RV VeKommunicate

DECEMBER 2019 VOL.5

POLICYPULSE

IN THIS ISSUE

- MACRO-ECONOMIC SNAPSHOT
- POLICY BRIEF
  - -PATENT PROSECUTION HIGHWAY (PPH) PROGRAMME
- FTA UPDATES
  - -US-MEXICO-CANADA AGREEMENT (USMCA)
- PHARMA & MEDICAL DEVICE NEWS
  - -ANVISA: NEARLY HALF OF ALL BRAZIL GMP CERTIFICATES NOW ISSUED UNDER MEDICAL DEVICE SINGLE AUDIT PROGRAM
  - -ANVISA READIES CHANGE APPLICATION SYSTEM, LISTS TOP MEDICAL DEVICE REGULATORY PRIORITIES
  - -SOUTH KOREAN MFDS REDUCES SUBMISSION REQUIREMENTS FOR HIGH-RISK MEDICAL DEVICES
  - -EU MDR READINESS CHECKLIST AHEAD OF MAY 2020 DEADLINE
- MARKET UPDATES
  - -EUROPEAN COMMISSION'S ANTI-DUMPING REGULATION ON UAN IMPORTS
  - -GULF STATES TO IMPLEMENT GHS BY MID-2020
  - -RUSSIA OPENS CHEMICAL INVENTORY IN MOVE TOWARDS EURASIA-REACH
  - -THAILAND PUBLISHES SECOND DRAFT OF NEW CHEMICAL LAW
  - -SIERRA LEONE PROPOSES AFRICA'S 'STRONGEST' CHEMICALS MANAGEMENT BILL

Thank You!

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

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

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

Your continued support is highly regarded and appreciated.

Best wishes

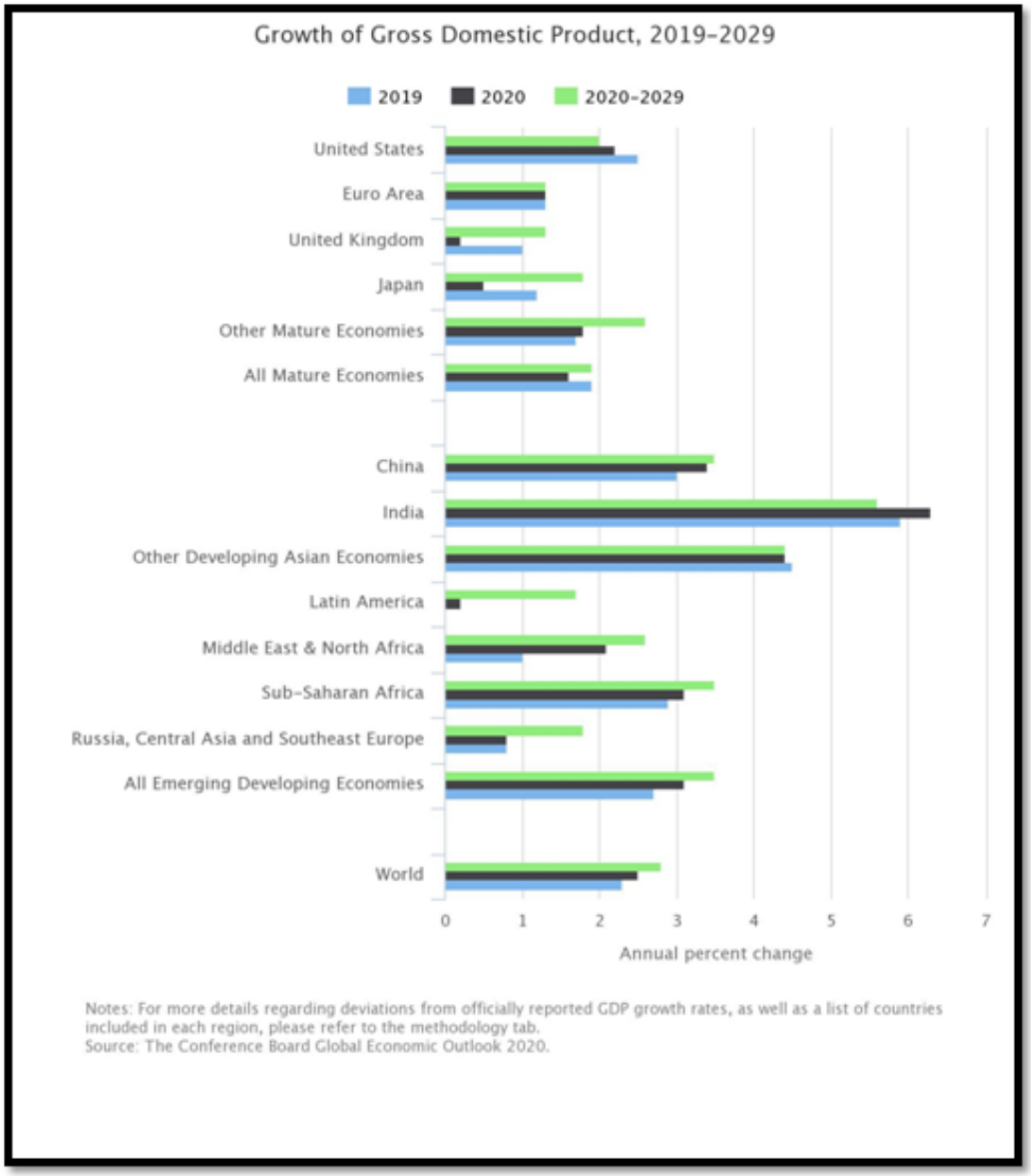
Team VeKommunicate

MACRO-ECONOMIC SNAPSHOT

Global Economy Outlook

World Economy

Global economic growth continued to moderate in most of the large economies during the third quarter of the year, with an emphasis on export related activity and the industrial sectors. The risks to the growth forecasts remain high. The realization of one or more of the risks may lead to an increase in volatility in the financial markets. Moderation in the rates of inflation and growth support a continuation of expansionary monetary policy by many central banks around the world.These factors support the continuation of a moderate bond yield environment also in the coming months.



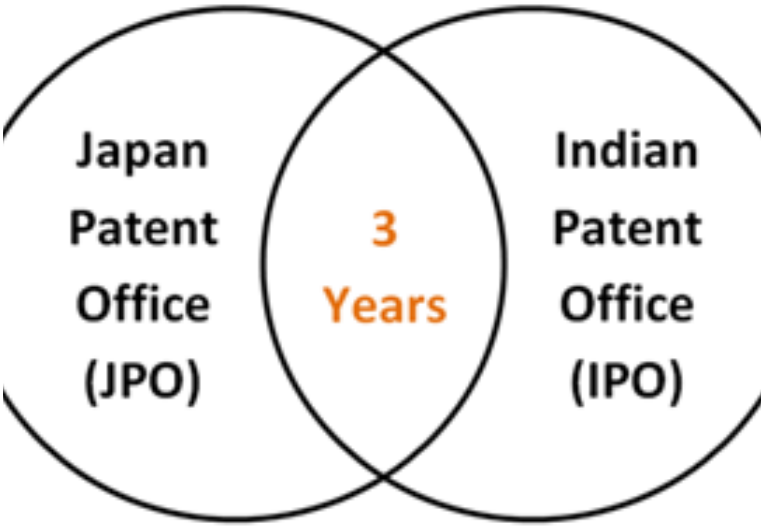
India: At A Glance

The Eight Core Industries comprise 40.27 per cent of the weight of items included in the Index of Industrial Production (IIP). The combined Index of Eight Core Industries stood at 127.0 in October, 2019, which declined by 5.8 per cent as compared to the index of October, 2018. Its cumulative growth during April to October, 2019-20 was 0.2 per cent.

1. Coal production (weight: 10.33 per cent) declined by 17.6 per cent in October, 2019 over October, 2018. Its cumulative index declined by 5.8 per cent during April to October, 2019-20 over corresponding period of the previous year.
2. Crude Oil production (weight: 8.98 per cent) declined by 5.1 per cent in October, 2019 over October, 2018. Its cumulative index declined by 5.8 per cent during April to October, 2019-20 over the corresponding period of previous year.
3. The Natural Gas production (weight: 6.88 per cent) declined by 5.7 per cent in October, 2019 over October, 2018. Its cumulative index declined by 2.6 per cent during April to October, 2019-20 over the corresponding period of previous year.
4. Petroleum Refinery production (weight: 28.04 per cent) increased by 0.4 per cent in October, 2019 over October, 2018. Its cumulative index declined by 1.7 per cent during April to October, 2019-20 over the corresponding period of previous year.
5. Fertilizers production (weight: 2.63 per cent) increased by 11.8 per cent in October, 2019 over October, 2018. Its cumulative index increased by 2.6 per cent during April to October, 2019-20 over the corresponding period of previous year.
6. Steel production (weight: 17.92 per cent) declined by 1.6 per cent in October, 2019 over October, 2018. Its cumulative index increased by 6.7 per cent during April to October, 2019-20 over the corresponding period of previous year.
7. Cement production (weight: 5.37 per cent) declined by 7.7 per cent in October, 2019 over October, 2018. Its cumulative index declined by 0.6 per cent during April to October, 2019-20 over the corresponding period of previous year.
8. Electricity generation (weight: 19.85 per cent) declined by 12.4 per cent in October, 2019 over October, 2018. Its cumulative index increased by 1.5 per cent during April to October, 2019-20 over the corresponding period of previous year

POLICY BRIEF

Patent Prosecution Highway (PPH) Programme



The Patent Prosecution Highway (PPH) of the Indian Government is a set of initiatives for providing accelerated patent prosecution procedures by sharing information between some patent offices.

The Union Cabinet has approved a proposal for adoption of Patent Prosecution Highway (PPH) programme by the Indian Patent Office (IPO) under the Controller General of Patents, Designs & Trade Marks, India (CGPDTM) with patent offices of various other interest countries or regions. The programme will initially commence between Japan Patent Office (JPO) and Indian Patent Office on pilot basis for a period of three years only.

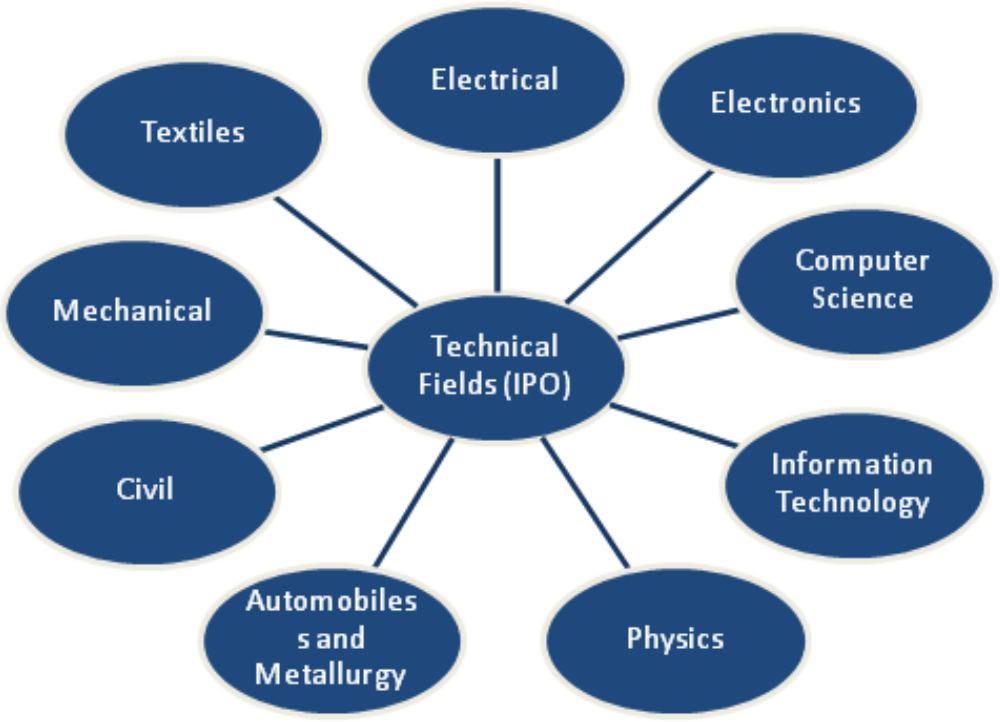
Under this Pilot programme, Indian Patent Office may receive patent applications in certain specified technical fields only, while JPO may receive applications in all fields of technology.

Under this Pilot programme, Indian Patent Office may receive patent applications in certain specified technical fields only, while JPO may receive applications in all fields of technology.

The PPH programme would lead to the following benefits for the Indian IP office:

- Reduction in time to dispose patent applications.
- Reduction in pendency of patent applications.
- Improvement in quality of search and examination of patent applications.
- Provide an opportunity for Indian inventors including MSMEs and Start ups of India to get accelerated examination of their patent applications in Japan.

It is expected that with the introduction of this PPH programme, the grant of patents and disposal of patent applications at the IPO shall rise to 25,000 and 60,000, respectively, unlike 15,000 grants and about 51,000 disposals of patent applications in the year 2018-19. Also, the examination time of a patent application is expected to be reduced to 12-16 months by March 2021.



In addition to the faster disposal of patent applications, this PPH programme shall promote applicants/inventors of India and Japan to apply for and obtain patents in both the jurisdictions. Success of this pilot programme may encourage the IPO to enter into such PPH programmes with other Patent Offices.

FTA UPDATES

US-Mexico-Canada Agreement (USMCA): US Still Thinking On Ratification

In 2018, the United States, Canada and Mexico announced they had reached a trilateral free trade agreement (in principle), concluding more than 13 months of negotiations. As of now, only Mexico and Canada have ratified the agreement. It's nearly 14 months, since the US had signed the agreement, but it is yet to ratify it.

The United States-Mexico-Canada Agreement (USMCA) is intended to replace the North American Free Trade Agreement (NAFTA) and creates a modernized free-trade system between the three parties that addresses recent and emerging critical issues, such as the harmonization of regulatory systems, e-commerce and the protection of intellectual property.In addition, the USMCA changes some of the rules and processes governing how certain goods are traded within North America and the mechanisms available for how trade disputes are resolved.

Next Steps

With ratification completed by Mexico and Canada, the onus is now on Washington to ratify the trade agreement. U.S. President Donald Trump has stated that he has a backup plan in the event the USMCA is not ratified, but did not provide clarification on what it is. However, he previously stated that if Congress won't pass the USMCA, he will withdraw from NAFTA, which would put Congress on a six-month timeline to either ratify the USMCA or risk losing free trade in North America.

From NAFTA To USMCA – Key Changes

Over the course of 13 months, the parties engaged in heated debate and lengthy negotiations regarding a number of issues that had varying degrees of importance and impact on each of the parties. Following are some of the key differences between NAFTA and the USMCA.

a) Dispute Resolution

The USMCA maintains Chapter 20 of NAFTA, which provided for a dispute-mechanism to resolve country-to-country disputes. More importantly, the USMCA maintains NAFTA Chapter 19, which provides for a bi-national dispute-resolution mechanism to resolve disputes over the imposition of anti-dumping and countervailing duties by one country on another.

Chapter 19 was a hotly debated issue during the negotiations. The United States had requested the dispute-resolution mechanism be removed, believing it infringed on U.S. sovereignty. Canada, which has effectively used Chapter 19 on more than one occasion to reverse the application of duties on Canadian imports into the U.S. (such as softwood lumber), insisted the dispute-resolution system be maintained.

However, NAFTA Chapter 11, the Investor-State Dispute System (ISDS), has been removed between the United States and Canada, but maintained for certain instances between the United States and Mexico. The ISDS was a mechanism that allowed private corporations to take legal action against a foreign government if it believes that foreign government's policies infringe on the corporation's rights to engage in commerce in that country in accordance with the terms of NAFTA. The removal of ISDS is considered more of a win for Canada than the United States as the United States government has never had to pay damages to a foreign corporation throughout NAFTA's history. Conversely, Canada has been forced to pay damages of more than $300 million to U.S. corporations through ISDS resolutions.

b) Automotive Rules of Origin and Regional Value Content

- Total North American content of a vehicle must equal 75% (up from 62.5%).
- 70% of all steel, aluminum, and glass used in the production of the automobile must originate in North America.
- Part content will be divided up into core, principal, and complementary parts with content requirements of 75%, 65%, and 60% respectively.
- 40% of an automobile and 45% of a light truck must be produced using an average labor wage of $16/hour.
- Quotas totalling 2.6 million Canadian and Mexican vehicles (well above the current 1.8 million) were established the USMCA
- Quotas of $32.4 billion in Canadian auto parts imports and $108 billion in Mexican auto parts imports were established in the USMCA

How and where vehicles and vehicle parts are manufactured under NAFTA were a key point of contention and provided much of the impetus behind the renegotiation of the agreement. The current United States administration believes NAFTA provided incentive for U.S. auto manufacturers to offshore their production to Mexico where labor rates are much lower than in the U.S.

After months of stalemate on the matter, the United States removed the requirement of 50% U.S. content and negotiated with Mexico to create a system by which a minimum of 45% of an automobile's content must be produced using laborers earning a minimum of $16/hour. The system is intended to bridge the gap between labor rates in all three countries and ensure there is more of a levelled playing field with respect to labor in the auto sector. At the same time, the new system works to do so in a manner that is not overly disruptive to the very complex supply chains of automakers and their auto parts suppliers. Those terms proved agreeable to Canada's negotiators and the impasse was broken.

c) Dairy Market Access

- Restrictions on the import of U.S. ultra-filtered milk into Canada have been removed
- U.S. producers will have access to an additional 3.6% of Canada's dairy market
- Canada's dairy supply management system, which places limits on foreign imports is maintained

d) Intellectual Property

- Pharmaceutical companies can maintain patents on biologics for a 10-year term, up from eight years
- The term of copyright was extended from 50 years after an author's death to 70 years.

Perhaps the most hotly contested issue around intellectual property within NAFTA was related to the length of term pharmaceutical companies can maintain patents on biologics. The United States currently provides for a 12-year term while Canada's system provided for only an eight-year term. The parties agreed to a 10-year term as a compromise, which is higher than the eight-year term Canada agreed to in the Comprehensive & Progressive Agreement for Trans-Pacific Partnership (CPTPP), a multilateral agreement involving 11 Pacific Rim countries.

The result will be that the creation of generic biologics as a cheaper alternative to the original brand-name products will be delayed coming to market by two years in Canada.

e) Sunset Clause

- The terms of USMCA will remain in effect for a period of 16 years, at which time the parties can choose to revisit and/or renegotiate those terms, or withdraw from the agreement altogether.
- However, after six years, the term of USMCA's sunset (16 years) can be revisited and potentially extended if the parties feel doing so would be beneficial

f) Section 232 Tariffs

- No resolution on steel and aluminum tariffs, or Canadian and Mexican counter measures
- Side letter developed to provide Canada and Mexico with consultation period before tariffs on autos can be applied.

In March 2018, the United States imposed tariffs of 25% on imported steel and 10% on imported aluminum, providing exemptions to a number of key trading partners, including Canada and Mexico. On June 1, 2018, those exemptions were removed and Canadian and Mexican steel and aluminum were subject to the tariffs. Both countries retaliated in kind with countermeasures on U.S. steel and aluminum, as well as consumer goods.Those tariffs were imposed under Section 232 of the Trade Expansion Act of 1962, which allows the U.S. President to impose tariffs on the grounds of national security, which includes undue harm to critical industries.

Also being considered under Section 232 are tariffs of 25% on auto imports, which the U.S. threatened to impose on Canadian and Mexican autos in the event no deal was reached on NAFTA.The USMCA provided side letters that essentially state that if the U.S. were to impose tariffs on automobile imports, Canada and Mexico would be exempt for a two-month period to allow the parties to work out their differences.

However, no resolution was reached on the imposition of steel and aluminum tariffs and the associated countermeasures put in place by Canada and Mexico. The parties have agreed to settle that matter outside the NAFTA negotiations.

PHARMA & MEDICAL DEVICE NEWS

ANVISA: Nearly half of all Brazil GMP certificates now issued under Medical Device Single Audit Program

A new report from Brazilian medical device market regulator ANVISA shows a significant increase in medical device manufacturers participating in the Medical Device Single Audit Program (MDSAP), with nearly half of all quality management system certifications issued in 2019 under MDSAP.

According to the ANVISA report (link in Portuguese), the number of device manufacturing sites in Brazil that participate in MDSAP totaled 5,002 in November 2019, up from 3,225 in 2017 and just 778 in 2017.

The number of Brazilian Good Manufacturing Practice (BGMP) quality system certificates issued under MDSAP parameters has also grown substantially in the past two years: from less than five percent of BGMP certificates issued in 2017 to nearly 49% of certifications in 2019.

Beyond Brazil: MDSAP Adoption Rates Up Worldwide

In a separate presentation ANVISA conducted in November (2019), the regulator discussed distribution of MDSAP certifications approved outside of Latin America. The US accounts for nearly half of all MDSAP certifications, with Canada and Germany in distant second and third places.

In addition, the ANVISA presentation mentioned that European Union regulators are still in the process of developing guidelines for accepting MDSAP audit reports; **VeKommunicate** will continue monitoring these developments and report on MDSAP implementation details in Europe as they become available.

ANVISA Readies Change Application System, Lists Top Medical Device Regulatory Priorities

Brazilian medical device market regulator ANVISA has outlined several near- and long-term oversight priorities pertaining to post-registration requirements, software as a medical device (SaMD), Unique Device Identification and other issues.

ANVISA announced these priorities during an event in early November commemorating 20 years of medical device regulation in Brazil.

Focus On Post-Market Device Modification Requirements

ANVISA plans to publish a public consultation in 2019 to establish a new three-tier system for managing submissions of modification applications that manufacturers of Class II, III and IV devices must provide when proposing changes to their products.

a) Required modification: These changes require petitioning, technical review and publication in order to be implemented. Major impact changes such as different raw materials would fall under this category.

b) Express implementation: Low-risk changes may be implemented immediately; however, these modifications still require petitioning and should be published in Brazil's Official Gazette even though technical reviews are not required. Changes in commercial names, for example, fall under this category.

c) Not reportable: Changes that do not require petitioning; a change of technical manager, for example, qualifies as a not-reportable modification.

Key ANVISA Regulatory Priorities for 2020 And Beyond

Along with ANVISA's planned change application system, the agency also listed several short- and long-term medical device regulatory priorities it plans to pursue. Key targets include:

a) Issuing a public consultation for the agency's regulatory approach to SaMD;

b) Revisions to INMETRO Ordinance 54/16 as well as RDC 25/01 and RDC 156/06 pertaining to used and refurbished medical devices;

c) Updates to the Normative Instruction on electromagnetic compliance certification;

d) Launching a new product labeling and instructions for use uploading system to replace VisaDoc; Implementing a UDI system encompassing all of the Brazilian medical device sector

South Korean MFDS Reduces Submission Requirements For High-Risk Medical Devices

The South Korean Ministry of Food and Drug Safety (MFDS) has moved to reduce registration submission requirements for Class IV high-risk medical devices. According to a notification (link in Korean) from the regulator, manufacturers of Class IV devices will no longer be required to prepare and submit full Summary Technical Documentation (STED) files along with Korean technical files when applying for South Korean market authorization.

In lieu of full STED files, MFDS will require the following STED-related documentation from Class IV device market applicants:

a) Flow charts showing each step of the device's manufacturing process;

b) Detailed explanations of processes that could affect the performance and/or effectiveness of the device;

c) Descriptions and indications of all sterilization methods, standards, validation cycles and conditions utilized in the device's manufacturing process.

The MFDS announcement is expected to reduce submission preparation timeframes for Class IV device applicants, potentially easing South Korean market entry for higher-risk device manufacturers.

EU MDR Readiness Checklist Ahead Of May 2020 Deadline

With the European Medical Devices Regulation (MDR) compliance a dominant topic of discussion for Pharmaceutical companies, this article presents an MDR readiness checklist whereby manufacturers can gauge their preparedness for the new Regulation.

MDR checklist items

The MDR readiness checklist covers a range of compliance issues such as quality management plans, supplier agreements, post-market activities and Notified Body partnerships:

• Do you have a quality management plan in place for transition to MDR?	• Do you have a post-market surveillance plan in place per MDR Annex III?
• Is your product a device according to MDR criteria?	• Does your device comply with new state-of-the-art EU standards?
• Do you need to comply with MDR on the May 2020 deadline?	• Have you updated your ER checklist according to GSPR requirements?
• Do your quality agreements reflect MDR requirements for economic operators?	• Are you prepared for UDI and Eudamed data entry rules?
• Does your CER reflect MEDDEV2.7.1 rev 4 for clinical evidence?	• Will your current Notified Body be designated to MDR?

Source: European Commission Regulatory Framework on Medical Devices

Changes to how medical devices are classified under MDR pose a significant hurdle for manufacturers. MDR introduces a series of new terms—implant, reagent, prediction, prognosis—for which guidance is available from the UK Medicines and Healthcare products Regulatory Agency (MHRA). Manufacturers may access this guidance to avoid last-minute compliance delays. A common thread throughout all these changes is a heightened sensitivity to risk under MDR.

MARKET UPDATES

European Commission's Anti-Dumping Regulation on UAN imports

On 8th October 2019, the European Commission has released a Commission Implementing Regulation (EU) 2019/1688 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of mixtures of urea and ammonium nitrate (UAN) originating in Russia, Trinidad and Tobago and the United States of America.

This EU UAN anti-dumping regulation is the first under the European Union's New Trade DefenceModernisation Rules. These new rules are aimed at modernising the EU's trade defence toolbox, enables the EU to impose higher duties in some cases by changing the 'lesser duty rule'; the use of the achieved non-injurious profits rates of EU industry; shorten the investigation period to accelerate the procedure; increase transparency and predictability of the system for EU firms; new account given to prospective (Emission Trading Scheme) ETS/environmental costs; and reflect the high environmental and social standards applied in the EU;The new rules will shorten the current 9 month investigation period to 7 months for the imposition of provisional measures and make the system more transparent. Companies will benefit from an early warning system telling them if provisional duties will be imposed, which will help them adapt to the new situation

Russia raised two concerns with regards to the EU:

· A decision to maintain a dumping duty order on ammonium nitrate (AN) even though the duties have been in place for more than 20 years; and

· The EU's continued use of its cost of adjustment methodology in the review on ammonium nitrate

.

The European Commission initiated two separate interim reviews on the existing (AN) duties on imports from Russia in August 2017:

· Interim Review numbered, R669 – Acron (A Russian producer of solid fertilizer-grade ammonium nitrate), submitted an application for partial interim review of the EU Anti-Dumping measures against Russian Imports of Ammonium Nitrate.

· Interim Review numbered, R674 – This review was a result of an application by Fertilizers Europe on behalf of producers representing more than 50 % of the total Union production of mixtures of urea and ammonium nitrate.

The investigation showed that dumping took place during the investigation period. The level of the dumping found was higher than the one during the investigation period which led to the imposition of the definitive duties.

The main raw material used in the production of Ammonium nitrite (AN) is gas, which accounts for 70% to 80% of the total production costs. The Commission analysed the average import prices of UAN. The price variations were significant, mainly due to the strong fluctuation of the price of gas, the main raw material of UAN. In view of this volatility of UAN import prices, to prevent injury to the user industry during the low and peak prices, the Commission concluded that a specific duty was more appropriate in this case. The regulation is expected to prevent further injury to the EU industry.

Gulf States To Implement GHS By Mid-2020

The trade bloc comprising six Gulf countries expects to adopt the UN's Globally Harmonized System (GHS) of classifying and labelling chemicals by mid-next year. The Gulf Standards Organisation (GSO) published a draft standard in October that would align its member countries with the fifth revised edition of GHS.

Upon adoption, each of the six countries in the Gulf Cooperation Council (GCC) – Bahrain, Kuwait, Oman, Saudi Arabia, the United Arab Emirates (UAE) and Qatar – would then need to transpose the voluntary standard into their domestic legislation, which could take two to three years.This time could act as the transition period for companies to adjust the international chemical industry's voluntary initiative promoting the safe production, handling and use of chemicals.

However, most large companies comply with GHS already, because the Gulf is an "export-oriented region" with trade partners in regions like Europe that have stringent labelling requirements. But while this is true for many multinationals based in the Gulf, some concerns remain about smaller companies' compliance, both because they have fewer resources and their business is more likely to be local.Small and medium enterprises in the region are likely to "lag behind" their bigger counterparts when it comes to chemicals management initiatives like product stewardship, another industry-led drive detailing how producers can minimise the harmful impact of chemicals throughout their life cycle.

Next Steps

The GSO is now meeting with environment officials in each Gulf country to plan transposing the standard into regulation. The association also hopes to create a regional committee for chemicals officials to meet and exchange best practices, as the relevant agencies don't always communicate.

Russia Opens Chemical Inventory In Move Towards Eurasia-REACH

The Ministry of Industry and Trade, Russia has informed domestic chemical companies that they should begin submitting information to a national inventory of chemicals. The move is seen as a first step towards the implementation of the long-awaited Eurasia-REACH Regulation.

The Eurasian Economic Union (EEU) member states – Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia – are expected to each create inventories as part of national registers of substances and mixtures. However, Russia opening its inventory, announced on 11 November, has leapfrogged a legislative obligation for EEU members to agree on secondary legislation, concerning three areas:

a) a list of chemicals that are restricted and banned;

b) a position on the grounds for refusing state registration of chemicals; and

c) rules for completing chemical safety reports.

There has been some confusion over the implementation of the chemicals management package. In August 2019, the Russian Federation decided to collect the inventory information. But it has not started as yet started and would only begin after the adoption of second tier legislation.

Submissions

Under the latest development, Russian companies must submit information to the country's governmental industry information exchange platform (GISP). They can do this themselves or through nominated representatives based in the country. Only the latter can do this for non-Russian legal entities – those in the Union and outside – using an official template.

a) Existing chemicals, or those planned for use on the Russian market, must be notified with the exception of:

b) chemicals used as pesticides;

c) chemical products intended for, or resulting from, research;

d) minerals that have not been chemically altered;

e) medicines and veterinary medicines;

There has been some confusion over the implementation of the chemicals management package. In August 2019, the Russian Federation decided to collect the inventory information. But it has not started as yet started and would only begin after the adoption of second tier legislation.

Submissions

Under the latest development, Russian companies must submit information to the country's governmental industry information exchange platform (GISP). They can do this themselves or through nominated representatives based in the country. Only the latter can do this for non-Russian legal entities – those in the Union and outside – using an official template.

a) Existing chemicals, or those planned for use on the Russian market, must be notified with the exception of:

b) chemicals used as pesticides;

c) chemical products intended for, or resulting from, research;

d) minerals that have not been chemically altered;

e) medicines and veterinary medicines;

f) perfume and cosmetic products;

g) chemical products that are a source of ionising radiation;

h) food products;

i) waste from the production and consumption of chemical products;

and

j) chemical products subject to the customs procedure for transit through the EEU.

Companies notifying about new chemicals must submit a comprehensive study of their hazardous properties and a chemical safety report. This needs to be carried out before the chemicals are marketed in Russia.

The deadline for inventory submissions is 1 January 2020. However, this might be extended until May 2020.

Thailand Publishes Second Draft Of New Chemical Law

Thailand's Food and Drug Administration (FDA) has released a second draft of its proposed new chemical law, which stipulates that overseas companies will be required to appoint only representatives (ORs) based in Thailand. The Thai authorities are using risk assessment approach used under EU REACH for assessment of chemicals. In April, Thailand published the first draft of a chemical law intended to replace the existing Hazardous Substance Act (HSA).If adopted, it will see the country shift towards a risk-based regulation and introduce a new system for registering and classifying chemicals.

Only Representatives

The second draft includes several changes to the wording but the most significant amendment is the addition of a section on ORs. Foreign manufacturers will be required to appoint ORs that are 'qualified' Thai entities. The draft says the FDA looked at requirements in the EU, China and South Korea to inform its decision.

The committee involved in developing the law will issue ministerial Regulations prescribing the rules, procedures, qualifications, responsibilities and conditions for their appointment, but it has not yet specified a date for release.

Thailand's Chemical Inventory

Currently, Thailand has only a preliminary existing chemicals inventory, which has been online since 2016 and includes data collected from 2012-15.It has approximately 16,000 substances searchable by CAS number. The official version has been delayed and is not expected before 2020.Authorities are currently focusing on developing the hazardous substance single submission (HSSS) tool. Companies can submit all documents online via the tool but must collect a physical copy of the licence from the Department of Industrial Works (DIW) office.A licence is required to manufacture, import or handle type 3 hazardous substances, which are those with a higher degree of hazard.

Sierra Leone Proposes Africa's 'Strongest' Chemicals Management Bill

Sierra Leone has drafted a regulation that would require importers and manufacturers to register all chemicals and pesticides in the country, and pay a fee for a licence to use or distribute them.The draft bill is currently with the country's justice ministry for legal review. It will then be sent to the cabinet of President Julius Maada Bio for approval, and then to Parliament.

It sets out a process for chemicals and pesticides to be registered, monitored and, in some cases, restricted from use in Sierra Leone.All chemical substances used in, or brought into, Sierra Leone must be registered. And importers and manufacturers must also obtain a licence in order to use a registered substance. Registrations will be valid for two years and can be renewed for another two years.

The draft bill sets out fees for the registration and licensing of chemicals and pesticides. The registration fee for one substance is 500,000 Leones, or around $104. A manufacturer licence is also $104, and a licence to import or export a substance $52.These fees will go into a fund for managing chemicals and pesticides, controlled by the board, which will be used to further ensure environmentally sound management in the country.

The bill says the fund will be used in part to raise public awareness of safe and appropriate handling, which the country has identified as a problem in the past.

When considering whether to grant a registration, the board will look at, among other things, whether the substance has been restricted or banned in other countries. Registration and licences will cost more, if the substance has been identified as restricted in Sierra Leone. And companies will need to provide details about how it will be used safely.

The draft bill does not set out a timeline for when this system will be in place, or cut-off dates for registration. It does set out provisions to address issues that have arisen in developing countries, such as the re-use of chemical containers to collect water without being properly cleaned, and deaths resulting from improper handling of highly hazardous pesticides.

When the board approves a chemical's registration, it will also designate a container for its handling and storage. Manufacturers or importers may then be required to dispose of them, the draft bill says, and they cannot be used for other purposes.It also requires landowners, doctors and public health officials to notify the registrar within 24 hours if they believe an injury or death was the result of chemical or pesticide exposure. The registrar can then launch an inquiry.

RV VeKommunicate

Global Business Communication Partners in Advocacy & PR, Reputation & Crisis Management, Research & Economic Data Analysis, with in-depth knowledge of Legal, Trade and Regulatory Affairs, specialising in various industries such as Mining, Manufacturing, Agriculture, Automotive, Pharma & Healthcare, Consumer Affairs and Tourism.
Based in India, working across various international regions:
Asia, EMEA, North and South America

VeKommunicate
1212 12th floor
Tower B, Emaar Digital Greens
Gurugram 121202

For Further Information:

T S Vishwanath: +91 9810977551;
vishwanath@vekommunicate.com

Krishnan Ramalingam: +91 9810042540;
krishnan.ramalingam@vekommunicate.com

Gracelle Gerber: +91 9650586622;
gracelle@vekommunicate.com