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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 51 **Issue No. 32** **22 to 30 August 2020**

Pharmaceutical Education and Research: Post the Covid-19 Pandemic

***Dr George Patani**, Associate Editor, Indian Drugs*

Dear Reader,

A wave of new innovative ideas utilizing the power of aggregation and information technologies, resulted in large disruptions across various industries with the creation of large virtual companies like Uber, Ola, Airbnb, Oyo etc. These companies,which were less capital intensive grew very fast globally, secured attractive valuations and looked certain to be the trend for new businesses for various other industries. However, the COVID-19 pandemic has brought many of these businesses to a virtual standstill. Air travel, tourism and the hotel industry are some of the industries severely affected by the COVID-19 pandemic. The education industry which has also been impacted by the COVID-19 pandemic has been quick to adopt digital technologies to overcome the adversity it was faced with. The entire spectrum of the education industry including schools, colleges and institutions of higher learning have adapted online technologies and started the academic year in June as it did every year. This thrust of technology on the education sector has resulted in the growth of companies providing education technology platforms such as Byjus, Educomp, Topper etc.The long-term socio-cultural impact of these new methodologies on the students are yet to be evaluated.

It is interesting that now both the pharmaceutical industry and academia are learning concurrently how to conduct the various aspects of their businesses using remote/online technologies. For example, as the pharmaceutical industry is learning to receive online audits of their quality systems, students are gearing up to be evaluated by online examination platforms. On a lighter note, it appears that industry could learn from these new graduates on the methodologies used in online monitoring/evaluations by academia. Further, it will also be very interesting to see if educational institutions will wait out until the travel/campus restrictions are eased and students return back to the campus or they will push ahead with new remote technologies to conduct the practical sessions too.

If we review pharmaceutical education in India, a need to upgrade the curriculum for the Bachelors program has been expressed by many stalwarts of the profession. While reiterating this observation of many experts, from academia and industry, it is hoped that the shift to online/ remote technologies will accelerate this need to review the curriculum. It is estimated that globally there are 190 COVID-19 vaccine candidates being studied. If we review the current curriculum, there is very little time/ credits devoted to the study of vaccine development and manufacturing. Many of these vaccine delivery platforms are novel and there is very little pre-existing data on their safety and efficacy. The development of these platforms has been driven by their use in potential cancer therapies. Hence, the experience from the outcomes of these safety and efficacy studies will influence drug research methodologies in the future.

It is also important to familiarize students with Quality Assurance systems such as deviation management,

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Dr Patani is currently the Hon General Secretary of the Indian Drug Manufacturers' Association and Chairman of IDMA's publication committee since 2012. He was the Treasurer of IDMA from 2017-2019 and Chairman of IDMA's Industry Institute Interaction Committee from 2014 to 2019. He has been a recipient of the Outstanding Alumnus Award 2016 and Distinguished Alumnus Award 2005 from Manipal University. He has served on various committees such as Crude Drugs and Herbal Products Committee of the Indian Pharmacopoeial Commission, the Reach Monitoring Committee of DST-TIFAC CORE in genomics at Manipal Academy of Higher Education and various other advisory committees.

change control and OOS practices early in their careers. The introduction of the Pharmacovigilance Program of India and the need to conduct a large number of post-marketing surveillance studies for products approved recently, requires upgradation of the Clinical skill sets of current pharmacy graduates. The development of large complex bio-similars is gaining popularity as compared to small molecule research. This requires different knowledge and skill sets for its development, commercial manufacture and analysis. In view of the long intervals between the periodic revisions, it may be in the interest of the profession to permit the progressive academic institutions to introduce optional electives, that will better train our pharmacists, in addition to the core curriculum.

National research laboratories like NCL, IICT and other CSIR laboratories have also played a notable role in providing the pharmaceutical industry with skilled research personnel. The COVID-19 pandemic has brought many pharmaceutical and diagnostic laboratories closer to these national research institutions. ICMR has been working closely with manufacturers of diagnostic kits, vaccine manufacturers/drug manufacturers to develop/repurpose their products for the management of COVID-19.

The conventional drug discovery program involves a long search and selection process followed by meticulous refinement, development, clinical testing before final market approval. The current COVID-19 crisis is helping regulatory agencies across the globe realize that the current drug regulatory processes are bureaucratic and need to be streamlined to prevent unnecessary loss of time/ lives, especially during these pandemic situations. In India the Regulators have recently amended the New Drugs and Clinical Trials Rules, 2019 to fast track permission to manufacture new drugs for Compassionate use, especially for COVID-19. This resulted in India becoming one of the first countries to successfully manufacture and supply drugs specifically to treat COVID-19.

According to latest data, there are 2984 clinical studies being conducted on COVID-19 by 113 countries. In India there are 30 studies being carried out at 70 locations and three vaccines are already undergoing advanced Clinical Trials. The race for the COVID-19 vaccine surely highlights how efficient protocols can be quickly drafted with no compromise on safety. It also highlights procedures in the drug discovery process can be run concurrently to optimize the time to market. One positive outcome of the COVID-19 crisis has been that it has pushed us out of our inertia and demonstrated that drug discovery and development can and does happen in India too.

Courtesy: Indian Drugs, Editorial, Vol. 57 (06) June 2020

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INDIAN PHARMACOPOEIA

IPC New Monograph for comments – reg.

On 20th August 2020, Indian Pharmacopoeia Commission uploaded in their website the following New draft monographs (Chemical) and Proposed amendments for Comments:

1. Ferrous Ascorbate (Revised on 17.08.2020)
2. Ferrous Ascorbate and folic acid tablets (Revised on 17.08.2020)
3. Ferrous Ascorbate and folic acid suspension (Revised on 17.08.2020)
4. Ivermectin Tablets (17.08.2020)
5. Remdesivir Injection (17.08.2020)
6. Remdesivir (Revised on 17.08.2020)
7. Remdesivir for Injection (Revised on 17.08.2020)
8. Ticagrelor Tablets (Revised on 17.08.2020)
9. Draft proposal for amendments (14.08.2020)

Members-concerned are requested to kindly visit IPC website: **www.ipc.gov.in** for more details or write to IDMA Secretariat at **Email: admin@idmaindia.com** for having a soft copy of the particulars by mail.

Development and Implementation of Eco System for timely disposal and monitoring of various applications filed with NPPA

NPPA Office Memorandum Ref. No. F. 20(08)/17/2020/Div.III, dated 26.08.2020

1. NPPA envisages a fully automated Eco System for timely attending to, disposing of and monitoring of applications filed under various provisions of DPCO, 2013 to promote the Ease of Doing Business for *'Atmanirbhar Bharat'*. While the same is under process, it has been decided to switch to an online time-bound system for addressing applications received under various provisions of DPCO, 2013 from Pharmaceutical Companies.

   Accordingly, following procedure has been established and adopted:

2. **Submission of Form-I (Application for the pricing of New Drug):** The applicant companies can submit application with all requisite documents (checklist in **Annexure-I**) on email ID:**pricing-nppa@gov.in.** Further,

   a) Confirmation of the receipt of application along with acknowledgement number would be provided via return e-mail.

   b) Incomplete application without the requisite documents would be returned and the same shall be informed to the applicant via email.

   c) Applicant can check the status of their pending applications on the NPPA website, which would be updated fortnightly.

3. **Submission of Form-II (Revised-Prices for Scheduled Formulations); Form-III (Quarterly Return in Respect of Production/Import and Sale of NLEM Drugs) and Form-V (Price List):** Presently, Form-II, Form-III and Form-V are submitted by pharmaceutical companies on Integrated Pharmaceutical Database Management System (IPDMS). The same procedure shall continue to be applicable and Pharmaceutical companies shall submit these Forms on IPDMS within the prescribed time lines.

4. **Submission of Form-IV (Discontinuation of Scheduled Formulation):** The applicant companies can submit Form-IV i.e. application for the discontinuation of the production of scheduled formulation with all requisite documents on email ID: monitoring-nppa@gov.in. Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return e-mail. Applicant can check the status of their pending applications on the NPPA website that would be updated on a monthly basis.

5. **Applications for Special price for packaging under paragraph 11(3) of DPCO, 2013:** Application can be submitted on email ID: **pricing-nppa@gov.in.** Further,

   a) Confirmation of the receipt of the application with acknowledgement number would be provided via return e-mail.

   b) Incomplete application without requisite documents would be returned and the same shall be informed to the applicant via email.

   c) Applicant can check the status of their pending applications on the NPPA website fortnightly.

6. **Holding of Authority meeting:** The Authority meeting would be held preferably every month. If due to certain circumstances the same could not be held in a particular month, the Authority meeting would be held in subsequent months as per requirement.

7. **Meeting of the Multidisciplinary Committee of Experts:** The meeting of the Multidisciplinary Committee of Experts, if required, would be held prior to the Authority meeting.

8. **Uniform Code of Pharmaceutical Marketing Practices (UCPMP):** UCPMP is a voluntary code of marketing practices for Indian Pharmaceutical Industry. It is to be effectively implemented by the Pharma associations and companies. Accordingly, all Indian Pharmaceutical Manufacturer Associations shall upload UCPMP on their website including the detailed procedure mentioned in the paragraph 10 of the UCPMP regarding lodging of complaints. All the associations shall provide on their website for uploading of complaint, the nature of complaint, details of the company against whom complaint is made, action taken by the committee under the association

on such complaints including the current status of the complaint. All such details should be maintained for the period of three years on their website. A quarterly report mentioning details of the complaint received and decision taken thereon shall be submitted by the concerned association to NPPA within 30 days of the end of the quarter via email on email ID: **monitoring-nppa@gov.in.**

9. **Helpdesk:** A helpdesk for dealing with the problems of applicants while submitting their applications has been set up. Applicants facing any documentary or technical issue in submitting their applications can email or contact helpdesk between 10 AM to 6 PM (excluding holidays). Helpdesk numbers and email ID are given at **Annexure II.**
10. Prescribed timelines for submission of application and disposal of the applications is given at Annexure-II.
11. This is approved by the Competent Authority.

Encl: Annexure-I and Annexure-II

S. S. Ojha, Director (Pricing), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

Annexure-I

Checklist for filing application for a New Drug Pricing

1. Company has to submit the duly filled Form-I prescribed in Schedule-II of DPCO, 2013.
2. Approval for new drug formulation granted by the DCG(I).
3. Currently valid manufacturing permission by State Licensing Authority.
4. Agreement /contract between manufacturer and marketer OR Joint undertaking by manufacturing and marketing company with respect to the new drug.
S. Declaration that new drug formulation is not prohibited by DCGI/MoH&FW.
6. Declaration regarding non-discontinuation/non-reduction in production of scheduled formulation under NLEM, 2015, which has been combined with the new drug or if the strength is proposed to be changed.
7. CA/CMA certified quarterly production, sales for last six quarters in respect of the schedule component of the new drugs.
8. Drug category of the new drug (a, b, c, d, etc.) as per Kokate Committee report for FDC's.
9. Status of the new drug as per Drug Technical Advisory Board.

Note: Form-I and all enclosures should be duly stamped and signed by Authorized Signatory

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Annexure-II

The Drugs (Price Control) Order, 2013 (prescribed timelines for disposal of applications received)

Sl. No.	Form No.	Purpose	Prescribed Timeline	Email ID for submission of application
1	FORM - I	New Drug Prices	Within 60 Days by NPPA	pricing-nppa@gov.in
2	FORM - II	Revised-Prices for Scheduled Formulations	Manufacturer shall file within 15 Days from the date of notification.	IPDMS
3	FORM - III	Quarterly Return in Respect of Production/Import and Sale of NLEM Drugs	Manufacturer shall file within 15 Days from the date of the end of quarter.	IPDMS
4	FORM - IV	Discontinuation of production of Scheduled Formulation.	Within 60 Days by NPPA	monitoring-nppa@gov.in
5	FORM - V	Price list	Manufacturer shall file within 15 Days from the date of notification.	IPDMS

Other applications/reports

Sl. No.	Purpose	Prescribed Timeline	Email ID for submission of application
1.	Application for Special price for packaging under Para 11(3)	Within 90 Days by NPPA	pricing-nppa@gov.in
2.	Quarterly report under UCPMP by the concerned association.	Within 30 days of the end of quarter.	monitoring-nppa@gov.in

Helpdesk

Sl. No.	Particulars	Email ID	Phone No.
1.	Form I	pricing-nppa@gov.in	011-23345175
2.	Form II, Form III, Form IV and Form V	monitoring-nppa@gov.in	011-23345177
3.	Technical IT/IPDMS related issues	nppa@nic.in	011-23360265

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Guidelines *re.* implementation of section 28DA of the Customs Act, 1962 and CAROTAR, 2020 - Rules of Origin under Trade Agreements (FTA/PTA/CECA/CEPA) and verification of CoO - reg.

Circular No.38/2020-Customs, dated 21st August, 2020

To,

All Chief Commissioners of Customs/Customs (Prev.),
All Chief Commissioners of GST,
All Chief Commissioners of GST and Customs,
All Directors General under CBIC.

1. Reference is drawn to Chapter VAA and section 28DA of the Customs Act, 1962, which has been inserted vide clause 110 of Finance Act, 2020, and to Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020 (hereafter referred to as the CAROTAR, 2020) issued vide Notification No.81/2020-Customs (N.T.) dated 21st August, 2020.

1.1 The aforementioned section and rules aim to supplement the operational certification procedures related to implementation of the Rules of Origin, as prescribed under the respective trade agreements (FTA/PTA/CECA/CEPA) and notified under the customs notifications issued in terms of section 5 of the Customs Tariff Act, 1975 for each agreement.

1.2 The CAROTAR 2020 shall come into force on 21st September, 2020, to provide sufficient time for transition and to ensure that the prescribed conditions in terms of rule 4 are compiled with. Necessary modifications in bill of entry format are being made to allow declaration in terms of rule 3(a) and 3(d) of CAROTAR, 2020.

1.3 This circular aims to provide procedure for sending verification request to the Verification Authorities in exporting countries in terms of trade agreements, section 28DA and CAROTAR, 2020, and further guidelines for implementation of aforementioned section and rules.

2. The CAROTAR, 2020 and Rules of Origin notified for a trade agreement in terms of sub-section (1) of section 5 of the Customs Tariff Act, 1975, broadly provide the following grounds for verification:

a) In case of a doubt regarding the genuineness of the Certificate of Origin (CoO) such as any deficiency in the format of the certificate or mismatch of signatures or seal when compared with specimens on record.

b) In case of a doubt on the accuracy of information regarding origin, i.e. where a doubt arises on whether the product qualifies as an originating good under the relevant Rules of Origin. In other words, these are cases where there is a reasonable belief that a product is not grown or not produced/manufactured in a particular country or required value addition/change in CTH/PSR etc., as the case may be, has not been achieved for the goods to qualify as originating.

c) Verification could also be undertaken on random basis as a measure of due diligence. For this purpose, factors such as the quantum of duty being foregone, the nature of goods vis-à-vis the country of origin, commodities that are prone to mis-declaration of country of origin, compliance record of the importer etc., may be given regard while selecting Certificates of Origin for random verification.

3. The Rules of Origin, by virtue of which a good attains origin of a country, have evolved with subsequent reviews of trade agreements. Most trade agreements have moved from single general rule to specific rule for most of the tariff lines, with inclusion of vast array of processes which can confer origin. Section 28DA makes it incumbent upon an importer to possess sufficient information as regards the manner in which country of origin criteria, including the regional value content and product specific criteria, specified in the Rules of Origin in the trade agreement, are

satisfied. For this purpose, CAROTAR, 2020 has provided a form, containing list of basic minimum information which an importer is required to obtain while importing goods under claim of preferential rate of duty. Therefore, in case there is a doubt with regard to origin of goods, information should be first called upon from the importer of the goods, in terms of rule 5 read with rule 4 of CAROTAR, 2020, before initiating verification with the partner country in terms of rule 6.

3.1. Section 28DA of the Act further states that mere submission of a certificate of origin shall not absolve the importer of the responsibility to exercise reasonable care to the accuracy and truthfulness of the information supplied. In case an importer fails to provide information in terms of section 28DA(1) (iii) of the Act and as prescribed under CAROTAR, 2020, or does not exercise reasonable care to ensure the accuracy and truthfulness of the information furnished, this fact should be informed to Risk Management Centre of Customs (RMCC) through written communication for the purposes of enabling compulsory verification of assessment of all subsequent import consignments in terms of rule 8(1) of CAROTAR, 2020. However, the compulsory verification of assessment should be discontinued once the importer demonstrates that he has established adequate system of controls to exercise reasonable care as required under the Act.

4. Verification request should be forwarded to the Board based upon following standard operating procedures:

(i) In case several certificates pertaining to identical item are under review or scrutiny, only representative certificates should be forwarded to the Board to cause verification along with list of all CoOs to which the field formation aims to apply the result of such verification. Representative CoOs may be selected in such a manner to ensure that they cover each of the exporters, importers and the prescribed originating criteria. For instance, if there are several CoOs issued to a single exporter, but originating criteria are different, then CoOs covering each of the originating criteria may be considered to be forwarded for verification, with specific queries.

(ii) The verification proposal should be complete, keeping in mind all components of the prescribed format of CoO and all relevant aspects of the Rules of Origin, in order to avoid multiple queries to the Verification Authority/exporting country. For instance, in case a CoO has been issued retrospectively, it needs to be seen whether there are provisions in the Rules of Origin to issue retroactive CoO and whether reasons for retroactive issuance need to be provided by the Verification Authority. Similarly, should the proper officer feel the need to verify documents to establish compliance of 'direct consignment' or third-party invoicing, if provided for in the Rules of Origin, then the same should be included in the verification proposal.

(iii) Requests for verification must be sent to the Board with the approval of the jurisdictional Principal Commissioner/Commissioner. The reference for verification must contain legible copies of the Certificate of Origin, invoice and the Bill of Lading/ Airway Bill. The request should also contain the information listed in the Annex.

(iv) Where verification is being considered for goods not cleared or cleared provisionally on grounds of verification of origin, such requests should be communicated immediately to the Board in case requests are in terms of rule 6(1)(a) or 6(1)(c) of CAROTAR 2020; and within 10 days from the date of receipt of requisite information and documents from the importer in case the request is being considered in terms of rule 6(1)(b).

(v) Mechanism should be devised to monitor the requests which have been forwarded for verification, with special focus on cases where the timeline for response from the Verification Authorities is about to expire.

5. For ascertaining correctness of a claim of preferential rate of duty under a trade agreement, information may be sought from the importer during the course of customs clearance or thereafter (e.g. during subsequent investigations or post-clearance audit). Likewise, a verification request may be made to an exporting country during the course of customs clearance of imported goods or thereafter. While the Act provides that information may be sought within a period of five years from the date of claim of

preferential rate of duty by the importer, this time limit is subject to any other time limit as may be specified for this purpose under the trade agreement.

6. The Rules of Origin under various trade agreements lay down the format of the certificate of origin, the period of validity, manner of obtaining the certificate and the procedure for verification of origin. One of the usual conditions for accepting the certificate is that it should be signed by the authorized signatories whose name, signature and seal have been communicated by the partner country through agreed channels. At present, the signatures and seals are received by the Board, either directly from the government of the partner country or through the Department of Commerce.

6.1 The Directorate General of Systems has built an online repository on ICES for storing the signatures/ seals to facilitate comparison by the assessing officers. DRI has been tasked with uploading the data in the database.

6.2 For the benefit of non-EDI customs locations, copies of specimen signatures and seals will be circulated by DRI. For other locations, the ICES online repository may be utilized.

6.3 In case the specimen seal/signature is not available in the ICES online repository, the issue may be referred to the Board for verification.

7. In terms of rule 6(5) of CAROTAR, 2020, Board has designated Director (ICD), CBIC as the nodal point for taking up verification of origin with partner countries. Hence all requests for verification should be addressed to:

Director (International Customs Division),
Central Board of Indirect Taxes & Customs,
Department of Revenue, Ministry of Finance,
Room No.49, North Block,
New Delhi-110001.
011-2309 3380 (off); 011-2309 3760 (fax.)
Email: ftaroo-cbic@gov.in

7.1 To help reduce time taken in communication of requests for verification of preferential country of Origin, it is advised to email all verification related correspondence to Board on ftaroo-cbic@gov.in. It may be noted that request through nic/icegate email ids will only be accepted. Such emails should include signed copy of the office letter and legible scanned copies of all relevant documents.

7.2 Where the information requested in terms of Rule 6 is received, the proper officer should within the prescribed timelines either restore preferential claim or issue notice for denying the claim in terms of section 28DA, read with section 28 of the Act where required, in order to conclude the verification.

7.3 Where a claim for preferential rate of duty is denied, the CoO should be forwarded to the nodal point in the Board for record and onward communication to the exporting country, where required.

8. It is requested to conduct frequent training sessions in the zones to familiarize the officers with provisions of Rules of Origin prescribed under various trade agreements. Verification may also be sought based on data analysis, keeping in mind any change in import trend of a commodity, exporter, importer or any amendments to duty rates. Attention may also be drawn to the fact that where originating criteria claimed is as per Product Specific Rules (PSRs), the HSN (harmonised system of nomenclature) version prescribed in the trade agreement shall apply. The preferential tariff treatment should be extended only in terms of the extant notification. For instance, provision for issuance of Back-to-Back CoO is presently available only under ASEAN-India FTA, and hence Back-to-Back CoO should not be accepted for goods imported under any other trade agreement.

8.1 It is also requested to share policy related feedback with the Board, through International Customs Division, to help analyse provisions of trade agreements which may require policy review.

9. Instruction no.31/2016–Customs dated 12.09.2016 stands superseded with the issue of this Circular.

10. Suitable Standing Order may be issued. Difficulties faced, if any, in implementation of this circular, may be immediately brought to the notice of the Board.

F.No.15021/18/2020(ICD)

Mandeep Sangha, Joint Commissioner (Customs), International Customs Division, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

Annex

[Please refer Paragraph 4(iii) of this Circular]

1. Name of the Commissionerate:
2. Name of the Free/ Preferential Trade Agreement:
3. Relevant Customs Notifications (Both Tariff and Non-Tariff notifications):
4. Reference No. of the Certificate of Origin:
5. Issuing Authority:
6. Name of the Consignee:
7. Name of the Consignor:
8. Description of goods:
9. Origin criteria as mentioned in the certificate:
10. Revenue involved (forgone):
11. Reason for requesting verification along with supporting documents, if any:

Please enclose:

1. A legible copy of the Certificate of Origin, invoice and Bill of Lading/Airway Bill.
2. Questionnaire for the Verification Authority, where required, with specific queries.

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CBIC amends Notification No.135/2016 for Extension of Deferred Payment of Import Duty to Authorized Public Undertakings - reg.

Notification No.78/2020-Customs (N.T.), dated 19th August, 2020

1. In exercise of the powers conferred by proviso to sub-section (1) of section 47 of the Customs Act, 1962 (52 of 1962), the Central Government, hereby makes the following amendment in the notification of the Government of India, Ministry of Finance (Department of Revenue) No.135/2016-Customs (N.T.), dated the 2nd November, 2016, published *vide* number G.S.R.1038(E), dated the 2nd November, 2016 namely:-

2. In the said notification,-

(i) after serial no. (i), the following entry shall be inserted, namely:-

"(ii) Authorised Public Undertaking.";

(ii) for the "Explanation" to the said notification, the following "Explanation" shall be substituted, namely:-

"Explanation: For the purpose of this notification:-

(i) AEO means Authorised Economic Operator;

(ii) Authorised Public Undertaking means Authorised Public Undertaking, approved by the Directorate of International Customs under the Central Board of Indirect Taxes and Customs."

3. This notification shall come into force with effect on the date of publication in the Official Gazette.

F.No.450/81/2016-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.135/2016-Customs(N.T.) dated the 2nd of November, 2016 was published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), vide number G.S.R.1038(E), dated the 2nd November 2016.*

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CBIC notifies Deferred Payment of Import Duty (Amendment) Rules, 2020 - reg.

Notification No.79/2020-Customs (N.T.), dated 19th August, 2020

In exercise of the powers conferred by proviso to sub-section (1) of section 47 and section 156 of the Customs Act, 1962 (52 of 1962), the Central Government hereby makes the following rules further to amend the Deferred Payment of Import Duty Rules, 2016, namely:-

1. Short title and commencement:-

(1) These rules may be called the **Deferred Payment of Import Duty (Amendment) Rules, 2020.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Deferred Payment of Import Duty Rules, 2016, Rule 4 shall be omitted.

3. Rules 5 to 8 shall be re-numbered as Rules 4 to 7, respectively.

F.No.450/81/2016-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.134/2016-Customs (N.T.) dated the 2nd of November, 2016 was published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), vide number G.S.R.1037(E), dated the 2nd November 2016, and was last amended by Notification No.28/2017-Customs (N.T.) dated the 31st of March, 2017, vide number G.S.R.321(E) dated the 31st March 2017.*

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CBIC notifies Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020 - reg.

Notification No.81/2020-Customs (N.T.), dated 21st August, 2020

In exercise of the powers conferred by section 156 read with section 28DA of the Customs Act, 1962 (52 of 1962), the Central Government hereby makes the following rules, namely:-

1. Short title, commencement and application.- (1) These rules may be called the **Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020**.

(2) They shall come into force on 21st day of September, 2020.

(3) They shall apply to import of goods into India where the importer makes claim of preferential rate of duty in terms of a trade agreement.

2. Definitions:-

(1) In these rules, unless the context otherwise requires,

(a) "Act" means the Customs Act, 1962 (52 of 1962);

(b) "Preferential rate of duty" means rate at which customs duty is charged in accordance with a trade agreement;

(c) "Preferential tariff treatment" means allowing preferential rate of duty to goods imported into India in accordance with a trade agreement;

(d) "Rules of Origin" means rules notified for a trade agreement in terms of sub- section (1) of section 5 of the Customs Tariff Act, 1975 (51 of 1975);

(e) "Tariff notification" means notification issued under sub-section (1) of section 25 of the Act specifying preferential rates of customs duty in accordance with a trade agreement;

(f) "Verification" means verifying genuineness of a certificate of origin or correctness of the information contained therein in the manner prescribed by the respective Rules of Origin;

(g) "Verification Authority" means the authority in exporting country or country of origin, designated to respond to verification request under a trade agreement.

(2) The words and expressions used herein and not defined in these rules but defined in the Act shall

have the same meanings respectively as assigned to them in the Act.

3. Preferential tariff claim:-

(1) To claim preferential rate of duty under a trade agreement, the importer or his agent shall, at the time of filing bill of entry,-

(a) make a declaration in the bill of entry that the goods qualify as originating goods for preferential rate of duty under that agreement;

(b) indicate in the bill of entry the respective tariff notification against each item on which preferential rate of duty is claimed;

(c) produce certificate of origin covering each item on which preferential rate of duty is claimed; and

(d) enter details of certificate of origin in the bill of entry, namely: (i) certificate of origin reference number;

(ii) date of issuance of certificate of origin;

(iii) originating criteria;

(iv) indicate if accumulation/cumulation is applied;

(v) indicate if the certificate of origin is issued by a third country (back-to-back); and

(vi) indicate if goods have been transported directly from country of origin.

(2) Notwithstanding anything contained in these rules, the claim of preferential rate of duty may be denied by the proper officer without verification if the certificate of origin-

(a) is incomplete and not in accordance with the format as prescribed by the Rules of Origin; (b) has any alteration not authenticated by the Issuing Authority;

(c) is produced after its validity period has expired; or

(d) is issued for an item which is not eligible for preferential tariff treatment under the trade agreement;

and in all such cases, the certificate shall be marked as "INAPPLICABLE".

Explanation: Clause (d) of sub-rule (2) includes the cases where goods are not covered in the respective tariff notification or the product specific rule mentioned in the certificate of origin is not applicable to the goods.

4. Origin related information to be possessed by importer.- The importer claiming preferential rate of duty shall-

(a) possess information, as indicated in Form I, to demonstrate the manner in which country of origin criteria, including the regional value content and product specific criteria, specified in the Rules of Origin, are satisfied, and submit the same to the proper officer on request.

(b) keep all supporting documents related to Form I for at least five years from date of filing of bill of entry and submit the same to the proper officer on request.

(c) exercise reasonable care to ensure the accuracy and truthfulness of the aforesaid information and documents.

5. Requisition of information from the importer:

(1) Where, during the course of customs clearance or thereafter, the proper officer has reason to believe that origin criteria prescribed in the respective Rules of Origin have not been met, he may seek information and supporting documents, as may be deemed necessary, from the importer in terms of rule 4 to ascertain correctness of the claim.

(2) Where the importer is asked to furnish information or documents, he shall provide the same to the proper officer within ten working days from the date of such information or documents being sought.

(3) Where, on the basis of information and documents received, the proper officer is satisfied that the origin criteria prescribed in the respective Rules of Origin have been met, he shall accept the claim and inform the importer in writing within fifteen working days from the date of receipt of said information and documents.

(4) Where the importer fails to provide requisite information and documents by the prescribed due date or where the information and documents received from the importer are found to be insufficient to conclude that the origin criteria prescribed in the respective Rules of Origin have been met, the proper officer shall forward a verification proposal in terms of rule 6 to the nodal officer nominated for this purpose.

(5) Notwithstanding anything contained in this rule, the Principal Commissioner of Customs or the Commissioner of Customs may, for the reasons to be recorded in writing, disallow the claim of preferential rate of duty without further verification, where:

(a) the importer relinquishes the claim; or

(b) the information and documents furnished by the importer and available on record provide sufficient evidence to prove that goods do not meet the origin criteria prescribed in the respective Rules of Origin.

6. Verification request:

(1) The proper officer may, during the course of customs clearance or thereafter, request for verification of certificate of origin from Verification Authority where:

(a) there is a doubt regarding genuineness or authenticity of the certificate of origin for reasons such as mismatch of signatures or seal when compared with specimens of seals and signatures received from the exporting country in terms of the trade agreement;

(b) there is reason to believe that the country of origin criterion stated in the certificate of origin has not been met or the claim of preferential rate of duty made by importer is invalid; or

(c) verification is being undertaken on random basis, as a measure of due diligence to verify whether the goods meet the origin criteria as claimed:

Provided that a verification request in terms of clause (b) may be made only where the importer fails to provided the requisite information sought under rule 5 by the prescribed due date or the information provided by importer is found to be insufficient. Such a request shall seek specific information from the Verification Authority as may be necessary to determine the origin of goods.

(2) Where information received in terms of sub-rule (1) is incomplete or non- specific, request for additional information or verification visit may be made to the Verification Authority, in such manner as provided in the Rules of Origin of the specific trade agreement, under which the importer has sought preferential tariff treatment.

(3) When a verification request is made in terms of this rule, the following timeline for furnishing the response shall be brought to the notice of the Verification Authority while sending the request:

(a) timeline as prescribed in the respective trade agreement; or

(b) in absence of such timeline in the agreement, sixty days from the request having been communicated.

(4) Where verification in terms of clause (a) or (b) of sub-rule (1) is initiated during the course of customs clearance of imported goods,

(a) the preferential tariff treatment of such goods may be suspended till conclusion of the verification;

(b) the Verification Authority shall be informed of reasons for suspension of preferential tariff treatment while making request of verification; and

(c) the proper officer may, on the request of the importer, provisionally assess and clear the goods, subject to importer furnishing a security amount equal to the difference between the duty provisionally assessed under section 18 of the Act and the preferential duty claimed.

(5) All requests for verification under this rule shall be made through a nodal office as designated by the Board.

(6) Where the information requested in this rule is received within the prescribed timeline, the proper officer shall conclude the verification within forty five days of receipt of the information, or within such extended period as the Principal Commissioner of Customs or the Commissioner of Customs may allow:

Provided that where a timeline to finalize verification is prescribed in the respective Rules of Origin, the proper officer shall finalize the verification within such timeline.

(7) The proper officer may deny claim of preferential rate of duty without further verification where:

(a) the Verification Authority fails to respond to verification request within prescribed timelines;

(b) the Verification Authority does not provide the requested information in the manner as provided in this rule read with the Rules of Origin; or

(c) the information and documents furnished by the Verification Authority and available on record provide sufficient evidence to prove that goods do not meet the origin criteria prescribed in the respective Rules of Origin.

7. Identical goods:

(1) Where it is determined that goods originating from an exporter or producer do not meet the origin criteria prescribed in the Rules of Origin, the Principal Commissioner of Customs or the Commissioner

of Customs may, without further verification, reject other claims of preferential rate of duty, filed prior to or after such determination, for identical goods imported from the same exporter or producer.

(2) Where a claim on identical goods is rejected under sub-rule (1), the Principal Commissioner of Customs or the Commissioner of Customs shall,

(a) inform the importer the reasons of rejection in writing including the detail of the cases wherein it was established that the identical goods from the same exporter or producer did not satisfy the origin criteria; and

(b) restore preferential tariff treatment on identical goods with prospective effect, after it is demonstrated on the basis of information and documents received, that the manufacturing or other origin related conditions have been modified by the exporter or producer so as to fulfill the origin requirement of the Rules of Origin under the trade agreement.

8. Miscellaneous:

(1) Where an importer fails to provide requisite information and documents by the due date prescribed under rule 5, or where it is established that he has failed to exercise reasonable care to ensure the accuracy and truthfulness of the information furnished under these rules, the proper officer shall, notwithstanding any other action required to be taken under these rules and the Act, verify assessment of all subsequent bills of entry filed with the claim of preferential rate of duty by the importer, in terms of sub-section (2) of section 17 of the Act, in order to prevent any possible misuse of a trade agreement. The system of compulsory verification of assessment shall be discontinued once the importer demonstrates that he is taking reasonable care, as required under section 28DA of the Act, through adequate record-based controls.

(2) Where it is established that an importer has suppressed the facts, made willful misstatement or colluded with the seller or any other person, with the intention to avail undue benefit of a trade agreement, his claim of preferential rate of duty shall be disallowed and he shall be liable to penal action under the Act or any other law for the time being in force.

(3) In the event of a conflict between a provision of these rules and a provision of the Rules of Origin, the provision of the Rules of Origin shall prevail to the extent of the conflict.

(4) The Central Government may, by notification in the Official Gazette, relax such provisions of these rules for such class of persons as may be deemed necessary.

Form I

(Please refer to rule 4)

Section I

(Guidance for filing up this Form)

1. In terms of section 28DA of the Customs Act, 1962, an importer making a claim for preferential rate of duty is required to possess sufficient information as regards the manner in which country of origin criteria, including the regional value content and product specific criteria, specified in the rules of origin in the trade agreement, are satisfied.

2. For the above purpose, this Form contains a list of basic minimum information which an importer is required to possess while importing the goods.

3. Section 28DA of the Act further requires that the importer shall exercise reasonable care to accuracy and truthfulness of the information supplied and the preferential claim. Hence, any additional information, as deemed fit to ascertain correctness of the country of origin criterion, may also be obtained.

4. Wherever necessary, technical terms used in the Form have been explained as below for general guidance. Each trade agreement, however, has its own set of Rules of Origin, and precise definition of each of the term listed below may vary. Importers are, therefore, advised to refer to the respective Rules of Origin also, as notified in terms of sub-section (1) of section 5 of the Customs Tariff Act, 1975.

i. **Goods Wholly Obtained (WO):** Goods produced or obtained without any non-originating input material incorporated.

ii. **Goods that are produced using non-originating materials**, i.e. not Wholly Obtained, are required

to undergo substantial transformation in a country for the good to be qualified as originating. This criterion can be met using following method in combination or standalone, depending upon the criteria assigned for a good,-

(a) Change in Tariff Classification (CTC);

(b) Regional or Domestic Value Content (RVC/ DVC); and

(c) Process rule.

iii. **Value Content Method:** This rule requires that a certain minimum percentage of the good's value originates in a country for the good to be considered as originating. The components of value and formula for calculating such value addition may vary from agreement to agreement.

iv. **Change in Tariff Classification (CTC) Method:** To qualify under this origin criterion, non-originating materials that are used in the production of the good must not have the same HS classification (e.g. Chapter level, Heading level or Sub Heading Level as may be required in the Rules of Origin) as the final good. Depending on the Trade Agreement requirements, the good would have to undergo either a change in Chapter (CC), Heading (CTH) or Sub Heading level (CTSH) in order to qualify for preferential treatment under the FTA. Producers and/or exporters should know the HS classification of the final good and the non-originating raw materials.

v. **Process Rule Method:** This rule requires the good which is being considered as originating, to be produced through specific chemical process in the originating country.

Note: Same good may be assigned different originating criteria in different trade agreements.

vi. **General Rule vs Product Specific Rule (PSR):** Many trade agreements have a single rule for all goods that are produced using non-originating materials. In some agreements, for some or all tariff headings there are Product Specific Rules (PSRs). Depending on the HS classification of the good, it needs to be seen which criteria has been used to claim origin.

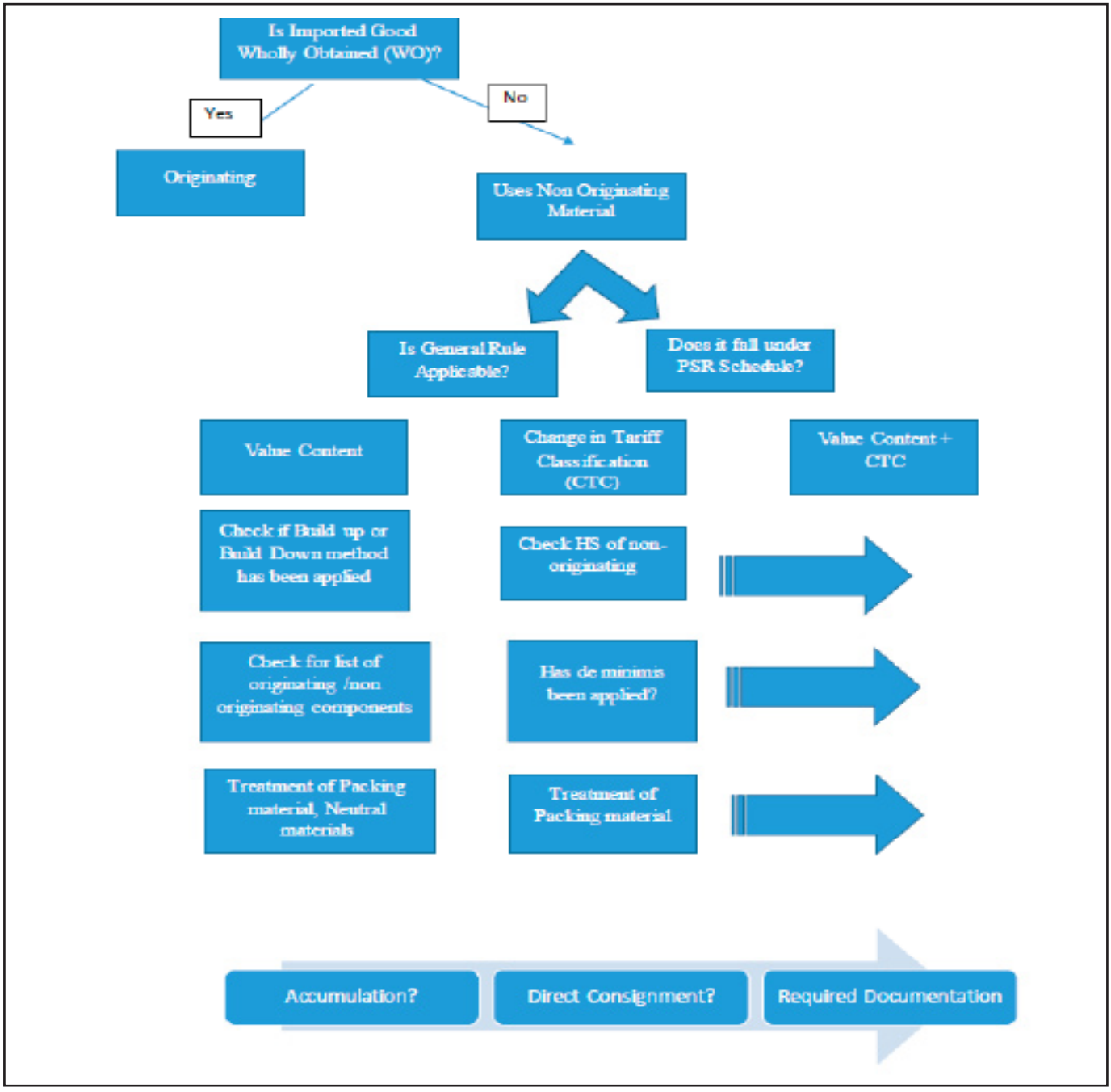
vii. **De minimis:** This provision allows that non-originating materials that do not satisfy an applicable rule may be disregarded, provided that the totality of such materials does not exceed specific percentages in value or weight of the good. This provision may or may not be there in an agreement and the percentage also varies from agreement to agreement.

viii. **Cumulation/Accumulation:** The concept of "accumulation"/"cumulation" allows countries which are part of a preferential trade agreement to share production and jointly comply with the relevant rules of origin provisions, i.e. a producer of one participating country of a trade agreement is allowed to use input materials from another participating country without losing the originating status of that input for the purpose of the applicable rules of origin. Otherwise said, the concept of accumulation/cumulation or cumulative rules of origin allows products of one participating country to be further processed or added to products in another participating country of that agreement. The nature and extent of such cumulation is defined in an agreement and may vary from agreement to agreement. Cumulation can be bilateral, regional, diagonal, etc.

ix. **Indirect/Neutral elements:** refer to material used in the production, testing or inspection of goods but not physically incorporated into the goods, or material used in the maintenance of buildings or the operation of equipment associated with the production of goods. For example, energy and fuel, plant and equipment, goods which do not enter into the final composition of the product, etc. Depending upon the trade agreement, these elements may be treated as originating or non-originating.

x. **Rule on treatment of packages and packing materials for retail sale:** Such rule provides the manner in which such material will be treated while calculating qualifying value content or tariff shift.

xi. **Direct Consignment:** Most agreements lay down the condition that good claiming originating status of a country should be directly transported from that country to the importing country. Certain relaxation may be provided in a trade agreement, subject to presentation of certain documents.



Section II

(To be filled after filing of Bill of Entry)

(a) Name of the importer:

(b) Bill of Entry (B/E)No. and Date:

(c) Customs Station where B/E was filed:

(d) Goods on which preferential rate of duty has been claimed:

Sl. No.	Description	Classification (8 digit)

Section III

(This information should be possessed before import of goods)

Part A:

1. Briefly describe the production process undertaken in country of origin with respect to production of the imported good. Also, state which of the originating criteria prescribed in the Rules of Origin has been claimed. For example, WO, RVC + CTH/CTSH or CTH or CC or RVC, etc.

   [WO: Wholly Obtained; RVC: Regional Value Content; CTH: Change in Tariff Head; CTSH: Change in Tariff Sub-Head; CC: Change in Chapter]

Note 1: Where the good is claimed to be "Wholly Obtained", mention the process through which it is claimed to fall under this category. Each trade agreement lists out such processes under a specific rule and may vary from agreement to agreement.

Examples:

- *goods obtained by hunting or trapping within the land territory, or fishing or aquaculture conducted within the internal waters or within the territorial sea of the Party;*
- *goods produced on board factory ships from the goods referred to in preceeding paragraph, provided that such factory ships are registered or recorded with a Party and fly its flag.*

Note 2: If the goods are not wholly obtained, the manufacturing/processing undertaken in country of origin must be ascertained.

Description of goods	Production process	Originating Criterion
1.		
2.		

Part B:

(To be filled if originating criteria is NOT wholly obtained, for each of such good under import, on separate sheets)

1. State the following information for each originating material or component used in production of good subject to this request. If no originating material/ components were used, same should be indicated as "None".

Description of good under import and its classification (8 digit):

Description of the originating Materials or Component	Whether manufactured by producer of final good	Whether procured by producer locally from a third party	In case procured from third party, did producer of final good seek conformation and documentary proof of origin of these component?
	(Yes/No)	(Yes/No)	(Yes/No)
1.			
2.			

Note: If origin of any of the components used in manufacture of final good cannot be ascertained, same should be treated as non-originating.

2.

a.	Is the de minimis provision used to determine whether the good subject to this request qualifies as an originating good?	o Yes o No If yes, describe such material and the percentage value or quantity as applicable.
b.	Is the accumulation/cumulation provision applied to determine whether the good subject to this request qualifies as an originating good?	o Yes o No If yes, describe the manner and extent of cumulation.
c.	Has any other additional criteria such as indirect/ neutral materials, packing materials, etc. used in ascertaining whether the good qualifies as an originating good.	o Yes o No If yes, provide the criteria used: Describe the material concerned:
d.	Is the originating criteria based on value content?	o Yes o No If yes, provide the following: (i) percentage of local value content: (ii) components which constitute value addition (e.g. material, profit, labour, overhead cost, etc.):
e.	Has CTC rule been applied for meeting Originating criteria?	o Yes o No If yes, provide HS of non-originating material/ components used in production of good:
f.	Has process rule been applied in ascertaining origin of good subject to this request?	o Yes o No If yes, provide the rule applied:
g.	Has the CoO been issued retrospectively?	o Yes o No If yes, provide reasons for same:
h.	Has the consignment in question been directly shipped from country of origin?	o Yes o No If not, then has it been ascertained that same is as per provisions of the concerned agreement? How has it been ascertained that goods have met the prescribed conditions of Direct Shipment?

F. No.15021/18/2020(ICD)]

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

Amendment in Schedule VII to the Companies Act, 2013 (18 of 2013) - reg.

Corporate Affairs Notification No.G.S.R.525(E), dated 24th August, 2020

1. In exercise of the powers conferred by sub-section (1) of section 467 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following further amendments in Schedule VII to the said Act, namely:-

In the said Schedule, for item (ix) and the entries thereto, the following item and entries shall be substituted, namely:-

"(ix) (a) Contribution to incubators or research and development projects in the field of science, technology, engineering and medicine, funded by the Central Government or State Government or Public Sector Undertaking or any agency of the Central Government or State Government; and

(b) Contributions to public funded Universities; Indian Institute of Technology (IITs); National Laboratories and autonomous bodies established under Department of Atomic Energy (DAE); Department of Biotechnology (DBT); Department of Science and Technology (DST); Department of Pharmaceuticals; Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); Ministry of Electronics and Information Technology and other bodies, namely Defense Research and Development Organisation (DRDO); Indian Council of Agricultural Research (ICAR); Indian Council of Medical Research (ICMR) and Council of Scientific and Industrial Research (CSIR), engaged in conducting research in science, technology, engineering and medicine aimed at promoting Sustainable Development Goals (SDGs)".

2. This notification shall come into force on the date of its publication in the Official Gazette.

E-F.No.CSR-07/2/2020-CSR-MCA

Gyaneshwar Kumar Singh, Joint Secretary,
Ministry of Corporate Affairs, New Delhi.

Note: *The Schedule VII to the Companies Act, 2013 was brought into force with effect from the 1st April, 2014 and was amended (effective from the 1st April, 2014) vide notification number G.S.R.130(E), dated the 27th February, 2014, Corrigendum number G.S.R.261(E), dated the 31st March, 2014, notification number G.S.R.568(E), dated the 6th August, 2014, notification number G.S.R.741(E), dated the 24th October, 2014, notification number G.S.R.390(E), dated the 30th May, 2019, notification number G.S.R.776(E), dated the 11th October, 2019, Corrigendum number G.S.R.859(E), dated the 19th November, 2019, and notification number G.S.R.399(E) dated the 23rd June, 2020.*

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Companies (Corporate Social Responsibility Policy) Rules, 2014 amended (1st Amendment of 2020) - reg.

Corporate Affairs Notification No. G.S.R.526(E), dated 24th August, 2020

In exercise of the powers conferred by section 135 and sub-sections (1) and (2) of section 469 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following rules further to amend the Companies (Corporate Social Responsibility Policy) Rules, 2014, namely:-

1. **Short title and commencement:**

(1) These rules may be called the **Companies (Corporate Social Responsibility Policy) Amendment Rules, 2020.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Companies (Corporate Social Responsibility Policy) Rules, 2014 (hereinafter referred to as the said rules), in rule 2, in sub-rule (1), in clause (e), the following proviso shall be inserted, namely:-

"Provided that any company engaged in research and development activity of new vaccine, drugs and medical devices in their normal course of business may undertake research and development activity of new vaccine, drugs and medical devices related to COVID-19 for financial years 2020-21, 2021-22 and 2022-23 subject to the conditions that-

(i) such research and development activities shall be carried out in collaboration with any of the institutes or organisations mentioned in item (ix) of Schedule VII to the Act.

(ii) details of such activity shall be disclosed separately in the Annual Report on CSR included in the Board's Report".

3. In the said rules, in rule 4, in sub-rule 1, the words "excluding activities undertaken in pursuance of its normal course of business" shall be omitted.

4. In the said rules, in rule 6, in sub-rule (1),- (i) first proviso shall be omitted;

(ii) In the second proviso, the word "further" shall be omitted.

E-F.No.CSR-07/2/2020-CSR-MCA

Gyaneshwar Kumar Singh,
Joint Secretary,
Ministry of Corporate Affairs,
New Delhi.

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.129(E), dated the 27th February, 2014 and were subsequently amended by notification number G.S.R.644(E), dated the 12th September, 2014, Notification Number G.S.R.43(E), dated the 19th January, 2015, Notification Number G.S.R.540(E), dated the 23rd May, 2016 and Notification Number G.S.R.895(E), dated the 19th September, 2018.*

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Can Cancer be beaten? The findings are surprisingly optimistic

Nano-ghost, developed by Prof. Marcel Machluf, is an innovative technology that enables the focused internal delivery and release of anti-cancer drugs. This innovative delivery system is aimed at preventing side effects of chemotherapy and at dramatically enhancing the treatment's efficacy. The Nano-ghost system got its name from its operating method that includes emptying stem cells of their content, reducing them in the laboratory to nanometric size, transforming them into types of engineered delivery nano-systems (nano-ghosts), and loading them with different medicines. During the treatment, the patient is injected with these nano delivery systems loaded with the medicines that make their way, via the blood vessels, to a specific tumor.

Prof. Machluf is the dean of the Biotechnology & Food Engineering Faculty at the Technion-Israel Technological Institute and a world-renowned researcher in the fields of medicine delivery, gene therapy, cell therapy, and tissue engineering.

"Stem cells know how to assign themselves to other types of cells and protect the body's immune system," she explains. "These cells treat infections and when there is no infection, the immune system 'relaxes' and is less focused on attacking the tumor."

In order to understand the interaction that develops between stem cells and the cells in the area of a cancerous tumor and the reason they remain there, Prof. Machluf and her team decided to investigate the nature of the human body, to transform stem cells into "nanometric ghost cells" and deploy them on their mission. The study they conducted revealed that at first the ghost cells wandered about the bloodstream but, upon sensing the cancer cells' signals, rushed within hours to the area under examination and went to work on the cancerous tumor.

"The nano-ghost cells acted like a 'trojan horse,'" she explained, "and the cancerous cells, which thought that they were coming to their aid, let them in. The findings when it came to the efficiency of the drugs were surprisingly good – the cancerous tumor shrunk after just a single injection of the nano-ghost."

After conducting many experiments, the Nano-ghost team realized that the solution was a biological one, rather than chemical or synthetic. "In a biological system like ours, there is no need to assemble the molecule. We engineer the cell while it is still alive, before we turn it into a ghost, in a way that allows it to express the desired characteristics of the membrane. This is a tremendous advantage over other systems in which the specific molecule needs to be isolated and assembled with the right orientation. Nevertheless, choosing a biological solution also has a significant disadvantage – the cell production method is relatively limited, and it always takes a long time to analyze and characterize the medication. On an overall industry level, Nano-ghost's delivery system won't suit every type of medication because we cannot encompass and experiment with them all, but the delivery of those medicines that we do adapt will have a significant impact for the patients."

The results of Nano-ghost's experiments are positive and encouraging, and the delivery system has already been shown to be efficient against different types of cancers: "So far, we have worked only with animals but now need to find methods that are better suited for humans," she says. "Furthermore, we also need to find a way to increase the system's production capabilities, to characterize the nano-ghosts, and to meet the criteria required by the regulatory entities so that we can use the material and inject it into humans."

The lab team discovered that the ghost cells influence not only different kinds of cancer tumors but also other conditions. According to Prof. Machluf, "For example, when the cells are returned empty to the body, without medicines, they influence inflammatory systems that are created due to the appearance of cancer. The lab experiments have generated a lot of information and the company needs to focus on the desired pharmaceutical direction and on proving the system's feasibility – on whether to choose a drug that has been entirely unsuccessful, a successful drug with side effects that we can improve, or on a cancerous tumor for which no treatment exists. We are also looking for a solution for the Corona virus. The goal here is to transform our ghost cells into a trap for the virus. We intend to express the BCE2 receptor as a virus on the membrane's surface and only then to turn it into a ghost."

Clinical Trials Within Three Years:

Nano-Ghost was officially founded in November 2019 following a complex phase of recruiting investors, but the process actually started three years previously. The professional team of employees emphasize the advantages

of Bio-convergence: each comes from a different field on the engineering spectrum – biological, chemical, and physical. "Our vision is to commence clinical trials within 3 years and to start raising the necessary capital. We have accumulated a great deal of knowledge in using this system and we are currently focusing on the first stage of being able to conduct clinical trials that will prove that the system itself is not harmful or problematic," Prof. Machluf summarizes.

By 2030 we will have a solution for most types of Cancer:

Groundbreaking thinking that creates synergy between different scientific fields is also a prominent characteristic of Prof. Avi Schroeder, a chemical engineer by training, who seven years ago founded a lab at the Technion for integrating nanotechnological solutions in medicine. Prof. Schroeder, who already has several startups and revolutionary developments in the fields of agriculture and precision medicine under his belt, estimates that mankind will solve most of its cancer-related problems within the next decade.

The basic underlying idea of Barcode Diagnostics – the company of which Prof. Schroeder is a founding partner, is the delivery and focus of medicines in liposomes – nanoparticles smaller than a cell from a human body – in order to lead it directly to the organ in need of treatment. The company has already successfully registered several patents related to this development.

"Creating a technology that provides a solution to problems in the fields of medicine or agriculture, has been one of the characteristics of my career," says Prof. Schroeder. "Barcode Diagnostics is an example of a company that was founded in response to a medical need, and where the technology was initially developed in academia. The Coronavirus is presently highlighting to us all how medical challenges can paralyze a country and the world's economy. As far as I'm concerned, this is a wake-up call to all parties responsible for funding national R&D to relate to the developmental and production ability in the fields of biotechnology and pharmaceuticals as a strategic need."

Personalized, Precision, and Economic Mass Medicine:

The major challenge facing the developers of pharmaceuticals and technologies is the need to join forces and connect all the relevant fields – essentially, bio-convergence. Prof. Schroeder believes that "today, contrary to the past, knowledge accumulated in research and medicine can be applied using artificial intelligence and be used to predict possible solutions. If we add to this our development and therapeutic ability, we can also combine robotics and nanotechnology to develop a new generation of more efficient smart medicines. Thanks to the combination of these fields, we can also lower development costs and reach a faster solution.

"In today's data-saturated age, the winning combination is that of economic mass medicine with personalized precision healthcare. The professionals know that different people react differently to disease and treatment, and this is especially true with diseases such as cancer where each patient experiences different intensities of the disease and treatment and reacts differently to medication. Research now has a better understanding of each patient's individual characteristics, but we still don't know how to provide for each person's specific medical needs. When we focus on personalized medicine, we will be able to heal better while also reducing suffering and side effects," he said.

A clear indication within 72 hours:

Barcode Diagnostics' development deals in precision medicine for cancer patients. "The company is developing a method to personally adapt drugs to treat cancer," says Ronen Eavri, CEO, and co-founder of Barcode Diagnostics. "Our method is aimed at identifying the optimal medication for each patient. The company intends to start a clinical study in breast cancer patients in 2021. Once we provide clinical evidence in breast cancer, the company will expand this technology platform to include additional cancer indications."

"The concept of the diagnostic method is similar to an allergy test where the doctor uses a low concentration of allergens and examines the body's allergic reaction. Using our diagnostic method, a tumor is injected with a tiny dosage of different medicines and the suitable treatment is then chosen according to the reaction. In this way, our development helps doctors receive a clear indication about the drug's efficacy and enables them to quickly make the optimal therapeutic decisions for each cancer patient in a personalized manner, while minimizing side effects and limiting the harm to healthy tissue.

"To deliver the medication, we use nanoparticles (liposomes) that are injected into the blood intravenously. In addition to the medicine, the nanoparticles also contain molecular barcodes that allow us to receive, within 72 hours, an indication regarding the cancerous cells that

reacted to a specific medication and about each drug's degree of influence on the tumor. If the medication proves effective, we will detect an increase in the number of dead cells with specific barcodes in the tumor," Eavri explains.

Prof. Schroeder describes the development as a significant breakthrough: "The talented team at Barcode Diagnostics, located in Nazareth and Yokneam, creates the nanoparticles with the barcodes, and we are scheduled to conduct the first clinical trial in breast patients at the beginning of 2021. For this purpose, we are collaborating with clinicians from Israel and abroad who are helping us characterize the technology."

Breast Cancer Patients First:

Barcode Diagnostics, which received financing from the Israel Innovation Authority, is preparing for the first clinical trial in breast cancer patients. The technology for delivering the drugs was initially developed at the Technion and the company's first steps towards foundation took place as part of the NGT3 Technology Incubator and with the support of the Innovation Authority. "We would not have been able to progress without the financial and organizational assistance of the Innovation Authority," says Eavri. "The incubator facilitated the early phases of our activity until we recruited the capital for the first clinical trial and a team that believed in the product."

At the same time, the company answered a call for proposals issued by the Innovation Authority regarding the Coronavirus. "The initiative came from the employees," Eavri describes. "The main idea is to produce kits for mass-scale Corona testing that are based on the company's advanced diagnostic capabilities. The personal samples will be identified at DNA level by a unique barcode after which it will be possible to concentrate the individually labelled samples belonging to different subjects in a single test tube. This method enables us to save time and use an advanced device that can simultaneously scan tens of thousands of subjects tested each day. A specially designated team at the company took on the project and is trying to advance it towards commercialization after receiving the necessary regulatory approvals."

"The Bio-convergence revolution will lead to integrated developments that will generate a revolution in the treatment of cancer and other diseases," concludes Prof. Schroeder. "Israel is in an excellent position to lead this revolution. Our scientists, engineers, and physicians are among the best in the world but our added asset is the ability to work together as a team, to combine our different fields – to bring the worlds of computing, artificial intelligence, robotics and nanotechnology into the world of medicine."

Dr. Ami Appelbaum, Chairman of the Israel Innovation Authority and Chief Scientist at the Ministry of Economy and Industry:

"The global economy is currently undergoing one of its greatest crises, due in part to the inability to respond rapidly to and contend technologically with the threat of pandemics. Countries are desperate for new and rapid diagnostic technologies, for the capability to continuously monitor viruses and biological threats, to economize, and to accelerate the development of vaccines. These challenges mandate the creation of inventive engines of innovation. The world of Bio-convergence, which fuses biology and engineering, is the answer to this challenge and will be the next technological revolution of the 21st century."

(The article was written in collaboration with the Israel Innovation Authority, responsible for the country's innovation policy. Its role is to nurture and develop Israeli innovation resources, while creating and strengthening the infrastructure and framework needed to support the entire knowledge industry.)

Source: calcalistech.com, 16.08.2020 (Excerpts)

India's Pharma Market to grow by 12 to 14 percent in three years: KPMG

India's domestic pharmaceuticals market is expected to grow by 12 to 14 percent in the next three years while the export market may grow by 8 to 14 percent, according to a new report by professional services firm KPMG. Backed by a 41 billion dollar Pharma industry, the country ranks as the third-largest market globally by volume and 13 largest by value. The epidemiological transition from communicable diseases to non-communicable diseases in the country is driving the Pharma market.

At the same time, said the report, India is a key component of the global life sciences industry. Its manufacturers are one of the largest sources of generic drugs, supplying 50 percent of global demand for a range of vaccines, 40 percent of generic demand in the United States -- where Indian firms are expanding -- and 25 percent of UK medicines.

However, there have been calls for a more robust domestic industry. This is particularly the time as the COVID-19 crisis emphasizes the importance of localizing parts of the value chain and ensuring multiple sourcing close to consumers. In March, the Government announced a 1.3 billion fund to encourage domestic manufacture of Pharma ingredients.

This follows severe supply chain disruption amid the Coronavirus pandemic due to India's dependence on imports from abroad. About 70 percent of the country's Active Pharma Ingredients (APIs) and 60 percent of penicillin are imported from other Asian countries. The Government is aiming to increase healthcare spending through schemes like Ayushman Bharat. The country also aims to increase its public health spending to 2.5 percent of its GDP by 2025.

The rising level of health consciousness among people and their awareness of treatment options as well as modern medicines are also contributing towards the growth of the Indian Pharma Industry.

Long known as a low-cost manufacturing location, the confidence in product quality has been a challenge However, said the KPMG report, new safeguards on manufacturing and product standards are providing much-needed reassurance to customers at home and abroad.

Source: ANI, The Indian Express, 19.08.2020

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Industry urges DoP to take steps to reinstate Weighted Deduction of 200% on expense of in-house R&D under IT Act

In order to boost indigenous Research and Development to produce innovative drugs, the Pharmaceutical industry has urged the Department of Pharmaceuticals (DoP) to take up with the Finance Ministry the matter of reinstatement of weighted deduction of 200 percent on expenditure incurred on in-house R&D under the Income Tax Act. Same incentives need to be provided for R&D carried out outside own premises, stated the industry.

The industry raised the issue, along with several other issues, at the second meeting of the Forum of Pharma Associations convened by the DoP recently. Chaired by Dr P D Vaghela, Secretary, DoP, the meet was attended by several Pharma Associations including IPA, OPPI, CIPI, BDMA and FOPE.

The Finance Act, 2016 has amended Section 35(2AB) of the Income Tax Act where it has been provided that the weighted deduction shall be reduced under Section 35(2AB) from 200 percent to 150 percent effective from April 1, 2017 till March 31, 2020. Thereafter, it will be phased out to 100 per cent only.

Besides this, the industry also appealed to DoP to support incremental innovation under Drugs Prices Control Order (DPCO), 2013 which mandates fixation of the ceiling price of scheduled drugs based on the simple average of the prices of all brands of that drug that have a market share of at least 1%. It mandates a 10% increase in prices of non-scheduled formulations comprising formulations developed through incremental innovation (an additional innovation over an existing quality) or novel drug delivery systems (continuous/ sustained release) year-over-year.

Approved by the Drugs Controller General of India (DCGI), the formulations developed through incremental innovation or Novel Drug Delivery Systems like lipid/ liposomal formulations, sustained release/controlled release etc should be recognized and supported under DPCO, 2013. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc, stated Dr Viranchi Shah, Senior Vice President, Indian Drug Manufacturers' Association (IDMA) while speaking at the second meeting of the Forum of Pharma Associations recently.

The order passed by Delhi High Court on July 17, 2018 in Modi-Mundipharma Pvt Ltd case also stated that drugs developed through incremental innovation or a Novel Drug Delivery System could only be included under the National List of Essential Medicines, 2015 (NLEM) for the purpose of fixing the ceiling price, procurement etc if they were explicitly listed.

Modi-Mundipharma approached the High Court against the order passed by the National Pharmaceutical Pricing Authority (NPPA) in relation to fixation of the ceiling price of the formulation "Tramadol 100mg CR 10" (Tramadol CR 10).

The petitioner contended that Tramadol CR 10 was only listed in the NLEM 2015 in the capsule and injection forms whereas their formulation uses a continuous controlled release dual mechanism drug delivery system (CR-technology), which was not specifically included in the NLEM-2015 and, thus, not a 'scheduled formulation' within the meaning of the DPCO-2013.

The High Court concluded that if there is an improved formulation, developed through incremental innovation involving technology, to overcome certain disadvantages associated with the use of conventional formulations, the same would not be read as part of the NLEM 2015 unless specifically mentioned. The petition was allowed and Tramadol CR10 was removed from the purview of the impugned notification ceiling its price.

To support R&D activities of indigenous drugmakers to meet unmet medical needs, IDMA has further urged the DoP to restrict benefits of amended DPCO, 2013 to domestic firms. On January 3, 2019 DoP amended the DPCO, 2013 to exempt new patented drugs and orphan drugs from price control for five years from the date of commencement of its commercial marketing by the manufacturer.

With this, any new drug can get exemption from price control if it is patented in India under Indian Patents Act, 1970 and developed and manufactured by any patentee across the globe. There were instances of global drug firms conducting R&D overseas and launching products in India to get exemption from price control under Para 32, DPCO, 2013.

Hence, we have appealed to DoP to exempt indigenously developed patented drugs from price control for five years from the date of commencement of its commercial marketing by the manufacturer, said Shah, pointing out that prior to amendment in Para 32 of DPCO, exemption for five years was available to only those new drugs which were patented in India but were not produced elsewhere and were developed through indigenous R&D.

Source: Laxmi Yadav, Pharmabiz, 24.08.2020

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AIDAN asks DoP to include NGOs and health experts in review meetings on UCPMP

The All India Drug Action Network (AIDAN) has urged the Department of Pharmaceuticals (DoP) to hold an urgent consultation meeting with civil society organizations and public health experts to seek their views and inputs for regulating pharmaceutical and medical device marketing practices.

Recently, the DoP had held a meeting with Pharma and medical device associations to review the status of implementation of the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) to which civil society organizations and public health experts were not invited.

"As you know, civil society has consistently advocated for bringing in a legal instrument to regulate marketing and promotion of pharmaceuticals and medical devices. The UCPMP, a form of self-regulation, is wholly inadequate for checking unethical practices in the industry and is unenforceable. Moreover, industry associations have refused to comply with even the most basic requirements of the UCPMP such as uploading the code to their website. We are surprised to learn that the DoP has invited suggestions from the industry to modify the already weak UCPMP, but has not sought any inputs from other stakeholders," Malini Aisola, Co-convenor, AIDAN, stated in a letter sent on behalf of the groups.

"We are therefore writing to request the DoP to seek views and inputs for regulating pharmaceutical and medical device marketing practices," the letter further stated. Copy of the letter has also been addressed to Shubhra Singh, Chairperson, National Pharmaceutical Pricing Authority (NPPA), Vinod Kotwal, Member Secretary, NPPA and Navdeep Rinwa, Joint Secretary (Policy, Medical Device, Scheme, Pricing), DoP.

At the meeting held by DoP in February this year, DoP Secretary Dr P D Vaghela had enquired how many pharmaceutical and medical device associations have uploaded the UCPMP on their website and have formed two committees — Ethics Committee for Pharma Marketing

Practices (ECPMY) for handling complaints related to UCPMP violation and Apex Ethics Committee for Pharmaceuticals Marketing Practices (AECPMP) to review the decisions of ECPMP.

He sought details of both the committees of all the associations along with contact number and procedure of filing complaint, which would be uploaded on the website of the department. Expressing his displeasure at the status of implementation of UCPMP, Secretary DoP in January this year exhorted all the associations representing pharmaceuticals and medical devices viz IDMA, OPPI, IPA, BDMA, FOPE, CIPI, CII, FICCI, ASSOCHAM, PHD Chamber of Commerce and Industry, American Chamber of Commerce in India, NATHEALTH, Small and Medium Pharma Manufacturers Association (SMPMA), National Alliance of Pharmaceutical Manufacturers Association (NAPM), AiMeD, Medical Technology Association of India etc to implement UCPMP without exception.

He had also asked the associations to quote exact provisions of laws of other countries as precedence/ reference while giving suggestions in respect of UCPMP. At the last meet, DoP Secretary also enquired whether any of the associations have handled any complaint for violation of UCPMP and whether any action has been taken against any company. Associations denied of having dealt with any complaint. OPPI stated that they are collating the information and would provide the report by March 2020.

In the earlier meeting held by DoP on December 23, 2019, it was decided that the associations would upload UCPMP on their website and comply with its provisions including formation of ECPMY and AECPMP, uploading details on the websites and submitting quarterly reports to NPPA.

In December last year the All India Drug Action Network had approached DoP against Novartis for offering inducements to doctors in the form of honorariums for participation in conferences, travel assistance, accommodation, food expenses, all of which are strictly prohibited under the UCPMP as well as the Indian Medical Council (Professional conduct, Etiquette and Ethics), Regulations 2002.

Source: Shardul Nautiyal, Pharmabiz, 24.08.2020

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DGTR recommends anti-dumping duty on DMF imported from China and Saudi Arabia

The Directorate General of Trade Remedies (DGTR), the investigation arm of the Union Commerce Ministry, has recommended imposition of anti-dumping duty on dimethylformamide (DMF), imported from China and Saudi Arabia to guard domestic players from cheap imports. DMF is used as a solvent in pharmaceuticals manufacturing, acrylic polymers manufacturer and pesticides formulations. It is used as a feedstock for synthesis of derivatives of DMF.

The dumped imports held about 78% of the Indian demand. India imported 34,039 metric tonne (MT) of DMF from China and Saudi Arabia in FY 2016-17. The import of DMF was reduced to 31,725 MT in FY 2017-18. It has again gone up to 44,848 MT in FY 2018-19. During the period of investigation (January 2019 to September 2019), the country imported 29,499 MT of DMF.

The DGTR has recommended the duty after conducting a preliminary probe on alleged dumping of the product by certain companies from these countries, following a complaint by domestic manufacturer Balaji Amines Ltd. Balaji has claimed to be the sole producer of DMF in India filed the application for dumping probe. As per the petition, Rashtriya Chemical & Fertilizers Ltd (RCF Ltd) was also a producer of DMF but has not produced it for quite some time.

The duty recommended is in the range of USD 318 per metric tonne to US$ 471 per metric tonne. The Finance Ministry takes the final decision to impose the duty. "The authority recommends imposition of provisional anti-dumping duty equal to the lesser of margin of dumping and the margin of injury, so as to remove the injury to the domestic industry," the DGTR has said in a notification.

In its probe, the directorate said it has concluded that the product has been exported to India from these nations below its associated normal value, which resulted in dumping and in turn impacting the domestic industry. The dumped imports held about 78% of the Indian demand and any fair share in demand to the domestic industry can be ensured by imposition of anti-dumping duties only, it stated.

As per global trade norms, a country is allowed to impose tariffs on such dumped products to provide a level-playing field to domestic manufacturers. The duty

is imposed only after a thorough investigation by a quasi-judicial body, such as DGTR, in India. The imposition of anti-dumping duty is permissible under the World Trade Organization (WTO) regime. The duty is aimed at ensuring fair trading practices and creating a level-playing field for domestic producers vis-a-vis foreign producers and exporters.

Source: Laxmi Yadav, Pharmabiz, 22.08.2020

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DoP agrees to continue implementation of UCPMP voluntarily by all stakeholders

The Department of Pharmaceuticals (DoP) has once again given its green signal to implement the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) voluntarily by the industry. A decision to this effect was taken at a review meeting held by the DoP with the industry associations.

The meeting was held under the Chairmanship of Dr P D Vaghela, Secretary, DoP through video conferencing to review the status of action taken on the decision taken during the meeting held on February 17, 2020. In the meeting, there was broad consensus to voluntarily implement the UCPMP by all concerned stakeholders. The meeting also discussed the hoarding and black marketing of essential drug issues rampant across the country and asked all stakeholders to address it on priority.

DoP Secretary urged all associations to give wide publicity of the arrangement made by them to receive complaints. Also they should appoint a nodal senior official for this work. At the meeting, Dr Vaghela directed all pharmaceutical and medical device associations to share a quarterly consolidated report on how they are addressing the concerns of the complainants approaching them and what is the procedure and mechanism they are following.

According to the UCPMP which has been in effect since 2015, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers, etc.

"Indian Drug Manufacturers' Association (IDMA) principally is in agreement with the Government's view of having a voluntary code of ethics in Pharma marketing. IDMA has already uploaded the UCPMP Guideline on its website. We have also set up the Apex Committee and Ethics Committee as required by DoP and the compliance has been informed to the DoP. We have also cited some suggestions regarding the code. However, due to disruption caused by pandemic, we agree with the view that the review of code can be deferred until a new normal is attained," said Dr Viranchi Shah, Vice President, IDMA.

According to IDMA website, it has uploaded the UCPMP on its website and has formed two committees— Ethics Committee for Pharma Marketing Practices (ECPMY) for handling complaints related to UCPMP violation and Apex Ethics Committee for Pharmaceuticals Marketing Practices (AECPMP) to review the decisions of ECPMP.

Dr Vaghela in its earlier meeting on February 17, 2020 sought details of both the committees of all the associations along with contact number and procedure of filing complaint, which would be uploaded on the website of the DoP. Organisation of Pharmaceutical Producers of India (OPPI) had earlier mentioned that they follow their own Code of Pharmaceutical Practices (OPPI Code 2019) that is based on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Expressing his displeasure at the status of implementation of UCPMP, Secretary, DoP exhorted all the associations representing pharmaceuticals and medical devices to implement UCPMP without exception. He also asked the associations to quote exact provisions of laws of other countries as precedence/reference while giving suggestions in respect of UCPMP.

In the earlier meeting held by DoP on December 23, 2019, it was decided that the associations would upload UCPMP on their website and comply with its provisions including formation of ECPMY and AECPMP, uploading details on the websites and submitting quarterly reports to NPPA.

In December last year the All India Drug Action Network (AIDAN) had approached DoP against Novartis for offering inducements to doctors in the form of honorariums for participation in conferences, travel assistance, accommodation, food expenses, all of which are strictly prohibited under the UCPMP as well as the Indian Medical Council (Professional conduct, Etiquette and Ethics), Regulations 2002.

Earlier OPPI had rejected the complaint against the Swiss drugmaker. In January this also the Pharma lobby group had hardly taken call on the complaint against AstraZeneca for pursuing unethical marketing practices

citing delay in filing complaint. As per UCPMP code, the complaint must be made within three month of breach of code.

According to AIDAN, besides Pharma and Medical Device Associations, DoP also needs to seek the views and inputs of civil society organisations and members of the public. Public health groups and civil society organisations have been demanding that the UCPMP, which is voluntary, be replaced with a statutory instrument for regulating marketing and promotion of pharmaceuticals and medical devices.

Source: Shardul Nautiyal, Pharmabiz, 22.08.2020

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Tread with caution on Vaccine Approval

While the entire world is standing aghast over the ever-increasing number of COVID-19 patients with no sign of any abatement in the foreseeable future, there is mad rush among the biotech companies across the world for developing a vaccine against this fatal disease which has so far claimed more than 7.5 lakh precious lives. Several countries, including India, are now running from pillar to post to develop a vaccine as over 120 Clinical Trials are presently happening globally with several of them in phase-1, phase-2 and even phase-3 stages of the Clinical Trial.

According to WHO, there are six vaccine candidates in phase-3 or phase 2 to 3 combined trials around the world and roughly another 120 in various stages of clinical testing. In India, three vaccine candidates are at different stages of human Clinical Trials. The country's first indigenous vaccine against COVID-19, Covaxin, being developed by Bharat Biotech in collaboration with the Indian Council of Medical Research, has successfully completed phase-1 trial and is gearing up for the phase-2 studies next month.

Another indigenous vaccine, ZyCoV-D, being developed by Zydus Cadila has already launched phase-II trials and the company has expressed hope that it will be able to launch the vaccine by March next year. Another Indian company, the Serum Institute of India, has been permitted for conducting phase-2 and phase-3 trials of the vaccine candidate, called AZD-12222, being developed by the Oxford University in association with AstraZeneca.

The vaccine, currently in phase-3 of its trials, which was considered to be the first one to get launched for the public in 2020 will be most likely available for public deployment by 2021. While all these developments are going on across the world, what has come as a real shocker to one and all, including scientists, experts and even the general public, is the sudden announcement of Russian Government, on August 12, giving regulatory approval for its vaccine 'Sputnik V' developed by Gamaleya Research Institute in collaboration with the Russian Defence Ministry.

The announcement has been met with excitement as well as skepticism due to the fact that the vaccine has been cleared without phase-3 human trials, which is normally considered an essential precursor to a regulatory approval. Even the phase-1 and phase-2 trials have been rushed, all of it being completed within two months.

Meanwhile, India appears to be in a hurry to procure the vaccine. Immediately after the Russian announcement, an expert committee headed by NITI Aayog member V K Paul met to consider the logistics and ethical aspects of procuring and administering the COVID-19 vaccine. There are two ways a vaccine can be approved for use in India. The Indian regulatory system requires at least late phase human trials to be conducted on local population before any vaccine, or drug, developed in other countries, can be approved for use in the country.

That is because a vaccine generally elicits different immune responses from different population groups. That would mean that the Russian developers, or their partners in India, would have to carry out phase-2 and phase-3 trials on the vaccine on Indian volunteers. This is the process which is being followed in the case of the vaccine being developed by Oxford University and AstraZeneca. Another method that can be considered is the 'emergency use authorization' from Indian drug regulator which is allowed in emergency situations.

That would allow the vaccine to be used without the late phase trials. The drug regulator can say that it is satisfied with the results of the human trials conducted in Russia, and considering the prevailing emergency situation, it can grant emergency approval to the vaccine, without the need for human trials in India. Recently, the drug Remdesivir was granted such emergency approval, to be administered to COVID-19 patients.

But, given the haste in which the vaccine was developed by Russia, the Indian Government should not consider the second option. A vaccine that is not properly tested can cause more harm than any benefit as apart from having a negative impact on health it will create a false sense of

security among the people. So, the Government should tread cautiously on the issue as it will have far-reaching adverse impact on the health of crores of people in the country.

Source: Ramesh Shankar, Pharmabiz-Editorial, 19.08.2020

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Centre should immediately release final e-pharmacy Rules: Dr Jagashetty

The Union Government should not delay the final regulations on the e-Pharmacy any further. In the wake of the National Digital Health Scheme announced by Prime Minister Narendra Modi on August 15, this e-pharmacy model is set to play a pivotal role in home delivery of medicines based on ethical prescriptions, said Dr B R Jagashetty, former National Advisor (Drugs Control), Ministry of Health and Family Welfare.

In the current circumstances of the COVID-19 pandemic, it is evident that e-pharmacies will be able to meet the medical needs of a large section of people in the country. So, the Government should immediately come out with the final Rules on e-pharmacy. The sooner the better for India's ailing population, he added.

The Government released the final guidance on telemedicine in a time bound manner during the onset of COVID-19 in April. In a similar fashion, the Government should work towards the e-pharmacy final norms too. The Government's expert committee should have arrived at concluding the guidance based on a combination of rules from the Drugs & Cosmetics Act and the Information Technology Act. The two laws mandate transparency in operations which is the ultimate in the business of e-pharmacy, Dr Jagashetty told.

When the Government agencies like Niti Aayog and DTAB and the industry associations like the FICCI are in favour of the e-Pharmacy model for India, there should be no question of postponement. Keeping the final guidance in abeyance is a gross injustice to the customers. In the absence of the formal regulation, the e-pharmacies have increased in the country. Several Mergers and Acquisitions have also taken place. A case in point is the recent report of Reliance taking over Netmed. In the wake of considerable competition in this space, it is the customer who should get the benefit of easy access to medication supplies at proper prices in a transparent, efficient and seamless manner, he noted.

However, in case of any violations, the onus is on the concerned officers of the State and Center to book them under the law, he said. The business model of e-pharmacy is also positioned to achieve the universal health coverage. Its combination of technology and healthcare is seen to dynamically transform the pharmaceutical ecosystem, when compared to the traditional brick-and-mortar retail model. From customer convenience to being cost effective, e-pharmacy is helping to bridge various glaring gaps to help demand meet supply.

The sector is expected to grow 100% after notification of e-pharmacy final rules. It may result in creating 25,000 additional jobs for skilled professionals. There is no reason whatsoever for such an inordinate delay of the final e-pharmacy Guidelines as it will have only a positive impact for the customer. Hence, the Government should think of releasing the same immediately. Policy makers should understand that this is of utmost advantage to the customers not only during this particular pandemic phase but also in general. Of course, further amendments to the rules can always be done any time based on practical challenges encountered, said Dr Jagashetty.

Source: Nandita Vijay, Pharmabiz, 20.08.2020

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Pharmexcil asks exporters to submit data on unrefunded input taxes to fix refund rates under RoDTEP scheme

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) has asked the member-exporters to submit data on unrefunded input taxes on goods and services consumed in production and distribution of exported pharmaceuticals from October 1, 2019 to March 31, 2020. The data will be used for fixation of refund rates under the proposed Scheme for Remission of Duties and Taxes on Exported Products (RoDTEP).

The member-exporters have been asked to submit the information before August 22, 2020. The data should be supported by copies of tax invoices of inputs used, shipping bills of export product, state Government Notifications regarding taxes/levies like electricity duty, mandi tax etc. If required, customs/central excise department can visit manufacturing units to verify the correctness of information, stated Uday Bhaskar, Director General, Pharmexcil.

Once collected from the member exporters, Pharmexcil will submit these data to a committee set up by the

Department of Revenue, Union Finance Ministry for fixation of refund rates under RoDTEP scheme. Data submitted should pertain to at least five units for each export product so as to be representative of the industry. The units should be carefully selected from amongst the small, medium as well as large manufacturer exporters.

The RoDTEP scheme is set to replace the popular Merchandise Export from India Scheme (MEIS) by December 2020. The aim of the RoDTEP scheme is to reimburse the taxes and duties incurred by exporters such as local taxes, coal cess, mandi tax, electricity duties and fuel used for transportation, which are not getting exempted or refunded under any other existing scheme such as Duty Drawback, GST refunds, central/state Government exemptions, subsidy, etc. The rebate would be claimed as a percentage of the Freight on Board (FOB) value of exports.

The Department of Revenue is set to hold a consultation meeting with Pharmexcil and other export promotion councils as well as stakeholders for determination of ceiling rates of unrefunded input taxes under RoDTEP scheme. The degree of benefit to be given under the RoDTEP Scheme, within the ceiling rates recommended by the RoDTEP Committee, will be decided by the Department of Commerce. The sequence of introduction of the scheme across sectors and prioritization of the sectors to be covered will be decided by the Department of Commerce in consultation with the department of revenue.

Source: Laxmi Yadav, Pharmabiz, 20.08.2020

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Industry urges Government to defer revision of NLEM till mid-2021 citing COVID-19 pandemic

The Pharmaceutical industry has urged the Central Government to defer revision of National List of Essential Medicines (NLEM-2015) until second quarter of 2021 citing COVID-19 pandemic crisis.

At a stakeholder consultation meet held by the Indian Council of Medical Research (ICMR) on revision of NLEM-2015, industry has strongly recommended to Government Consultative Committee to consider essentiality as the main criteria and not its turnover for a drug to be listed in NLEM-2015. Notified in 2015 and implemented in 2016, NLEM-2015 includes all the drugs that fall directly under the Government's price regulation mechanism. Plans are ongoing to revise the NLEM with special focus on adding drugs used to treat cancer, diabetes and thyroid.

Prof Y K Gupta, Vice Chairperson of the Standing National Committee on Medicines (SNCM) — a panel constituted by the Ministry of Health and Family Welfare to revise NLEM — chaired the meet on August 17. Dr Vijay Kumar, head, basic medical sciences division of ICMR, A K Pradhan, Deputy Drug Controller from Central Drugs Standard Control Organization (CDSCO) and Dr Nilima Kshirsagar, National Chair Clinical Pharmacology, ICMR, also attended the meeting.

During the virtual meet, the industry stakeholders cited issues related to streamlining supply chain and efforts to avoid drug shortages due to COVID-19. During the meeting, industry stakeholders also raised issues like specific medicine strengths and dosages should be mentioned in the list, only one drug should be incorporated in each category, patented drug should be excluded from the list, only DCGI-approved drugs should be part of the upcoming NLEM list, sustained-release drugs should be specifically mentioned in the list and some high priced drugs like cancer medicines which were already under trade margin rationalisation should not be further included in the upcoming NLEM list. Indian Drug Manufacturers' Association (IDMA), Indian Pharmaceutical Alliance (IP Alliance), US-India Business Council (USIBC), US-India Strategic Partnership Forum (USISPF) and Organisation of Pharmaceutical Producers of India (OPPI) attended the meet.

Regulated by National Pharmaceuticals Pricing Authority (NPPA) NLEM list includes all the formulations, which fall directly under the Government's price regulation mechanism. The manufacturer cannot randomly increase prices without prior approvals. Using Para 19 of the Drug Price Control Order, 2013 — the law that Governs the pricing of medicines in India — the central Government expands the price control mechanism.

The rates of drugs included under the NLEM are capped on the basis of their ceiling prices, which are calculated by taking the simple average of all drugs falling under the same category, but with market share of at least 1 percent. For other drugs — which are not included in the NLEM — the manufacturers can raise the prices by up to 10 percent every year.

Source: Shardul Nautiyal, Pharmabiz, 19.08.2020

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RBI allows import of palladium & other precious metals on advance payment for use in drug manufacturing

The Reserve Bank of India (RBI) has given green signal to import palladium and other precious metals on advance payment for use in production of pharmaceuticals following a representation from Indian Drug Manufacturers' Association (IDMA) in this regard.

The association had made a representation on July 10, 2020 to Shaktikanta Das, Governor of RBI urging him to allow import of palladium and other precious metals on advance payment. The industry body in its representation stated that drug companies have been regularly importing palladium metal from Japan on advance payment before the implementation of RBI Notification which disallowed advance remittance for import of precious metal.

Drug makers are facing challenges in importing the precious metal since the circular came into force. Suppliers of palladium metal have refused to supply material without advance payment. They are also not willing to accept payment through a letter of credit issued by the bank as an alternative, it added. Palladium metal is used as catalyst in manufacture of several life-saving drugs including pregabalin (neuropathic pain), aceclofenac (anti-inflammatory), alpha ethyl PAB (Alzheimer disease), trimetazidine (anti angina), dabigatran (heart stroke and systemic embolism), and lisinopril (anti-hypertensive).

Taking serious note of the representation of the IDMA, RBI on July 30, 2020 asked the industry to submit specific details of the cases that have been declined by the apex bank of India. IDMA immediately submitted the same. On August 7, 2020 Jyoti Sayankrit, AGM Trade, Foreign Exchange Department, RBI had written to the industry body asking it to inform its members to approach the regional offices concerned of RBI through their respective AD banks with such requests.

Besides RBI, IDMA has also written to Prime Minister's Office (PMO), Dr Ajay Bhushan Pandey, Finance Secretary, Dr Anup Wadhawan, Commerce Secretary and Dr P D Vaghela, Secretary, Department of Pharmaceuticals in this regard.

Source: Laxmi Yadav, Pharmabiz, 19.08.2020

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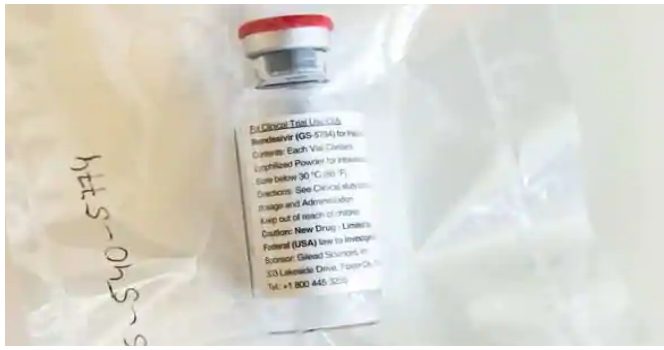
Covid-19: Three Indian Companies start supply of life-saving Remdesivir to Nepal

Three Indian Pharmaceutical Companies have started supplying Nepal with life-saving anti-viral Remdesivir to be used for the treatment of COVID-19 patients. "We have confirmed three companies for supply of Remdesivir. Mylan, Cipla, and Hetero Drugs will be supplying the drugs as per our demands. We will be permitting the use of anti-viral supplied on by these companies only," Narayan Prasad Dhakal, the Director-General of Department of Drug Administration confirmed.

"Among them, Mylan has started supplying the anti-viral to Nepal. At first, we have ordered 570 vials of it and has been delivered. Indian companies are easy to reach and the cost also comes low so we confirmed them," he added. Remdesivir has been proved to be efficient for patients who have been put in the Intensive Care Unit and take them out of danger zone but wasn't available in the Himalayan nation.

"It would cost around 7,800 Nepali rupees per vial when it comes to the Nepali market. It would save extra expenses of the family," DG Dhakal said.

Nepal's Medical Council's directive (Interim Clinical Guidance for COVID-19) also has enlisted Remdesivir drug for the primary medication. Family of the patients who were in critical condition had to bring it from India under special arrangements but with availability on the local market, it will save on their expenses.



More than half of 123 companies permitted to import medicines from other nations are Indian companies

As per the Director-General of the Department of Drug Administration of the Himalayan nation, it is always the Indian companies who race forward to export drugs and pharmaceuticals to the nation.

More than half of 123 companies permitted to import medicines from other nations are Indian companies who work on various forms for parent companies headquartered in Europe or America.

(This story has been published from a wire agency feed without modifications to the text. Only the headline has been changed.)

Source: livemint.com, 21.08.2020 (Excerpts)

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Drugmakers want Modi Government to defer revision of essential medicines list, cite Covid crisis

At a stakeholder consultation meeting held by the Indian Council of Medical Research (ICMR) Monday, 17.08.2020. Indian drugmakers requested the Narendra Modi government to defer the process to refresh the list of essential medicines to next year citing the Covid-19 crisis, The Print has learnt.

The ICMR is working on a plan to revise the National List of Essential Medicines (NLEM) with special focus on adding drugs used to treat cancer, diabetes and thyroid. The list, which was notified in 2015 and implemented in 2016, includes all the drugs that fall directly under the government's price regulation mechanism. During the virtual meet, the drugmakers made the request citing their struggles fixing the supply chain and efforts to avoid drug shortages due to Covid outbreak.

"The different lobbies and pharma company representatives have highlighted that it's not an appropriate time to start an exhausting exercise to refresh the NLEM. They want us to postpone the process till the second quarter of 2021," a senior government official told. "We will consider the industry's point in our further, internal discussions. We are working for 'public interest' and we need to weigh in all factors before postponing the revision," said the official, who did not wish to be named.

Lobbies representing foreign-based pharma giants also requested top government officials to "not include the patented drugs under the purview of price control and only include specific strengths of the drugs under the list".

Apart from Indian lobbies such as the Indian Drug Manufacturers' Association (IDMA) and the Indian Pharmaceutical Alliances, several lobbies representing foreign pharma companies also attended the meet. These included American business advocacy organisation, US-India Business Council (USIBC), US-India Strategic Partnership Forum (USISPF) and Organisation of Pharmaceutical Producers of India (OPPI).

Dr. Y.K. Gupta, Vice-Chairperson of the Standing National Committee on Medicines (SNCM) — a panel constituted by the Ministry of Health and Family Welfare to revise NLEM — led the meet. Gupta is a former Professor and Head of Department of Pharmacology, All India Institute of Medical Sciences.

Dr Vijay Kumar, Head, Basic Medical Sciences Division of ICMR, A.K. Pradhan, Deputy Drug Controller from Central Drugs Standard Control Organization, and Dr Nilima Kshirsagar, National Chair Clinical Pharmacology, ICMR, also attended the meeting.

'Essentiality, not turnover, should be criterion':

Apart from seeking postponement of the NLEM refresh process, the industry also requested the government panel to consider "essentiality" of the drug as the only criterion for inclusion under the NLEM and not the "turnover" of the drug.

"We have also requested the government to keep patented drugs out of the purview of NLEM. Moreover, only specific strength of the drugs should be included in the list and not all the varieties and dosage forms," said an industry representative who was part of the meeting.

"The industry has also highlighted that if a drug for a particular disease is already added in NLEM, then more drugs for the same disease should not be added."

What is NLEM, and why its revision is signficant:

The NLEM is regulated by the Department of Pharmaceuticals arm, National Pharmaceuticals Pricing Authority, which is the country's drug price and availability watchdog. The list includes all the formulations, which fall directly under the government's price regulation mechanism. The manufacturer cannot randomly increase prices without prior approvals. Using Para 19 of the Drug Price Control Order, 2013 — the law that governs the pricing of medicines in India — the Central Government expands the price control mechanism.

The rates of drugs included under the NLEM are capped on the basis of their ceiling prices, which are calculated by taking the simple average of all drugs falling under the same category, but with market share of at least 1 percent. For other drugs — which are not included in the NLEM — the manufacturers can raise the prices by up to 10 percent every year.

In 2019, in a written reply to a question in Parliament on the benefits received by citizens due to a reduction in the price of essential medicines, Minister for Chemicals and Fertilisers D.V. Sadananda Gowda had said "a saving of Rs 2,644 crore was made under NLEM 2015 from March 2016 till date".

Source: Himani Chandna, Theprint.in, 18.08.2020

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Government may consider amendments in PLI scheme, submit recommendations: Dr Eswara Reddy

Dr Eswara Reddy, Joint Drug Controller General of India has asked industry associations to make the representations on the amendments required in the recently released detailed production linked incentive (PLI) scheme. He has asked the trade bodies to submit the representations in the next one to two days.

In a virtual conference conducted by the PHD Chamber of Commerce, Reddy noted concerns raised by the industry and their requests for support from government authorities. He said that the detailed guidelines of PLI scheme have been released after considering recommendations from industry associations and expert suggestions/ recommendations.

Commenting on one of the points raised by the industry, i.e. the minimum net worth eligibility criteria, he said that it has been set to ensure that the applicant pharma companies have the capabilities to continue activities even after getting incentive schemes so that production can be without any withdrawals.

However, he also admitted that there are certain points which need further analysis and have scope for amendments in the existing detailed PLI scheme. So, he directed pharma associations to submit their representations along with scientific evidence to prove their points. Then the authority can discuss the matter with the Secretary of Department of Pharmaceuticals before beginning the selection criteria of PLI scheme applicants. He also informed that the authority has started receiving applications related to PLI scheme.

Source: Usha Sharma, Express Pharma, 26.08.2020

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INTERNATIONAL NEWS

Japan develops novel method to create several building blocks of pharmaceutical drugs

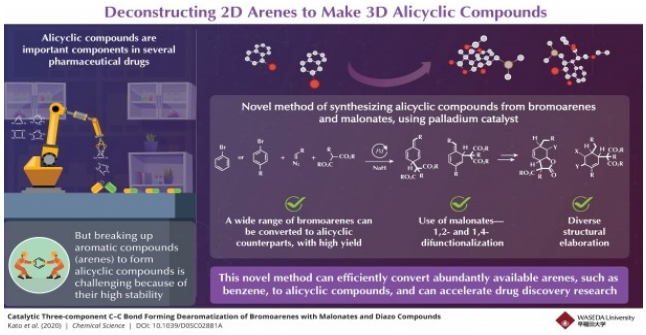

Image credit: Waseda

Japan-based Waseda University scientists have recently demonstrated a new method of producing a specific class of organic compounds, which promises to accelerate drug discovery research for several diseases.

Drugs, including those for depression, schizophrenia, and malaria, would not be if not for a type of organic chemical compound called alicyclic compounds. These compounds are

3D structures formed when three or more carbon atoms join in a ring via covalent bonds, but the ring is not aromatic. Aromatic compounds are another class of organic compounds which are 2D structures with reactive properties distinct from those of alicyclic compounds.

By dearomatizing arenes, one can get alicyclic compounds. Dearomatization is one of the most powerful ways of obtaining alicyclic compounds. But some of the most abundantly available arenes, such as benzene and naphthalene, are very stable, and breaking them up to construct alicyclic compounds has been challenging.

In the novel method, bromoarenes are reacted with two other classes of organic compounds, diazo compounds, and malonates, in the presence of a palladium catalyst, under optimal conditions of concentration, temperature, and time. Subsequently, good produced.

The use of malonates as a reactant is what allows this multi-functionalization, setting this novel method apart from existing methods, which are often highly specific in terms of the products possible. 2D bromoarenes were reacted with diazo compounds and malonates in the presence of a palladium catalyst to yield highly functionalized 3D alicyclic compounds, which are extremely prominent in pharmaceuticals.

Source: biospectrumasia.com, 20.08.2020

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

GUJARAT STATE BOARD, AHMEDABAD

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A HYBRID CONFERENCE

on 4th of September, 2020

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