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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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IDMA BULLETIN

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IDMA Representation to Chairman, CBIC for extension of due date for filing of GSTR 9 and GSTR 9C and implementation date of e-Invoice – reg.

The Association has submitted the following representation on 9th September 2020 to Shri M Ajit Kumar, IRS, Chairman, Central Board of Indirect Taxes and Customs, New Delhi with a copy to Dr Ajay Bhushan Panday, IAS, Revenue Secretary & Ex-Officio Secretary to GST Council, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

IDMA was formed in the year 1961 and is the only Association in India with a Membership strength of over 1000 wholly-owned Indian Small, Medium and Large scale Pharmaceutical manufacturers situated throughout the length and breadth of our country. IDMA, as the premier National Association, has successfully completed 58 glorious years of providing support to its members who have provided affordable quality medicines, not only to the people of India, but also to people all over the world.

Considering the difficulties for businesses and taxpayers at large, the Government has announced timely relief measures related to indirect tax regulations and compliances to enable them to cope up with the unprecedented crisis. We welcome the host of initiatives taken by the Finance Ministry to help the taxpayers in times of unprecedented crisis created by Corona Virus Pandemic.

Still something more may have to be done till normalcy returns. Amid rising number of Coronavirus cases, the tax department will need to come out with more measures and further extend the timelines to help the taxpayers comply with the statutory norms. Considering the current situation, more and more relief measures may require to be introduced from time to time for the taxpayers to keep their companies afloat and the economy running.

We appreciate that the Income Tax Department has extended the due date of furnishing return of income for all assessees for the Financial Year 2019-20 to November 30, 2020 in place of July 31 and October 31, 2020. Hence, all the assessees who are required to file ITR by July 31, 2020, or October 31, 2020 can file their return of income till November 30, 2020, without paying any late fee charges.

Similarly, we request your good self to provide appropriate relaxation to the registered person by extending due dates of filing GSTR 9, 9A and 9C for FY 2018-19 under GST i.e. 30th September 2020. Also request for postponing Implementation of e-Invoice for Large Taxpayers which is scheduled on 1st October 2020.

This would provide needed relaxation to the trade, in combating the circumstances arising out of Corona Virus and focus on driving economic activities.

Suggestion/Request:

1. It is suggested that the due date of filing of GSTR 9, 9A and 9C for FY 2018-19 be extended from 30th September 2020 to 31st December 2020.
2. Secondly, Implementation of e-Invoice may be extended by at least 6 months i.e. 31st March 2021.

This would provide needed relaxation to the taxpayers to focus on much needed economic activities to revive. We look forward to a favourable response. Thanking You".

● ● ●

Unique Quantity Codes (UQC): IDMA Representation

The Association has submitted the following representation on 11th September 2020 to Dr Anup Wadhawan, IAS, Secretary, Ministry of Commerce & Industry in response to Public Notice dated 18 August 2020 issued by Office of the Commissioner of Customs, Jawahar Lal Nehru Custom House, Nhava-Sheva with copies to Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, Shri Amit Yadav, IAS, Director General of Foreign Trade, Ministry of Commerce & Industry, New Delhi, Shri Sunil Kumar Mall, Commissioner of Customs, Jawahar Lal Nehru Customs House, Nhava-Sheva, Raigad on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We would like to draw your kind attention to the recently issued Public Notice by JNPT as above relating to implementation of Unique Quantity Codes (UQC), which has deleted many Unit of Measures (UOMs) which were prevalent earlier in Pharmaceutical Exports. A copy of the Public Notice is attached for your immediate reference.

Our members, carrying out export activities, have informed us that, due the sudden change in the Unit of Measure (UOM), they are facing severe hardships in clearing of their export as well as import consignments at the Customs. Many of the exporters, who are exporting pharmaceutical goods under Advance Authorization/ Advance License have received license issued by DGFT mentioning, for example, 'BOTTLES', are not able to generate Shipping Bill due to 'Bottle' not being specified in the UOM list in the Public notice referred above.

As you will be aware, unit of measurement for Pharmaceuticals differ company to company and dosage form to dosage form and cannot be measured in kgs/ltrs for all the shipments and they are generally shipped in PACKS/DRUMS/BOTTLES/VIALS/STRIPS etc.

Our members are informed by the authorities to get the Advance Authorization/Advance License amended to new UOM. The exports are already affected due to COVID-19 pandemic and Labour issue for the past many months and any changes during such unprecedented times will further impact our Exports and our economy. As you are aware, in the present COVID-19 pandemic situation, to get the amendment carried out would take considerable time. This delay in Customs is adding to the cost of shipment due to demurrage, and other charges.

Keeping in view the problems expressed by the industry, we would request you to kindly take up the matter with the Customs Authorities and DGFT for allowing the shipments meant for exports by making/restoring possible changes in EDI system.

We request your office to kindly restore the UOM as prevailing before the issuance of Public Notice dated 18.08.2020 as above or direct the Customs to allow the exporters already holding Advance License or Authorization to carry out their export activities. We look forward to a favourable response at the earliest. Thanking you."

Encl: Public Notice No.101/2020, dated 18.08.2020 of Commissioner of Customs.

Streamlining of UQCs in Bills of Entry and Shipping Bills – reg.

Public Notice No.101/2020, dated 18th August 2020

1. Attention of Importers/Exporters, Custom Brokers, Trade and other stakeholders is invited to the above mentioned subject.

2. Board had undertaken an exercise towards standardization of Unit Quantity Codes (UQCs) for purposes of export / import declarations filed on EDI. It was noted that many importers and exporters use UQCs like BGS, BTL, BOX, CTN, GGR, HPT, KPC, ODD and DRM etc which are neither stipulated in the Customs Tariff Act nor prevalent in the normal business transactions. These nonconvertible/ inappropriate UQCs lead to a poor quality of data capture and related implications.

3. As a first measure, declaration of quantities in Statistical UQCs (SQCs) as prescribed under the Tariff Act have been made mandatory in both imports

(since Feb 2019) and exports (since Feb 2020) for every item in addition to the quantities declared in the commercial units as per the invoice. The SQC declarations are being captured in the Single Window table of the Bills of Entry and Shipping Bills.

4. In order to further improve data quality, even among the commercial UQCs declared for the items as per the invoice, henceforth only codes as mentioned in the Annexure would be permitted in BEs/SBs. Declarations in any other UQC will not be accepted.

5. The above changes will come into effect from 20.08.2020.

6. Difficulty, if any, faced in implementation of this public notice may be brought to the notice of the Addl. /Joint Commissioner (Appraising Main (Import)) through email at **appraisingmain.jnch@gov.in.**

7. This Public Notice should be considered as Standing Order for the purpose of officers and staff of department.

Annexure: As above

F.No.S/22-Gen-20/2020-21/AM(I)/JNCH

Sunil Kumar Mall, Commissioner of Customs (NS-I), Office of the Commissioner of Customs (NS-I), Appraising Main (Import), Nhava- Sheva,Tal-Uran, Dist. Raigad, Maharashtra.

ANNEXURE

UQC	Description
CBM	CUBIC METER
CCM	CUBIC CENTIMETER
CMS	CENTIMETER
CTM	CARAT
DOZ	DOZEN
FTS	FEET
GIF	GRM FISSILE ISOTOPE
GMS	GRAMS
GRS	GROSS
GYD	GROSS YARDS
HKS	HANKS
INC	INCHES
KGA	KILOGRAM ACTIVITY
KGS	Kilograms
KLR	KILOLITER
KWH	KILO WATT HOUR
LBS	POUNDS
LTR	LITERS
MGS	MILLI GRAMS
MTR	METER
MTS	METRIC TON
NOS	NUMBERS
PCS	Pieces
PRS	PAIRS
QTL	QUINTAL
SET	SETS
SQF	SQUARE FEET
SQI	SQUARE INCHES
SQM	SQUARE METER
SQY	SQUARE YARDS
TBS	TABLETS
THD	THOUSANDS
TKW	THOUSAN KILO WATT HR
UNT	UNITS
VLS	Vials
YDS	YARDS

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Procedure to be followed for regularisation of FDCs declared as rational in respect to 294 FDCs by DTAB - reg.

DCG(I) Circular Ref. F.No.04-146/2007-DC(Part-I), dated 9th September 2020

To
All State/UT Drugs Controllers:

This is in continuation to this Directorate letter of even number dated 27.02.2019 whereby a detailed pathway was issued for obtaining permission from this Directorate in respect of 83 FDCs declared as rational (copy enclosed)*. Subsequently, the date for submission of such applications was also extended vide this office letter dated 19.08.2019. However, there have been concerns that there is no mention of strength and dosage forms in the said list.

It is pertinent to mention here that as regard to strength and dosage forms of such FDCs mentioned in 83 rational FDCs list, it is to clarify that if the manufacturer submits copy of product license issued by SLA to any firm indicating that the product in specific dosage form and strength was licensed prior to 28.11.2007, the same will be considered for issuance of permission by this office in accordance with the defined pathway.

As per the report of DTAB dated 29.07.2020, there are 3 more FDCs which have been considered as rational under 294 FDCs category. The pathway for obtaining permission w.r.t. these 3 FDCs will also remain same as already defined under this office letter No. 04-146/2007-DC (Part-I) dated 27.02.2019. The details of these FDCs are as under:

Sr. No.	Name of the FDC
1.	Atenolol + Losartan + Hydrochlorothiazide
2.	Duloxetine + Mecobalamin
3.	Mecobalamin + Vit. B6 + Folic Acid

Further, it has been observed that only a few applicants who are already having manufacturing licenses for such FDCs issued by SLA have applied for obtaining approval from this office. Now, it has been decided that manufacturers/stakeholders who are already holding license for these FDCs from SLA may submit their applications latest by 31.03.2021.

In view of above, you are requested to ask the manufacturers who are already holding licenses of these (83+03) FDCs under your jurisdiction to submit the applications to this Directorate as per defined pathway as no further extension will be considered in such cases.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, Fixed Dose Combination Division, Directorate General of Health Services, New Delhi.

(*Published in IDMA Bulletin Issue dated 14th March 2019 Page No. 14)

Auto Let Export Order under Express Cargo Clearance System (ECCS) - reg.

Circular No.41/2020-Customs, dated 7th September, 2020

To,
All Principal Chief Commissioners/Chief Commissioners of Customs,
Principal Directors General/Directors General of Customs.
Principal Commissioners/Commissioner of Customs.

1. In order to facilitate exports by courier and to enhance the global competitiveness of India's exporters, Board has decided to allow the facility of Auto Let Export Order (LEO) under the Express Cargo Clearance System.

2. The facility of Auto LEO has been developed by Directorate General of Systems & Data Management and is ready for launch.

3. The Courier Shipping Bills (CSBs) filed for clearance of export goods under ECCS are subjected to Risk Management System (RMS), after the registration of the goods by the Custodian (arrival scan and weight record). The RMS either facilitates or interdicts a Courier Shipping Bill (CSB) as per risk parameters.

4. It has been decided, that export goods which are covered under CSBs, and are fully facilitated by RMS (no assessment, no examination) and cleared by customs x-ray scanning shall be automatically given LEO by the ECCS. This is expected to considerably reduce the dwell time of clearance of export shipments through courier.

5. Public Notice and Standing order, for guidance of the stakeholders and officers may please be issued.

6. Difficulty, if any, may be brought to the notice of the Board.

F.No.451/13/2020-Cus.V

Dr Swati Bhanwala, OSD (Land Customs),
Central Board of Indirect Taxes & Customs,
Department of Revenue,
Ministry of Finance, New Delhi.

● ● ●

CBIC notifies New Exchange Rates w.e.f. 04th September 2020 - reg.

Notification No.84/2020-Customs, (N.T.), dated 03rd September, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.80/2020-Customs (N.T.), dated 20th August, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 4th September, 2020**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods. .

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	54.85	52.50
2.	Bahraini Dinar	200.60	188.25
3.	Canadian Dollar	57.10	55.05

4.	Chinese Yuan	10.90	10.55
5.	Danish Kroner	11.85	11.40
6.	EURO	88.20	85.05
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	247.65	232.00
9.	New Zealand Dollar	50.85	48.55
10.	Norwegian Kroner	8.40	8.10
11.	Pound Sterling	99.35	95.95
12.	Qatari Riyal	20.75	19.50
13.	Saudi Arabian Riyal	20.15	18.90
14.	Singapore Dollar	54.70	52.85
15.	South African Rand	4.50	4.20
16.	Swedish Kroner	8.55	8.25
17.	Swiss Franc	81.90	78.70
18.	Turkish Lira	10.20	9.60
19.	UAE Dirham	20.60	19.30
20.	US Dollar	74.10	72.40

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	70.25	67.65
2.	Korean Won	6.35	6.00

F.No.468/01/2020-Cus.V

Radhakrishnan Ananth, Deputy Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

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CBIC amends Notification No.92/2017-Customs (N.T.), dated 28th September, 2017 *re.* Jurisdiction of concerned officers - reg.

Notification No.85/2020-Customs (N.T.), dated 4th September, 2020

In exercise of the powers conferred by sub-section (1) of section 4 of the Customs Act, 1962 (52 of 1962), the Central Board of Indirect Taxes and Customs hereby makes the following further amendment in the Notification of the Government of India in the Ministry of Finance (Department of Revenue) No.92/2017-Customs (N.T.), dated the 28th September, 2017, namely:-

In the said Notification, in paragraph 1, for the provisos, the following proviso shall be substituted, namely:-

"Provided that each of the officers as mentioned in column (2) of the Table, shall have jurisdiction in relation to an order or decision of the officers sub-ordinate to all other officers as mentioned in column (3) thereof, in respect of the bill of entry entered for home consumption under sub-section (1) of section 46 or for warehousing under section 68 of the said Act for goods imported at a customs station in the jurisdiction of the officers as mentioned in the corresponding entry in said column (3) of the said Table against their own which are assigned to them electronically in the Customs Automated System for the purposes of sub-section (5) of section 17 and section 18 of the said Act.".

F.No.437/48/2014-Cus.IV

Ananth Rathakrishnan, Deputy Secretary (Customs), Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Note:- *The Principal Notification No.92/2017-Customs (N.T.), dated the 28th September, 2017, was published in the Gazette of India, Extraordinary, vide number G.S.R.1210(E), dated the 28th September, 2017, and was last amended by Notification No.63/2020-Customs (N.T.), dated the 30th of July 2020, published in the Gazette of India, Extraordinary, vide number G.S.R.482(E) dated the 30th of July 2020.*

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All India roll-out of Faceless Assessment - reg.

Circular No.40/2020-Customs, dated 4th September, 2020

To,

All Principal Chief Commissioners/Chief Commissioners of Customs/ Customs (Preventive), All Principal Chief Commissioners/Chief Commissioners of Customs & Central tax,

All Principal Commissioners/Commissioners of Customs/Customs (Preventive), All Principal Commissioners/Commissioners of Customs & Central tax,

All Principal Director Generals/Director Generals under CBIC.

1. Kind reference is invited to Board Circulars No.28/2020-Customs, dated 05.06.2020 and No.34/2020- Customs, dated 30.07.2020, launching Phases I and II of Faceless Assessment, respectively, under the umbrella of the next generational **Turant Customs** programme.

2. The key elements of the Turant Customs programme are *Faceless, Contactless and Paperless* Customs clearance processes. This includes faceless or anonymised assessment, self-registration of goods by importers, automated clearances of bills of entry, digitisation of Customs documents, etc. The objectives sought to be achieved are exponentially faster clearance of goods, reduced interface between trade and Customs officers and enhanced ease of doing business. The phased launch of the Turant Customs programme in select ports of import was aimed at testing in a real-life environment, the IT capabilities as well as the responsiveness of the trade and Customs officers to the various initiatives. The results have been reviewed and these have confirmed that the stated objectives are being met. The stage is now set for extending the Turant Customs programme across all Customs ports pan India and thereby ushering in a more modern, efficient, and professional Customs administration with resultant benefits for trade and industry.

3. Faceless Assessment, duly supported by Paperless and Contactless Customs clearance processes, is a critical reform. As you are aware, the pilot programme of Faceless Assessment was launched in Chennai on 14.08.2019 for primarily electrical machineries falling under Chapter 85 of the Customs Tariff Act, 1975. This pilot programme was subsequently expanded to Ahmedabad, Bengaluru, Delhi, Mundra and Visakhapatnam for goods primarily falling under Chapters 39, 84, 86 to 92, 72 to 83 and 50 to 71 of the Customs Tariff Act, 1975. These pilot programmes helped test Faceless Assessment, first in the same Zone (e.g. imports at Chennai seaport and air-cargo were assessed by Customs officers in either location instead of only in the port/air-cargo of import) and then across Zones (e.g. imports at Chennai sea/air-cargo were assessed by Customs officers at Bengaluru air-cargo/ICD and vice versa). These pilot programmes were followed by the launch of Phase I of Faceless Assessment on 05.06.2020, cutting across the Customs formations in Chennai and Bengaluru for articles primarily falling under the Chapters 84 and 85 of the Customs Tariff Act, 1975. Phase II of Faceless Assessment, which was begun on 03.08.2020 at Customs formations in Chennai, Bengaluru, Delhi, for goods falling under the Chapters 50 to 71, 84, 85 and 86 to 92 of the Customs Tariff Act, 1975 and at Customs formations in Mumbai, for goods failing under the Chapter 29 of the Customs Tariff Act, 1975. As aforestated, the results have been encouraging.

4. **Board has decided to roll-out the Faceless Assessment at an All India level in all ports of import and for all imported goods by 31.10.2020**. The detailed roll-out plan in phases covering different Customs Zones and Chapters of the Customs Tariff Act, 1975, including the existing Phases I and II, is given in Annexure I.

5. **Constitution of National Assessment Centres (NACs):**

5.1 Vide para 4 of Circular No.28/2020-Customs, dated 05.06.2020, it was intimated that the designated nodal Commissioners would be precursors to the National Assessment Centres (NACs). Accordingly, Board has decided to constitute total 11 NACs, as mentioned in the Annexure II. These NACs are organized commodity-wise according to the First Schedule to the Customs Tariff Act, 1975. The rationale for the selection of a Zone in the NAC is the share of volume of the import of the particular commodity group(s) in its Zone as compared to the All India imports and/or share of contributed by the said commodity group(s) or the share of import of the particular commodity group(s) in their own Zones, while the rationale for the selection of a Conveners for the NAC is its share of the All India revenue contributed by the said commodity group(s) or the

share of the revenue contributed by the particular commodity group(s) in their own Zones.

5.2 Each NAC shall be co-convened by the Principal Chief Commissioners/Chief Commissioners of the Zones mentioned in Column 4 of Annexure II.

5.3 Each NAC shall consist of the Principal Commissioners/Commissioners of Customs from the Zones indicated in Column 3 of Annexure II as a member.

5.4 For each NAC the Principal Chief Commissioners/ Chief Commissioners, having jurisdiction over the Zones, shall nominate a nodal Principal Commissioners/Commissioners. The rationale for the nomination would be the volume of the import of the particular commodity group(s) in the Zone as compared to the All India imports and/or share of import of the particular commodity group(s) in their own Zones. The Board shall be informed about the nomination of the Principal Commissioners/ Commissioners and the same shall be published on the departmental website.

Responsibilities of NAC:

5.5 The NACs have a critical role in the successful implementation of Faceless Assessment. In addition to their existing work, the NACs need to work in a coordinated manner to ensure that all assessments are carried out in a timely manner and there is no delay or hold up of the Bills of Entry. The NACs would also examine the assessment practices of imported goods across Customs stations to bring about uniformity and enhanced quality of assessments. The important responsibilities of the NACs shall include the following:

(I) Monitor the assessment practice for enhancing uniformity of classification, valuation, exemption benefit and compliance with import policy conditions.

(II) Assess the application of Compulsory Compliance Requirements (CCRs) and ensure uniform practices in accordance with the relevant statutes/Legal provisions.

(III) Study audit objections and take corrective actions regarding assessments, wherever necessary and provide inputs to the concerned ports of import.

(IV) Analyse the RMS facilitated Bills of Entry pertaining to Chapters falling under their purview and advise the DGARM regarding possible interventions or review of risk parameters.

(V) Liaise with Principal Commissioner/ Commissioner of Customs at ports of import about interpretational issues pertaining to classification, valuation, scope of exemption notifications and trade policy conditions.

(VI) Interact with sectoral trade and industry for inputs, and on issues relating to assessment.

(VII) Function as a knowledge hub or repository for that particular Chapter(s);

(VIII) Examine the orders/appellate orders in relation to assessment practices pertaining to goods assigned to each Faceless Assessment Group and provide inputs to the Commissionerates for uniformity of assessment orders before legal fora.

(IX) Constitute Working Groups for matters relating to:

a) Monitoring for timely assessment of Bills of Entry.

b) Valuation and related issues.

c) Classification and related issues.

d) Restrictions and prohibitions and Co-ordination with PGAs.

e) Communication and Outreach for departmental officers and trade.

f) Any other matter relevant to timely and uniform assessment, as may be decided.

Responsibilities of Co-conveners of NAC:

5.6 The Co-conveners of NAC shall provide overall leadership and monitor the functioning of the NACs. The important responsibilities of NAC Co-conveners in regard to the NAC shall include the following:

I. Nomination of Principal Commissioners/ Commissioners as Members of the NAC from the Zones mentioned in column 3 of Annexure II.

II. Ensure setting up of Working Groups within NACs for smooth functioning of NACs.

III. Ensure that NACs develop expertise over the assigned Faceless Assessment Group in different facets of assessment such as classification, valuation, prohibitions & restrictions etc.

IV. Co-ordinate with other Directorates and NACs for various functions mentioned in paras 5.7 & 5.8 of this Circular.

V. Make recommendations to Board for policy considerations.

Co-ordination Among NAC Commissioners:

5.7 Since the Nodal Principal Commissioners/ Commissioners are spread across different geographical locations, following co-ordination measures may be institutionalised at the initial phase, which will go a long way in bringing efficiency to the functioning of NACs:

I. Continuous assessment – Ensure that verification of the assessment is not held up if there is an official holiday for the members of the FAG in a particular location. This could be done by having this work done at multiple locations.

II. Daily Web meeting – The Working Groups may virtually meet for a short duration every day at a scheduled time to review timeliness of assessment, identify bottlenecks and take measures to remove difficulties. The link shall be made available to the Chairman, Member Customs, Zonal Member(s) and Joint Secretary (Customs), CBIC and the Co-convenors of concerned NAC, to enable participation in the online meeting room.

III. Weekly web meeting – The Working Groups may have a web meeting for a short duration once a week at a scheduled time to review classification, valuation, exemption notifications, prohibitions and restrictions in order to identify divergent practices and ensure uniformity.

IV. Monthly web meeting by Co-convenors: The Co-convenors of the NAC shall have a web meeting, at least once in a month to review the functioning of the NACs.

Co-ordination of NACs with Other Directorates:

5.8 NACs shall also co-ordinate with:

I. Directorate of Revenue Intelligence (DRI) and Directorate General of GST Intelligence (DGGI) related to management of alerts undertaken by the NAC.

II. Directorate General of Valuation (DGoV) to enhance expertise related to sensitive commodities handled. DGoV shall also appoint nodal person for every NAC for better co-ordination.

III. Directorate General of Analytics and Risk Management (DGARM) to provide feedback and enhance risk assessment and accuracy of CCR Instructions.

IV. National Academy of Customs and Indirect Taxes (NACIN) to hold capacity building sessions for departmental officers.

V. Directorate General of Taxpayer Services (DGTS) to enhance outreach measures to the taxpayers by providing content, faculty for holding webinars, workshops etc.

VI. Directorate General of Audit (DG Audit) and Audit Commissionerates related to audit objections and feedback.

VII. Directorate General of Systems and Data Management (DG Systems) in regard to System issues and enhancements.

VIII. Any other formations in CBIC to fulfil the stated objectives.

Pre-launch preparation for Faceless Assessment:

5.9 Before the rollout of Faceless Assessment, the Nodal Commissioners in the NAC shall co-ordinate to take all measures to ensure that Faceless Assessment is smooth and creates no disruption in the assessment and clearance of goods. The following important measures may be undertaken by the NAC before the launch:

I. The Customs locations within each Zone, performing Faceless Assessment may be identified. The volume of import and availability of adequate officers may be taken into consideration for such identification.

II. Nominate sufficient number of officers for the Faceless Assessment. The officers should be more than two at all levels, to ensure availability. To the extent possible, dedicated team of officers may be posted to the Faceless Assessment Groups.

III. Identify variations, if any, in assessment practices and harmonise them for application across FAGs.

IV. Take into account audit objections, judicial and quasi-judicial decisions accepted by

the Department relating to the assessment of the goods to be handled by the Faceless Assessment Groups under the concerned NAC and circulate among the FAGs for uniformity of assessment.

V. Organize training on roles and functionalities in ICES related to Faceless Assessment including MIS Reports and Dashboards.

5.10. To ensure smooth implementation of Faceless Assessment & to sensitize both the departmental officers and the trade, Directorate General of Taxpayer Services (DGTS) in coordination with Customs Policy Wing shall organize extensive outreaches via online webinars/ promotional videos etc.

6. Conference on Tariff & Other Customs Matters:

6.1 Joint Secretary, Customs, (CBIC) would be responsible for coordinating with the NACs in organizing a Conference on Tariff & Other Customs Matters every 6 months to review the functioning of the NACs and FAGs. The Conference would be chaired by Member (Customs).

7. Further, Board has issued Notification No.85/2020-Customs (N.T.) dated 04.09.2020 by virtue of which the Commissioners of Customs (Appeals) are empowered take up appeals filed in respect of Faceless Assessments pertaining to imports made in their jurisdictions even though the Faceless Assessment officer may be located at any other Customs station. To illustrate, Commissioners of Customs (Appeals) at Bengaluru would decide appeals filed for imports at Bengaluru though the Faceless Assessment officer is located at any other port of the country, say Delhi.

8. All other clarifications and guidelines on Faceless Assessment, as provided vide Circular No.28/2020-Customs and Instruction No.09/2020-Customs, both dated 05.06.2020 may kindly be referred to.

9. The Principal Chief Commissioners/Chief Commissioners of Customs are requested to issue Public Notices and guide the trade suitably to ensure the smooth roll out of Faceless Assessment.

10. Any difficulties faced in the implementation of this Circular may please be brought to the notice of Board.

F.No.450/26/2019-Cus IV(Pt.)

Ananth Rathakrishnan, Deputy Secretary (Customs), Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, New Delhi

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Annexure I

Implementation Phases for All India Roll-Out of Faceless Assessment

Phase	Roll-Out Date	% Coverage of All India Bills of Entry	Faceless Assessment Group Clusters	Zones and Faceless Assessment Groups
(1)	(2)	(3)	(4)	(5)
I	05.06.2020	14 %	5 & 5A - Bengaluru & Chennai	(a) Bengaluru – 5, **5A** (b) Chennai – **5**, 5A
II	03.08.2020	21%	(i) 3,5,5A,5B – Bengaluru, Chennai & Delhi (ii) Mumbai I,II,III – 2A	(a) **3**, 5, 5A, **5B** – Bengaluru (b) 3, 5, 5A, **5B -** Chennai (c) **3, 5, 5A**, 5B – Delhi (d) **2A** - Mumbai I, II , III

III	15.09.2020	50 %	(i) 5,5A,5B - **Ahmedabad,** Bengaluru, Chennai, Delhi, **Mumbai I, II & III, Visakhapatnam** (ii) 4 - **Ahmedabad, Bengaluru, Bhubaneshwar, Chennai, Delhi**, Visakhapatnam (iii) 3 – Bengaluru, Chennai & Delhi, Delhi (Prev.), Kolkata, **Thiruvananthapuram, Tiruchirappalli (Prev.), Patna (Prev.), Guwahati** (iv) 2G – Ahmedabad, **Bengaluru, Bhopal, Chennai, Delhi, Meerut and Nagpur, Pune** (v) 2A – Mumbai I, II, III, **Chennai and Hyderabad**	(a) 2A,**5, 5A, 5B** - Mumbai I, II, III (b) 2A – Hyderabad (c) 2G, **4, 5, 5A, 5B** – Ahmedabad (d) **2G**, 3, **4,** 5, 5A, 5B – Bengaluru (e) **2G**, **2A** 3, **4,** 5, 5A, 5B – Chennai (f) **2G,** 3, **4,** 5, 5A, 5B – Delhi (g) **2G** – Bhopal, Meerut, Nagpur, Pune (h) **3** – Delhi (Prev.), Kolkata, Patna (Prev.), Guwahati, Thiruvananthapuram, Tiruchirappalli (Prev.) (i) **4** – Bhubaneshwar (j) 4,**5, 5A, 5B** – Visakhapatnam
IV	01.10.2020	86.0%	(i) 5,5A,5B – Ahmedabad, Bengaluru, **Bhopal, Bhubaneshwar,** Chennai, Delhi, **Guwahati, Hyderabad, Kolkata, Delhi (Prev.), Meerut,**Mumbai I, II & III, **Nagpur, Patna (Prev.), Pune, Thiruvananthapuram, Tiruchirappalli (Prev.),** Visakhapatnam (ii) 4 – Ahmedabad, Bengaluru, Bhubaneshwar, **Bhopal,** Chennai, Delhi, **Delhi (Prev.), Kolkata, Meerut, Mumbai I, II,III, Nagpur, Pune,** Visakhapatnam, **Hyderabad** (iii) 3 – **Ahmedabad,** Bengaluru,	(a) 1,2A, **2G, 2K, 3, 4**, 5, 5A, 5B, 6 – Mumbai -II (b) **1,1A,** 2G, 2A, 3, 4, 5, 5A, 5B, **6** - Chennai (c) 1A, 2A, **2G, 3, 4**, 5, 5A, 5B, 6 – Mumbai-I (d) 2A, **2G, 3, 4**, 5, 5A, 5B – Mumbai-III (e) 2A, **4, 5, 5A, 5B** – Hyderabad (c) **1A, 2A,** 2G, **2K, 3,** 4, 5, 5A, 5B – Ahmedabad (d) **1A, 2A,** 2G, 3, 4, 5, 5A, 5B – Bengaluru (f) **2A,** 2G, 3, 4, 5, 5A, 5B**, 6** – Delhi (g) 2G, **4, 5, 5A, 5B** – Meerut, Nagpur, Bhopal, Pune (h)1, 3, **4, 5, 5A, 5B** – Kolkata (i) 3, **4, 5, 5A, 5B** – Delhi (Prev.)
			Chennai & Delhi, Delhi (Prev.), Guwahati, Kolkata, **Mumbai I, II & III,** Patna (Prev.), Thiruvananthapuram, Tiruchirappalli (Prev.), (iv) 2G – Ahmedabad, Bengaluru, Bhopal, Chennai, Delhi, **Hyderabad, Meerut, Mumbai I, II & III,** Nagpur, Pune, **Thiruvananthapuram, Tiruchirappalli (Prev.)** (v) 2A – **Ahmedabad,** Chennai, Delhi, Hyderabad and Mumbai I, II, III	(j) **2G,** 3, **5, 5A, 5B** – Thiruvananthapuram, Tiruchirappalli (Prev.) (k) **1A, 2A,** 4, 5, 5A, 5B – Visakhapatnam (l) 5, 5A, 5B, 4, 1A – Bhubaneshwar (m) 3, **5, 5A, 5B** – Patna (Prev.), Guwahati

			(vi) 1A – **Ahmedabad, Bhubaneshwar, Mumbai-I, Visakhapatnam** (vii) 1,6 – **Chennai, Delhi, Kolkata, Mumbai-II, Visakhapatnam** (viii) 2K – **Ahmedabad, Mumbai-II, Tiruchirappalli (Prev.)**	
V	31.10.2020	100%	(i) 5,5A,5B – Ahmedabad, Bengaluru, Bhopal, Bhubaneshwar, Chennai, Delhi, Delhi (Prev.), Guwahati, Hyderabad, Kolkata, Mumbai I, II & III, Nagpur, Pune, Thiruvananthapuram, Tiruchirappalli (Prev.), Patna (Prev.), Visakhapatnam (ii) 4 – Ahmedabad, Bengaluru, Bhubaneshwar, Bhopal, Chennai, Delhi, Delhi (Prev.), Kolkata,Meerut, Mumbai, I,II,III, Nagpur, Pune, Visakhapatnam, Hyderabad,**Patna (Prev.), Thiruvananthapuram, Tiruchirappalli (Prev.), Guwahati** (iii) 3 – Ahmedabad, Bengaluru, **Bhopal, Bhubaneshwar**, Chennai, Delhi, Delhi (Prev.), Guwahati**, Hyderabad,** Kolkata, **Meerut,** Mumbai I,II &III, **Nagpur,** Patna (Prev.), **Pune,** Thiruvananthapuram, Tiruchirappalli (Prev.),	(a) 1, **1A, 2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J**, 2K, 3, 4, 5, 5A, 5B, 6 – Mumbai II (b) 1,1A, **2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K,** 3, 4, 5, 5A, 5B, 6 - Chennai (c) **1,**1A, **2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K**, 3, 4, 5, 5A, 5B, 6 – Mumbai-I (d) **1, 1A, 2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K**, 3, 4, 5, 5A, 5B – Mumbai -III (e) **1, 1A, 2,** 2A, **2B, 2C, 2D, 2E, 2F, 2G, 2H, 2I, 2J, 2K**, 4, 5, 5A, 5B, **6**– Hyderabad (c) **1,** 1A, **2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J**, 2K, 3, 4, 5, 5A, 5B, **6** - Ahmedabad (d) **1,** 1A, **2,** 2A**2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K,** 3, 4, 5, 5A, 5B, **6** – Bengaluru (f) **1, 1A, 2,** 2A, **2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K,** 3, 4, 5, 5A, 5B,6 – Delhi (g) **1, 1A, 2, 2A, 2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K, 3,** 4, 5, 5A, 5B, **6** – Meerut, Nagpur, Bhopal, Pune
			Visakhapatnam (iv) 2G – Ahmedabad, Bengaluru, Bhopal, **Bhubaneshwar,** Chennai, Delhi, **Delhi (Prev.), Guwahati,** Hyderabad, **Kolkata,** Meerut, Mumbai I, II & III, Nagpur, **Patna (Prev.),** Pune, Thiruvananthapuram, Tiruchirappalli (Prev.), Visakhapatnam (v) 2A – Ahmedabad, **Bengaluru, Bhopal, Bhubaneshwar,** Chennai, Delhi, **Delhi (Prev.), Guwahati,** Hyderabad, **Kolkata, Meerut,** Mumbai I, II, III, **Nagpur,**	(h)1, **1A, 2, 2A, 2B, 2C, 2D, 2E, 2F, 2G, 2H, 2I, 2J, 2K**, 3, 4, 5, 5A, 5B, **6** Kolkata (i) **1, 1A, 2, 2A, 2B, 2C, 2D, 2E, 2F, 2G, 2H, 2I, 2J, 2K**, 3, 4, 5, 5A, 5B**, 6**- Delhi (Prev.) (j) **1, 1A, 2, 2A, 2B, 2C, 2D, 2E, 2F,** 2G, **2H, 2I, 2J, 2K,** 3, **4,** 5, 5A, 5B**, 6**- Thiruvananthapuram, Tiruchirappalli (Prev.) (k) **1,** 1A, **2, 2A, 2B, 2C, 2D, 2E, 2F, 2G, 2H, 2I, 2J, 2K, 3,** 4, 5, 5A, 5B,**6** – Visakhapatnam (l) **1,** 1A, **2, 2A, 2B, 2C, 2D, 2E, 2F, 2G, 2H, 2I, 2J, 2K, 3,** 4, 5, 5A, 5B, **6**- Bhubaneshwar (m) **1, 1A, 2, 2A, 2B, 2C, 2D, 2E,**

			Patna (Prev.), Pune, Thiruvananthapuram, Tiruchirappalli (Prev.), Visakhapatnam (vi) 1A – Ahmedabad, **Bengaluru, Bhopal,** Bhubaneshwar, **Chennai, Delhi, Delhi (Prev.), Guwahati, Hyderabad, Kolkata, Meerut,** Mumbai I**, Mumbai II & III, Nagpur, Patna (Prev.), Pune, Thiruvananthapuram, Tiruchirappalli (Prev.),** Visakhapatnam (vii) 1,6 – **Ahmedabad, Bengaluru, Bhopal, Bhubaneshwar,** Chennai, Delhi, **Delhi (Prev.), Guwahati, Hyderabad,** Kolkata, **Meerut,** Mumbai I, **Mumbai II & III, Nagpur, Patna (Prev.), Pune, Thiruvananthapuram, Tiruchirappalli (Prev.),** Visakhapatnam (viii) 2K – Ahmedabad, **Bengaluru, Bhopal, Bhubaneshwar, Chennai, Delhi, Delhi (Prev.), Guwahati, Hyderabad, Kolkata, Meerut, Mumbai I,** Mumbai II **& III, Nagpur, Patna (Prev.), Pune, Thiruvananthapuram,** Tiruchirappalli (Prev.), **Visakhapatnam** (ix) 2,2B,2C,2D, 2E, 2F, 2H, 2I, 2J - **Ahmedabad, Bengaluru, Bhopal, Bhubaneshwar,**	**2F, 2G, 2H, 2I, 2J, 2K,** 3, **4,** 5, 5A, 5B, **6**- – Patna (Prev.), Guwahati
			Chennai, Delhi, Delhi (Prev.), Guwahati, Hyderabad, Kolkata, Meerut, Mumbai I, II & III, Nagpur, Patna (Prev.), Pune, Thiruvananthapuram, Tiruchirappalli (Prev.), Visakhapatnam	
31st Oct 2020: All India – All Zones - All Imports under Faceless Assessment#				

 # Excluding Land Customs Stations.

Note : *Zones and Faceless Assessment Groups in bold in columns 4 and 5 and are newly added as on the roll-out dates in column 2.*

Annexure II

National Assessment Centres

National Assessment Centre	Faceless Assessment Groups (Chapters covered by Customs Tariff Act, 1975)	Nodal Commissioners from Zones	Conveners (Pr.CC/CC of the Zone)
(1)	(2)	(3)	(4)
Primary Products	1 (1-26)	1. Bengaluru 2. Bhubaneshwar 3. Chennai 4. Kolkata 5. Tiruchirappalli (Prev.) 6. Thiruvananthapuram 7. Vishakhapatnam	Kolkata
		1. Ahmedabad 2. Delhi 3. Delhi(Prev.) 4. Guwahati 5. Mumbai II 6. Mumbai III 7. Patna (Prev.)	Guwahati
Mineral Products	1A (27)	1. Ahmedabad 2. Delhi 3. Mumbai I 4. Mumbai II 5. Mumbai III 6. Pune	Ahmedabad
		1. Bengaluru 2. Bhubaneshwar 3. Chennai 4. Kolkata 5. Tiruchirappalli (Prev) 6. Visakhapatnam	Bhubaneshwar
Chemicals 1	2A,2B,2C,2D,2E and 2F (28-38)	1. Ahmedabad. 2. Delhi 3. Delhi (Prev.) 4. Meerut 5. Mumbai II 6. Mumbai III	Mumbai II
		1. Chennai 2. Hyderabad 3. Kolkata 4. Mumbai I 5. Thiruvananthapuram 6. Visakhapatnam	Visakhapatnam
Chemicals 2	2G (39)	1. Chennai 2. Hyderabad 3. Mumbai I	Mumbai II

		4. Mumbai II 5. Mumbai III 6. Visakhapatnam 7. Thiruvananthapuram	
		1. Ahmedabad 2. Bhopal 3. Delhi 4. Delhi (Prev.) 5. Kolkata 6. Meerut 7. Patna (Prev.)	Bhopal
Chemicals 3	2H,2I,2J,2K (40-49)	1. Bengaluru 2. Bhopal 3. Chennai 4. Kolkata 5. Nagpur 6. Tiruchirappalli (Prev.) 7. Thiruvananthapuram 8. Visakhapatnam	Chennai
		1. Ahmedabad 2. Delhi 3. Delhi (Prev.) 4. Meerut 5. Mumbai II 6. Mumbai III 7. Mumbai I 8. Patna (Prev.) 9. Pune	Patna (Prev.)
Textile Products	3 (50-71)	1. Ahmedabad. 2. Bengaluru 3. Delhi 4. Delhi(Prev.) 5. Kolkata 6. Patna (Prev.)	Bengaluru
		1. Chennai 2. Mumbai I 3. Mumbai II 4. Mumbai III 5. Tiruchirappalli (Prev.). 6. Thiruvananthapuram	Tiruchirappalli (Prev.)
Metal Products	4 (72-83)	1. Ahmedabad 2. Delhi 3. Delhi(Prev.) 4. Guwahati 5. Meerut 6. Mumbai I 7. Mumbai II 8. Mumbai III 9. Kolkata	Delhi (Prev.)
		1. Bengaluru 2. Bhopal 3. Chennai	Nagpur

		4. Hyderabad 5. Nagpur 6. Pune 7. Vishakhapatnam 8. Thiruvananthapuram	
Mechanical Machineries	5 (84)	1. Ahmedabad 2. Delhi 3. Delhi(Prev.) 4. Mumbai II 5. Mumbai III	Mumbai III
		1. Bengaluru 2. Chennai 3. Hyderabad 4. Kolkata 5. Thiruvananthapuram	Hyderabad
Electric Machineries	5A (85)	1. Delhi 2. Ahmedabad. 3. Mumbai I 4. Mumbai II 5. Mumbai III	Delhi
		1. Bengaluru 2. Chennai 3. Hyderabad 4. Kolkata Thiruvananthapuram	Meerut
Automobiles and Instruments	5B (86-92)	1. Bengaluru 2. Chennai 3. Hyderabad. 4. Kolkata 5. Thiruvananthapuram	Chennai
		1. Ahmedabad 2. Delhi 3. Delhi(Prev.) 4. Mumbai II 5. Mumbai III	Pune
Misc. products/Project Imports	6 (93-98)	1. Ahmedabad. 2. Kolkata 3. Mumbai I 4. Mumbai II 5. Mumbai III 6. Hyderabad	Mumbai I
		1. Bengaluru 2. Chennai 3. Delhi (Prev.) 4. Delhi 5. Thiruvananthapuram 6. Visakhapatnam	Thiruvananthapuram

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CRA4 Form for filing cost audit report time extended

Corporate Affairs General Circular No.29/2020, dated 10th September 2020

To
All Regional Directors,
All Registrars of Companies,
All Stakeholders.

1. Representations have been received from various stakeholders for extension of last date of filing of CRA-4 (Form for filing of cost audit report) due to impact of COVID-19 pandemic.

2. In view of the extraordinary disruption caused due to the pandemic, it has been decided that if cost audit report for the financial year 2019-20 by the cost auditor to the Board of Directors of the companies is submitted by 30th November, 2020 then the same would not be viewed as violation of rule 6(5) of Companies (cost records and audit) Rules, 2014. Consequently, the cost audit report for the financial year ended on 31st March, 2020 shall be filed in e-form CRA-4 within 30 days from the date of receipt of the copy of the cost audit report by the company. However, in case a company has availed extension of time for holding Annual General Meeting then e-form CRA-4 may be filed within the timeline provided under the proviso to rule 6(6) of the Companies (Cost Records and Audit) Rules, 2014.

3. This issues with the approval of the competent authority.

File No:17/52/2020-CL-V

Atma Sah, Deputy Director, Ministry of Corporate Affairs, New Delhi.

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Technical Members for Patents, Trademarks and Copyrights in IPAB notified

Notification Ref. No.10/4/2019-EO(SM-II), dated 21st July 2020

1. Department for Promotion of Industry and Internal Trade's OM No. P-24017/72/2017-IPR-I dated 25.11.2019 refers.

2. The Appointments Committee of the Cabinet has approved the following proposals for appointment to the posts of Technical Member (Patents), Technical Member (Trade Marks) and Technical Member (Copyrights) in Intellectual Property Appellate Board (IPAB) with a Pay of Rs.2,25,000/- and other terms and conditions as per Tribunal, Appellate Tribunals and other Authorities (Qualifications, Experience and other Conditions of Service of Members) Rules, 2020 for a period of four years w.e.f. the date of assumption of the charge of the post, or till attaining the age of 65 years, or until further orders, whichever is the earliest:

Sr. No.	Name (S/Shri/Ms./Smt)
Technical Member (Patents) - (01 Post):	
1.	**Birendra Prasad Singh,** Joint Controller of Patents and Designs.
Waitlisted Name:	
1	**R Devan,** Joint Controller of Patents and Designs.
Technical Member (Trademarks) – (02 Posts):	
1	**Lakshmidevi Somanath,** Advocate.
2	**Mr Vijay Kumar,** Advocate/Patent Agent.
Waitlisted Name:	
1	**Dipak Girdharlal Parmar,** Advocate.
Technical Member (Copyrights) – (02 Posts):	
1	**N Surya Senthil,** Advocate.
2	**S P Chockalingam,** Advocate.

Rajeev Lochan, Under Secretary (EO-SM.II), Secretariat of the Appointments Committee of the Cabinet, Department of Personnel & Training, Ministry of Personnel, Public Grievances & Pensions, Government of India, New Delhi.

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Vitamin D deficiency may raise risk of getting COVID-19

In a retrospective study of patients tested for COVID-19, researchers at the University of Chicago Medicine found an association between Vitamin D deficiency and the likelihood of becoming infected with the Coronavirus. "Vitamin D is important to the function of the immune system and Vitamin D supplements have previously been shown to lower the risk of viral respiratory tract infections," said David Meltzer, MD, Ph.D., Chief of Hospital Medicine at UChicago Medicine and lead author of the study. "Our statistical analysis suggests this may be true for the COVID-19 infection."

The research team looked at 489 UChicago Medicine patients whose Vitamin D level was measured within a year before being tested for COVID-19. Patients who had Vitamin D deficiency (< 20ng/ml) that was not treated were almost twice as likely to test positive for the COVID-19 Coronavirus compared to patients who had sufficient levels of the vitamin.

The study, Association of Vitamin D Status and Other Clinical Characteristics with COVID-19 test results, was published September 3 in JAMA Network Open. Findings were previously reported on medRxiv, a preprint server for the health sciences. Half of Americans are deficient in Vitamin D, with much higher rates seen in African Americans, Hispanics and individuals living in areas like Chicago where it is difficult to get enough sun exposure in winter.

"Understanding whether treating Vitamin D deficiency changes COVID-19 risk could be of great importance locally, nationally and globally," Meltzer said. "Vitamin D is inexpensive, generally very safe to take, and can be widely scaled." Meltzer and his team emphasize the importance of experimental studies to determine whether Vitamin D supplementation can reduce the risk, and potentially severity, of COVID-19. They also highlight the need for studies of what strategies for Vitamin D supplementation may be most appropriate in specific populations. They have initiated several Clinical Trials at UChicago Medicine and with partners locally.

Source: University of Chicago Medical Center, Science Daily, 03.09.2020 (Excerpts)

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US FDA-approved ointment found to treat, kill viral infections including COVID-19

A US pharma company has successfully tested a Food and Drug Administration-approved over the counter ointment as the first line of defence against the deadly Coronavirus that has so far killed over eight lakh people globally. Scientists associated with the project said the FDA-registered non-prescription over the counter (OTC) ointment has been proven to prevent, treat and kill viral infections including Coronavirus.

"As per the lab report states, no infectious virus was detected after 30 seconds of T3X treatment," the Pharma company said in a statement.

"We believe this will be a breakthrough that will reduce the likelihood of becoming infected with Coronavirus through the nose, which is where most cases are contracted," said Dr Brian Huber, CEO and founder of Advanced Penetration Technology, which is based out of Indiana and Texas.

"This is a big deal. It is the type of protection a lot of people have been hoping for and could be a first line of defence against the COVID virus. It is a powerful and effective layer of prevention," Huber said.

He was speaking after the company released the results of an independent laboratory evaluation of a topical medical formulation that mitigates Coronavirus from entering the body through the nasal passages, thereby significantly reducing the likelihood of people becoming infected with the virus.

A recent study by the Massachusetts Institute of Technology (MIT) concluded that people contract COVID-19 and other viruses primarily through the nose. However, virus may still enter a body through the mouth and the eyes.

"T3X is an FDA registered, over-the-counter formulation, which means that no prescription is needed. It is easy to use and can be self-administered without the assistance of medical personnel or technicians," the company said.

Source: PTI, ET-Healthworld, 22.08.2020 (Excerpts)

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Researchers design and test protein that may lead to COVID-19 therapeutic

A novel receptor protein that binds to the SARS-CoV-2 virus and prevents it from entering cells may hold promise for treating COVID-19 and other Coronavirus-related diseases, according to research published online August 4 in the journal SCIENCE. As scientists race to find treatments for COVID-19, many are focused on a specific protein called angiotensin-converting enzyme 2, or ACE2, which is found on various cell surfaces throughout the human body. Its purpose is to generate smaller proteins that regulate functions within the cell. Using the spike-like protein on its surface, the SARS-CoV-2 virus binds to ACE2 prior to entry and infection of cells. Thus, ACE2 acts as a receptor for the virus that causes COVID-19.

In the study, Dr Erik Procko and scientists at the University of Illinois engineered a novel receptor that resembles ACE2, with the intent of using it as a "decoy" that can bind to the virus before it can latch onto ACE2 at the cell surface and invade the cell. First, Procko examined more than 2,000 ACE2 mutations and created cells with the mutant receptors on their surfaces. By analyzing how these interacted with the Coronavirus spike protein, he found a combination of three mutations that made a receptor that bound to the virus more strongly and made it a more "attractive" target for the virus.

After Procko posted his findings to a preprint server, a colleague connected him with the US Army Medical Research Institute of Infectious Diseases. USAMRIID scientists, including Dr Andrew Herbert of The Geneva Foundation, agreed to test the receptor in cells using live SARS-CoV-2. "We were already in the process of testing several therapeutic candidates for SARS-CoV-2, and Erik's approach seemed novel--and certainly compelling enough to give it a shot," commented Herbert.

USAMRIID's team determined that the decoy receptor has potent neutralizing activity against SARS-CoV-2, activity that is on par with the best neutralizing antibodies identified to date. Furthermore, they found that the decoy receptor not only neutralizes SARS-CoV-2, but also acts to neutralize SARS-CoV-1, a closely related virus that uses the same cellular receptor. "Once we confirmed neutralizing activity against SARS-CoV-2, it made sense to test for pan-coronavirus activity against other Coronaviruses that also use ACE2 to enter cells," said Herbert.

Additional research is required to determine whether the decoy receptor could be used to effectively treat or prevent COVID-19 and related Coronavirus diseases, according to Herbert. The team hopes to secure funding for animal studies to help answer those questions.

Source: World Pharma News, 19.08.2020 (Excerpts)

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Observational study identifies drug that improves survival in sickest COVID-19 patients

Researchers at Hackensack Meridian Health, New Jersey's largest and most comprehensive health network, have utilized its statewide observational database of more than 5,000 hospitalized COVID-19 patients to show that a drug normally used in rheumatoid arthritis and cancer treatments, tocilizumab, improves hospital survival in critically-ill patients admitted to the Intensive Care Unit (ICU).

The findings were published in The Lancet Rheumatology on August 14, and Hackensack Meridian Health researchers have updated the U.S. Food and Drug Administration and other national leaders of the findings to potentially accelerate improved outcomes. "Our clinicians and researchers at Hackensack Meridian Health have moved quickly and intelligently since the start of this global health crisis," said Robert C. Garrett, FACHE, Chief Executive Officer of Hackensack Meridian Health. "Their work in treating this terrible virus, and learning more about it each day, continues to benefit thousands of patients as the pandemic continues."

The study included 630 patients who were admitted to the ICUs of 13 Hackensack Meridian Health hospitals from March 1 to April 22 - the height of the pandemic in New Jersey. Among other treatments, tocilizumab was considered for off-label usage for the patients whose respiratory symptoms were declining; many of whom were requiring mechanical ventilator support. In the observational study 210 patients received tocilizumab, and the other 420 did not.

COVID-19 has three phases: the early or viral phase (with fast viral replication), the pulmonary phase (marked by inflammation and pneumonia as the body tries to fight the virus in the lungs) and the inflammatory phase (in which excessive inflammation reaches and affects many organs and patients are often in the ICU). As part of both the pulmonary and inflammatory phases the immune system is "supercharged" and secretes in the blood

numerous cytokines, particularly interleukin (IL)-6, which induces further inflammation. Tocilizumab is a monoclonal antibody, which binds and blocks the interleukin (IL)-6 receptor and helps damper the inflammatory response. The activity of tocilizumab was first shown in chimeric antigen receptor (CAR) T-cell therapy, where a similar phenomenon of overactive and growing T cells induce a "cytokine storm." This provided a rationale to try tocilizumab in COVID-19 patients.

The findings showed a statistically-significant decrease in hospital-related deaths among the patients who received the tocilizumab: a roughly 36 percent decrease in hospital related mortality among the ICU patients who received the drug, as compared with patients in the ICU who didn't receive it. The data from the outcomes was adjusted to account for multiple factors, including comorbidities, and was assessed using statistical survival models.

Importantly, it appeared that higher levels of a blood test marker of inflammation, C-reactive protein, could predict which ICU patients might benefit most from the tocilizumab therapy, potentially allowing doctors to tailor therapy to those most in need. "These real-time findings have helped to point us the way forward," said Ihor Sawczuk, M.D., FACS, Hackensack Meridian Health Regional President, Northern Market and Chief Research Officer. "Our clinicians and scientists were at the forefront of COVID research from the beginning of the pandemic."

The results are based on evidence collected in the HMH Universal Observational Database for COVID-19, or RE-COV-RY, which compiles outcomes from 13 Hackensack Meridian Health hospitals throughout New Jersey, using Electronic Health Records (EHRs). The outcomes division of the John Theurer Cancer Center (JTCC) at Hackensack University Medical Center, under the leadership of Dr Stuart Goldberg and Dr. Andrew Ip, created a database to guide the analysis of more than 3,000 patients admitted to Hackensack Meridian Health facilities for urgent care. The database has been used to constantly assess COVID-19 treatments over the last several months, including the most promising and high-profile drugs and interventions.

"We need to know more as soon as possible," said Stuart Goldberg, M.D., hematologist/oncologist and chief of the Division of Outcomes and Value Research at John Theurer Cancer Center at Hackensack University Medical Center in New Jersey. "Our database has allowed us to rapidly expand our knowledge of COVID-19 throughout the Hackensack Meridian Health hospital network. We are moving fast to help guide interventions - and potentially save lives."

The lead co-authors on this study are John Theurer Cancer Center hematologist-oncologists Andrew Ip, M.D., from the Division of Outcomes and Value Research and Noa Biran, M.D., from the Division of Myeloma. Both had experience with tocilizumab as part of the JTCC active CAR-T cell transplant program and recognized the potential of this immune modulating therapy in COVID-19. "This is a great example of our science having impact far beyond cancer," said Andre Goy, M.D., M.S., physician-in-chief of Oncology, Hackensack Meridian Health.

Source: Hackensack Meridian Health, Eurekalert, 19.08.2020 (Excerpts)

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Government approves Bulk drug park at Odisha

The Odisha Government on Friday, 04.09.2020 accorded in principle approval to a proposal for setting up a bulk drug park in Tata SEZ at Gopalpur in Ganjam district for creation of employment opportunities in non-mineral sector. The project will be implemented through a Special Purpose Vehicle (SPV) with Odisha Industrial Infrastructure Development Corporation (IDCO) as the lead promoter and Tata Steel Special Economic Zone (TSSEZ) as the co-promoter.

Official sources said the cost of the infrastructure development in the park has been estimated at around Rs.1,500 crore. The project will be implemented through financial support from both the Centre and State Government. The park will create employment opportunities for around 5,000 people. The project feasibility was discussed at a high-level meeting presided over by Chief Secretary Asit Kumar Tripathy. He directed officials to send the proposal to the Centre within September 25, 2020.

Principal Secretary in the Industry department Hemant Sharma said the location of the park is well connected with port and railway. It is less than two hours to reach from the Biju Patnaik International Airport, he said and added there is also an air strip at Gopalpur which can be utilised for the required communication. Sharma said the land parcel of around 1000 acre required for the park is available in the SEZ. Besides, the land is well connected with NH-16 which is considered as the spine for the Odisha Economic Corridor.

He said the park will have all the advanced infrastructure facilities including Central Affluent Treatment Plant, solid waste management, warehousing, dedicated power distribution system, steam generation and distribution system, common cooling system, advanced testing laboratories, centre of excellence, technology business incubator and Intellectual Property Right services.

Source: The Health Master, 05.09.2020

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Despite Government's claims of clearance of pending dues of ₹6,800 crore, Pharma MSMEs yet to get it from PSUs

Even though the Central Government has announced that its ministries and Public Sector Undertakings (PSUs) paid out pending dues of Rs. 6,800 crore to Micro, Small and Medium Enterprises (MSMEs) in the last three months, Pharma MSMEs claimed that they have yet to receive pending dues from PSUs.

More than Rs.6,800 crore has been paid by the Ministries and Central Public Sector Enterprises (CPSEs) in the last three months alone. Almost three-fourths of the monthly dues have been paid during the same month by most of the Ministries and CPSEs. The pending amounts are expected to be released in the normal course of business and within 45 days, said MSME Ministry in a statement.

Contrary to the MSME Ministry's claims, pending dues of Pharma MSMEs are yet to be cleared by PSUs, said a MSME player on condition of anonymity. The Pharma MSMEs are under financial distress in the wake of the economic crisis caused by COVID-19 pandemic. They have approached the Department of Pharmaceuticals (DoP), a parent body of Pharma PSUs seeking clearance of their pending dues after Finance Minister Nirmala Sitharaman announced in May that MSMEs' dues pending with the Government and Central Public Sector Enterprises would be cleared within 45 days.

The Finance Ministry on May 20, 2020 advised all concerned administrative ministries of CPSEs to direct their respective CPSEs to release the pending payments to MSMEs immediately in line with the Government announcement made recently. Following MSMEs' appeal, the DoP in July directed Pharma PSUs to clear outstanding dues of MSMEs. The PSU section of DoP had on July 16, 2020 written to Chairman and Managing Director of Indian Drugs and Pharmaceuticals Ltd (IDPL) and Managing Directors of Hindustan Antibiotics Ltd (HAL)

and Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) instructing them to take steps to clear dues of Pharma MSMEs.

Despite the department's instruction, Pharma PSUs have yet to initiate the process to clear outstanding dues of MSMEs, he stated. There are scores of Pharma MSMEs struggling to survive amid mounting losses caused by the Coronavirus pandemic. Most of them are awaiting clearance of their dues pending with Pharma PSUs viz IDPL, HAL, RDPL since years. Jocund India Limited which supplied raw material to IDPL, Rishikesh in 2011 is awaiting dues worth Rs.1,07,14,497.50 since February 2011 and earlier. Medicamen Biotech Limited which supplied raw material to HAL is yet to receive dues of more than Rs. one crore from the Pharma PSU.

Pharmchem is also awaiting dues worth Rs.3,424,453 from RDPL since March 2014. RDPL also owes dues of more than Rs.11 lakh to Medicamen Organics Ltd. Besides the four drug units, there are scores of MSME suppliers waiting for their dues from Pharma PSUs. When contacted T V Somanathan, Secretary, Department of Expenditure for comments on steps taken by the department in ensuring release of MSMEs' pending dues with Pharma PSUs following instruction from the Finance Ministry, he did not respond.

Source: Laxmi Yadav, Pharmabiz, 07.09.2020

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Pharma sales back in red in August as anti-infective drugs struggle

Sales of medicines in India declined again in August after two months of growth as the struggle for anti-infective drugs continued amid the covid-19 pandemic, data from market research firm AIOCD-AWACS showed. Overall sales in the Indian Pharmaceutical Market were down 2.2% year-on-year at 12,162 crore in August.

In June and July respectively, total medicine sales in the country were up 2.4% and 0.2% aided primarily by chronic therapy areas like anti-diabetic and cardiac care. In August, sales of cardiac and anti-diabetic drugs grew 11.5% and 1.6% respectively, while vitamins also grew 6.2%. On the other hand, anti-infective drugs continued to witness a decline in sales for the fifth straight month in August, indicating that patient continued to avoid visits to doctors' clinics and hospital out-patient departments amid fear of contracting the infection.

Another potential factor that some doctors have pointed to is the number of infections itself may have reduced as people primarily stayed home. In August, while anti-infectives declined 11% y-o-y, sales of associated therapies like gastro-intestinal drugs and pain and analgesic medicines were down 3.1% and 9.8% respectively. Respiratory drug sales fell 12.4%, a sharp decline from the 2% slip reported in July. Among Corporates, all top 10 drugmakers in India, barring Cipla and Macleods Pharmaceuticals, reported 1.1-7-7% decline in sales.

Some companies that manufacture Covid-19 drugs bucked the tred. Cipla reported a 7.4% growth in sales during August. The Mumbai-based pharmaceutical company has the largest portfolio of Covid-19 drugs in India, which include Favipiravir, Remdesivir and Tocilizumab.

Glenmark Pharmaceuticals Ltd, the first firm to launch Favipiravir, posting almost a one-third jump in sales at 347 crore, while Ipca Laboratories, one of the world's largest producers of Hydroxychloroquine, posted a 9.8% growth in sales at Rs.200 crore. Glenmark and Ipca have posted double digit growth during April-August, even as sales in the Indian Pharmaceutical Market has declined 3.7%. Cipla's sales have seen a 0.3% growth during the same period.

Source: Live Mint, 07.09.2020

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Pharmacoeconomics a promising sector for optimizing cost, efficacy of drugs and therapies during COVID-19

Pharmacoeconomics holds immense potential for India in the current times of the pandemic when there is need to compare costs of available drugs and therapies. With an impending shortage of human resources, pharmacoeconomics is a promising field for pharmacists to specialize in. Going by the need to evaluate drug pricing and the costing of healthcare in India and globally too, creating a pool of experts specialized in this area will bridge the gap of this huge unmet need, said Ravi Iyer, Director, Global Health and Economics Research, Teva Pharmaceuticals.

Healthcare expenditures are high and growing exponentially. Decision makers in healthcare need to make tough decisions. This is where pharmacoeconomics, which deals with the analysis of cost and the consequences of pharmaceuticals and related services on healthcare systems and patients, comes into the picture, he added.

These are studies that attempt to identify, measure and evaluate clinical, economic and human outcomes. During research, throughout the product cycle, pharmacoeconomics helps to develop the economic modeling frameworks for phase 3 clinical trials.

It helps to understand the burden of illness on treatment patterns, besides assess the gaps in care and develop a cost-effective model. It provides real world comparative studies to help create a real-world economic modeling platform to devise a budget impact model, said Iyer at a webinar organized by the Karnataka Registered Pharmacists Association.

Speaking on the 'Role of Pharmacoeconomics and Outcomes Research in Drug Development and Beyond', Iyer highlighted the cost-benefit, cost-effectiveness, cost-minimization, cost-of-illness and cost-utility analyses to compare pharmaceutical products and treatment strategies. This branch of pharmaceuticals refers to the scientific discipline that compares the value of one pharmaceutical drug or therapy to another. It brings to the fore the need to measure the value of the product. This is because price and value are not the same, he said.

There has been extensive adoption of pharmacoeconomics during the HIV phase as a value driver to assess an efficient mix of interventions. These studies have provided a cost-effectiveness of drugs. Pharmacoeconomics provides Pharma companies a clear picture on whether to continue a drug in the market by analyzing its cost and effectiveness. Therefore, pharmacoeconomics is not about determining the cheapest healthcare alternatives, but it is about determining those alternatives that provide the best healthcare outcome for per monetary unit spent, said Iyer.

Sunil Chiplunkar, Advisor, KRPA and Vice President, Business Development, Group Pharmaceuticals, said that in pharmacoeconomics, there is scientific assessment of the cost and benefits of healthcare. There is also a comparison of value offered by one drug over another. Recently, ICMR has taken into consideration India's vast clinical experience with HCQ (Hydroxychloroquine) not only in cases of malaria, but also in use for autoimmune disease including rheumatoid arthritis.

During this pandemic, pharmacoeconomics helped in repurposing HCQ as a prophylactic to healthcare workers involved in COVID-19 care. Similarly, the use of simple antacids for elderly mild GERD patients makes pharmacoeconomic sense, since proton pump inhibitors are known to cause renal stress on long term use.

Source: Nandita Vijay, Pharmabiz, 07.09.2020

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India scaling up production of Active Pharmaceutical Ingredients: Kant

India, a global hub for generic drugs, has launched a new scheme to boost production of Active Pharmaceutical Ingredients that are greatly dependent on the Chinese supply chain, according to NITI Aayog CEO Amitabh Kant. Speaking at the 14th Annual BioPharma and Healthcare Summit, he said India is now gearing up for innovation in its pharmaceutical ecosystem focusing on speedy and scaled up delivery of new vaccines and personalised medicines.

He said that India has launched a new scheme to boost production of Active Pharmaceutical Ingredients that are greatly dependent on the Chinese supply chain. "We are planning to do complete manufacturing in India," he said at the virtual summit organised by the USA-India Chamber of Commerce on Friday, 04.09.2020.

The day-long virtual summit was attended by major players from the US pharmaceutical sector, whose combined annual Research and Development budget is more than USD 45 billion. Relations between the US and China, the world's leading manufacturer in a number of sectors, have deteriorated after the Coronavirus outbreak spread across the world from the central Chinese city of Wuhan.

President Donald Trump has squarely blamed Beijing for allowing the virus to spread across the world that has led to the death of over eight lakh people and triggered an unprecedented global health crisis. Bilateral tension between Washington and Beijing has also spiked over security concerns and human rights violations in Xinjiang and Tibet. This has led to a number of countries looking at India as a substitute to China for their manufacturing bases and key commodity production.

Kant said the Indian Government is committed to achieve its 'Pharma Vision 2020', which aims to make the country a global leader in drug discovery, innovation, and drug manufacturing. India is working towards robust innovation landscape awareness, innovation facilitators such as human capital investment in Research and Development, safety-legal environment, regulatory environment to provide truly world class biopharma research, he said.

The Government has carried out far-reaching reforms to streamline the Clinical Trial and regulatory approval process to facilitate drug discovery in partnership with the private sector, he said. Bio incubators have been set up to monitor and nurture scaling of technologies. India is developing world class Clinical Trial infrastructure to increase the number of beds per thousand population.

"Prime Minister (Narendra Modi) launched the National Digital Health Commission on our Independence Day, (now) electronic health records will be created for individuals which will be immensely valuable for research purposes," Kant said. Professor K Vijay Raghavan, Principal Scientific Advisor to the Government of India, said the dramatically changing context, after the COVID-19 outbreak this year, hugely favours India.

He said personalised medicines are the future in healthcare. Personalised medicine was till recently seen as a "fancy way of having individual-oriented medication" but today in India -- due to the dramatic scaling up of telemedicine and a variety of tele-consulting ways -- one is going to see personalised medicine at the grassroot-level in a population of more than a billion, Raghavan said. "This opens up a very critical aspect for innovation, which is feedback. Feedback from people will drive innovation enormously," he said.

Karun Rishi, President of USAIC, said it's a great opportunity for India to play a critical role in the biopharma Research and Development process. President of Takeda Pharmaceuticals, R&D, Andrew Plump said Prime Minister Narendra Modi introduced a new healthcare plan that offered care to over half a billion people, referring to the Ayushman Bharat scheme.

"We have started to see innovation on the Clinical Trial front. If you go back a decade ago, the number of global Clinical Trials that were run in India were little over a dozen. Today we have close to 200. It's not where it needs to be. But it's amazing progress that we're seeing in this wonderful country which we have immense commitment to," he said.

(Only the Headline and picture of this report may have been reworked by the Business Standard staff; the rest of the content is auto-generated from a syndicated feed.)

Source: Business Standard, 08.09.2020 (Excerpts)

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Bharat Biotech gets DCGI nod for PHASE II trials of COVAXIN

According to a report by The Indian Express, the Drugs Controller General of India (DCGI) has given clearance to Bharat Biotech for conducting Phase II human Clinical Trials of its indigenously developed Covaxin.

The report informed that the Subject Expert Committee (SEC) has recommended that the trial will be conducted on 380 participants. A letter from Joint Drugs Controller Dr S Eswara Reddy, dated September 3, has notified the company about this.

Reportedly, the first phase of the Covaxin trial was done with 375 participants from across 12 sites. Zydus Cadila and Serum Institute of India have also started conducting Phase II trials for ZyCoV-D and Covishield (by Oxford-AstraZeneca) in India.

Source: Express Pharma, 07.09.2020

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Experts and parliamentarians urge Centre to extend deadline for comments on draft HDM Policy till November 26

Public health policy experts and parliamentarians have urged Union Health Minister Harsh Vardhan to extend deadline for public comments on the draft Health Data Management (HDM) Policy till November 26, 2020. The Ministry had released the draft HDM on August 26, 2020 and has given only one week for the public to comment on this complex data storing infrastructure that will have far reaching implications for individual privacy.

At present there exists no data protection law that governs such an exercise and in its attempts to safeguard data collected under the National Digital Health Mission (NDHM). Stakeholders had earlier also asked for further extension of the September 3 deadline for submitting recommendations on draft HDM Guidelines as part of NDHM to comprehensively discuss issues associated with it, according to sources associated with the development. Binoy Viswam, Member of Parliament, Rajya Sabha also made a representation on the same with the Centre.

In his speech on August 15, 2020, Prime Minister Narendra Modi spoke about the NDHM that seeks to provide efficient and affordable health coverage through a wide-range of data and infrastructure service. At the core of this programme is the collection and aggregation of health related information for citizens across the country. While the NDHM has been made a voluntary service for any citizen that wishes to join it, there have been major concerns about the safety and security of the data that is being collected under the programme.

NDHM is aimed to create a system of digital personal and medical health records which is easily accessible to individuals and health service providers. It is purely voluntary in nature based on the consent of individuals, and in compliance with international standards such as ISO/TS 17975:2015.

Aligned with the vision of Prime Minister Narendra Modi to provide health services to every Indian citizen, the successful implementation of NDHB would immensely benefit all Indians by lowering out of pocket expenses and ensuring realization of Universal Health Coverage (UHC). NDHM is also aimed to increase awareness of the importance of data privacy and instill a privacy-oriented mindset among the members of NDHM and its ecosystem partners. This will also ensure national portability in the provision of health services.

The Union Health Ministry had released the final National Digital Health Blueprint (NDHB) report in November 2019 to strengthen Digital India and UHC. This is also aimed at establishing a comprehensive and nationwide integrated digital health ecosystem in the country. Union Health Minister had released the draft report at a function in New Delhi on July 15, 2019. Speaking on the occasion, the Minister had said that the Government is committed to ensuring high quality healthcare accessible to all up to the last mile.

The draft HDM policy outlines how data collected under the NDHM will be collected, processed, stored and shared. It includes sensitive personal data including details about their finances, physical and mental health, sex life, medical records, gender and sexuality, caste, religious and political beliefs as well as genetic and biometric records.

"The vast implications of this policy must be examined in detail and a one week time period for public comments is both undemocratic and unlawful. It is common practice that at least 1 to 3 months is given to seek responses from the public. Lastly, it is important to point out that our country is still dealing with a deadly pandemic that has made everyday life difficult and constrained," rue experts.

Source: Shardul Nautiyal, Pharmabiz, 04.09.2020

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DCGI extends deadline by 4 months to submit notarized documents for import of medical devices and IVDs

The Drugs Controller General of India (DCGI) has further extended deadline up till 4 months or till normalization of COVID-19 scenario to submit notarized documents through online Sugam portal for import of medical devices and *in vitro* diagnostics (IVDs) from the earlier deadline of April 24, 2020. In its April 24, 2020 notice, it had directed all the concerned to do the needful. DCGI office had received representation about difficulties in submission of notarized or apostilled regulatory documents such as Power of Attorney, QMS certificate, free sale certificate etc for applications for import of medical devices and *in vitro* diagnostic kits under medical device rules, 2017 due to COVID-19 pandemic.

According to DCGI Dr V G Somani, "The matter has been examined carefully in view of the situation due to COVID-19 outbreak and it has been decided that the applicant may submit applications for import license as per the provisions of Medical Device Rules 2017 along with such documents which are self-attested and an undertaking that they will submit the notarized/apostilled documents after obtaining the same from the concerned authority after normalization of the situation in light of COVID-19 or within four months whichever is earlier." "Such applications, as and when received, will be processed and, if found satisfactory, import license may be issued with the condition that the firm shall submit apostilled/notarized documents," DCGI further added.

In its earlier notice, DCGI had clarified that imported IVDs shall be used by Indian research institutions for academic research purpose only and not for any diagnosis or therapeutic purpose in diagnostic labs and hospitals. Following quality issues with imported rapid antibody kits, the Indian Council of Medical Research (ICMR) had earlier mandated states to stop using it for COVID-19 for some time to review complaints related to it. India had taken delivery of 500,000 rapid antibody test kits from China in April 2020 which were reportedly facing quality issues. In an advisory to all states, ICMR had stated that the national task force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID- 19 has been revised further.

As per protocol for using rapid antibody test for epidemiological studies and surveillance, gold standard frontline test for COVID-19 diagnosis is real time PCR based molecular test, which is aimed at early virus detection. The rapid antibody test cannot replace the frontline test. "In this regard, it is to clarify that the products meant for Research Use Only (RUO) to be used in academic research institutions are not meant for any diagnostic or therapeutic purpose. They are not being regulated under provisions for Drugs and Cosmetic Act and Medical Device Rule thereunder," stated DCGI.

He further stated, "However, the applicant needs to submit an undertaking in this regard at the concerned port office of Central Drugs Standard Control Organisation (CDSCO) stating that the imported products shall be used by the research institutions for academic research purpose only and shall not be used for any diagnosis or therapeutic purposes in diagnostic labs and hospitals. Such products shall be labeled as "for research use only." ICMR and DCGI had recently jointly come out with Guidelines for validation and batch testing of COVID-19 diagnostic kits.

Source: Shardul Nautiyal, Pharmabiz, 03.09.2020

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COVID-19 slashes Pharma production in Uttarakhand

Uttarakhand based Pharma companies have seen a decline in Pharma production due to the rapid spread of Coronavirus in the state. Presently, the state has a total of 240 Pharma units located in the Uttarakhand, out of which nearly 120 Pharma units are in the district of Haridwar and approximately 60 Pharma units are in the Dehradun.

These are the two major Pharma clusters of Uttarakhand, however, there are around 30-40 Pharma units located in Rudrapur district as well. Pharma units based in Haridwar are gearing up to start 100 percent production from next week.

Sanjay Kumar Sikaria, Secretary, Drug Manufacturers Association, Uttarakhand said, "Because of the mandatory enforcement of increased COVID-19 testing in the state, there will be a dip in the production cycle of Pharma products in the State, which is likely to be around 10-15 percent. But, Pharma units in the Haridwar are in a better state now than those in Dehradun."

"As per the District Magistrate order, it is a compulsion to carry out COVID-19 tests on a minimum 10 percent of the total workforce in each company. Recently, in the Dehradun unit of Natco Pharma, 13 positive cases of Coronavirus virus were found. Although, there are no containment zones as such, prescribed SOPs need to be followed. It takes a minimum of 72 hours to resume production after following the given Guidelines of sanitisation programmes," he explained. "Therefore, to extend support to our industry, we have collaborated with Dr Path Labs and have set up a unit in the Selaqui Pharma Cluster of Dehradun.

Besides offering convenience to Pharma units, we have also negotiated on testing charges. And as per the agreement, for each COVID-19 test, Pharma companies need to spend Rs.795 as against approximately Rs.2000." Speaking about the situation in Haridwar, Harindra Kumar Garg, Chairman, Sidcul Manufacturers Association Uttarakhand, informed, "Unlike other states, the proportion of migrant labours in Haridwar is less, therefore it did not see a major impact on that front.

However, with the given Guidelines and increased testing enforcement by the local authorities, it is likely that the state Pharma production may be slashed by around 25 percent. So far, in the Haridwar, over 10,000 tests have been carried out by different industries of which around 3500 tests were for the Pharma Sector."

He continued, "Till August 20, the situation in Haridwar was very critical and industry was in a state of panic, however, now we are gearing up to resume 100 percent production activities to meet the domestic as well as international market requirements." He recalls, "The first batch of export consignment of Hydroxychloroquine for the US market was manufactured from the unit located in Haridwar.

And now we are hopeful that from the coming week onwards, we will be able to utilise full production capacity with 100 percent attendance." D C Jain, Chairman, Akums Drugs and Pharmaceuticals shared, "In Haridwar, we have a total of nine units with huge production capacities and capabilities.

Though there is a surge in the positive cases of Coronavirus in the state, we have taken all the required precautions to prevent the spread of the virus in our units." Giving out details, he said, "We have taken a 76-bedded hotel and converted it into a COVID centre for our employees.

We are also providing sanitised transportation facilities to each of our employees. Besides this, we are also providing immunity boosters to them. So far, none of our employees have been tested positive. Therefore, we do not see any dip in our business, in fact, companies like Torrent Pharma, Intas Pharmaceuticals, Sun Pharma are outsourcing their manufacturing activities to us.These were supposed to be managed by their Sikkim units but the impact of COVID-19 on the Pharma industry still persists in Sikkim".

Source: Usha Sharma, Express Pharma, 05.09.2020

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Restoration of MEIS scheme with Rs.2 crore cap to benefit MSME Pharma Exporters

The Commerce Ministry's decision to restore an online system for exporters to apply for availing tax incentives under Merchandise Export from India Scheme (MEIS) with a cap of Rs two crore per exporter from September 1 to December 31, 2020, will benefit MSME Pharma Exporters. The online system was shut down by the Ministry from July 23, 2020 due to shortage of funds post COVID-19 after the Department of Revenue has asked the Department of Commerce to examine the coverage of MEIS tariff lines and rates to reduce the incentive level to Rs. 9,000 crore this year.

The Directorate General of Foreign Trade (DGFT) in a Notification stated that an IEC (Import Export Code) holder does not claim reward under MEIS exceeding the ceiling of Rs.2 crore for exports made in the period September 1, 2020 to December 31, 2020. The ceiling will be subject to further downward revision to ensure that the total claim under MEIS for the period (September 1 to December 31, 2020) does not exceed the prescribed allocation by the Government, which is Rs.5,000 crore, the Directorate said.

An IEC holder who has not made any exports for a period of one year preceding September 1, 2020 or any new IECs obtained on or after September 1, 2020 would not be eligible for submitting any claim under this scheme. Commerce and Industry Minister Piyush Goyal in a tweet said, "98 percent of exporters especially MSMEs will benefit under MEIS with a reward cap of Rs.2 crore/IEC from September 1 to December 31, 2020. This will remove uncertainty and protect genuine exporters while ensuring Make in India-Make for the World."

Welcoming Goyal's statement, Nipun Jain, Chairman of Small and Medium Pharma Manufacturers Association (SMPMA) stated "Pharma MSME exporters are in agreement with the Commerce Minister. We are battling challenges in fulfilling export orders in the wake of COVID-19 pandemic outbreak. The MSME exporters are in a tight financial situation since the COVID-19 induced lockdown. The stoppage of MEIS scheme has added to their financial woes. The Government's decision to restore MEIS benefits will definitely improve sentiments of MSME exporters."

The SMPMA had earlier written to Dr P D Vaghela, Secretary, Department of Pharmaceuticals (DoP) urging him to take up the issue related to stoppage of MEIS benefits with the Commerce Ministry. Under MEIS, the Government provides duty benefits depending on product and country. Rewards under the scheme are payable as a percentage of realised free-on-board value and MEIS duty credit scrip can be transferred or used for payment of a number of duties, including the Basic Customs Duty.

The MEIS scheme, introduced in April 2015, will be wound up by December 31, 2020, and the Remission of Duty or Taxes on Export Products (RoDTEP) scheme approved by the Union Cabinet will replace MEIS from January 1, 2021. Under the RoDTEP scheme, a mechanism would be created for reimbursement of taxes/duties/ levies, at the central, state and local level, which are currently not being refunded under any other mechanism, but which are incurred in the process of manufacturing and distribution of exported products. RoDTEP is a combination of the current MEIS scheme and Rebate of State and Central Taxes and Levies (RoSCTL) scheme. Jain said the RoDTEP scheme should factor in MSME exporters in line with the MEIS scheme.

Source: Laxmi Yadav, Pharmabiz, 03.09.2020

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As cases mount, India studying Russian proposal for COVID-19 vaccine

As Covid-19 cases continue to mount in India, the Russian Ambassador, Nikolay Kudashev, has said Moscow is talking to the Indian Government "on different levels" about cooperation that could include "supplies, co-development and coproduction" of Sputnik V, the first anti-Covid vaccine in the world. The vaccine, according to a Lancet study, has been found in initial trials as causing no serious side effects. Official sources here confirmed to ToI that Russia had shared formally modalities of cooperation with India on the vaccine and that the Indian Government was examining the details.

Russian vaccine safe, induces antibody response in small human trials: Lancet study:

"As far as we know, after some necessary technical steps, the vaccine would be ready to be widely used, including abroad," said Kudashev. The issue is also likely to come up during Foreign Minister S Jaishankar's visit to Moscow this week. Kudashev also said that though Russia hoped to work with India for a "just and multipolar" world order at a time some countries were playing "geopolitical games" despite the pandemic and creating "close-door exclusive blocs".

Covid: Russia shares initial vaccine info with India:

This is significant as India, in the face of increasing Chinese military adventurism, looks to give teeth to its Indo-Pacific and Quad policies. In fact, the Government only last week announced it will be holding the second Quad ministerial meeting this year in India.

Covid pandemic Despite its grand military exercise with India in the Andamans, and also its recent discussions with India and Japan for a trilateral mechanism, Moscow continues to abhor even the term Indo-Pacific, calling it a US-led initiative meant to contain Beijing. India though has sought to address some of these doubts by emphasising in bilateral meetings that the Indo-Pacific is a free, open, transparent and inclusive concept with ASEAN at its centre and that it doesn't exclude any country.

"Unfortunately we have to admit that in spite of the pandemic some countries keep playing geopolitical games and unilateral extraterritorial sanctions (sic), trying to create close-door exclusive blocs, politicise international institutions including the UN, OPCW, WHO and others. Such policy is obviously increasing mistrust, instability and uncertainty taking us away from the vital solutions," said Kudashev, addressing a conference.

Kudashev said there was a lack of goodwill and constructive approach and that this had led to chances of enhanced confrontation, arms race and global disorder. "We hope to further expanding our cooperation with India and other friendly countries to prevent such scenarios (and) move towards just and equal multipolar world order, democratisation of global governance, collective solutions to global and regional problems and close coordination for this purpose at various multilateral institutions," said Kudashev, adding that the two visits by Defence Minister Rajnath Singh to Moscow this year, and the upcoming one by Jaishankar, were of huge significance for the same reason.

Source: Trailer Launch, The Times of India, 07.09.2020 (Excerpts)

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DoP to set up empowered panel to come out with drug authentication mechanism to rein in counterfeiting

The Department of Pharmaceuticals (DoP) has initiated the process of forming an empowered committee of drug regulatory officials and representatives of pharmaceutical industry to examine varied Track & Trace technologies and come out with an authentication mechanism to address spurious drug issues.

Dr P D Vaghela, Secretary, DoP informed industry representatives about the steps being taken by the Department to set up a panel to devise uniform Track and Trace system at the second meeting of the Forum of Pharma Associations recently. The uniform Track and Trace mechanism will do away with various drug authentication measures adopted by the Health Ministry, DoP, Commerce Ministry, Niti Aayog, informed industry sources.

In fact, the Union Commerce Ministry has been trying to implement barcoding for exports of drugs since 2011 but it is yet to be executed smoothly. Last year, the Central Drugs Standard Control Organisation (CDSCO) had issued a draft Notification mandating every Active Pharmaceutical Ingredient (API) manufactured or imported in India shall Quick Response (QR) code on its label at each level packaging that store data or information readable with software application to facilitate Tracking and Tracing.

The DoP in its revised Public Procurement (Preference to Make in India), Order, 2017 dated January 14, 2019 had made it mandatory for all medicines procured under public procurement to have barcode/QR code at primary level packaging from April 1, 2019. Later DoP deferred its implementation till April 1, 2020.

In 2018 CDSCO came out with a Track and Trace mechanism for top 300 drug brands. The CDSCO's proposal, cleared by the Drugs Technical Advisory Board during a meeting in May 2018, was to print a 14-digit number on the labels of the top 300 pharmaceutical brands identified by it on the basis of moving annual total data obtained from AIOCD AWACS, along with a mobile number of the manufacturer.

Since the numbers would be unique to each strip and bottle sold in the market, a consumer could easily check authenticity of drugs by sending a message to the given number and get details of the manufacturer, batch number, expiry data etc. The implementation of barcoding on drug packs was of voluntary nature. Taking serious note of the spread of counterfeit drugs, Niti Aayog proposed a plan to put the entire drugs inventory made and consumed in the country on blockchain which stops the entry of fake drugs into the supply chain.

Expressing concern over multifarious directions regarding tracing and tracking being issued by various departments, the drug industry demanded implementation of a single drug authentication system. Earlier in July this year a high-level panel, headed by Union Health Secretary, was set up to work on a framework to implement unique QR code for drug packs following a meeting of key officials from the Health Ministry, DoP, Commerce Ministry, Niti Aayog and Prime Minister's Office in this regard. The panel was supposed to submit its report in three weeks.

Taking exception to the implementation of QR code to prevent the sale of spurious drugs in the domestic market, the Pharma industry has appealed to the Ministry to evaluate varied tracking and authentication technologies in a pilot study rather than zeroing in on unique QR code which has limitations of addressing the issue.

Said Dr Viranchi Shah, Senior Vice-President of Indian Drug Manufacturers' Association (IDMA), "Even though the pharmaceutical industry is with the Government in their efforts in using technology for weeding out the spurious drugs, we reiterated the need for implementation of a simple, patient and doctor friendly system that is efficient (detection of falsified – spurious drugs), affordable (capex and opex) and industry friendly (ease of application and minimum impact on productivity)."

Currently there are various Track and Trace technologies ranging from Quick Response (QR) code to barcode, SMS based mechanism etc to combat counterfeiting of pharmaceutical products. Each option needs to be evaluated in a pilot study and consensus be built on use of any one of the Track and Trace technologies based on its effectiveness and its adaptability to Indian conditions. The capital investment and adoption of technology on cost of product need to be looked into before its implementation, he said.

Source: Laxmi Yadav, Pharmabiz, 02.09.2020

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MSMEs seek extension of implementation of barcoding for Pharma Packaging

Even as the GS1 is firm on early implementation of the barcoding system for Pharma packaging, the MSME sector has been seeking a further extension of deadline saying it is not fully equipped to implement the system. MSMEs feel the DGFT's circular extending the deadline to October 1, 2020 is not sufficient.

Cost of capital and manpower, besides fall in production output are challenges faced by MSMEs. Hence, it would be prudent for the Government to extend this deadline to Q2 of next year, said Harish K Jain, General Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association and Director, Embiotic Labs.

Agreeing with Jain, Kaushik Desai, Pharma Consultant, said MSMEs face multiple issues with implementation of barcodes. This requires heavy investment which does not match their manufacturing volume. They are already suffering issues with cash flow and workforce due to the ongoing lockdown. Besides, the Pharma manufacturers have not exhausted their inventory because of low volume of production and face several supply chain issues. Although bar coding is a good initiative to curb counterfeit drugs, it is not right to enforce it during these trying times.

Further, Desai also said the issue of parent child norms right up to primary packaging is not fully resolved. The industry is apprehensive. From primary packaging to the final outer box, the barcoding needs to be uniform to ensure traceability. Even the barcoding is not practical for primary containers particularly for small single unit pack of ampoules.

Around 70 to 80 percent of products use blister packing, for which barcoding presents a technical problem. Blister packing comes with knurling and barcode scanners cannot read them since they require a smooth surface. Using barcodes on the outer box involves additional cost, said Jain.

In India, several large and mid-size Pharma companies have adopted this but despite several extensions, small units are yet to comply with it. MSMEs have been facing woes for the last several years but they need to adopt changes at some point of time by making investments and bringing about changes in their processes. It makes sense to adopt barcodes since it is mandated for all exports, S Swaminathan, COO, GS1 India told.

GS1 India, under Ministry of Commerce, provides barcode implementation and training, besides with Pharmexcil helps exporters gain supply chain visibility. The Track & Trace system is required in the wake of allegations of counterfeiting made by global companies. This requires barcoding on secondary and tertiary packaging with 14-digit GTIN along with the batch number, expiry date etc, besides maintaining a 'parent-child' relationship between various packaging levels, he added.

Manufacturers must barcode their products using GS1 standards to facilitate authentication of exported pharma drugs. This does not require additional cost since companies already have the infrastructure. Adopting GS1 standards enables encoding information to be decoded by all trading partners and importers. This also helps compliance with international regulations and several tender requirements, said Swaminathan.

GS1 identification is open with technology-independent standards permitting full interoperability and compatibility. It also offers logistic benefits like warehousing/FIFO management/trucking efficiency. However India needs to come up with one harmonized coding system for identifying drugs and devices, towards achieving trace and track, recall and counterfeit detection, he said. API barcoding is essential to track imported or locally made Pharma raw materials to ensure transparency and check if it has come through an approved channel. GS1, undertook a pilot for 15-20 companies with a software that required just a mobile app.

Source: Nandita Vijay, Pharmabiz, 02.09.2020

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COVID-19 restrictions boost India's online Pharmacy Sector

E-Commerce giant Amazon and Reliance Industries provide the fledgling industry with a shot in the arm but traditional chemists worry about the impact on their businesses. India's online pharmacy sector is seeing healthy growth during the Covid-19 pandemic, boosted by lockdown restrictions that are driving purchases of over-the-counter and prescription drugs through the internet, industry insiders say.

However, the rapid rise in online sales means there is an urgent need to put long awaited regulations in place to bolster confidence in the e-pharmacy sector. "We are at an all-time high in terms of the top line," says Prashant Tandon, the co-founder of online pharmacy 1mg, one of India's largest companies in the sector that delivers to more than 1,000 cities.

"With Covid, everything that is digital healthcare-related has received a massive boost," explains Mr Tandon, who is also the Chairperson of the Federation of Indian Chambers of Commerce and Industry's (FICCI) ePharmacy Working Group. "Perhaps what would have taken three to five years happened over three to five weeks, and we expect to grow pretty rapidly from here." The number of households in India using e-pharmacy services during the nationwide pandemic-induced lockdown surged by about 2.5 times to 8.8 million, according to an industry report by FICCI. This was despite supply chain disruptions that were a challenge for the industry during the early weeks of the lockdown.

With people largely confined to their homes when the lockdown came into effect in March – one of the strictest in the world – buying medicine online became a much easier option for consumers. As the number of Covid-19 infections continue to surge in India, which now has more than 4 million confirmed cases, some restrictions still remain in place, and many consumers favour online purchases. "There's no doubt that with increased smart-phone and internet penetration, online pharmacies will be an inevitable part of the healthcare culture in the country," says Gurpreet Sandhu, the President of the Council for Healthcare and Pharma, a global think tank. "The Covid-dictated restrictions have only accelerated this transition." With the sector's rise, major companies are moving in to grab their share of the market. A report by global professional services firm EY reveals that India's potential market for e-pharmacies will increase to $18.1 billion (Dh66.4bn) by

2023 compared with $9.3bn in 2019. US e-commerce giant Amazon last month launched an online pharmacy service in India's tech hub Bangalore in south India, offering over-the-counter and prescription medicines. "This is particularly relevant in present times as it will help customers meet their essential needs while staying safe at home," the company said in a statement to announce the launch of Amazon Pharmacy. Just days later, Reliance Industries, run by Asia's richest man, Mukesh Ambani, invested $83 million to buy a 60 percent stake in Chennai-based online pharmacy Netmeds.

Experts say that the industry is ripe for investment during the pandemic. "It is a combination of tech and health," says Aayush Narang, International Business Manager at New Delhi-based pharmaceuticals company Rowan Bioceuticals. "Nothing better than it."

Madhur Singhal, the Managing Director and Practice Leader, Pharma and Life Sciences, at Praxis Global Alliance, says: "Owing to the shifts in consumer behaviour towards e-commerce and online pharmacies, augmented by the Covid-19 pandemic, the online pharmacy sector has added to the appeal of deep-pocketed companies like Amazon and Reliance Retail, who are trying to harness this fast-growing segment on the back of their strong e-commerce capabilities."

Mr Singhal adds that the big name companies' entry in the market is a shot in the arm for the sector and will help to attract more consumers. Even before the pandemic, the fledgling e-pharmacy sector was growing rapidly, with more than 50 online pharmacy companies in India. Sales growth has been helped by factors including discounts on medicines and the expansion of internet use in the country, along with rising incomes and the proliferation of chronic diseases, which are driving demand in the Indian Pharmaceutical Market more broadly.

The entry of Amazon and Reliance could change the landscape for the sector, analysts say. "With the launch of online platforms, we will see a lot of consolidation in the market and also see the cost of drugs coming down eventually, which will in turn help the consumer," says Chandan Bagwe, the founder and Managing Director of C Com Digital, an Indian digital marketing firm. "It's understood that the large players have clearly seen huge potential in this segment."

The Indian e-pharmacy industry received $700m investment in the last financial year to the end of March, according to FICCI, with strong interest from venture capital and private equity investors. It forecasts that, propelled by the impact of the pandemic, the sector could reach 70 million households in India by 2025. But with the growth of online pharmacies, traditional brick-and-mortar chemists are worried about the impact this will have on their businesses, and it could ultimately lead to some stores closing down.

"We cannot ignore the fact that these online pharmacies do make the availability of medicines easy to people of different regions," says Mr Narang at Rowan Bioceuticals. "But we just cannot neglect the negative impact on the industry. Firstly, the major impact will be on brick-and-mortar pharmacies. These physical pharmacies give employment to many others." Opponents also claim that online pharmacies could facilitate the misuse of medicines. As a result, there is a consensus for the need of clear, formal regulation of the sector in India. Akash Karmakar, a Partner at the Law Offices of Panag & Babu, describes the online pharmacy market as an "industry plagued with regulatory uncertainty".

The sector is not entirely unregulated. He says that online pharmacies are currently subject to the Drugs and Cosmetics Act 1940, as well as the Consumer Protection (e-commerce) Rules 2020. The Indian Government is planning to introduce further regulation for the sector, but this has yet to be finalised. "The digitisation process brings operational challenges including customer identification checks, prescription collection, and abuse of dominance via predatory pricing," says Mr Karmakar.

"While the promulgation of a law is often a long drawn process, Guidelines issued in this regard providing relaxations to online pharmacies would go a long way in providing impetus [to the industry]," he adds. Nakul Pasricha, the President of ASPA and Chief Executive of PharmaSecure, says that "since the beginning of e-pharmacies in the country, there has been an ongoing debate if medicines sold online being fake, expired or substandard". He adds: "While there have been instances when consumers have complained about receiving fake medicines from pharmacies, we see that pharmacies are making all the effort to keep the system clean of any fake products." Moreover, such fraudulent products are not limited to the e-pharmacy sector alone, but are a problem across the industry. "An updated, specific and specialised regulatory framework would define an unambiguous future direction for the [e-pharmacy] industry," says Mr Pasricha.

The major threat for traditional chemists, however, is the discounted prices of drugs offered by e-pharmacies.

"The aim to capture the pharmaceutical market has led to online pharmacies offering heavy discounts on products," says Sonam Chandwani, the Managing Partner at Mumbai-based KS Legal & Associates. "Thus regulations striking the right balance between addressing the subsisting challenges of the industry with the traditional brick and-mortar pharmacies are the need of the hour."

It is not just brick and mortar pharmacies that are concerned about deep discounts. With the entry of Reliance and Amazon, there are fears in the e-pharmacy sector that with their deep pockets and fiercer competition, prices of medicines may drop further. EY's report reveals that online pharmacies are already burning cash, with discounts of up to 35 percent on some medicines, exceeding margins of 30 to 32 percent. But Mr Tandon at 1mg says the entry of Amazon and Reliance will be positive for the online pharmacy industry and will help it to grow "as long as their view on the sector is not predatory".

Source: The National, 06.09.2020 (Excerpts)

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National Digital Health Mission

In his Independence Day speech on the occasion of the country's 74th Independence Day on August 15 this year, Prime Minister Narendra Modi announced the launch of the National Digital Health Mission under which every citizen of the country will get a unique health ID card in which confidential medical data such as a person's medical history, prescriptions, discharge summaries and records such as tests, diagnostic reports, and treatments will be stored in a digital form as database.

Patients can give their doctors, or health providers, one-time access to this data during visits to the hospital or for consultation. This 'One Nation One Health Card' scheme will help people get better healthcare facilities in the country. These can be accessed by an authorised person from anywhere in the country. If and when a card-holder gets a test, diagnosis or treatment for any medical condition, the reports will be saved in the card.

This will reduce the burden of carrying around medical records and reports, in case a patient needs to travel to other parts of the country for treatments. The doctors will be able to access such medical records with the help of the unique ID of the card. The unique health ID card, that will ease access to medical services, is expected to be a part of the National Health Stack - a digital backbone of the country's healthcare system, as proposed by the country's policy think-tank NITI Aayog way back in 2018.

The National Health Stack aims to bring together various stakeholders in the ecosystem to improve efficiency, transparency and citizens' experience with linkage across public and private healthcare. It is expected that private players will also be invited for development of Personal Health Record (PHR) and Electronic Medical Record (EMR) systems. However, core responsibilities related to developing the scheme's IT infrastructure, generating digital health ID cards and verification of facilities will rest with the Government.

Definitely, this is an ambitious scheme which can play a crucial role in transforming the way healthcare is delivered in the country. This digitization effort couldn't have come at a more appropriate time than this when people are realizing the true potential of digital healthcare on the back of the scenario created due to the COVID-19 pandemic. Definitely, this is a step in right direction in getting the ecosystem of providers, insurance and digital health players to work together and make Indian healthcare accessible, affordable, and patient centric.

The scheme will create a digital infrastructure for healthcare delivery, which will include personal health IDs and e-records for citizens. This will greatly facilitate tele-medicine, e-pharmacy, and collection, consolidation and inter-operability of health data. Besides, the scheme will also allow patients to access health services remotely through tele-consultation and e-pharmacies, as well as offer other health-related benefits. The new scheme will make sure the fragmented ecosystem of providers and insurers can now come together and work more efficiently. This will allow for more standardization across the ecosystem, predicting healthcare demand and supply much better. The digitized interoperable health ecosystem will put patients at the centre-stage and will provide power in their hands in the form of unique ID for availing quality care and gaining better access to healthcare facilities and doctors. The scheme is also likely to be extended to include pharmacies and medical stores into the servers as well, in the future. The Government has initiated a commendable step towards further fuelling digitization in Indian healthcare. No doubt, this completely technology-based initiative will revolutionize the healthcare sector in the country.

Source: Ramesh Shankar, Pharmabiz-Editorial, 02.09.2020

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Technical Members for Patents, Trademarks and Copyrights appointed in IPAB

The Department for Promotion of Industry and Internal Trade (DPIIT) has vide Notification dated July 21, 2020 approved the following proposals for appointment to the Posts of Technical Member (Patents), Technical Member (Trademarks) and Technical Member (Copyrights) in IPAB for a period of four years.

Sr. No.	Name (S/Shri/Ms./Smt)
Technical Member (Patents) - (01 Post):	
1.	**Birendra Prasad Singh,** Joint Controller of Patents and Designs.
Waitlisted Name:	
1.	**R Devan,** Joint Controller of Patents and Designs.
Technical Member (Trademarks) – (02 Posts):	
1.	**Lakshmidevi Somanath,** Advocate.
2.	**Mr Vijay Kumar,** Advocate/Patent Agent.
Waitlisted Name:	
1.	**Dipak Girdharlal Parmar,** Advocate.
Technical Member (Copyrights) – (02 Posts):	
1.	**N Surya Senthil,** Advocate.
2.	**S P Chockalingam,** Advocate.

The appointment of the above members was placed on record by the Union of India before the Delhi High Court in the matter - *Indian Drug Manufacturers' Association v/s Union of India.* The current Chairman Shri Justice Manmohan Singh is due to retire on September 22, 2020. As per the information, the process for appointment of new Chairman has already been initiated as per the Tribunal Rules, 2020.

Significance:

The IPAB has been dysfunctional since a long period of time. As regards copyright matters, the appointment of the Technical Member-Copyright is significant as the appointment comes just in time before the expiry of the **Copyright Board Order of 2010** which is due to expire on September 30, 2020. The CRB order of 2010 fixed the royalty rate for the broadcast of sound recording on FM radio by providing a revenue sharing model as 2% of net advertisement earnings of each FM radio station to be distributed on a pro-rata basis. The music label industry has been at loggerheads with the radio broadcasters over this CRB order of 2010. Moreover, the Compulsory and Statutory Licensing Provisions under Section 31, 31A, 31B, 31C, 31D which have not seen the light of the day since the Copyright Amendment of 2012 coming into effect may now be tested and royalty rates may be fixed. Experts however state that it may be difficult for the IPAB to fix the royalty rates in such a short span of time and there could be a possibility of the radio broadcasters seeking an extension of the CRB Order of 2010.

The Statutory Licensing Provisions under Section 31D have been challenged before several courts out of which the challenge by Lahari Music is pending in the Supreme Court and by Eskay Video before Calcutta High Court. The IPAB website has not yet updated the list of these new technical members and further information on the Board hearing the matters is awaited.

The Intellectual Property Appellate Board (IPAB) was established on 15th September, 2003 in Chennai under Section 83 of the Trade Marks Act, 1999 to hear appeals against the decisions of the Registrar of Trade Marks and Geographical Indications and Controller of Patents. The IPAB consists of Chairman, Vice-Chairman and Five Technical Members-IPAB and One Technical Member from Plant Varieties Protection Appellate Tribunal (PVPAT) by invoking 'Transitional Provision' under Section 59 of the Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act 2001, to hear appeals against the decision of Registrars of Copyrights, Trade Marks, Geographical Indication Registry, and Controller of Patents. Besides Principal Bench at Chennai, the Circuit Bench sits at Mumbai, Kolkata, Delhi and Ahmedabad also.

The main objectives of the establishment of the Appellate Board are:-

- to provide a mechanism for quick disposal of cases;
- to develop sound precedents and practices;
- to ensure that appeal from the Registrar's decision is dealt with by judicial and technical experts promptly, and
- to avoid conflicting decisions which have been given by various High Courts in the past.

The Delhi High Court vide its order dated September 27, 2018 in the matter of *Radio Next Webcastion Pvt Ltd v/s Union of India* had held that the vacancy in the IPAB with respect to a Member Technical (Copyright) does not in any manner impinge upon the jurisdiction of the Appellate Board as constituted under Section 83 of the Trademark Act. Ideally, IPAB should have been fully functional even in the absence of the Technical Members.

Source: Anushree Rauta, iprmentlaw.com, 11.08.2020 (Excerpts)

Pharma sector needs Global collaboration: Industry Leaders, Government Officials

The need of global collaboration in the Pharma sector from Research and Development to drug manufacturing has never been as great as it is now amid the deadly COVID pandemic, industry leaders and officials from India and the United States said on Sunday, 30.08.2020.

Ahead of the 14th edition of the annual BioPharma and Healthcare Summit, that bring stakeholders from India and the United States on one platform, officials and industry leaders said the global health crisis requires a global solution, which can be achieved through global collaboration. India and the United States can play a lead role in this, they said.

"The pandemic has two important lessons. We have come together with speed to take current research to the benefit of the patient without compromising quality. Yet, the breakdown of global supply chains has affected industries, livelihoods and lives," said K Vijay Raghavan, Principal Scientific Adviser to the Government of India ahead of the annual summit hosted by USA India Chamber of Commerce (USAIC).

"Now, we have a task to ensure that we embed the positive into our processes and create new global collaborations so that the negatives do not happen again. These new collaborations will be anchored on mutual trust and value," Raghavan said ahead of the day-long virtual summit on September 4, which previously had been held in Boston.

"The earlier braid that tightly held science, industry, health and economics has come apart. We now have the task of plaiting a new braid that can deliver the fruits of research faster and better to help people lead healthier lives," Raghavan said, hoping that the panels and discussions of the summit will show the way forward to a new way of collaboration. He is also a USAIC Advisory Board member.

The event will bring together global leaders from across the industry including Senior Executives from biotech and pharmaceutical companies, academia, the investment community and policymakers to engage in active debate and idea generation for successful collaboration between India and the global healthcare ecosystem, USAIC said.

"It's heartening to see how quickly our industry leaders have joined forces to discover, develop and deliver potential solutions to address COVID-19," said Andrew Plump, President of R&D, Takeda and chair, USAIC Biopharma & Healthcare Summit. "We're creating new models for COVID-19 and operating at a speed that's unprecedented. These learnings should be applied moving forward — past today's pandemic and beyond a 'new normal,' to create a 'new exceptional'," Plum said. NITI Aayog CEO Amitabh Kant said the institutes of national importance in India have a large talent pool of researchers and scientists with specialized expertise in BioPharma, providing an opportunity for international collaboration in drug discovery, innovation and R&D.

"Even though there was a decline in pharmaceutical production in April 2020 due to the Covid-19 pandemic, India's indigenous pharmaceutical industry quickly recovered and registered a strong growth of 34.6 percent in June 2020," Kant said, adding he looks forward to hearing from global BioPharma leaders during the summit on ways to drive collaborative R&D in BioPharma and promote global partnerships in India.

"In these unprecedented times we need to stay positive and motivated — and more importantly, sustain an active dialogue that is forward-looking and aspirational," said Karun Rishi, President, USAIC. As a service to the global BioPharma community, the USAIC is offering free registration to summit participants this year, said Rishi. US-India collaboration has enormous potential in discovering, developing and manufacturing innovative therapeutics, said Hari Bhartia, Co-Chairman, Jubilant Life Sciences and USAIC Advisory Board member, who has been attending USAIC's annual summit for over a decade.

This year is of particular significance since Covid has highlighted the importance of a collaborative approach to R&D and market access to tackle pandemics, address unmet medical needs and make healthcare innovation affordable and accessible in a timely manner, he said. Noting that every nation, rich or poor has faced human suffering, loss of lives and economic hardship due to the Covid-19 pandemic, Rishi said this is indeed a global health crisis which requires a global solution. USAIC has been advocating the approach of global collaborative partnerships for BioPharma Research and Development for the last fifteen years he said. Combined annual R&D budget of few BioPharma leaders participating in the summit is more than

USD 45 billion. It is rare to see such a large number of decision-makers committed to the cause of innovation and patients at a conference, said Rishi. Some of the Global BioPharma leaders participating in the summit are: Kenneth Frazier, Chairman & CEO of Merck & Co, Roy Vagelos, Chairman of Regeneron; Stelios Papadopoulos, Chairman of Biogen; Andrew Plump, President of R&D, Takeda; Mathai Mammen, Global Head of Janssen R&D, Johnson & Johnson; Hal Barron, President R&D, GlaxoSmithKline; David Reese, Head of R&D, Amgen; Richard Hatchett, CEO, CEPI; and Elias Zerhouni, former Director of NIH.

Source: PTI, Financial Express, 31.08.2020 (Excerpts)

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ICMR EOI for Conducting Phase I Clinical Trial on Phytopharmaceutical Drug for Prediabetes

Dated: 8th Sept, 2020

Indian Council of Medical Research (ICMR), New Delhi has previously published an Expression of Interest (EOI) inviting Bid applications for Designing, Conducting, Analyzing and Reporting of Phase I clinical trial on a Phytopharmaceutical Drug in Healthy Volunteers on 28th July, 2020. The last date for receiving applications was September 4th,2020.The date for above EOI(No. ICMR / MPD / NTF/PRE-DIAB/EOI/2) has now been extended up to 28 Sept, 2020. Accordingly, interested party may now submit their application for the above Bid till 28th Sept, 2020, 5.30 PM. Any queries and clarification related to this EOI can be sought telephonically on 24th Sept, 2020 between 11.00 AM-5.00 PM. The Bid applications would be opened on 30th Sept, at 11.30 AM in the virtual presence of the bidders and Technical and Financial selection committee members.

The EOI document and other details are downloadable and available on ICMR official website (Link: https://main.icmr.nic.in/what-s-new) and CPPP portal of Government of India (Link: https://eprocure.gov.in/eprocure/app).

SYNCOM

UNDER EXPANSION PLAN, WORKING CONDITION PHARMA MACHINES ARE ON **SALE** IN **NEGOTIABLE PRICE**

MACHINES FOR SALE

S. No.	MACHINE DETAIL	SPECIFICATIONS	MAKE	QTY
1.	**BOILER** (Good working condition) for Steam Coal/Wood Fire Boiler/Multipack - Model IFB20D/10.54/10 - Year 2006 Evaporation - 2000 kg/hr - Output 1254 MW - Working Pressure - 10.54 kg/cm sq.	2 Ton	Thermax	1
2.	**DG SET 125 KVA -** Working Condition with Control Penal / M/c No. - 9421118-156 Armature make - Kirloskar Electric co. Ltd. Control Panel - Greaves make / Year - 1995	125 KVA RPM 1500 - AMP - 174	Greaves Ltd.	1
3.	**VAC 125 TON** Model - A 213 / Type - DE Steam Pressure - 3.0 kg/cm sq. G-Sr. No. 17 Mfg. Date - Feb.1995	125 Ton Capacity - 150 Nom. B.T.	Enmax (Thermax)	1
4.	**HPLC -** Working Condition Pump - LC 10 ATVP - Director - SPD 10AVP Software - Winchrom	QC-77	Shimadzu	1
5.	**DM WATER PLANT -** Working Condition - Cation Bed / Anion Bed / Mix Bed - Capacity 3 mtr cub. sq. / Hr. **DM PLANT BLOWER** (Degasser) with Motor	1.5 HP	Seion Watertech	1
6.	**AUTOCLAVE - IAB006**	600x600x1200 mm	M.F. Mktg.	1
7.	**COATING PAN (48")** with Hot Air Blower / Electric Penal	Conventional	Elicon Pharma	8
8.	**COATING PAN (60")** with Hot Air Blower / Electric Penal	Conventional	Elicon Pharma	2
9.	**TABLET COMPRESSION MACHINE**	37 STN "B" Tooling	Chamunda	1
10.	**TABLET COMPRESSION MACHINE**	GIGA 75 STN "BB" Tooling	Chamunda	1
11.	**RONDO TRAY PACK MACHINE**		AH Industries	3
12.	**OPTICAL INSPECTION MACHINE**	For Ampoules & Vials	Petals / Saral	5
13.	**BUNG MACHINE**		Ambika Pharma	1
14.	**SHIFTER**			1
15.	**FBD**	100 Kg	Bombay Owen	1
16.	**MULTIMILL**			1

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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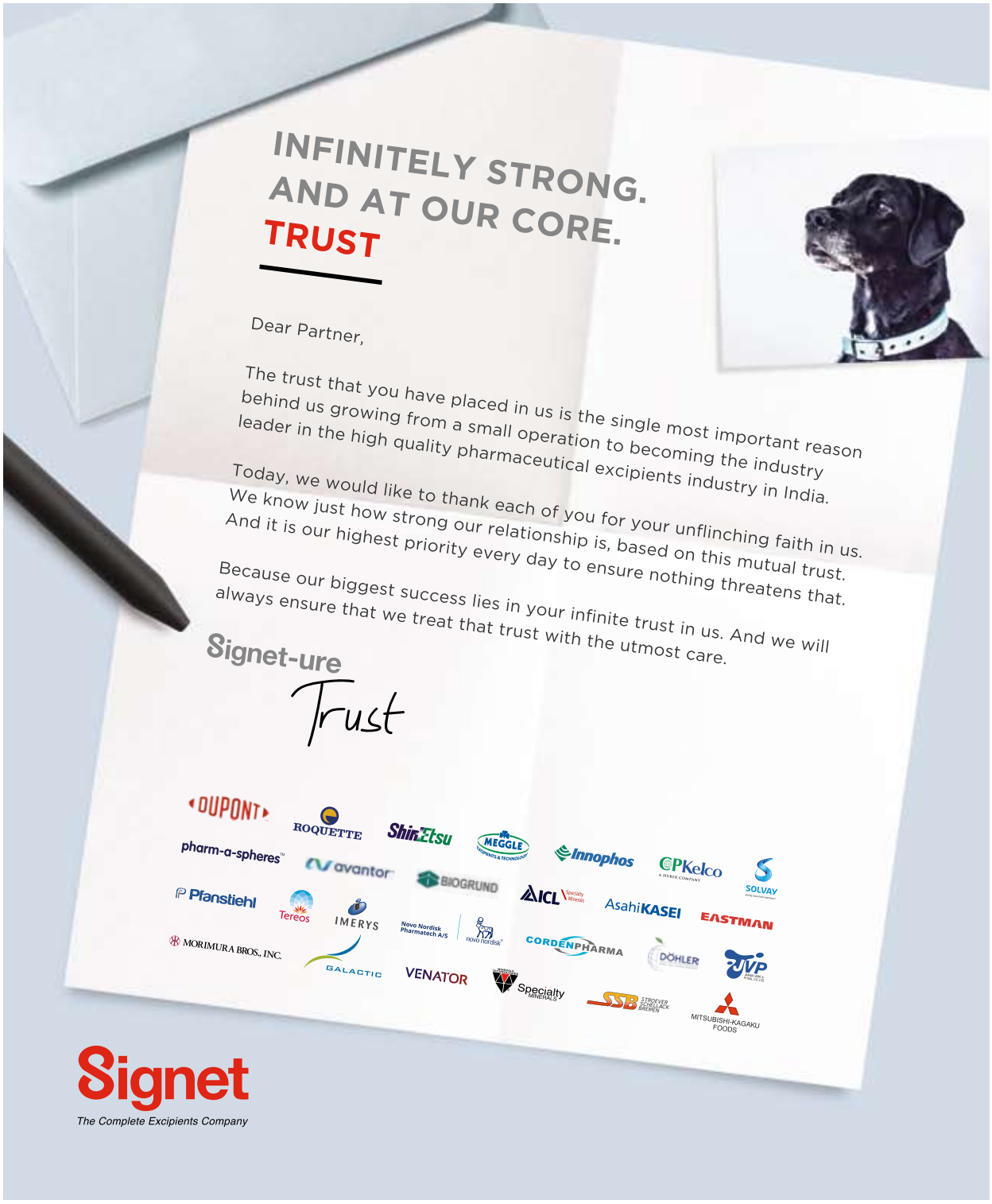
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AND AT OUR CORE.
TRUST
Dear Partner,
The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
Because our biggest success lies in your infinite trust in us. And we will always ensure that we treat that trust with the utmost care.
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