BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

NEWS LETTER

APRIL – MAY 2022

TOP STORIES:-

- *Appeals and Review Mechanism under GST*
- *Govt imposes anti-dumping duty on DDC*
- *Indian pharma sees CEPA with UAE*
- *India exports $2.47 billion worth of APIs*
- *IPC releases IP 2022*
- *Indian pharma needs to identify gaps in industry-academia*

BULK DRUG MANUFACTURERS ASSOCIATION (INDIA)
C-25, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD-500018
PH:040-23706718,3910, Email id: info@bdmai.org, Web site: bdmai.org

Appeals and Review Mechanism under

Introduction

Tax laws (or any laws, for that matter) impose obligations. Such obligations are broadly of two kinds: tax-related and procedure-related. The taxpayer's compliance with these obligations is verified by the tax officer (by various instruments such as scrutiny, audit, anti-evasion, etc.), as a result of which sometimes there are situations of actual or perceived non-compliance. If the difference in views persists, it results into a dispute, which is then required to be resolved. Tax law recognizes that on any given set of facts and laws, there can be different opinions or viewpoints. Hence, it is likely that the taxpayer may not agree with the "adjudication order" so passed by the tax officer. It is equally possible that the Department may itself not be in agreement with the adjudication order in some cases. It is for this reason that the statute provides further channels of appeal, to both sides.

However, since the right to appeal is a statutory right, the statute also places reasonable fetters on the exercise of that

right. The time limits prescribed by the statute for filing of appeals and the requirement of pre-deposit of a certain sum before the appeal can be heard by the competent authority are examples of such fetters on the statutory right. GST being implemented in our country is a dual GST i.e. to say every supply attracting the levy will be leviable to both central tax and state tax. So does this mean that if a taxpayer is aggrieved by any such transaction, he will have to approach both the authorities for exercising his right of appeal? The answer is a plain NO. The Act makes provisions for cross empowerment between CGST and SGST/ UTGST officers so as to ensure that if a proper officer of one Act (say CGST) passes an order with respect to a transaction, he will also act as the proper officer of SGST for the same transaction and issue the order with respect to the CGST as well as the SGST/UTGST component of the

same transaction. The Act also provides that where a proper officer under one Act(say CGST) has passed an order, any appeal/review/revision/rectification against the said order will lie only with the proper officers of that Act only (CGST Act)So also if any order is passed by the proper officer of SGST, any appeal/review/revision/rectification will lie with the proper officer of SGST only.

Appellate Mechanism

A person who is aggrieved by a decision or order passed against him by an adjudicating authority, can file an appeal to the Appellate Authority (AA, for short). It is important to note that it is only the aggrieved person who can file the appeal. Also, the appeal must be against a decision or order passed under the Act. It is to be noted that no appeals whatsoever can be filed against the following orders:-
(a) an order of the Commissioner or other authority empowered to direct transfer of proceedings from one officer to another officer;
(b) an order pertaining to the seizure or retention of books of account, register and other documents; or
(c) an order sanctioning prosecution under the Act; or
(d) an order passed under section 80 (payment of tax in instalments).
The time limit for the party to file an appeal before the AA is 3 months from the date of communication of the impugned order. But the AA may condone a delay of up to one month, if he is satisfied that there was sufficient cause for such delay.
The AA has to follow the principles of natural justice – such as hearing the appellant, allowing reasonable adjournments (not more than 3), permitting additional grounds (if found reasonable), etc. The AA can also make such further inquiry as may be necessary.
On conclusion of the appeal process, the AA will pass his order (Order-in-Appeal) which may confirm, modify or annul the decision or order appealed against but shall not refer the case back to the authority that passed the said decision or order. The AA can also increase the “rigour”

of the order appealed against by enhancing any fee or penalty or fine in lieu of confiscation or confiscating goods of greater value or reducing the amount of refund or input tax credit, but this can only be done after the AA has given to the appellant a reasonable opportunity of showing cause against the proposed order. Further, if the AA is of the opinion that any tax has not been paid or short-paid or erroneously refunded, or where input tax credit has been wrongly availed or utilized, no order requiring the appellant to pay such tax or input tax credit shall be passed unless the appellant is given notice to show cause against the proposed order and the order is passed within the time limit specified under section 73 or Section 74 of the CGST Act, 2017. The Order-in-appeal has to be a "speaking order" i.e. it should state the points for determination, the decision thereon and the reasons for the decision. The law provides an advisory time limit of 1 year from date of filing of appeal for the AA to decide the appeal.

Appeals before Tribunal

The Tribunal is the second level of appeal, where appeals can be filed against the orders-in-appeal passed by the AA or order in revision passed by revisional authority, by any person aggrieved by such an order-in-appeal/Order in revision.
The law envisages constitution of a two tier Tribunal i.e. National Bench/Regional Benches and the State Bench/ Area Benches. Jurisdiction of the two constituents of the GST Tribunal is also defined. If place of supply is

one of the issues in dispute, then the National Bench/ Regional benches of the Tribunal will have jurisdiction to hear the appeal. If the dispute relates to issues other than the place of supply, then the State/Area Benches will have the jurisdiction to hear the appeal. An appeal from the decision of the National Bench will lie directly to the Supreme Court and an appeal from the decision of the State Bench will lie to the jurisdictional High Court on substantial questions of law.
Appeal to the Tribunal by the aggrieved person is to be

filed within 3 months from the communication of the order under appeal. Further, Tribunal has the power to condone delay (of up to 3 months in case of appeals or 45 days in case of cross objections, beyond the mandatory period) on being satisfied that there is sufficient cause for the delay. The Tribunal has the discretion not to admit any appeal involving an amount of Rs. Fifty Thousand or less. The law also provides for filing of cross-objections by the respondent against such part of the order against which the respondent may initially not have chosen to file an appeal. It is provided that on receipt of notice that an appeal has been filed (by the appellant), the party against whom the appeal has been preferred (i.e. the respondent) may, notwithstanding that he may not have appealed against such order or any part thereof, file within 45 days a memorandum of cross-objections against any part of the order appealed against and such memorandum shall be disposed of by the Appellate Tribunal as if it were an appeal presented within the time specified for the initial appeal.

Condonation of delay

(on sufficient cause) applies here also, but only to the extent of further 45 days from the date of expiry of the period for filing cross objections. The form, fees, etc. for the appeals to Tribunal shall be as prescribed by Rules. .

The Tribunal after hearing both sides may pass such orders thereon as it thinks fit, confirming, modifying or annulling the decision or order appealed against or may refer the case back to the AA or to the revisional authority, or to the original adjudicating authority, with such directions as it may think fit, for a fresh adjudication or decision, as the case may be, after taking additional evidence, if necessary. For reasons of natural justice (reasonable opportunity) it is also provided that the Tribunal may, if sufficient cause is shown, grant up to 3 adjournments to either side.

Concept of pre-deposit

As mentioned earlier, the right to appeal is a statutory right which operates within the limitations placed on it by the law. One such limitation flows from the principle that an appellant must first deposit the adjudged dues before his further appeal can be heard. However, often an appellant may succeed in his appeal, and hence it would (in retrospect) be unfair to saddle him with this financial burden. To balance these factors, tax laws mandate some "pre-deposit" so as to discourage frivolous appeals and also safeguard the bonafide interests of both the taxpayers and the revenue.
The CGST Act, 2017 require an appellant before AA to pre-deposit full amount of tax, interest, fine, fee and penalty, as is admitted by him, arising from the impugned order and a sum equal to 10% of the remaining amount of tax in dispute arising from the impugned order.
In so far as appeals to the Tribunal is concerned, no appeal can be filed before the Tribunal unless the appellant has deposited in full, such part of the amount of tax, interest, fine, fee and penalty arising from the impugned order, as is admitted by him, and a sum equal to 20% of the remaining amount of tax in dispute, in addition to the amount deposited before the AA, arising from the said order, in relation to which appeal has been filed.
If the pre-deposit made by the appellant before the AA or Tribunal is required to be refunded consequent to any order of the AA or of the Tribunal, as the case may be, interest at the rate specified in Section 56 shall be payable from the date of payment of the amount (and not from the date of order of AA or of the Tribunal) till the date of refund of such amount. .

Appeals by the Department (CGST/SGST) before the AA/Tribunal

At times, the Department itself is not in agreement with the decision or order passed by the (initial) adjudicating authority or the appellate authority. The GST Law provides that in such cases, the Department can file what is commonly known as a "review application/appeal". The GST Law gives powers to the Commissioner to review any order passed by his subordinates acting either as an adjudicating authority, or the appellate authority or revisional authority. If the Commissioner is of the view that any order passed by such authorities are not legal and proper, he can direct any officer subordinate to him to apply to the competent authority. For example, if the order of adjudicating authority is reviewed, he can order his subordinate to file an appeal before the appellate authority. If the order of the appellate authority or the revisional authority is reviewed, he can direct his subordinate to file an appeal before the Tribunal. The grounds for appeal will be mentioned in his order. The review of the order and the consequent filing of appeal by the subordinate has to be done within a period of six months from the date of communication of the order. The resultant review application is required to be dealt with by the AA or the Tribunal as if it were an appeal made against the decision or order of the adjudicating authority and the statutory provisions relating to appeals shall, so far as may be, apply to such application.

Revision by Commissioner (CGST/SGST)

The GST Act also provides for the mechanism of revision, by the Revisional Authority, of the orders passed by his subordinate officers. If the Revisional Authority on

examination of the case records is of the view that the decision or order passed by any officer subordinate to him is erroneous in so far as it is prejudicial to the interest of the revenue, and is illegal or improper or has not taken into account material facts, he may, if necessary, stay the operation of such decision or order for such period as he deems fit and after giving the person concerned an opportunity of being heard and after making such further inquiry as may be necessary, pass such order, as he thinks just and proper, including enhancing or modifying or annulling the said decision or order.

The above power is subject to the condition that non-appealable orders and decision cannot be revised. Further the power of revision cannot be exercised if: -

(a) the order has been subject to an appeal before AA or Tribunal or High Court or Supreme Court; or

(b) the period of six months (from the date of communication of order) has not yet expired or more than three years have expired after the passing of the decision or order sought to be revised. .

Or

(c) the order has already been taken for revision at an earlier stage; or. .

(d) the order sought to be revised is a revisional order in the first place:

If the said decision or order involves an issue on which the Appellate Tribunal or the High Court has given its decision in some other proceedings and an appeal to the High Court or the Supreme Court against such decision of the Appellate Tribunal or the High Court is pending, the period spent between the date of the decision of the Appellate Tribunal and the date of the decision of the High Court or the date of the decision

of the High Court and the date of the decision of the Supreme Court shall be excluded in computing the period of limitation of 3 years where proceedings for revision have been initiated by way of issue of a notice under section 108 of the CGST Act, 2017. However, the Revisional Authority may pass an order on any point which has not been raised and decided in an appeal before AA/Tribunal/HC/SC, before the expiry of a period of one year from the date of the order in such appeal or before the expiry of a period of three years from the date of initial order, whichever is later.

Concept of authorised representative

Any person who is entitled or required to appear before a GST Officer or the AA or the Tribunal in connection with any proceedings under the Act, may appear through an authorised representative (except when he is required under the Act to appear personally for examination on oath or affirmation).
For this purpose, "authorised representative" has been defined in the Act itself. Broadly, it includes a relative, a regular employee, an advocate, a chartered accountant, a cost accountant, a company secretary, or any person with prescribed qualifications. It is also provided that indirect tax gazetted officers can appear as authorised representative after one year from retirement.
The GST law also provides for some disqualifications for an authorised representative such as dismissal from government service, conviction under some specified Acts, insolvency, misconduct, etc. Such orders of disqualification are, however, required to be passed after following the principles of natural justice.

Appeal to the High Court

The law provides that either side (department or party) if aggrieved by any order passed by the State Bench or Area Bench of the Tribunal may file an appeal to the High Court and the High Court may admit such appeal if it is satisfied that the case involves a substantial question of law. It is to be noted that on facts, the tribunal is the final authority.

Appeals to the High Court are to be filed within 180 days, but the HC has the power to condone delay on being satisfied of sufficient cause for the same. On being satisfied that a substantial question of law is involved, the High Court shall formulate that question, and the appeal shall be heard only on the question so formulated. However, the High Court has the power to hear the appeal on any other substantial question of law if it is satisfied that the case involves such question. The High Court shall decide the questions of law so formulated and deliver such judgment thereon containing the grounds on which such decision is founded and may award such cost as it deems fit. The High Court may determine any issue which has not been determined by the Tribunal or has been wrongly determined by the Tribunal, by reason of a decision on such questions of law.

Appeal to the Supreme Court

The law provides for appeals to the Supreme Court from any judgment or order passed by the High Court, in any case which, on its own motion or on an oral application made by or on behalf of the party aggrieved, immediately after passing of the judgment or order, the High Court certifies to be a fit one for appeal to the Supreme Court. A (direct) appeal shall also lie to the Supreme Court from any orders passed by the National/Regional Bench of the Tribunal. It may be noted that the National/Regional Bench of the Tribunal has jurisdiction to entertain appeal if the dispute or one of the issues in dispute involves place of supply.

DoP enlists 213 drugs for which public procurement agencies could not find local manufacturers

The Department of Pharmaceuticals (DoP) has initiated efforts to address the issue faced by the Central government's procurement agencies including the Ministry of Railways and Employees' State Insurance Corporation (ESIC) in procuring 213 medicines including antibiotics, anti-diabetes and others for which these agencies could not find eligible local suppliers. .

The DoP has received various representations from these Central Procuring Agencies regarding non-availability of Class I or Class II suppliers for a list of 213 medicines. The list of medicines has now been put on the public domain through a public notice by the DoP, recognising that the manufacturers of these drugs may be spread across the country and they should be given a reasonable opportunity. .

The notice is to collect details of local manufacturers, manufacturing the alternate and equivalent medicines for smooth implementation of the Public Procurement Policy which gives preference to domestic manufacturers with sufficient local content. .

The DoP has issued a guideline on December 30, 2020, for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, to encourage Make in India and promote manufacturing and production of goods and services related to pharmaceutical sector in India with a view to enhance income and employment. .

Under the guideline, the public procurement agencies should purchase minimum local content for pharmaceutical formulations from Class I local suppliers - suppliers with local content equal or more than 80 per cent - and Class II local suppliers - with local content of more than 50 per cent but less than 80 per cent. Another categorisation as per the guideline is the non-local suppliers, who have local content less than or equal to 50 per cent. .

A five-member Committee chaired by the managing director of Karnataka Antibiotics & Pharmaceuticals Ltd was also formed through the notification in December, 2020, to independently verify the self declaration of the bidders. .

The latest notice inviting local manufacturers for the Public Procurement is for medicines including anticoagulants, apixaban tablets or capsules, aftanib 20 mg tablet 30 mg and 40 mg, biphasic insulin lispro IP and injection, brolucizumab, buprenorphine transdermal patch, canagliflozin tablet, ceftaroline 600 mg/vial, ceritinib tablets or capsules, cetuximab 100 mg and 500 mg, dapagliflozin 10 mg tablets, detemir insulin 100iu/ml 3ml pen, dulaglutide injection, inactivated influenza vaccine, emicizumab injection, empagliflozin 10 mg tablet (Jardiance), golimumab, haemostatic, hum along mix 50 pencil 75/25,25, human

albumin, human coagulation factor VII injection, ranibizumab injection, insulin glargine, lenvatinib tablet or capsule, linagliptin 5 mg, novomix-50, pembrolizumab injection, pneumococcal vaccine, among others.

DoP requested the local manufacturers of these drugs to share their details to the Department till 5.30 pm on March 15, 2022.

"If no information is received by the due date, further action will be taken, on the basis that local manufacturers are not available for these drugs," said the notice.

It may be noted that the DoP has recently released a list of medical devices in the Class I and II category seeking the manufacturer's details as the procurement agencies could not identify domestic suppliers. Following the notice, the DoP has identified representation from around 63 stakeholders.

Govt imposes anti-dumping duty on Dicyclohexylcarbodiimide used in antiretroviral drugs

The Union Finance Ministry has imposed anti dumping duty on N N Dicyclohexylcarbodiimide (DCC), the key ingredient used in antiretroviral drugs like valaciclovir and amikacin, imported from China based on the final findings from the Directorate General of Trade Remedies (DGTR) in February, this year.

The DGTR has recommended imposition of dumping duty based on an application filed by Clean Science and Technology Ltd (CSTL), which has started manufacturing the ingredient in India in January, 2020.

In the final findings, the DGTR said that the product has been exported to India at a price below normal value, resulting in dumping and this has materially retarded the establishment of domestic industry in India. The non imposition of the anti-dumping duty will adversely and materially impact the indigenous production, while imposition of the anti-dumping duty will not materially impact the consumers or the downstream industry or the public at large.

The notification by the Ministry of Finance has imposed an amount of $493.73 per metric tonne (MT) as an anti-dumping duty on DCC

exported from Shandong Huihai Pharmaceutical and Chemical Company Ltd, China, and $826.75 per MT imported from any other companies in China, to India. .

The anti-dumping duty imposed under this notification shall be levied for a period of five years, unless revoked, superseded or amended earlier, from the date of notification, and shall be payable in Indian currency.

The Directorate General of Trade Remedies (DGTR) has initiated the investigation through a notification on February 25, 2021. DCC is mainly used in amikacin, glutathione dehydrates as well as in synthesis of acid anhydride, aldehyde, ketone and isocyanate, and in synthesis of peptides, esters, ethers, nitriles etc. It is widely used in medical, health, make-up and biological products.

.

The designated authority of the DGTR has considered the Period of Investigation (POI) as January 1, 2020 to December 31, 2020 (12 months). The injury investigation period covers the periods April 2017-March 2018, April 2018- March 2019, April 2019-December 2019 and the POI. .

CSTL is the first and only company engaged in the production of DCC the company claimed that it has a capacity to address 89 per cent of the domestic market and the imports at below the cost of production has impacted its market. Prior to CSTL's entry, the product was imported from China and the price was around Rs. 1,171 per kilogram. However, after the establishment of CSTL's plant, the price of the imported product has drastically reduced. .

While CSTL projected a price of Rs. 900 per kg, the landed value of imports was Rs. 589 per kg during the POI. While the Authority noted with respect to the total demand in India, the company may not cater to 89 per cent of the domestic demand, it opined that the domestic manufacturer is in a situation of price suppression and not able to raise the sales price to the projected level. However, it is not in a situation of price depression, since the landed value is higher than selling price of CSTL, it added. .

The Authority issued public notice to six Chinese companies, including Shandong Huihai Pharmaceutical and Chemical Company Limited, Zhanhua Jiashi Chemical Company Limited, Zibo Tiantangshan

Chemical Company Limited, Zhejiang Tianyu Pharmaceuticals Company Limited, Xinjiang Da Jiang Run Yang Chemical Company Limited and Farmasino Pharmaceuticals (Jiangsu) Company Limited, of which it has received response only from Shandong Huihai Pharma. .

It has also approached the importers including Aurobindo Pharma, Mylan Laboratories, Hetero Drugs Ltd, Dasani Lab Pvt Ltd, Srini Pharmaceuticals Pvt Ltd, Honour Lab, MSN Laboratories Pvt Ltd, Indswift, Aarti Industries and SMS Lifesciences, calling for necessary information, apart from intimating associations including Federation of Indian Chamber of Commerce and Industry (FICCI), Associated Chambers of Commerce and Industry of India (ASSOCHAM) and Confederation of Indian Industry (CII). However, none of the importers and users or associations have submitted responses to the questionnaires issued to them by the DGTR. .

Indian pharma sees CEPA with UAE to reap significant benefits with automatic registration & market authorization

The recently signed India-UAE trade pact is expected to reap significant benefits for pharma and medical devices sector in the country. The Comprehensive Economic Partnership Agreement (CEPA) is estimated to accelerate revenue generation to touch $1 billion. For the first time in a trade agreement there has been a separate annex for pharma enabling automatic registration and market authorization of Indian generic formulations in 90 days. .

According to Manoj Palrecha, general secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association and managing director, Lake Chem, India-UAE trade pact will augment exports. It will be a gateway to give an impetus Indian pharma exports to the entire Middle East region. However, we need to get more details on the trade agreement to ascertain the actual advantages of the trade pact. While it clearly indicates that if we get product registration in Dubai, it would allow us to extend our trading prospects and again entry to more markets. .

Jatish N Sheth, director, Srushti Pharmaceuticals was upbeat and noted that the move is a positive one for India as UAE is a good market for formulation manufacturers but not the API players as large production units are not that many in the region. But if a formulation is registered in the US or EU or any other stringent regulatory authority, then it is easy to

get an entry to supply to buyers in the region. Further, the UAE opens up promising prospects to widen the scope of trade across other countries in the region. Although it is a re-export market, the challenge for some companies in India is to get it repacked for dispatch to other countries. Moreover, the signing of CEPA comes at a time when trade is just beginning to ease as the ongoing pandemic affected the supply chain and shipping logistics for Indian pharma during the global and national lockdowns that ensued. .

Anjan K Roy, chairman, Ray Lifesciences stated CEPA with UAE is seen to be an advantage even through the ratio cost versus quantity is not that impressive. Even though the quantum of exports from India is not that much, we do see scope to expand for trade in an easier manner. Besides, there would be a better chance for India over Europe for formulation exports to the UAE. Ray Lifesceinces being in the space of API, has a small presence in the region. .

It is reported that UAE in drug expenses is estimated to be valued at $8.8 billion by 2029. This is driven by pandemic and altering disease profile giving scope for biosimilars and biologics to be marketed from India. The country is known for its rising health expenditure, inclination towards innovative drugs, vigorous investments in healthcare infrastructure.

India exports $2.47 billion worth of APIs in April to October, 2021

India has exported active pharmaceutical ingredients (APIs) including bulk drugs and drug intermediates worth $2.47 billion during the first seven months of the current fiscal year, which is around 57 per cent of the total API exports from the country in the previous year. The API exports over the three years from 2018-19 has reported a growth of 13.1 per cent. .

According to the data from the Ministry of Commerce and Industry, India has exported APIs worth $2.47 billion during the period from April to October, 2021. This is almost 57 per cent of the $4.40 billion export registered during the 12 month period from April 2020 to March, 2021.

The exports has seen a growth from $3.89 billion 2018-19, to the $4.4

billion in 2020-21, though it has seen a slight decline in the year 2019-20, when it was reported at $3.87 billion. .

“APIs such as diloxanide fur oats, cimetidine, famotidine, heterocyclic compounds, other antibiotics and erythromycin and its derivatives, together account for approximately 50% share in the total value of India’s API exports,” said Anupriya Patel, minister of state in the ministry of commerce and industry recently in the Lok Sabha. .

Responding to a question, she said the no country-wise restrictions have been imposed on import of APIs in the country. .

It may be noted that the country has registered the highest value of exports in drugs and pharmaceuticals in the year 2020-21, at $24.4 billion in, which was the kind of growth that happened after eight years.

Pharmaceutical exports have registered growth in the last few years, following a 2.92 per cent growth it registered for the year 2017-18, at $17.28 billion. The year 2018-19 has seen a growth of 10.72 per cent to $19.13 billion compared to the previous year, 2019-20 with a growth of 7.57 per cent to $20.58 billion, before hitting an eight year high or 18.19 per cent growth to $24.47 billion in the year 2020-21. .

However, the country has been facing challenges in terms of availability of APIs, intermediates and key starting materials (KSMs), and depended on China for many of the key ingredients. In the wake of Covid-19 pandemic impacting global supply chain for various materials including the key raw materials for essential medicines and the resultant price increase, the Government of India has decided to increase the domestic production of APIs, drug intermediates and KSMs, also to reduce India’s dependency on other countries for critical inputs and bulk drugs in the long run. .

This include the scheme on promotion of bulk drug parks for financing common infrastructure facilities in three bulk drug parks with financial

implication of Rs. 3,000 crore for next five years, production linked incentive (PLI) scheme for promotion of domestic manufacturing of critical KSMs/drug intermediates and APIs and for domestic manufacturing of pharmaceuticals, among others, said the Minister in Lok Sabha.

IPC releases IP 2022, 92 new monograph, 27 APIs added: Read details

It is the mandate of IPC to publish a new edition and addenda of the Indian Pharmacopoeia.

In a bid to promote the highest standards of drugs for use in humans and animals, the Indian Pharmacopoeia Commission (**IPC**) has released Indian Pharmacopoeia 2022 containing 92 new monographs, 21 vitamins, minerals, amino acids, fatty acids and 27 active pharmaceutical ingredients (APIs).

The Indian Pharmacopoeia which is likely to be effective from December 1, 2022, also includes:

- 3 new biotechnology derived therapeutic products,
- 2 herbs & herbal products,
- 2 blood & blood related products,
- 33 dosage forms (chemicals),
- 4 vaccines and immunosera for human use
- 12 new general chapters

The chemicals which have been added to IP include:

- 2-deoxy-D-glucose,
- 2-deoxy-D-glucose sachet,

- Amifostine,
- Amifostine for injection,
- Amlodipine and valsartan tablets,
- Apremilast, apremilast tablets,
- Aprotinin injection,
- Azithromycin eye drops,

- Bosutinib,

- Bosutinib tablets,
- Brivaracetam,
- Brivaracetam tablets,

- Ceftriaxone and sulbactam for injection,

- Desogestrel,
- Desogestrel and ethinyl estradiol tablets,
- Dextran 1,
- Dextran 40,
- Dextran 70,
- Dextropropoxyphene hydrochloride and paracetamol tablets,
- Diclofenac potassium,
- Diclofenac potassium tablets,

- Epalrestat,
- Epalrestat tablets,
- Estradiol hemihydrate,
- Ethyl acetate,
- Ethynodiol diacetate,
- Ethynodiol diacetate and ethinyl estradiol tablets,

- Fexofenadine hydrochloride and pseudoephedrine hydrochloride prolonged-release tablets,
- Gglipizide and metformin tablets.

A slew of chemicals which have also been integrated into IP are:

- Itraconazole,
- Lenvatinib mesylate,
- Lenvatinib capsules,
- Mesna tablets,
- Oxetacaine,

- Polymyxin B sulphate,
- Polymyxin b for injection,
- Prasugrel and aspirin gastro-resistant capsules,

- Repaglinide and voglibose tablets,
- Ribavirin capsules,

- Risperidone syrup,
- Rocuronium bromide,
- Rocuronium injection,

- Sodium starch glycolate (type B),
- Sofosbuvir,
- Sofosbuvir and daclatasvir tablets,
- Sofosbuvir tablets,
- Sugar spheres,

- Tofacitinib citrate,
- Tofacitinib tablets,
- Trazodone hydrochloride,
- Trazodone tablets,
- Teneligliptin and metformin hydrochloride prolonged-release tablets,
- Triamterene and hydrochlorothiazide tablets,

- Valacyclovir hydrochloride,
- Valacyclovir tablets,
- Valganciclovir hydrochloride,
- Valganciclovir tablets,
- Vildagliptin and metformin tablets,
- Zanamivir.

In addition to this, newly added vitamins, minerals, amino acids, fatty acids to IP are:

- Oil- soluble vitamins capsules,
- Oil- soluble vitamins oral solution,
- Oil- soluble vitamins tablets,
- Water-soluble vitamins capsules,
- Water-soluble vitamins tablets,
- Alpha lipoic acid,
- Biotin,
- Calcium citrate malate,
- Cchromium picolinate,
- Copper gluconate,
- Glutamic acid,

- Inositol,
- Lutein,
- Lysine hydrochloride,
- Phenylalanine,
- Selenomethionine,
- Selenious acid,
- Threonine,
- Tryptophan,
- Valine,
- Zinc citrate.

Apart from this, Chitrak and Siri are newly added herbs and herbal products to IP 2022.

The IP 2022 contains:

- 265 chemical monographs,
- 47 vaccine monographs,
- 17 vitamins, minerals, amino acids, fatty acids monographs,
- 7 phytopharmaceutical monographs,

- 43 monographs of herbs and herbal products,
- 14 monographs of blood and blood related products,
- 6 biotechnology derived therapeutic product monographs,
- 14 veterinary monographs.

The IP has omitted general chapters on assay of human anti-D immunoglobulin methods B and C. Monographs of lorcaserin hydrochloride hemihydrate and lorcaserin hydrochloride tablets have been omitted by IPC vide a notification on March 10, 2021.

In 2018 IPC had released the Eighth Edition of Indian Pharmacopoeia (IP-2018) which contains 220 new admissions, 366 revisions and 7 omissions.

It is the mandate of IPC to publish a new edition and addenda of the Indian Pharmacopoeia.

Indian pharma needs to identify gaps in industry-academia collaboration

Indian pharma needs to identify gaps in industry-academia collaboration. The extensive researches undertaken in colleges and universities are confined to the four walls of the academic campuses, said Harish K Jain, president, KDPMA and sr. vice president, FOPE.

Thesis submissions gather dust in the libraries of academic institutes. While the industry views that not much novel research is done by the colleges, academic institutions feel that industry is not recognizing their efforts. It is here we see the need for constant interactions between industry and academia as the solution to maximise talent, he added.

Now the Pharmacy Council of India is contemplating to have a forum where industry and academia can come together. This would be platform for presentations on research carried out and discussions on exchange of views. We hope this plan sees the light of the day at the earliest, Jain stated. .

If India pharma has to realize its true potential and move up the ladder both in terms of value and volume, the way forward is industry-academia collaboration. So long, we have restricted ourselves to merely providing placement, training, permit industry visits, partner for statutory obligations and engage academia for all events. But we need to look beyond these, he noted. .

It is also a fact that in next few years US$ 250 billion worth of medicines will be off patent. The industry just cannot sustain on merely relying on generics and have to develop innovative products, processes & technology platforms as well as New Chemical Entities to in order to move up the value ladder. Efforts of the industry has to be potentiated by knowledge of the academia in research for mutual benefit. It will be an opportunity to utilizing the strengths of both sectors, he said.

However, industry sees that collaboration with academia does not merely end in research but can extend across novel solutions in logistics & distribution, disease mapping, market intelligence, prescription habits & monitoring, pharmacovigilance, retail among others. Further, academia can also proactively develop proof-of-concept products which can be transferred to industry against royalty payment. .

It is high time that Indian pharma requires multi-disciplinary approach. In addition to expertise in pharmaceuticals, there is need for a broad understanding in basic science, chemical engineering, digital technology, artificial intelligence, big data analytics, algorithms, intellectual property knowledge, anti-counterfeit technology etc. Most of this knowledge is not available in-house in the industry. This makes industry-academia collaboration important, said the KDPMA chief. .

Recently the Union government has permitted students to pursue two full-time and same-level degree programmes in physical mode simultaneously either at the same university or from different universities. Pharmacy students should take advantage of this new development and add value to themselves and the profession, he said.

The young talent are seen to adept in technology which can shorten development time of medicines & reduce research cost. The launch of 5G, can accelerate tech adoption extensively.

In order to have an amiable partnership, between industry and academia, there is need for statutory inspection of colleges by the industry experts and suggest remedial measures. Similarly academic experts should be roped in for regulatory inspections of industries. The need of the hour is to coexist and identify gaps in industry-academia collaboration, said Jain.

THANK YOU