11321.28	12399.00
GDP- Per Capita, Constant Prices (%)	2.88	0.55	6.03
Inflation- Average Consumer Prices (%)	4.54	3.34	3.62
Inflation- End of Period Consumer Prices (%)	5.77	2.73	3.85
Government Net Borrowing (% of GDP)	-7.44	-7.42	-7.30
Current Account Balance (% of GDP)	-1.13	-0.59	-1.42

Source: IMF

Performance of Eight Core Industries

- The Eight Core Industries comprise 40.27 percent of the weight of items included in the Index of Industrial Production (IIP). The combined Index of Eight Core Industries stood at 137.0 in March, 2020, which declined by 6.5 percent as compared to the index of March, 2019. Its cumulative growth during April to March, 2019-20 was 0.6 percent.
- Out of the eight core industries, except crude oil, all other sectors such as coal, refinery products, fertilizers, cement, steel, natural gas and electricity sector have witnessed a negative growth in March 2020 in comparison to the rate of growth in March 2019.



Source: PIB and Ministry of Finance

FTA UPDATES

COVID-19 Brings Greater Cooperation Between China and ASEAN

In recent months, ASEAN and China reaffirmed their commitment to forge closer cooperation and further strengthen their strategic partnership. During the 21st ASEAN-China Joint Cooperation Committee meeting held on 23rd April 2020, both parties discussed the progress made in the implementation of the ASEAN-China Plan of Action 2016-2020. Progress has been made in areas such as political-security, trade, transport, tourism, education, public health, culture and information, media, environment, and narrowing the development gap. A new Plan of Action is also being prepared to further enhance cooperation for the next five-years (2021-2025).

ASEAN and China continue to strengthen trade and investment relations, through the implementation of the Protocol to upgrade the ASEAN-China Free Trade Area as well as enhancing regional connectivity. People-to-people exchanges are also being advanced through collaboration in areas such as tourism and education, including through the implementation of flagship projects such as the ASEAN-China Young Leaders' Scholarship Programme.

The meeting also discussed activities under the ASEAN-China Digital Economy Year 2020 which would help enhance cooperation in areas such as e-commerce. The meeting emphasised the efforts made by ASEAN and China in addressing the COVID-19 pandemic, including the Special ASEAN-China Foreign Ministers Meeting on COVID-19 held in February 2020. Both sides further underlined the need to step up ASEAN-China cooperation through existing frameworks in mitigating the pandemic and its impact through ensuring the regional supply chains, especially for essential goods such as food, commodities, medicines and medical supplies.

Post COVID: Possibilities of Trade Shift?

Various sectoral chains have reacted differently to the new political and economic conditions. The textiles, clothing and footwear companies are scouting for low labour cost countries. The automobile manufacturing companies are aggregating in or around the prime demand destinations such as China, India and the US. The electronics supply chains are centred primarily in high-tech locations such as the US, Europe, Japan, South Korea and Malaysia, though some have also relocated to Vietnam, India and Mexico. Japan has already announced an initiative to set up a fund of $2.2 billion to encourage companies to move out of China. Given the

eagerness of the US to probe the Chinese role in the pandemic and take punitive measures against it, the manufacturers of medical equipment, pharmaceuticals and other essential goods may relocate the production of these items in their own and Economic Prosperity Network (EPN) countries.

The US is considering setting up an 'Economic Prosperity Network' (EPN) which will be a grouping of trusted partners like Japan, India, South Korea, Vietnam, Australia and New Zealand which will work on the basis of similar standards on everything, from digital business, energy, infrastructure, research to trade, education and commerce. This focus of creating a group of countries is to drive an agenda which would balance the economic, political and security imperatives.

Given the backdrop of events and speculations, the 29th RCEP Trade Negotiating Committee Meeting was held via video conference on 20, 22 and 24 April with 15 RCEP Participating Countries, i.e. ASEAN member states, Australia, China, Japan, Korea, and New Zealand. The participating member countries have reaffirmed their commitment to sign the RCEP agreement in 2020, stressing that as a region-wide free trade area, RCEP will provide a more stable and predictable economic environment to support the much-needed recovery of trade and investment in the region, which has been adversely affected by the COVID-19 pandemic.

What does this mean for India?

India has historically relied upon deep political, cultural and societal ties to exercise a high degree of influence over ASEAN states. However, China has used state-backed financing, marketed in recent years as the Belt and Road Initiative, to offer the types of large-scale infrastructure projects to ASEAN countries, and that India simply does not have the resources to match. India has already opted to move out from the RCEP, however, other member countries are gearing up for a regional integration to tackle the economic disruption. Since, majority of countries are banking on their decision to move out of China, such a move may give an added advantage to ASEAN countries over India. The growing economic and bilateral eco-system between China and ASEAN may give a smooth transition for companies to move out of China to ASEAN countries. If such transition happens, India would certainly lose a golden opportunity to become the leading economy of the world. The Government of India, at present, is focusing on developing policies to become self-reliant. However, there is also a need of the hour to also look at sustainable global policies which may swung the pendulum back from the ASEAN and will give a major push to fill the possible vacuum that may be created due to trade shift.

POLICY/REGULATORY BRIEF

Section I: Larger Policy/Regulatory Updates

GMP Certifications for Pharmaceuticals: An Opportunity in COVID-19 Crisis

The COVID-19 pandemic has wreaked havoc on a fledgling economy and brought to the fore some harsh realities, that world government and industry have to face. This pandemic has called to attention the complex and intricate interdependencies of global supply chains, with particular focus on the pharmaceutical industry. But, as also otherwise, in times of crisis too, there are lessons to be learned and new avenues to explore. With a shift in supply chains forthcoming, market access in several developed and developing countries may be up for grabs. The Indian pharmaceutical industry has the capacity to capitalize on this opportunity. In addition to catering to the needs of the domestic demand, the exports of generics in particular is one of its key strengths, earning itself the moniker of "pharmacy of the world".

GMP Certifications: A Way In?

Regulatory supervision and quality monitoring of medicines and other products is one of the cornerstones of the pharmaceutical industry. Over the years, there has been an increase in the number of non-tariff measures taken by countries to regulate the trade of these products. One such measure is the Good Manufacturing Practices (GMP) Certification requirement. Exporters of pharmaceutical goods are now facing an enhanced scrutiny of their quality and manufacturing practices. Import alerts are issued against violations of these practices and non-compliance is cost-intensive and often results in bans on exporting units.

Indian pharmaceutical exporters also face barriers in major markets such as Germany, due to lack of agreements on mutual recognition of good manufacturing practices. This lack of agreement acts as an impediment when foraying into new markets.

An exhibit of this is the recent decision of the Brazilian government to selectively allow remote inspection mechanisms carried out by means of videoconferencing technologies to replace inspections of sanitary measures carried out by ANVISA (Brazil's Health Regulatory Agency) for the purposes of Certification of Good Manufacturing Practices. This temporary measure, taken due to the COVID crisis, is however only eligible for Foreign Regulatory Authorities who are members of PIC/S (Pharmaceutical Inspection Cooperation Scheme) or MDSAP (Medical Device Single Audit Program).

These are international collaborations between regulatory authorities seeking to improve the standards of manufacturing requirements among its members. Members get benefits such as decreased duplication of inspection, information sharing and export facilitation. India however, is not a member of either of these programs.

It may be indicative that the world's top 10 countries exporting pharmaceuticals are all members of PIC/S. More than 60% of India's pharma exports are also destined for PIC/S members. Thus, in such a scenario, it is difficult to ignore the advantages of joining such international collaborations which accord it members with multiple benefits, not the least of which is market access.

It is clear with the announcement of the Policy on of Domestic Manufacturing of Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs), that the government recognizes the need for a push for the pharma industry. Perhaps it is also time for India to consider other methods of maintaining a competitive edge in the trade of pharmaceutical goods.

(This article has been prepared by Ms. Aishwarya, Research Associate, RV-VeKommunicate)

Section II: Region/Country Updates

EURASIA REACH: Russia Postpones Inventory Notification Deadline

The Russian Ministry of Industry and Trade announced that the deadline of the country's existing chemical inventory notification, which was previously scheduled to end on May 1 this year, will be postponed to August 1, 2020 as a result of the COVID-19 outbreak.

Earlier in November 2019, the Russian Ministry of Industry and Trade started to collect existing substance nominations. This was part of the moves to facilitate the upcoming implementation of the technical regulation of Eurasian Economic Union on Safety of Chemical Products i.e. EURASIA REACH.

EURASIA REACH applies to five Eurasian Economic Union (EAEU) countries: Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan. It was adopted on March 3, 2017 and will enter into force on June 1, 2021 if all the five member states reach an agreement on the second-level legislations. The other member states are expected to develop their own inventory of existing chemicals as well. The inventories will together form a common one for the EAEU. After the EURASIA REACH takes effect, all chemical substances that are not listed on the inventory will be considered as new substances and subject to complicated notification requirements before they can be placed on the EAEU market.

India's total chemical product exports to the EURASIAN countries were US$ 340 million and to Russia were US$ 317 million in in 2019. India's major export basket of chemical products Russia were organic chemical followed by miscellaneous chemicals and tanning and dyeing extracts, etc.

A company without a legal entity in the Russian Federation can appoint an Authorized Representative (AR) to submit information on its behalf and cover importation by its customers in Russia. The appointment of an AR and timely submission allows a non-EAEU company to maintain an uninterrupted supply chain into the region and support its EAEU customers.

Given the strategic importance of Russian market for India, companies are expected to need to secure AR support in Russia to ensure that their commercial interests are compliant.

Temporary Relaxations and Measures Creates An Opportunity in Brazil

Over the last two months, the National Health Surveillance Agency (ANVISA), Brazil has issued a series of resolutions and announcements directly pertaining to the COVID-19 pandemic and the need for critical medical supplies.

The aim of these temporary resolutions and announcements is to streamline the trade of health products, PPEs, ventilators, masks and other medical equipment.

New Regulations Streamline Processes and Temporarily Lift Requirements

- Temporary Brazil Good Manufacturing Practice (B-GMP) certification procedures for health products related to the COVID-19 outbreak.
- Expedited registration of medicines, biological products, and IVDs indicated for COVID-19
- Expedited registration of personal protective equipment (PPE), ventilators, and other medical devices indicated for the prevention or treatment of COVID-19. The expedited registration allows for exemption from B-GMP certification and Brazilian Compliance Assessment System (SBAC) certification
- Authorize the use of surgical masks, FFP2, and N95 respirators with a Certificate of Approval from the Ministry of Economy, Brazil for use in health services, without requiring additional authorization from ANVISA
- Temporarily suspends deadlines for ANVISA procedures, including review timelines for medical device and IVD petitions, as well as manufacturers' deadlines for the submission of documents
- Temporarily exempts manufacturers and importers of the following products from registration, Operating License (AFE) requirements, and other health authorizations:
  - Surgical masks;
  - Respirators;
  - Goggles and face shields;
  - Disposable hospital gowns, caps, and props; and
  - Valves, circuits, and respiratory connections Expedited Approvals for Medical Device Manufacturers
- Applicants can request priority review of products intended for the diagnosis of COVID-19 and other agents that cause respiratory infections

- Operating License (AFE) applications from importers and industries who intend to carry out activities related to products for the diagnosis, prevention, and treatment of COVID-19 will be prioritized upon request (through e-mail) by the applicants

Keeping in mind these temporary regulatory relaxations, health products and medical equipment exporters may look at exploring the opportunities in Brazil. However, companies which already have a track record of exporting these products to Brazil can reap the benefits of these temporary exemptions adopted by ANVISA. However, new entrants may find it difficult to easy entry into Brazil.

OFFBEAT

Rise Of Meatless Meat

There has been an increase in consumer demand for plant-based products in the past few years. Change in lifestyle has led to an increased number of consumers switching to plant-based diets. As more and more consumers seek alternatives, the plant-based product market is growing rapidly. The current global COVID-19 pandemic is considered one of the growth factors for the global plant-based meat market in the coming months. The fear of increasing animal borne illnesses among consumers, rising vegan population, healthier lifestyles and rising awareness about nutritional benefits offered by plant based products has driven the growth of the plant-based meat industry.

The Global Plant Based Meat Market is expected to be worth more than US$ 7 Billion by the end of 2025. The high numbers reported shows a promising trend for plant-based meat companies. (Source: Research and markets) What are plant-based meats?

Plant-based meat products are made to mimic properties found in natural meats and are considered to be meat substitutes. These are made using plant and other non-animal products to look, taste, feel and cook like conventional meat. Plant-based meats resemble meat products in texture, flavour and appearance. These can be in the form of a burger patty, nuggets, crumbles, sausages to name a few.

In comparison to meat products,

plant-based meats are environmental friendly and more sustainable meat alternatives. Almost every plant-based meat has different ingredient, but are usually made from extracted plant protein or whey protein, spices and binding ingredients. While, they being higher in sodium content but are similar to real meat in terms of calories and has more fiber and less cholesterol.

Major players Some

key players in this market include Beyond Meat, Impossible Foods, Maple Leaf Foods Inc., The Meatless Farm Co., Raised and Rooted, Nuggs, Morning Star, The Jackfruit Company and Garden Protein International. Some products which are developed by these companies include plant-based ground beef, sausages, fishless fish made form pea protein, plant-based steak, meatless bacon, chickenless nuggets made out of pea protein, wheat protein, bamboo fiber and egg whites.

The companies, Beyond meat and Impossible foods have noted rise as fast food chains, high-end restaurants and grocery stores have included their products in their chain. The impossible burger contains heme that is a molecule found in plants and animals that makes the burger taste similar to real meat. It was one of the first products that really changed the game of plant-based meat.

Market Share

As per the Plant Based Food Association (PBFA) and SPINS (a wellness focused data technology company and a key provider of data and insights for natural, organic and specialty foods) following observations have been made respect to the US retail sales plant based industry:

- USD sales of plant-based foods in 2019 grew to 11.4% in comparison to total food of 2.2%.
- The total plant based market sales growth was 29% in the time period 2017-2019 accounting for 38% for plant-based meats.
- The total plant-based market value has reached a value of $5 billion in 2019.
- The plant-based meat category is worth more than $939 million with sales above 18% in 2019 in comparison to 2.7% of animal meats in the same period.
- Refrigerated plant-based meat is driving the growth with 63% as recorded for the period of 2019.

Where does India stand?

The good Food Institute conducted a research on comparison of consumer attitude towards plant-based meats across China, USA and India. The results indicate the Indian perspective and potential for plant-based meats in India. 63% of Indian consumers, 62% of Chinese consumers, and 33% of U.S. consumers were “very or extremely likely to purchase plant-based meat regularly.”

Over the last decade, there has been progress in the alternative proteins or plat-based protein sector. Various new sources of protein are being studied including algae and mycoprotein among others as potential replacements in the products. In India, several plant-based food product companies such as Good Dot, Vezlay, Unived and Ahimsa food have come up to provide alternative protein options to consumers and have been well received in the market. Vezley provides a large variety of soya meats including soya chop, soya seekh kebab and veg meat. While Good Dot makes plant-based meats from plants and grains.

Recognizing vast potential in alternative proteins, many established food corporations like Nestle, Tyson Foods, Cargill and Tesco are expanding their product scopes.

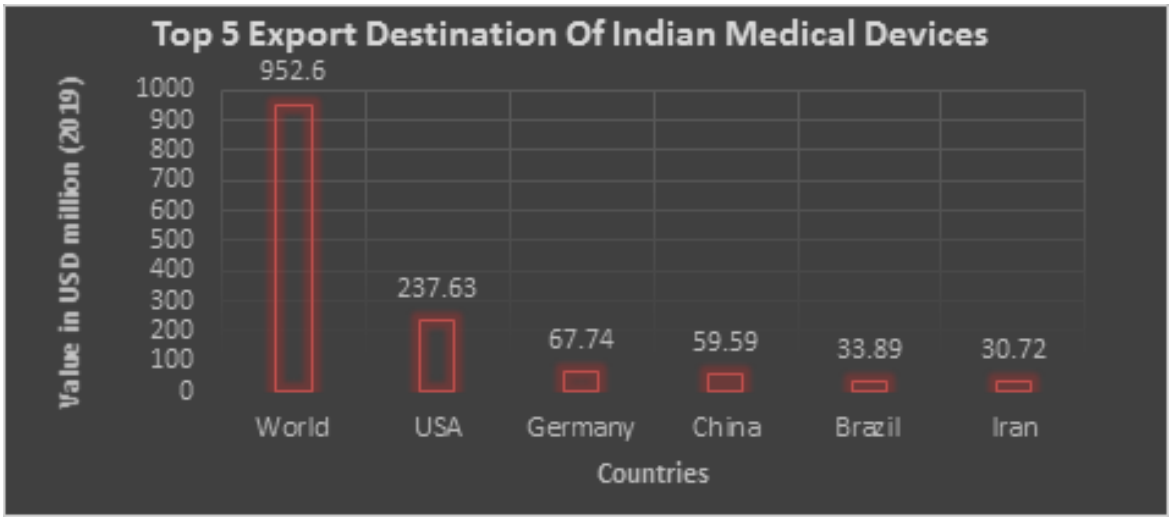
To provide the increasing population with healthier food options, there is a need for shift in the traditional foods system, away from resource intensive, animal agriculture towards sustainable and new-sources of nutrition.

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

Comparison Of Medical Devices Laws

Medical devices are fundamental commodities of the health care sector. Across the globe and in India, the trade in medical devices in terms of both export and import is significant. Due to these reasons, the medical devices industry is highly regulated. The following review focuses on the regulatory framework of the top 5 export markets of the Indian Medical Devices industry. It provides a comparison of the provisions under these regulations vis-a-vis the regulatory framework in India.

Medical devices as defined by World Health Organization (WHO) is "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.". For the year 2019, India's total export of medical devices to the world was USD 952.60 million. India exports majority of the medical devices to United States of America (USA), Germany, China, Brazil and Iran.



Source: ITC Trade Map

I. Regulatory Framework

Import Provisions	USA	Germany	China	Brazil	Iran
Competent Authority	The United States Food and Drug Administration (FDA)	• The Federal Institute for Drugs and Medical Devices (BfArM) • The German Institute of Medical Documentation and Information (DIMDI)	National Medical Products Administration (NMPA) {Formerly China Food and Drug Administration or CFDA)}	The Brazilian Health Regulatory Agency (ANVISA)	Food and Drug Administration of Iran
Regulated under	• Title 21 Code of Federal Regulations (21 CFR) Parts 800 – 1299.	• EU's Medical Devices Directive 93/42/EEC, (MDD) • The Act of Medical Devices (MPG) • The Ordinance on the Medical Device Safety Plan (MPSV) • The Ordinance on Clinical Investigations with Medical Devices (MPKPV)	• CFDA Medical Device Regulations.	• Resolution RDC 185/2001 • Resolution RDC 40/2015 • Resolution RDC 36/2015 • RDC-16/2013- Brazilian good manufacturing Practices	• Medical Cure and Medical Education Act
Classification	Title 21, Code of Federal Regulations (CFR), 862- 892. • Classification depends on the intended use of the device and also upon indications for use: • Class I: General controls a) With exemptions b) Without exemptions • Class II: General Controls and Special Controls a) With exemptions b) Without exemptions • Class III: General Controls and Premarket Approval. • In addition, classification is risk based: • Class I: lowest risk • Class II: moderate risk • Class III: greatest risk.	The rules for classification are mentioned in Annex IX of the Council Directive 93/42/EEC • Classified into 4 based on risk: • Class I (Low risk): Provided non-sterile or do not have a measuring function • Class II a (low to medium risk): surgical gloves, hearing aids, ultrasound machines, etc. • Class IIb (medium to high): long-term corrective contact lenses, surgical lasers, defibrillators, and others • Class III (High): cardiovascular catheters, aneurysm clips, hip-joint implants.	Classifies medical devices based on their potential risk. • Class I (lowest risk): Safety and effectiveness can be ensured through routine administration. • Class II: Requires further control in order to ensure their safety and effectiveness. • Class III (highest risk): Used for life support or sustenance, pose a potential threat to patients' health, and are implanted into the body.	Classifies based on risk into four classes (RDC 185/2001, Part 2): Class I(Low risk): Simple surgical instruments, tongue depressor Class II (Low-Moderate): Digestive catheters, infusion pumps, and Â powered wheelchairs Class III (High moderate) : Dialyzers, and orthopedic implants Class IV (High risk): Coronary stents. Further , ANVISA categorizes medical devices into four types: • medical equipments • materials for health use • orthopedic implants • in vitro diagnostics	• **Class A (Low risk): Simple surgical instruments, tongue depressor.** • **Class B (Low-Moderate): Digestive catheters, infusion pumps, and powered wheelchairs** • **Class C (Moderate-High): Dialyzers, and** orthopedic implants. • Class D: Coronary stents

Chart Area

Import Provisions	USA	Germany	China	Brazil	Iran
Regulatory requirements	• Establishment registration • Identification of United States agent (U.S. agent) for that establishment. • Manufacturers must list their devices with the FDA • If require, submit a premarket notification (510k) • Class III product or devices found not substantially equivalent to Class I and II requires pre- market approval • Investigational Device Exemption (IDE) allows manufacturers to use the device in question in clinical studies to collect evidence that proves its general safety and effectiveness. • Quality System Regulation • Labeling • Medical Device Reporting (MDR) - Importers are required to report to the FDA and the manufacturer of any death or any serious injuries has been caused by their medical devices.	Should bear the CE marking[1], if following has been fulfilled: • Essential requirements according to Section 7 of the act. • Conformity assessment procedure prescribed according to the ordinance pursuant to Section 37, sub-section 1 has been conducted. • Non-EU manufacturers must appoint an Authorized European Representative[2] • Class I: Self – certified and declaration of conformity. Other Classes: manufacturers must have a Quality Management System (QMS). The most widely accepted QMS is the ISO 13485 certification. • In addition to CE-Mark, devices are required to go through additional registration processes, including product registration with the DIMDI in order to receive market clearance.	• Determine classification of medical device from Medical Device Classification Catalog.[3] • Appoint an Agent located in China. • Proof of home country approval with documentation such as a CFS or CFG[4]. • Submission of notarized "proof of qualification of the manufacturer." • Prepare "Product Technical Requirement" document • Class II and III devices: Testing to be carried out by an NMPA-authorized test center. Prepare China Clinical Evaluation. • Class I devices: Prepare technical documentation. • Class II and III devices: Prepare registration dossier including testing reports, Agent authorization letter, CFS/CFG, clinical evaluation. • Class I devices will undergo an Administrative review only. • Class II and III devices: full application review, including technical and administrative review. • NMPA issues	• Appointment of a Brazilian Registration Holder (BRH) i.e., Local Representative. • All medical devices are required to comply with Brazil's Good Manufacturing Practices (BGMP) • Class I and II: ANVISA will not conduct an audit of GMP compliance Class III and IV: These devices will be audited for compliance and will need to submit a GMP certificate with their registration. • Class I and II: must follow "Cadastro" registration process. Prepare technical dossier including legal documents and labeling information. • Class III and IV: Follow the "Registro" registration process. Prepare application documents including: general device information, certificate of free sale, GMP, instruction manual, labeling, clinical data, clinical studies (if applicable). • ANVISA who will review application. • Device registration will be published in the official journal (DOU).	• Appointment of a Local Authorized Representative. • All EAR99 medical devices qualify for the general license unless they appear on the exclusion list. • Preparation of a common submission dossier template (CSDT) • CSDT includes classification and description of medical device, labeling information, Quality Management Certificate (ISO 13485), and CE approval. • Class C and D: Additionally requires summary of safety and effectiveness studies, risk management report, and material specifications. • The Medical Device Board (MDB) will then review dossier and grant registration. * EAR99 is a classification for an item indicating a particular item is subject to the Export Administration Regulations (EAR), but not specifically described by an Export Control Classification Number (ECCN) on the Commerce Control List (CCL). The exportation of any item that is subject to the EAR (including an EAR99 item) to Iran without a license is prohibited under regulations maintained by the Department of the Treasury's Office of Foreign Assets Control (OFAC)

[1] Conformitè Europëenne (CE) Mark is the mandatory conformity marking for regulating the goods sold within the European Economic Area (EEA)

[2] The representative can be based in any of the EU member states.

[3] Announcement No. 104/2017

[4] CFS = Certificate of Free Sale; CFG= Certificate to Foreign Government (CFG).

Import Provisions	USA	Germany	China	Brazil	Iran
			Class I Record Filing Certificate and publishes on website. • Class II and III devices: Following a successful review, NMPA issues registration certificate and posts online.		
Validity of Registration	Unlimited as long as there are no substantial changes to the device.	• The CE certification: 5 years. • The ISO 13485 Certificate: 3 years. • DIMDI notification: unlimited validity.	• Class I: Unlimited • Class II and Class II: 5 years	• Class I and II: Unlimited • Class III and IV: 10 years	Validity: 4 years
Local Content Requirements	NO	NO	NO	No	NO

II. Regulatory framework comparison with India

Regulated under: In India, the Central Drugs Standard Control Organisation (CDSCO) is the main regulatory authority for medical devices. These are regulated under Medical Devices Rules, 2017 and Medical Devices Amendment Rule, 2020.

Classification: The medical devices in India are classified based on risk into four classes: A, B, C and D.

- Class A: Low risk devices (Absorbent cotton wools, surgical dressing, alcohol swabs etc)
- Class B: Low- moderate risk devices (Thermometer, BP monitoring device, disinfectants etc)
- Class C- Moderate- High risk devices (Implants, hemodialysis catheter etc)
- Class D: High risk devices (Angiographic guide wire, heart valve)

The Indian classification system of medical devices is similar to the system followed by Iran. Further, like USA and Brazil, India also classifies medical devices based on their intended use.

Local Representation: Foreign companies seeking permission to export medical devices to India are required to appoint a local authorized agent in India. This practice is followed in each of the countries mentioned above in the table. In India, the local agent is required to be registered with CDSCO. Furthermore, the agent should have wholesale drug license under 20B and 21B.

Regulatory Implication: Across countries, there are additional requirements for moderate- high and high risk medical devices while low risk devices require no audits to be conducted by the competent authorities. India, Germany and Iran

require ISO 13485 certification, which specifies requirement for quality management system; however other countries do not impose such requirements.

Additionally, India does not have GMP requirements unlike Brazil where the importers should be mandatorily compliant of GMP requirements. Furthermore, India requires a Free Sale Certificate (FSC) which denotes that the imported product is freely sold in the open market in the exporting country and is approved for export. This provision is similar to China's requirement of CFS/CFG. In India, the application for obtaining the import license must be filed using form MD-14 in SUGAM online portal by an authorized agent. The import license is further granted in form MD-15, by the Central Licensing Authority.

Validity Period: There are remarkable differences in terms of validity period of registration. India provides the least validity period of 3 years as opposed to countries like USA and Brazil where the certification has an unlimited validity and 10 years of validity, respectively.

Local Content: In India, medical devices are required to have a minimum local content of 25-50% as per para 5 of Public Procurement Order (PPO), 2017 of the Department of Pharmaceuticals (DOP). Under this order, there will be purchase preference for public procurement. Thereby, purchase preference should be given to local suppliers by all procuring entities as per para 3 of PPO, 2017. There have been serious concerns over this requirement as it might restrict patient's access to certain necessary medical devices in India. However, the above mentioned countries do not have such a provision.

It is clear from the comparison that broadly, the regulatory regime for these 5 countries is similar. Most of the requirements were a part of the regulatory framework of all 5 countries and had equivalent provisions in the Indian system, with the notable exception of the local content requirement. It is anticipated that with the recent restructuring in terms of medical devices being regulated as drugs from 1 April 2020, and the upcoming Medical Devices Bill, the regulatory framework is bound to see some changes. It remains to be seen whether these changes will lend more efficacy to the overall system.

(This article has been prepared by Ms. Himani, Research Analyst, RV-VeKommunicate)

Summary of Coronavirus Response Plans by Country

Country	Delays	Individual Taxes	Business Taxes	Consumption Taxes	Other
Australia	Delayed payroll taxes in some states, case-by-case deferrals for GST		Temporary immediate and accelerated expensing for business investment	Faster refunds and credits for GST (importers qualify as well)	Relief payments to unemployed and other eligible individuals and subsidized loans for some businesses; six-month wage-subsidy of $1,500 every two weeks per employee; land tax relief granted if passed on to tenants
Austria	Case-by-case deferrals on VAT	Prepayment reduction	Prepayment reduction	VAT payment and deferment available by application; payment deadline of June 30 extended; VAT exemption for protective masks	
Belgium	Corporate, income, and VAT payment deadlines extended for two months		Businesses may be eligible to receive early refunds from February's tax filings by April 30; increased tax credit for prepayments	VAT filing and payment deadlines extended	
Canada	Payment deferrals for individuals and businesses; audits suspended for four weeks; ; federal Goods and Services Tax (GST) filings and payments are postponed until June 30 for payments due in March-May				Twelve-week wage-subsidy of 75 percent to all businesses; three-month wage subsidy of 10 percent to small businesses
Chile	Corporate tax payments, VAT, and income tax payments delayed until June 30	Targeted delays of taxes	Early tax refunds for small and medium-sized businesses		350 million Chilean UF in relief
China	May VAT filings and payments delayed by one week		Eight-year carry forwards for qualifying businesses (up from five years)	VAT reduced from 3 percent to 1 percent for small businesses until the end of May; VAT cut on supplies related to the coronavirus outbreak; interest on loans for small businesses VAT-exempt; VAT and duty exemption for importers into special zones until the end of the year	1.3 trillion Yuan relief package

Country	Delays	Individual Taxes	Business Taxes	Consumption Taxes	Other
Denmark	Delay on VAT payments and four-month delay on labor contributions		Advanced refund of R&D credits for loss-making businesses		Workers sent home can receive a 90 percent wage subsidy for three months; expansion of sick leave coverage; certain taxes paid in the past can be taken as interest-free loans
European Union			Provided a temporary framework for member states that are providing state aid to businesses during the crisis	Waiving VAT and tariffs for imported medical equipment	€540 billion in financing and direct support for member states
France	Suspension of payments for some taxes; direct tax payments delayed for three months			Accelerated VAT refunds and temporary VAT discounts	Wage subsidy for affected workers and a €1 billion solidarity fund for affected businesses
Germany	Case-by-case deferral options for businesses that apply by the end of 2020; advance payments delayed		Tax base reduction for trade taxes; social security contributions for lost hours of short-time employees covered by the government	2019 annual VAT return is postponed to May 31; VAT for catering food services have been temporarily reduced from 19 percent to 7 percent	Wage subsidies for affected workers as well as €50 billion in support for businesses and €500 billion in liquidity measures for businesses
India	Tax filing delayed to the end of June.	25 percent reduction in TDS rates	Faster income tax refunds	Faster refunds for GST and customs duties	Economic package of Rs. 20 lakh crore (nearly US$ 264 billion); schemes for MSMEs, real estate, agriculture, etc.
Indonesia	Six-month delay for income tax payments; corporate and income tax on imports delayed		Hotel and restaurant tax temporarily suspended; corporate income tax rate cut from 25 percent to 22 percent for 2020 and 2021, and to 20 percent starting in 2022; qualifying businesses will receive a 30 percent reduction of corporate income tax installments	Advanced VAT refunds to qualifying businesses from April-September's tax period	Stock exchange tariffs are lowered to 3 percent
Italy	Extended deadlines through May 31 for affected areas		Qualifying businesses may defer their April and May tax payments until June 30, and loan payments are suspended through	50 percent tax credit for sanitation expenses; banks have option to convert some loss deductions to tax credits	€100 bonus will be given to qualifying workers

Country	Delays	Individual Taxes	Business Taxes	Consumption Taxes	Other
			September 30; 60 percent tax credit on commercial rent		
Japan	Income, consumption, and gift tax deadlines are extended one year for taxpayers with 20 percent loss of revenue		Qualifying businesses may delay consumption, corporation, and income taxes for one year; small businesses can claim a tax refund for tax loss carrybacks		Deadlines for the self-employed extended from March to April
Malaysia	The due dates for making installments of tax (due on April 15) were extended to May 31; the time for making monthly tax installment payments has been deferred for three months for small and medium-sized businesses and for six months for the tourism sector; the monthly tax installment payments to accompany CP500 form for March and May 2020 can be deferred without penalties; deadline for submitting a CbCR has been extended			Exemptions from sales tax, services tax, and import duties	
Mexico	Tax lawsuit deadlines extended until April 19; state and local tax authorities extended certain deadlines for compliance with tax return filings and tax payments	Extended deadline to file individual tax returns for 2019 until June 30	Possibility to defer social security payments for up to 48 months, and upon a 20 percent upfront payment for the employer quota and 100 percent of the worker quota, with a monthly interest rate that ranges between 1.26 percent and 1.82 percent	Value-added Tax credit repayments will be accelerated; the current deadline is 40 days	
Netherlands	Three-month delay for personal tax, corporate tax, VAT, and other indirect taxes; since April 25, deferral of payments of longer than three months can be granted subject to certain conditions	Late payment interest fees reduced to 0.01 percent	Late payment interest fees reduced to 0.01 percent; when lower profits are expected in 2020, companies can amend the preliminary tax	Late payment interest fees reduced to 0.01 percent; no VAT will apply on the supply of medical staff and donated medical supplies	Subsidies for 90 percent of wages for distressed businesses

Country	Delays	Individual Taxes	Business Taxes	Consumption Taxes	Other
			assessment and get a refund for the paid taxes		
New Zealand	Goods and Services Tax filing has been suspended		Reintroduction of depreciation deductions for commercial and industrial buildings; threshold for provisional tax increased; early claiming of R&D tax credits; carrybacks and carry forwards for tax losses		Loan schemes to provide additional funding for businesses
Russia	Small and medium-sized businesses can defer for six months all tax (except VAT) and social insurance payments; tax holidays for taxes and social security contributions until May 1 for companies engaged in tourism and aviation industries; tax audits are suspended until June 1		Social insurance rate reduced to 15 percent (from 30 percent) for salaries exceeding the minimum wage	Pharmaceutical and medical supplies and equipment will be exempted of import duties payments	
Singapore	Corporate income tax payments are deferred for three months; GST payments delayed from April 11 to May 11; automatic deferment of income tax payments by three months for self-employed		Corporate income tax rebate of 25 percent of tax payable, capped at SGD 15,000; accelerated tax depreciation for plant and machinery over two years and over one year for expenditures on renovation and refurbishment		Property tax rebates will be given to hotels, restaurants, and affected stores; grants are being extended to support employers
South Africa	Up to 20 percent of payroll taxes can be delayed between April 1 and July 31; provisional tax payments can be deferred		Accelerated payments of employment tax incentives	VAT is waived on imports of essential goods	Tax subsidies are being provided for lower-income individuals
South Korea	Corporate tax filing deadline extended from April 4 to May 4; VAT filing and payment deferred up to three months	Tax deduction for personal credit card spending; temporary deduction increase from March 1-June 30	Corporate income tax reduction for small and medium-sized businesses in designated disaster zones	VAT filing threshold increased from KRW 30 million to KRW 48 million for 2020	Tax preferences for replacing cars
Spain	Tax deferrals for six months' VAT payments delayed to May 30 for				€100 billion in loan guarantees

Country	Delays	Individual Taxes	Business Taxes	Consumption Taxes	Other
	businesses with less than €600,000 in annual revenues				
Thailand	Personal income tax filing delayed from June 30 to August 31; business tax deadlines extended from March and April into May	Income withholding tax cut from 3 percent to 1.5 percent for six months; doubled tax benefit for investing in long-term mutual funds			Direct cash support to 3 million people
United Kingdom	Wave business property taxes for 12 months for retail, leisure, and tourism sectors; delaying £30 billion in VAT payments until June 30; phase two of Making Tax Digital has been delayed for one year	Expanding Universal Credit and working tax credit by £1,000	Direct support for the self-employed aimed at replacing 80 percent of average earnings	Import taxes on medical equipment waived; accelerated a planned VAT reduction on e-books	
United States	Tax payments delayed to July 15	Significant tax rebates for individuals and expansion of unemployment insurance coverage	Carry-back of losses; refundable tax credits for payroll taxes; loosened interest deduction rules		Short-term expansion of paid sick leave; $750 billion in loans to businesses to support payroll costs

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