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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022, Hotel Sahara Star, Mumbai

(Details on Page: 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 39** **15 to 21 October 2021**

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
1961 – 2021 (60 Glorious Years)

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Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com / Website: www.idma-assn.org

Dear Member,

IDMA 60TH YEAR CELEBRATIONS 2022

Friday, 7th & Saturday, 8th January 2022
Hotel Sahara Star, Mumbai

We are happy to inform you that our Association will be completing 60 glorious years in 2022. The 60th Year Celebrations will be organized on 7th & 8th January 2022 in Mumbai. We intend to commemorate this historic occasion of the completion of 60 years of our Association, with a two day long celebration consisting of Panel Discussions, Technical Sessions and Entertainment Program to boost the image of our Association as the Premier Association of the Indian Pharmaceutical Industry. The main objectives of the celebrations are:

- Showcasing Pharmaceutical and Allied Industries across the Globe
- Disseminating knowledge on various subjects
- Highlighting the achievements of IDMA

This year at the 60th Year Celebrations, we have invited Eminent National and International personalities to address our members over two days. We will also be recognizing Top Achievers in the Indian Pharmaceutical Industry, who have made India Proud and respected world over as providers of affordable quality medicines.

As part of the Celebrations, the winners of the:

1. IDMA Margi Memorial Best Patent Awards
2. IDMA ACG-SCITECH Research Paper Awards
3. IDMA Corporate Citizen Awards

would be announced and the Awards would be presented.

Your Association has come a long way and many milestones have been met in the last 60 Years and specially the last two years which have been different, difficult and trying times. You would be pleased to note that during Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government and Regulators. Nevertheless, it is due to your untiring efforts and commitment to the wellbeing and prosperity of our Association that we will be completing 60 years of glorious service to our Pharma Industry and to our great Nation.

We are sure you will be an integral part of the Grand Celebrations.

IDMA 60th ANNUAL PUBLICATION 2022

The IDMA 60th Annual Publication 2022, an up-to-date and most informative compendium will be released at the Annual Celebrations. This Annual Publication will present statistics, vital data and information on the Pharmaceutical industry. This Publication has also come to be recognized as the indispensable reference book of the Indian Pharmaceutical Industry.

AN OFFER NOT TO BE MISSED

Advertisers can, through this single medium, reach their target audience such as Bulk Drug Manufacturers, Formulators, Researchers, Analysts, Traders, Scientists, Students, Consultants, various Government Officials etc and leave an enduring impression on everyone connected with the Industry.

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We invite sponsors for our 60th Year Celebrations as below:

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REGISTRATION FEES:

To participate in the 60th Year Celebrations, the registration fee would be as under:

Reception Committee Member	Rs.7,500/- plus GST @ 18%
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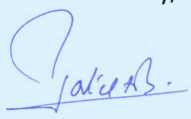
Your active participation & interaction with the cream of the Pharmaceutical Industry as well as Ministry Officials and Bureaucrats, from the Centre as well as States, will not only add value to your business but also ensure that the flag of our Association continues to fly higher in the Global Pharmaceutical Industry.

Looking forward to your usual fine cooperation in making this historic event a 'सुपर से भी ऊपर' Success.

Thanking you,

Yours faithfully,



Daara B Patel
Secretary–General

Mr. Daara B Patel, Secretary – General being interviewed by Mr. Prabhu Chawla, Editorial Director, the New Indian Express and Ms. Kaveree Bamzai, Author & Senior Journalist

TRANSCRIPTION

e-expressions

On

Future of Indian Pharma as the Global Hub

In Conversation with:
Mr DAARA B PATEL
Secretary-General, Indian Drug Manufacturers' Association

MR PRABHU CHAWLA
Editorial Director, The New Indian Express

The host:

Ms KAVEREE BAMZAI
Author & Senior Journalist

Ms Bamzai: Hello and welcome to another edition of e-expressions. Today we have **Mr Daara Patel** who is the *Secretary-General of IDMA (Indian Drug Manufacturers' Association)* and we have **Mr Prabhu Chawla** (*Editorial Director, The New Indian Express)* and I am the host **Kaveree Bamzai.**

Mr Chawla first said that the Pharma industry is the only hope we have really, and the best way to begin the conversation today Mr Patel, it's truly is one of the few bright spots in the Indian economy, isn't it?

Mr Patel: Yes.

Ms Bamzai: We are the world leaders in generic drug manufacturing, what does it take to make us the leaders in the patented drug market?

Mr Patel: Well, it has taken us well almost more than 40 years to come to this position we are today, so it will certainly take us some more time, certainly we are going in the right direction. What we used to do, the facility which we had in 2005, versus patent, we could re-engineer and make products compete in the market, that's why today we are the third largest manufacturer of formulations in the world and our value is almost 12-13th. It is because of our very competitive prices.

So we are on the right track and once we understand that generics are not the only thing to live with, generics business is low value, high volume. If you want to increase the value, then you need to shift from the value chain – cost arbitrage that we have today to intellectual arbitrage. We need to spend more money on R &D, more time on R&D, we need to have more thorough interaction between Industry and Academia.

We need Government support also on various taxes and benefits on R & D, because if earlier you see we had special 200% tax benefit on R & D spend, which was reduced to 150% and today it is 100%. Now if you want us to do innovations, R & D, spend money for development and come up in the value-chain by having more and more patented products, then we need support from the Government. I am sure with this support and encouragement; we will not be very far from being leaders in patented products also.

Ms Bamzai: Mr Patel, but the world of course doesn't like the fact that we do supply cheaper drugs, at very competitive prices.We do come up against a lot of issues globally. How do we resolve this?

Mr Patel: I don't think we need to resolve this, it is a good thing, our prices are very competitive, that's why we are, what we are today. We supply to more than 200 countries so you can imagine that everybody is looking at India, we are the *'Pharmacy of the world.'* We are very proud of the fact that our prices are very competitive. We were chiefly catering to our people for some decades. In India we don't have very affluent people, we need to supply to the masses so price is a very important concern. Hence we have been passing on the same benefit to other countries also.

Now as we have come along and we need to move to the patented drugs and increase our value worldwide then there will be some price increase in our products because we will spend on R & D and time too, we will get ready-made people in our Pharma sector. Unfortunately, what is happening is that pharma is not the first choice of employment for many people, it is always the second choice.

Ms Bamzai: That's very strange, isn't it? Why it has not been able to attract talent, as much as it should?

Mr Patel: Traditionally, they feel that IT and other sectors are more glamourous, they are paid well. It's not that the Pharma industry doesn't pay well, but certainly today we are the second option. Once we change our business practices, we go in for our patented products and compete in the international arena, I would like to say, today, it is not just the market, the best countries and the best companies will only survive.

Ms Bamzai: That's the way we will come up against some issues… when it comes to global approvals – FDA approvals, they are tough, they are tougher.

Mr Patel: I am happy to inform you that IDMA has spearheaded the movement of harmonization of Pharmacopoeias.Today what happens is that I don't want to name the countries, but the countries which are *at par* with India, maybe even below, they have their own Pharmacopoeias, and they don't approve products that are approved in India. In fact, some of them don't even approve WHO GMP manufacturers. Indian Pharmacopoeiais *at par* with the others. I don't say about the highly regulated markets, but atleast the ones which are *at par* with us they must straight away give approval to Indian products.

Mr Chawla: Mr Patel, we are looking into vaccines, where Covaxinis not being recognized now, we are able to prepare vaccines of our own. As you rightly pointed out, that we are the pharmacy of the world. With this pandemic, we have not just come up with one but two vaccines, but see what people are saying? The way the UK is behaving? How do you handle this?

Mr Patel: This is a very good question and I think we are all very concerned about it. According to me, I think this has nothing to do with the efficacy of our vaccines, this is more of a perception they have, that too of a political nature. Even before these Covid related vaccines that we came up with, we should not forget that every third tablet consumed in the world is *Made in India.* Every third child vaccinated in the world is by a vaccine *Made in India*. So how come suddenly they have a concern about our vaccines? We have vaccinated 30% of our population absolutely.

Mr Chawla: The vaccines manufactured there, have a brand name. The ones, which are made in India, with them they have a problem. But those made abroad, they have no problem, how's this differentiation? That is the challenge.

Mr Patel: That is the challenge, but I don't think it will continue for long. If 200 countries are accepting our products, everywhere for every particular disease, then how come suddenly they are concerned about our vaccines.

So, I don't think it will go on for long. Ultimately, they will have to fall in line and Covaxin will be acceptable globally and Covishield will be sold throughout the world. The vaccines are made here with the same ingredients and with the same technology.

Mr Chawla: That's why I said that when a brand is Indian, then they have a problem. The challenge is when economy of scale achieved by Covaxin and Covishield is much more than the capacity of other vaccines, all put together.

Mr Patel: I think it's the wrong perception, it's the image they have created of convenience, when it suits them they run after Indian products, when they feel threatened, they try these type of stunts. This won't last long; I am very sure.

Ms Bamzai: I think your experience of 20 years with IDMA has taught you that the world has to come around to what is right. But there must be some kind of back room kind of negotiations, a lot of educational advocacy that you have to do to make countries believe that. Right?

Mr Patel: I think that is already a process, that is on. Otherwise, we would not have these types of approvals. You should be knowing that outside the US, it is Indian companies that have US FDA approved plants. That itself speaks volumes, and it is not that simple or easy to get US FDA approvals.

Ms Bamzai: Let's shift the focus and talk about challenges that you feel now, in coming years and what do you feel the Pharma industry and Government need to do to work together to become the 'Worlds Pharmacy' even in patented drugs.

Mr Patel: First of all, as you know our drugs and cosmetics act is pretty old, while amendments have taken place time and again to be at par with global standards, there is a lot to be done. And we are on the right track and we are working very closely with CDSCO and Drugs Controller which will give us a better image of our products outside India. Secondly, it's our pricing policies, which are quite firm, we are very patient-centric. We keep patients in mind while manufacturing.

Let's not forget, to compete in the global world we need money to plough back into innovation, in the research to give them the best. So for all that we need support from the Government. We need better pricing policies, today our pricing policies are such that if there is a price decrease, the Government issues a notification and expects us to decrease the prices immediately.

The length and breadth of India we have, with more than seven lakh chemists, so what I am trying to tell them is why price increase should be prospective from the next batch, it can't be retrospective. This is one major issue, secondly, we need an OTC policy also. Today we don't have a policy for OTC products, and that's another good chunk of business. So we need to look at that also when we come up with policy.These are the products which we need to sell over the counter.

As I said harmonization is very important so that we get quick approvals from every country. Even our companies that have USFDA approvals are not put on the fast track by other countries. That is something very strange.

Then we need ready-made people in Pharma. The curriculum has to be upgraded, updated, today it takes time, if you get a fresher, he takes 6 months to get trained, takes another 2-3-4 years to come upto the real standards, to face the challenges independently.

Ms Bamzai: I also wanted to ask, because this is something, that we are deeply interested in. What are exciting discoveries which we should look forward to? What are the drugs and diseases which India can contribute to ending/ curing?

Mr Patel: I think for drugs for cancer, we need to give a lot of thrust.

Ms Bamzai: Are we anywhere close to some kind of miracle drug?

Mr Patel: Some of the companies are doing a very good job. We should be able to get our own molecule. It takes time and money both, the Indian MNC's are trying to do their best. Even in other lifestyle medicines like diabetes and BP, we need to have more molecules and products for these kinds of diseases. Like Covid has happened or some other bacteria happens, we need to be prepared, how to come up with these kinds of medicines. There is a Covid pill on the anvil, so I don't think we should lag behind in that, we should also try and see that we come up with these types of products.

Mr Chawla: Dr Talwar was trying to develop some vaccine for TB, he was not able to do it properly finally what happened I am not up to date. But how much emphasis do other countries give to R & D for drug manufacturers?

Mr Patel: Even I am not updated about that…

…Over there lots of facilities are given for the R & D. The expenditure they do on R & D is given as a tax benefit to them. Even universities are given some subsidies so that they support the industry to develop new molecules, that's the type of incentives they should give, which I think they are working now with NIPERs and various other Government bodies. In the next 1-2 years you should see solid support coming from the Government of India to see that our companies spend more on R & D and also start working closely with Academia.

Mr Chawla: I have heard PM Modi complaining that industries are not spending enough money on R &D. What kind of support you are expecting from the Government?

Mr Patel: We have been telling them why have you reduced tax incentive from 200% to 100%? It should go up so that our spending is equal to what our MNCs abroad spend. I am sure now that it has come up from PM himself, something should happen in our favour and they will be able to give us this type of benefit. Otherwise, people won't be able to spend money on R & D, why should they? After all, Pharma is also a business for which people want profits. We don't believe in profiteering, but profits are required.

Mr Chawla: R and D is a big problem in all the corporate sectors in India?

Mr Patel: We are trying to remove that perception that patents in India are not respected. People are wary about getting patents. But it's not the case, in India we have to see what is good for our country and for our people. Indian pharma and IDMA believe that it is the Patient first,Patents should be next, but we are not saying that we don't want patents to be respected. Yes, within reasonable limits we will see that the person who has the patent is rewarded but no back door entry of continuing with the patents will be allowed. Yes, if it is a proper patent, that has to be respected and remunerated well. Otherwise, our companies who have ventured into R&D and discovering molecules would also be at a loss.

Ms Bamzai: Opportunity for Ayurvedic medicines, do you see that as big an opportunity as the world is coming down to alternative healing/ medicines?

Mr Patel: Yes, Ayurveda is certainly what we are going to look at very seriously because we have been the pioneers in that. We are certainly trying to see that we do well. We don't have those kinds of facilities to check the standards of plants from the initial stages, which we are now developing. It will take time, but Ayurveda is not something, which you can ignore or avoid. Our members especially are very seriously looking at it. We are conducting trials properly and we are working with the Government to see that they have proper standards to define quality etc.

Mr Chawla: For that, we need to give credit to Baba Ramdev. Foreign companies are giving importance to Indian plants and Indian medicinal values into their own formulations and we are buying from them. Indigenous things are bought by foreign MNCs and sold to us. How do you look at that? If all of it is manufactured locally so that no money goes out.

Mr Patel: There is an exception everywhere. Baba Ramdev is an exception. We must give him this credit; he has done well very for himself. So many new products he keeps introducing every year. So maybe our CEOs also adopt the same culture and develop some yogic skills, we need to copy that.

Ms Bamzai: What is the biggest lesson that India learnt from Covid? What is the biggest takeaway from Covid?

Mr Patel: We do not go too much in the technical side of it, like developing vaccines but if we work very closely with the Government, and the bureaucrats, I think we can achieve anything. What used to happen years ago was

that we both were on the opposite sides, so we couldn't work together, the way we wanted to or the way the Government wanted to.

But from the last couple of years, we are realizing that Government understands us, we understand the Government and we have been working quite closely, but during the Covid pandemic it was something very exceptional. Like we were all working 24 hours. We worked with the Government at the Centre, State, Police, Bureaucrats, Drugs controller, that close interaction saw to it that we achieve our goal.

If you recall, in the month of March 2020, the production capacity utilization was hardly 20%, this close working and making the Government understand, running an extra mile, like the companies accommodated their workers in hotels or guest houses near the factories, arranged for their food, transport, suppliers supplying raw materials and packaging materials to us, that's how we brought production capacity from almost 20% to 80% by end June.

This is something phenomenal. Even the Regulator had to work hard and burn the midnight oil. So everyone right from Department of Pharmaceuticals to the Commerce Ministry, Health Ministry, our Regulator, our Police, AIOCD, Transporters and all Associations i.e.IDMA, OPPI & IPA we all worked together, we were on the same side. The goal post was only one, who gives the pass, who shoots the goal, was not important, we wanted the goal to be met so that people get medicines and people did get it.

Ms Bamzai:I wish that continues, has it continued?

Mr Patel: So far it has.

Ms Bamzai: It's not just a wartime thing, it has lasted in peace as well.

Mr Patel:I think it should continue, they have also realized.

Mr Chawla: During Covid, many people lost their family members, there was the problem of medicines though. People died because of a shortage of medicines, in a country like India, for people like me had to run from pillar to post to get medicines, injections.

Mr Patel: It was a very bad situation for some time. I am not trying to cover up for Industry's shortfall but we were not ready for that kind of demand. But most of it was panic buying, people were afraid. Like if you wanted *Remdesivir*, they will tell 10 people and 10 people will run after 20 sources. So there was a shortage, ultimately you need 1 or maybe 5 *Remdesivir*, so there was a bad name given to the industry that this product is not available.

We used to tell Pharmacists that there are enough medicines we are going to produce and supply. Don't encourage people to do panic buying. For just one month requirement they will buy three months' stock. So we were trying to inculcate this practice into the people. Now there is so much of stock lying that stockiest/ retailers are telling us to take it back.

Mr Chawla: There is no shortage of medicines, there is a shortage of how to get them. There is no procedure in line. In future, if such an emergency arrives, you have to put the procedure in place. The supply chain should be insync with the Government procedure.

Mr Patel: So that is why there are SOPs in place, earlier when you wanted medicines you will yourself run to the chemist. Now there are systems in place where hospitals are responsible, who have to give it to the patient. There are a lot of things streamlined. The pricing, the availability is monitored by areawise FDA officials, Chemists etc. We are now much better prepared than we were at that time. I am sure we will not see those days again.

Ms Bamzai: What kind of support do you need to attract the right kind of talent? Is there a number that you are short of for trained manpower?

Mr Patel: Not exactly to that extent but let me tell you if you see an IIT Graduate, they may want to go to another industry but not to Pharma, but now we have started working closely with these Institutes, our people go and make presentations. They have also realized what the Pharma industry is like, Indian MNCs becoming very famous and sought after, so things are improving. But, we have to work closely with the academia, institutes and we have to see to it that they also improve their curriculum. Things will improve because Pharma Industry is also gaining popularity.

Ms Bamzai: What kind of Curriculum change you would like to see and at what level?

Mr Patel: Everywhere, right from MRs, digitization is taking place, we have to see to it that people are skilled

that way. Doctors don't want to see the patients and MRs to the extent they were seeing. They prefer virtual meetings or a hybrid form. How do you develop that skill? That is important, quality control, quality excellence is important. How do you ensure that the product you supply to a company is not questioned? Very few checks are done and it is issued for production, then we have R & D, there are so many new things are happening in the industry. We need these students to be trained. Audits are taking place virtually.

Mr Chawla: Is there a mechanism to check the quality of the chemists? There is adulteration in the drugs which are required all the time. We don't know if we are getting genuine medicines or not?

Mr Patel: So there are two things: one we talked about Pharmacies, fortunately, you must have heard that within Maharashtra, licenses of 200 chemists were cancelled because they did not have dedicated pharmacists on their premises. As far as adulterated products are concerned, I think there is a big *halla* (noise) that is made, I think the company which wants to survive, which wants to do well, will certainly not indulge in it. It's only fly by night operators who manufacture these types of products and vanish from the scene.

That is where the regulator, police and law enforcers need to be more vigilant. I can assure you that the adulterated products or spurious products in India are very minuscule. There are 50000 formulations, we have 3000-4000 registered manufacturers, we have 10000 manufacturing units, it's a herculean task for our regulators. Our Industry makes medicines which their families also consume. But there are black sheep's everywhere.

Mr Chawla: The kind of prices hospitals charge from the patients, has become a big issue. Is there a mechanism to have a cap on what profit margin hospitals can charge? Medicines are overcharged.

Mr Patel: The Government should also realize that they need to increase health spending. Today it is hardly 1-1.5% of GDP. So if that happens the overall requirement and sales would increase. Hospitals are given competitive rates because they are buying in bulk. We also consider that, because some hospitals keep patients at a very low cost. Some patients are totally free of cost. That is the reason, Government has to be strict with the hospitals that if you get it at this price then better you give it to the patient at that price. The industry can't take care of that.

Ms Bamzai: What is your dream for made in India label in this sector?

Mr Patel: If it is medicines, it should be 'Made in India', the world should think about us. When they buy from India they should be satisfied, they should be convinced that yes, I have bought the right medicine and I am going to be treated well. That's our dream.

Mr Chawla: Why can't you have a brand like Pfizer? Why can't we have a global brand?

Mr Patel: Our Indian companies also have a reputation world over. We have some good Indian companies doing very well abroad. They have offices there; they have factories there. Indian companies are acquiring multinationals; we have a dozen companies that have a reputation like that of Pfizer or Glaxo. After all, these companies have been there for decades. I am an MNC man, I have worked for MNCs far longer than I have worked for Indian companies. So I know how they get support from their Head Office and what support Indian entrepreneur gets here. So if you see all that and give us some time, we will be able to fulfil our dream.

Ms Bamzai: Maybe it stands for reliability…

Mr Patel: Yes, reliability, pricing and timely delivery. We are working in that direction now, closely with the Government, other Associations, Earlier IDMA and OPPI weren't working very closely. Now we interact very regularly and it is an open book. The day is not far that people will say, you want medicines, buy from India.

Ms Bamzai: Wonderful, we look forward to that day.

Thank You, Mr Chawla, thank you Mr Patel.

Eye-opening to listen to you. All the very best.

PS: This is ad Verbatim transcription. No edits have been done to document but grammatical inputs and punctuation have been given for better readability.

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IDMA Dussehra Celebration

IDMA Staff celebrate Dussehra with Prayers and Simple get-together

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NIPER - INDUSTRY CONNECT: Strengthening Partnership between NIPER & Industry held on 18th, October 2021

IDMA Telangana State Board Chairman, Mr Shaik Janimiya addressing at NIPER- INDUSTRY CONNECT

Reconstitution of DTAB - reg.

S.O. 4326(E), dated 18th October, 2021

In pursuance of sub-sections (1) and (2) of section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in supersession of the notification of the Government of India in the Ministry of Health & Family Welfare, No. S.O. 1929(E) dated the 15th May, 2018, the Central Government hereby reconstitutes the Drugs Technical Advisory Board (DTAB) consisting of the following members, namely:—

Sr. No.	Name/Official Designation of the Member	Status in DTAB	Section of the Drugs and Cosmetics Act, 1940 under which appointed/nominated/ elected
(1)	(2)	(3)	(4)
1.	The Director General of Health Services, New Delhi	Chairman ex-officio	Appointed under Section 5(2)(i) of the Act
2.	The Drugs Controller, India, New Delhi	Member ex-officio	Appointed under Section 5(2)(ii) of the Act
3.	The Director, Central Drugs Laboratory, Kolkata	Member ex-officio	Appointed under Section 5(2)(iii) of the Act
4.	The Director, Central Research Institute, Kasauli	Member ex-officio	Appointed under Section 5(2)(iv) of the Act
5.	The Director, Indian Veterinary Research Institute, Izatnagar, Bareilly, U.P.	Member ex-officio	Appointed under Section 5(2)(v) of the Act
6.	The Chairman, National Medical Commission, India	Member ex-officio	Appointed under Section 5(2)(vi) of the Act
7.	The President, Pharmacy Council of India	Member ex-officio	Appointed under Section 5(2)(vii) of the Act
8.	The Director, Central Drug Research Institute, Lucknow	Member ex-officio	Appointed under Section 5(2)(viii) of the Act
9.	Commissioner, FDA, Madhya Pradesh	Member	Nominated under Section 5(2)(ix) of the Act
10.	Commissioner, FDCA, Gujarat	Member	Nominated under Section 5(2)(ix) of the Act
11.	Prof. (Dr.) Shailendra Saraf, University Institute of Pharmacy, Pt. Ravishankar Shukla University	Member	Elected under Section 5(2)(x) of the Act
12.	Dr. Vijay Oza, Member (PGMEB), NMC	Member	Elected under Section 5(2)(xi) of the Act
13.	Shri Sudhir Mehta, Chairman, Torrent Pharmaceuticals	Member	Nominated under Section 5(2)(xii) of the Act
14.	Dr. Jerin Jose Cherian, Scientist D, Division of Basic Medical Sciences, ICMR	Member	Elected under Section 5(2)(xiii) of the Act

15.	Dr. J.A. Jayalal, National President, Indian Medical Association	Member	Elected under Section 5(2)(xiv) of the Act
16.	Dr. T.V. Narayana, President, Indian Pharmaceutical Association	Member	Elected under Section 5(2)(xv) of the Act
17.	Government Analyst, Drugs Testing Laboratory, Bengaluru, Karnataka	Member	Nominated under Section 5(2)(xvi) of the Act
18.	Government Analyst, Food & Drugs Laboratory, Vadodara, Gujarat	Member	Nominated under Section 5(2)(xvi) of the Act

2. The Drugs Controller (India) shall be the Member-Secretary of the Board.

3. This Notification shall come into force on the date of its publication in the Official Gazette.

F. No. X-19012/2/2009-DFQC(Pt)

Dr. Mandeep K Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

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GOVERNMENT COMMUNICATIONS

To enhance production of hand sanitizer and to ensure its availability to the consumers in view of Covid-19 outbreak - reg.

F.No.1(2)12020-SP-I, dated 20th October, 2021

To,
The Chief Secretaries/ Administrators
(All State Governments/ UT Administrations)

1. Kindly refer to this Department's letter of even number dated 31.12.2020 (copy enclosed) where it was requested to extend the necessary permissions to distilleries/ other units manufacturing hand-sanitizer, an essential material in the fight against Corona virus/ COVill 19, till 31.12.2021.

2. Responding to the request of this Department, most of the State Governments/ UT Administrations issued necessary licences to distilleries/ other units for the production of hand sanitizer. Due to these efforts, the production capacity of hand sanitizer could be enhanced to around 30 lakh litre per day and more than 5 crore litre of hand sanitizer could be produced. Also the export of hand sanitizer has been allowed and now India is exporting sanitizer to other countries.

3. However, you will also appreciate that the COVID pandemic is not over yet and the role of hand sanitizer will continue to be important in fight against COVID. To ensure sufficient availability of hand sanitizer at reasonable price in the domestic market, you are kindly requested to issue necessary directions to the Drug Controllers/Competent Authorities in your State/UT to extend the necessary permissions to distilleries/ other units manufacturing hand-sanitizer for one more year beyond 31.12.2021 i.e. till 31.12.2022.

Subodh Kumar Singh, Joint Secretary (Sugar & Admn.), Ministry of Consumer Affairs, Food & Public Distribution, Department of Food & Public Distribution, New Delhi.

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Enlistment under Appendix 2E to issue Certificate of Origin (Non - Preferential) for All India Jurisdiction - reg.

DGFT Public Notice No.29/2015-2020 dated 18th October 2021

1. In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy, 2015-20, the Directorate General of Foreign Trade authorizes agencies currently enlisted under Appendix 2E to issue Certificate of Origin (Non-Preferential) (Co0 NP) for all India jurisdiction. Accordingly, all currently enlisted agencies under Appendix 2E can now issue Co0 (NP) on an all India basis. Further, any new application for enlistment under Appendix 2E will be considered for all India Jurisdiction and separate applications for enlistment of branch offices for already enlisted agencies will not be required.

2. All Agencies as notified under Appendix-2E are required to ensure the on-boarding exercise for mandatory electronic filing of Co0 (NP) through the Common Digital Platform (URL: https://coo.dgft.gov.in) latest by 31st October 2021 failing which the agencies may be de-notified from Appendix 2E.

3. An application for grant of Co0 (NP) may be made by the Registered/Head Office/Branch Office/Factory of the applicant to any agency registered under Appendix 2E in India.

4. **Effect of this Public Notice:** All agencies enlisted under Appendix 2E of FTP-2015-20, who have on-boarded on Common Digital Platform for electronic Certificate of Origin (Non - Preferential), can issue Co0 **(NP) on all India basis w.e.f. 01.11.2021.**

File No. 01/93/180/27/AM-19/PC.II(B)/e- 27749

Amit Yadav, Director General of Foreign Trade & Ex- officio Addl. Secretary, GoI, Ministry of Commerce & Industry Departmentof Commerce, Directorate General of Foreign Trade New Delhi.

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Enlistment of Agency(ies) under Appendix 2E of FTP, 2015-2020 - authorized to issue Certificate of Origin (Non-Preferential) – reg.

DGFT Public Notice No.30/2015-2020 dated 18th October 2021

1. In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy (FTP) 2015-2020, the Director General of Foreign Trade hereby authorizes the following agencies to issue Certificate of Origin (Non Preferential):

i. Export Promotion Council for EOUs & SEZs
8G 8th floor, Hansalaya Building, 15,
Barakhamba Road,
New Delhi-110001 Tele No.011-23329766-69,
Fax 011-23329770 E-mail: epces@epces.in
Website: www.epces.in

ii. Urban Exim Care Association
9, Ground Floor, Ankinini House
Near NABARD, Near Usmanpura Garden,
Ahmedabad, Gujarat-380 013
Tele/Helpline No.7600003377/9727298288
E-mail: urbaneximcare@gmail.com
Website : https://www.ueca.in

iii. Federation of Industries & Associations
FIA Bhavan, R-11, New Green City, GIDC
Housing Zone, Near D-Market, Sector 26,
Gandhinagar, Gujarat-382026
Tele No.079-23289311, Mob.9925007221
E-mail: fiagujarat@gmail.com
Website: www.fia-gujarat.org

2. Accordingly, name of the above agencies are added as under in Appendix 2E [List of Agencies Authorized to issue Certificate of Origin (Non-Preferential)] to Appendices & Aayat Niryat Forms of FTP (2015-2020):

Name of Agency	State	Serial No.
Export Promotion Council for EOUs & SEZs	Delhi	20
Urban Exim Care Association	Gujarat	15
Federation of Industries & Associations	Gujarat	16

3. Effect of this Public Notice:

Three new agencies are enlisted under Appendix 2E of FTP, 2015-2020 for issuing Certificate of Origin (Non-Preferential).

F.No.01/93/180/55/AM-21/PC.II(B)/e-26250

Amit Yadav,
Director General of Foreign Trade &
Ex-officio Addl. Secretary to GoI,
Directorate General of Foreign Trade,
Ministry of Commerce & Industry,
Department of Commerce,
New Delhi.

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Extension of Date for Mandatory electronic filing of Non-Preferential Certificate of Origin (CoO) through the Common Digital Platform to 31st October 2021 - reg.

Trade Notice No.21/2021-2022, dated 18th October, 2021

To,

1. *All Exporters/Members of Trade*
2. *All Issuing Agencies as enlisted under Appendix 2E of the FTP.*

1. In continuation to this Directorate's earlier Trade Notice Nos.42/2020-2021 dated 19.02.2021, 48/2020-2021 dated 25.03.2021 and 10/2021-2022 dated 19.07.2021, it is informed that the electronic platform for Certificate of Origin (CoO) (URL: https://coo.dgft.gov.in) which was made live for issuing preferential certificates under different FTAs, has now been expanded to facilitate electronic application for issuance of Non-Preferential Certificates of Origin as well.

2. On the request of certain Chambers/Associations notified under Appendix-2E, **the existing system of manual/paper-based submission and processing of non-preferential CoO applications is being extended further upto 31st October 2021** only and the online system is not being made mandatory.

3. All Agencies, as notified under Appendix-2E, are required to ensure that the on boarding exercise is completed latest by 31st October 2021 failing which the agencies shall be de-notified from Appendix 2E. The concerned agencies may reach out over email to ddg2egov-dgft[at]gov[dot]in for any guidance or clarifications in regard to the on-boarding process.

4. The **revised Appendix 2E, containing the list of only those agencies which have been on-boarded, shall be notified post the said timelines.**

This issues with the approval of the competent authority.

File No.01/02/54/AM21/EG&TF/E-24628

Sanjay Kumar Tiwari, Dy. Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, New Delhi.

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Amendment in Export Policy of Melt Blown Fabric

DGFT Notification No.37/2015-2020 dated 14th October 2021

1. In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes following amendment in Notification No. 28/2015-20 dated 18.08.2020:

S. No	ITC HS Codes	Description	Existing Policy	Revised Policy
207 C	560312 560392 560311 569313 560314 560391 560393 560394	Melt Blown Fabric of any GSM	Prohibited	Free

2. Effect of this Notification:

The Melt Blown Fabric of any GSM has been made freely exportable with immediate effect.

F.No. 01/91/180/21/AM20/EC/E-20261

Amit Yadav, Director General of Foreign Trade, Ex-Officio Additional Secretary, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, GoI, New Delhi.

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Amendment in Export Policy of Syringes

DGFT Notification No.38/2015-2020 dated 14th October 2021

1. In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes following amendment to the Notification No.34/2015-2020 dated 4th October, 2021 pertaining to Chapter 90 of Schedule — 2 of ITC (HS) Export Policy, 2018 related to export of Syringes:

Current Policy (As per Notification No. 34 dated 4.10.2021)

S. No	ITC HS Codes	Existing Description	Export Policy
207AD	90183100	Syringes with or without Needles	Restricted

Revised Policy

S. No	ITC HS Codes	Revised Description	Export Policy
207AD	90183100	Syringes with or without Needles of the following denominations : - 0.5 ml/ 1ml AD syringes. - 0.5 m1/1 ml/2 m1/3 ml disposable syringes. - 1m1/2 m1/3 ml RUP Syringes.	Restricted

2. Effect of this Notification:

- **The export of Syringes with or without Needles of denominations (i) 0.5 ml/ 1 ml AD syringes (ii) 0.5 m1/1 m1/2 m1/3 ml disposable syringes and (iii) 1m1/2 m1/3 ml RUP Syringes falling under HS code specified above or under any other HS code has been put under Restricted category with immediate effect.**

- **All other syringes falling under HS code specified above or under any other HS code are freely exportable. The procedure for submission and approval of applications for export of syringes has been notified vide Trade Notice No.20/2021-22 dated 5th October, 2021.**

F.No.01/91/180/005/AM22/EC /E-29234

Amit Yadav, Director General of Foreign Trade, Ex-Officio Additional Secretary, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, GoI, New Delhi.

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Amendment in Export Policy of Diagnostic kits - reg.

DGFT Notification No. 39/2015-2020, dated 14th October 2021

In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act. 1992 (No. 22 of 1992), as amended. read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20. the Central Government hereby makes following amendment in **Notification No. 09/2015-20 dated 10.06.2020 and Notification No. 18/2015-20 dated 16.08.2021:**

S.No	ITC HS Codes	Description	Existing Policy	Revised Policy
207 G	Ex3822	• **VTM kits and reagents** • **RNA extraction kits and reagents** • **RT–PCR kits and reagents**	Restricted	Free
207 H	Ex39269099 Ex701790 Ex84199090 Ex90189099 Ex3822	15ml falcon tube or cryovials	Restricted	Free
2071	Ex300590 Ex3822	Swabs sterile synthetic fibre swabs (Nylon,Polyester, Rayon, or Dacron)	Restricted	Free
207 J	Ex90279090 Ex3822	Silicon columns	Restricted	Free
207 K	Ex38220090 Ex38220019	Poly adenylic Acid or Carrier RNA	Restricted	Free
207 L	Ex38220090 Ex38220019	Proteinase K	Restricted	Free
207 M	Ex9027 Ex3822	Magnetic stand	Restricted	Free
207 N	Ex38220090 Ex38220019	Beads	Restricted	Free
207 0	Ex38220090 Ex38220019	Probes (specific for COVID-19 testing)	Restricted	Free

207 P	Ex38220090 Ex38220019	Primers (specific for COVID- 19 testing)	Restricted	Free
207 Q	Ex3507 Ex3822	Taq Polymerase enzyme	Restricted	Free
207 R	Ex3507 Ex3822	Reverse transcriptase enzyme	Restricted	Free
207 S	Ex2934 Ex3822	Deoxy nucleotide triphosphates	Restricted	Free
207 AC	Ex3822 Ex3002	COVID-19 Rapid Antigen testing Kits	Restricted	Free

2. Effect of this Notification:

The export policy of all diagnostic kits and reagents (including instruments/apparatus), made 'Restricted' vide Notification No. 09/2015-20 dated 10.06.2020 and Notification No. 18/2015-20 dated 16.08.2021 is being made 'Free' with immediate effect.

F.No.01/91/180/21/AM20/EC/Part-III/E-21044

Amit Yadav, Director General of Foreign Trade, Ex-Officio Additional Secretary, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, GoI, New Delhi.

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Allocation of quantity of 8424 MT (raw/refined) Sugar to USA under TRQ scheme for the year 2021-22 - reg.

DGFT Public Notice No.28/2015-2020 dated 14/10/2021

1. In exercise of powers conferred under Para 1.03 and 2.04 of the Foreign Trade Policy, 2015-2020, the Director General of Foreign Trade hereby allocates quantity of 8424 Metric Ton of Raw/Refined Sugar, under Tariff Rate Quota (TRQ) to USA for the year 2021-22 (Upto September 30, 2022).

2. As per Notification No. 3/2015-20 dated 20.04.2015, export of sugar (HS Code 17010000) to USA under TRQ is 'Free' subject to the conditions notified in the `Nature of Restrictions' in the above notification.

3. Certificate of Origin, if required, for preferential export of sugar to USA, shall be issued by Additional Director General of Foreign Trade, Mumbai. Other certification requirement, if any, prescribed specifically for export of sugar to USA would continue to be followed.

4. The reporting requirement as notified vide Notification No. 3/2015-2020 dated 20.04.2015 read with Notification No. 20 dated 07.09.2015 would be followed.

5. Effect of this Public Notice:

The quantity of 8424 MT sugar (raw and/or white sugar) to be exported to USA under TRQ scheme from 01.10.2021 to 30.09.2022 has been notified.

F.No.01/91/180/879/AM08/EC (Vol.VIII)/E-20749

Amit Yadav,
Director General of Foreign Trade,
Ex-Officio Additional Secretary,
Directorate General of Foreign Trade,
Ministry of Commerce & Industry,
Department of Commerce,
GoI,
New Delhi.

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ITPO: India's participation in the Meditech and Healthcare Fair concurrent to Non-woven Tech Africa Exhibition to be held at Kenyatta International Exhibition Centre, Kenya from Feb 23-25, 2022

Ref.ITPO/MHG/26/Exh/Mob/2021, dated 8th October 2021

We are pleased to inform that India Trade Promotion Organisation (ITPO), an Enterprise under the Department of Commerce, Government of India will be organising India's participation in the Meditech and Healthcare Fair concurrent to Non-woven Tech Africa Exhibition scheduled to be held at Kenyatta International Exhibition Centre, Nairobi (Kenya) from February 23-25, 2022, which is exclusively a Busines-2-Business Fair. ITPO is taking part in this Fair for the first time to test the Kenyan market. The Embassy of Kenya in New Delhi (India) has recommended participation in this fair.

As per information received by ITPO, 150 companies from around 10 countries are expected to participate in this Exhibition and it will be visited by around 10,000 buyers I trade visitors not only from Kenya but also from the neighbouring countries. The product profile of the show includes, Medical Devices, Medical Textiles, Hygiene and Sanitization Equipment, Alternative Medicine & Care Products, Medical Infrastructure, Anti-Epidemic Supplies, Service & Supply Providers, Non-woven Bags, Non-woven Fabric, Non-woven Melt-blown Fabric, Non-woven Machinery, Non-woven Hygiene Textile, Non-woven Medical Textile.

During the financial year 2019-20, Kenya's import of Medical Devices, Medical Furniture, Ortho Appliances, Wound Care, Therapeutic Appliances, etc. was to the tune of US$ 89.7 million and the import by African Countries, which includes South Africa, Kenya, Tanzania, Uganda, Zimbabwe, Ethiopia, Djibouti was to the tune of US$ 373.08 million.

Tentative rentals of Rs. 27,000/- per sq.mtr. will be charged for a built up booth of 9 sq.mtr. ITPO has taken up with the Department of Commerce, Government of India for extending MAI subsidy for participation in this Fair. In case the subsidy is approved for this event, the participation charges are expected to significantly reduce to Rs.15000/- per sq.mtr. under Shell Scheme. A Standard Booth of 09 sq.mts. will include, one table and two chairs, 3 side walls, fitted in standard booth systems frame, fascia board with company name (15 letters) and stand number (in standard lettering) and ITPO LOGO, single phase connection through one plug point, 3 spotlights (100 watt each), company delegates entry to the exhibition (1 badge for each), general cleaning of the aisles and waste basket, pavilion security (from 6.00 p.m. till 9.00 a.m.). The space can be booked in multiples of 3 sq.mtrs. event, the participation charges are expected to significantly reduce to Rs.15000/- per sq.mtr. under Shell Scheme. A Standard Booth of 09 sq.mts. will include, one table and two chairs, 3 side walls, fitted in standard booth systems frame, fascia board with company name (15 letters) and stand number (in standard lettering) and ITPO LOGO, single phase connection through one plug point, 3 spotlights (100 watt each), company delegates entry to the exhibition (1 badge for each), general cleaning of the aisles and waste basket, pavilion security (from 6.00 p.m. till 9.00 a.m.). The space can be booked in multiples of 3 sq.mtrs.

Thanking you,

Devender Pal, Deputy General Manager, A Government of India Enterprise, India Trade Promotion Organisation.

'Covaxin instilled self-confidence'

Dr Balram Bhargava, Director-General, Indian Council of Medical Research (ICMR)

Indigenous COVID jab proved India is a vaccine superpower: ICMR chief

The development of Covaxin has instilled the confidence that India is now much more than the pharmacy of the world and that it is a vaccine superpower, says Balram Bhargava, Director-General, Indian Council of Medical Research (ICMR). Excerpts:

The ICMR co-developed India's first indigenous COVID-19 vaccine with Bharat Biotech. What have been the crucial learnings from this public-private partnership (PPP)?

In the development of this vaccine and this partnership, I think the most important aspects have been complete trust and the level of mutual appreciation for each other's calibre between the public and the private partner. It worked both ways — the ICMR's trust in Bharat Biotech and Bharat Biotech's faith in the ICMR.

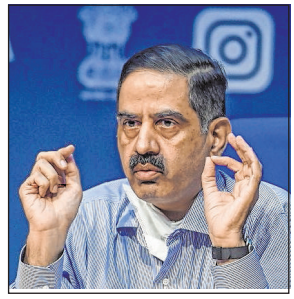
Right at the outset, we had clearly decided that the steps we follow must have a clear scientific basis and whatever we do should be documented in scientific journals.

Now as we know, the international academia has appreciated the scientific evidence on Covaxin published in over 15 papers. These publications in highly acclaimed, peer-reviewed global scientific literature cover the entire spectrum of vaccine development, whether it be preclinical development, development, small animal studies, hamster studies, large animal studies and all phases of clinical trials, including the phase-III trial, which is one of the largest in the world. These studies also include the vaccine's efficacy against the emerging virus variants, Alpha, Beta, Gamma, Delta.

How has this experience of co-developing Covaxin enriched science and public health in the country?

First, this experience has instilled self-confidence in us that India is now much more than the pharmacy of the world. It is also a vaccine superpower.

This confidence in being able to develop new vaccines from scratch now pervades the industry and the academia, and it is the right time to use our learnings from these experiences to develop new vaccines for other diseases and scale them up.



Second, for decades, we were largely known as a powerhouse for generic drugmaking. This experience in COVID-19 has acted as a catalyst for us to move up the value chain and take a leap into drug discovery or vaccine discovery space, to be specific. If this has to take off, the industry and the academia will have to collaborate in a big way.

Do you think this experience of developing a vaccine in PPP mode can be replicated for other diseases?

Yes, I think this exemplary model, where the public and private partners worked with scientific rigour on a fast-track mode to deliver a product on time can serve as a template for developing vaccines for other diseases. When we worked together, we were always working on a timeline even when we were racing against time. All along there was mutual respect, clear communication, and the setting of concrete goals in the project. This generated a momentum that I feel should not be lost and should be utilised for other projects.

India has developed a safe and efficacious vaccine that is beneficial not only for the global south but even for the global north.

Are you confident of India reaching its target of vaccinating all adults by the year-end?

I think our system is currently working like a turbocharged, well-oiled machinery vaccinating at a very fast rate, and we are advancing rapidly to reach that target. I think the world is watching us and will be witness to the fact that our vaccination drive has not only been very agile but also very responsive and responsible.

What are the steps that are helping India reach its 100-crore vaccination goal?

The dedication and efforts of our frontline workers and healthcare professionals involved in the vaccination drive. Second, the rich experience of carrying out one of the world's largest universal immunisation programmes and third, an aligned holistic approach of different arms of the Government with a singular focus to make vaccination drive a success contributed to this journey.

Also what is working is the ability of the whole of the Government to work together as well as strike successful public-private partnerships, where needed, that has resulted in a series of victories in these times of extreme uncertainties.

Whether it be the development of CoWIN, or the pragmatic way we prioritised vaccination for different groups, getting right many of those small steps nestled within the large vaccination drive resulted in the country achieving this milestone.

Beyond all, the country showed a clear commitment to public health, and that paid off.

Source : Bindu Shajan Perappadan, The Hindu, 21.10.2021

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IPR MATTERS

Collaborations only way out of the pandemic, say major pharma firms

Dub IP-waiver proposal a distraction though driven by good intention

Big pharmaceutical companies have reiterated their commitment to supply Covid vaccines to the the World Health Oganization-supported Covax facility, and added that collaborations were the way out of the pandemic.

"Other proposals, while well intentioned, are a distraction," said a note from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), referring to the proposal seeking an Intellectual Property (IP) waiver on Covid products, made by India and South Africa, at the World Trade Organisation.

It's been a year since India and SA made the proposal for a temporary IP waiver on medicines, diagnostics, and vaccines, among others, used in tackling Covid. The proposal to facilitate better access has since received support from a 100-odd countries, including the US, with the Biden administration throwing in its weight behind a waiver for vaccines.

Supplies in place

The IFPMA, however, points out that supplies are in place. "The vaccine production effort is estimated to reach 12.5 billion doses by the end of 2021 and double again to 24 billion doses by June 2022, at which time vaccine supplies will most likely outstrip global demand," said a statement ahead of a meeting of the G-20 heads of state in Rome later this month. The numbers show that the premise of an IP waiver "to help address an assumed shortage of vaccines as the solution to vaccine equity has been overtaken by the facts", said the IFPMA.

The solution to vaccine equity resides in "dose sharing, continuing to optimise output through manufacturing scaling up and voluntary licensing; as well as working together to enable countries to efficiently and effectively vaccinate their people", they said.

Their statement comes even as public health voices, including the WHO and humanitarian organisation across the world, call out the lop-sided distribution of Covid vaccines, with developed countries receiving a lion's share of the supplies.

IFPMA members include Pfizer, Eli Lilly, Roche, Johnson and Johnson, Merck, AstraZeneca and Moderna, all of who have critical Covid vaccines, anti-virals, and biological therapeutic products in their portfolio.

The association pointed out that Covid vaccine manufacturing output, driven principally by the US, the EU, China, and India, was over one billion vaccines each month. "The 9.3 billion Covid vaccine dose output by the end of October, and the estimated production of 12.5 billion by the end of the year, demonstrates the industry's success in trebling global vaccine capacity in less than a year," said the IFPMA, adding that about 300 voluntary collaborations were formalised during the pandemic period to support production.

Source : PT Jyothi Datta, The Hindu Business Line, 19.10.2021

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IP waiver for Covid-19 vaccine on Piyush Goyal-WTO chief meet agenda

Piyush Goyal (Photo: PTI)

The latest push by India and South Africa on Trade-Related Intellectual Property Rights (TRIPS) waiver on Covid-19 vaccine is one of the agenda

Union Commerce and Industry Minister Piyush Goyal is expected to meet World Trade Organization (WTO) Director General Ngozi Okonjo-Iweala in New Delhi this week to discuss key issues related to global trade. Okonjo-Iweala's maiden visit to India since her appointment in February comes in the backdrop of the crucial WTO 12th ministerial conference (MC12) that will be held on 30 November-3 December in Geneva.

This ministerial conference is the highest decision-making body of the WTO and can even take decisions on all matters under any of the multilateral trade agreements. The MC customarily meets every two years, but this time it is being held after a gap of four years as it was postponed due to the outbreak of the pandemic.

"The meeting between Goyal and Okonjo-Iweala is expected to take place on October 22. A meeting may also take place between Prime Minister Narendra Modi and the WTO DG," a senior government official said.

Long-pending issues related to agriculture and fisheries are likely to be discussed in the meeting. The latest push by India and South Africa on Trade-Related Intellectual Property Rights (TRIPS) waiver on Covid-19 vaccine is also the agenda. Moreover, various reforms at the WTO can also be discussed.

"As such, with respect to any reforms, India will pitch for reforms (if and when needed) should be inclusive. Apart from that the WTO, as such, should be a consensus-based body and every policy implemented by any country must be transparent," another government official said.

"India is not the only country that the (WTO) DG is meeting ahead of WTO's MC12. She is meeting representatives from other countries as well in person, to understand every nation's point of view on key trade related issues," he added.

Source: Shreya Nandi ,Business Standard, 18.10.2021

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NATIONAL NEWS

Nirmala Sitharaman highlights need to keep supply chains open for vaccine raw materials to combat COVID-19

Last month, India said that it will resume export of surplus COVID-19 vaccines in the fourth quarter of 2021 under the ''Vaccine Maitri" programme and to meet its commitment to the COVAX global pool.

Finance Minister Nirmala Sitharaman has highlighted the need of an international financial architecture to fight the COVID-19 pandemic across the globe and stressed on the need to keep the supply chains open for vaccine raw materials.

Ms. Sitharaman, participating in the 36th Annual G30 International Banking Seminar virtually here on Sunday, spoke on the panel about Financing the Commons, Climate and pandemic security, the Finance Ministry tweeted.

She "stressed on focused mobilisation and #equitableallocation of finances and #techsolutions to successfully harness the global #commongood of #climate and #pandemic security," it said.

Ms. Sitharaman highlighted the need of an international financial architecture to fight the COVID-19 pandemic across the globe and supported the need of new financial instruments to focus and press forward green initiatives.

She underlined the need for the World Health Organisation (WHO) to be strengthened for a more effective response to new challenges.

She stressed on the need to keep open supply chains for vaccine raw materials, the ministry said.

India has been highlighting the importance of enhancing the resilience of supply chains and greater engagement in the Indo-Pacific region, especially after the pandemic caused disruptions in the existing supply chains.

Sitharaman, arrived here on Friday after her visit to Washington DC, also addressed a gathering of women entrepreneurs of Indian-origin in New Jersey, where she spoke on India's robust economic recovery and the road ahead and the opportunities India has to offer to the world. In Washington, she participated in the annual meetings of the World Bank and the International Monetary Fund.

She began her week-long US visit with a trip to Boston, **where she met CEOs, addressed a roundtable meeting of investors** and executives and addressed students and faculty at the Harvard Kennedy School.

India, the world's largest producer of vaccines overall, suspended exports of COVID-19 vaccines in April to focus on inoculating its own population following a sudden spike in infections.

Last month, Union Health Minister Mansukh Mandaviya announced that **India will resume the supplies abroad.**

India said that it will resume export of surplus COVID-19 vaccines in the fourth quarter of 2021 under the ''Vaccine Maitri" programme and to meet its commitment to the COVAX global pool.

Source : The Hindu, 18.10.2021

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Covaxin for children? Making trial data public will create trust in paediatric-use vaccines

As the drugs regulator mulls over approval for Covaxin, Bharat Biotech needs to keep in mind that its case is helped with trial data put in the public domain for independent experts to examine.

With very few Covid-19 vaccine candidates having received any form of approval for paediatric use across the globe—even those that have are restricted to a clutch of developed jurisdictions.

A subject expert committee of the Central Drugs Standard Control Organization has recommended the grant of accelerated approval to Covaxin for use among 2-18 year olds. The recommendation is based on safety and efficacy data submitted by Bharat Biotech from a trial involving 525 children across three age groups 2-6 years, 6-12 years and 12-18 years. Though the Drugs Controlled General of India is yet to give approval, this is a promising first step.

With very few Covid-19 vaccine candidates having received any form of approval for paediatric use across the globe—even those that have are restricted to a clutch of developed jurisdictions. But, with the ever-present threat of virulent and infectious variants, many countries are looking at vaccine options for children. In Israel, a spike of cases among children post the opening of schools led the government to approve vaccination for minors. Till date, 84% of the country's 16–19 year olds and 53.7% of 12–15 year olds have been fully vaccinated.

The US has granted emergency use approval to Pfizer and Moderna for 12-15-year-olds and is likely to do this for younger age groups soon, against a backdrop of a spike in cases among children— according to government data, as many as 750,000 children have been infected within the last month. While Covid-19 mortality among children has been relatively much lower among children, the risks for children with co-morbidities remain high; moreover, the shadow of long Covid and the risks of associated immunopathologies reported across the world among children from the viral infection would make a vaccine for the young an imperative.

Most important, with the need to reopen schools a badly felt need across geographies, the transmission risk for the adult population from unvaccinated children is too significant to ignore. Cases among children have risen in some parts of India, but on the whole, remain a small fraction of the overall number of infections reported. However, the country's under-18 population is estimated to be be 30% of the population—and only a mere 20% of the population has received full vaccination (two doses) so far. And with the clamour for reopening of schools growing—a non-negotiable if the future of lakhs of children from poor households is not to be put in jeopardy—it is hard to imagine stalling for paediatric Covid-19 vaccines for too long.

As the drugs regulator mulls over approval for Covaxin, Bharat Biotech needs to keep in mind that its case is helped with trial data put in the public domain for independent experts to examine. To be sure, keeping the data for the regulator's eyes only is the company's privilege and there is no requirement to make the data public. But, an avoidable controversy had marred the accelerated approval given to the vaccine for adult use, stoked by trial data remaining unpublished at the time.

Indeed, to engender wide trust in paediatric use of the vaccines, not just Bharat Biotech, but others in the line—Serum Institute, Pfizer, Zydus Cadilla—must consider putting trial data out in the open, in the formal peer-reviewed process. The government, for its part, needs to carefully strategise the roll-out of any paediatric-use vaccine it approves; it could perhaps start with a focus on children with co-morbidities.

Source: The Financial Express, 18.10.2021

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Intas launches the World's first SB-100mg Itraconazole

One of the world's leading pharmaceutical companies, Intas Pharmaceuticals, has made a progressive breakthrough in the Antifungal Therapy domain with the launch of the world's first Super Bioavailable Itraconazole-SB 100mg by the Brand Name of Itaspor-SB Forte/Subawin. It has been recently approved by Indian Regulatory Authorities. Conventional Itraconazole mainstay drug to fight fungal infection has high result variance and low patient compliance because of dosing dependence upon food, acidic beverage, antacids consumption etc. and overall cost of treatment.

Itaspor SB Forte/Subawinis expected to improve patient compliance and reduce the Doctor's counselling time. It will reduce dosing to half. Furthermore, patients can take it with or without a meal with just water or as directed by the physician. The cost of the therapy is also reduced substantially.

As per published literature and clinicians' experience, the Itraconazole molecule has low blood drug concentration, affecting safety and efficacy when taken orally. These blood levels highly vary from patient to patient. Moreover, the recommendation to take it with a full fatty meal and an acidic beverage further reduces patient compliance and adds to the problem of desired blood drug concentration. Another factor is the cost of therapy for fungal infection patients, as treatment duration varies from 3 to 8 weeks.

"Intas' newest formulation within the 25-year-old brand Itasporis formulated with Super Bioavailable (SB) Technology that makes 1 Itaspor-SB Forte capsule equivalent to conventional 200mg Itraconazole," said Dr Alok Chaturvedi, Senior Vice-President, Head - Medical Affairs, Intas Pharmaceuticals.

"Given the benefits of Super Bioavailable (SB) Technology like half the drug, no inter-patient variability, freedom to prescribe with/without food, any beverage, even with Antacids, and that too with a reduction in overall treatment cost certainly seems to be a win-win proposition.", said Dr R D Kharkar, Senior Consultant Dermatologist, Mumbai.

About Intas Pharmaceuticals Ltd. is a leading, vertically integrated pharmaceutical company based in Ahmedabad, India, having end-to-end capabilities of formulation development, manufacturing and marketing along with backward integration of APIs. Intas has more than 18,000 employees, sells products in more than 85 countries and has 14 manufacturing sites worldwide. The Intas group's revenues amounted to USD 2.1 bn in FY 2020, and the compounded annual growth rate of Intas' revenues has exceeded 25% in the past 10 years.

Source: ANI, 17.10.2021

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Dr Reddy's Labs launches copy of BI drug; move may lead to legal battle

Under its brand Vicra, Dr. Reddy's is expected to sell the drug in India at less than a third of the price charged by Boehringer Ingelheim. According to sources the 10 mg

variant of Dr. Reddy's brand may cost Rs15 per tablet against Rs 51 of the innovator's brand.

Hyderabad-based Dr Reddy's Labs has launched copies of Jardiance, a hit anti-diabetes pill sold by German drug maker Boehringer Ingelheim (BI). The drug has valid patent in India until 2025 and experts say the launch is likely to take a controversial spin and head for a court battle. BI may seek temporary restraining order and claim damages for patent infringement.

Jardiance leads a class of drugs named **SGLT-2** (sodium glucose co-transpoter-2) that works by helping the kidneys cut glucose from the blood stream and minimize renal damage and other debilitating complications linked with chronic diabetes. Sales of Jardiance stood at roughly ₹250 crore till August this year, based on the 12-month moving annual total (**MAT**), according to **IQVIA**, a global data science and pharma consulting firm.

Under its brand Vicra, Dr. Reddy's is expected to sell the drug in India at less than a third of the price charged by Boehringer Ingelheim. According to sources the 10 mg variant of Dr. Reddy's brand may cost ₹15 per tablet against ₹51 of the innovator's brand. For the 25 mg variant, the price will be ₹18 per tablet against ₹62 of BI's drug. Online pharmacy 1mg shows Jardiance is sold at a 25% price discount.

Getty Images
(Representational image)

The decision of Dr. Reddy's surprised many in the industry since this will be the first instance that the company has launched copies of a brand with a valid patent.

In a similar action, in April 2013, Mumbai-based Glenmark had launched cut-price versions of US giant Merck's blockbuster Januvia, under its brand name Zita. After an acrimonious court battle revolving around patent infringement, Glenmark lost the case in Supreme Court in 2015 and ordered to withdraw its brand from the market.

In response to questions from ET, a spokesperson from Boehringer Ingelheim notes, "We have information about a generic empagliflozin molecule launch by a domestic pharma manufacturer, which could be an instance of patent infringement. We are exploring options to protect our rights as the active patent holder of empagliflozin. We have faith in the Indian Patent system and the enforcement of patent rights, which is imperative to drive patient-centred progress and innovation."

It added we expect all responsible corporate citizens to uphold Boehringer Ingelheim's valid patent for empagliflozin. Dr. Reddy's did not respond to queries from ET.

According to IQVIA data as of Aug. 2021, India's anti-diabetes drugs market was at Rs. 16306 crore, growing annually at 9%. Of that, SGLT2 plain and combinations swelled to Rs. 969 crore and 487 crore respectively, which is the fastest among all other class of anti-diabetes drugs.

Source: Vikas Dandekar, ET Bureau 18.10.2021

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Dr. Reddy's gets USFDA nod for generic anti-cancer drug

Dr. Reddy's Laboratories has received U.S. Food and Drug Administration (USFDA) approval for a generic version of anti-cancer drug Revlimid (lenalidomide) capsules.

The health regulator gave final approval for the company's ANDA (abbreviated new drug application for Lenalidomide capsules), 2.5 mg and 20 mg strengths and tentative approval for 5 mg, 10 mg, 15 mg and 25 mg strengths. With the approval, the company will be eligible for 180 days of generic drug exclusivity for Lenalidomide capsules 2.5 mg and 20 mg, Dr. Reddy's said in a release on Tuesday.

"We are pleased with the approval of Lenalidomide capsules, 2.5 mg and 20 mg and being eligible for 180-day market exclusivity... look forward to bringing a more affordable generic version of this drug to market," said Marc Kikuchi, CEO-North America Generics.

In September 2020, Dr. Reddy's had announced a settlement agreement of litigation with Revlimid maker Celgene, relating to patents for the branded drug. In settlement of all outstanding claims in the litigation, Celgene, which is wholly-owned subsidiary of Bristol Myers Squibb, had agreed to provide Dr. Reddy's with a license to sell volume-limited amounts of generic lenalidomide capsules in the U.S. beginning on a confidential date after March 2022 subject to regulatory approval.

The agreed-upon percentages remain confidential. As part of the settlement, Dr. Reddy's is also licensed to sell

generic Lenalidomide capsules in the U.S. without volume limitation beginning January 31, 2026, the release said.

Source: The Hindu, 19.10.2021

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More than 300 covid-19 vaccines are being developed: WHO

According to the WHO, 126 vaccines are in clinical development and 194 in pre-clinical development stage

According to the latest update with WHO, some Indian vaccines are in the pre-clinical trial phases.

NEW DELHI: With Covid-19 pandemic entering into second year, pharmaceutical companies across the world are developing more than 300 vaccines against the coronavirus. According to the latest update of landscape of novel coronavirus vaccines candidate development worldwide, compiled and maintained by WHO, 126 vaccines are in clinical development and 194 vaccines are in pre-clinical development stages.

While India has developed Covaxin and manufacturing covishield, several new vaccines are in the offing. The covid-19 vaccine tracker and landscape compiles detailed information of each covid-19 vaccine candidate in development by closely monitoring their progress through the pipeline.

Explaining the phases of clinical trials, Dr Gagandeep Kang, the vice chair, Coalition for Epidemic Preparedness Innovations (CEPI), a global non-profit aiding vaccine development platform for the covid-19 pandemic, and professor at the Christian Medical College (CMC), Vellore, Tamil Nadu said that the first and foremost are pre-clinical studies--these are done in animals and are primarily for safety/ toxicity, bit can also include animal disease models. "Phase 1 in humans: these are small studies to evaluate vaccine safety. These can include 20-40 people and if the vaccine causes reactions, it will not progress. Phase 2 studies in humans, these are studies that measure the immune response to the vaccines, they are also used to decide the number of doses, and what is in each dose. Usually these have a few hundred participants," said Kang.

"Phase 3 studies in humans, people are given the vaccine and you wait for them to develop disease. Because disease is unpredictable, you need to have a few thousand people and do the studies in places where disease is likely. If vaccinated people get less disease than unvaccinated ones, then you know the vaccine is working.

After these studies are done, then the vaccine manufacturer can apply for a license, and when they have, they can start to make the vaccine. After the vaccine is licensed, safety continues to be monitored, and you can also see how the vaccine performs in real-life--this is called an effective study," she said.

According to the latest update with WHO, some Indian vaccines are in the pre-clinical trial phases. For example, vaccine manufacturer Indian Immunologicals and Griffith University in Australia have partnered to develop a potential vaccine candidate against covid-19. The partners intend to create a live attenuated vaccine using codon de-optimisation technology, which would offer longer protection with a single dose. The vaccine is expected to provide long-lasting protection with a single dose administration with an anticipated safety profile similar to other licensed vaccines for active immunisation.

Similarly, Bharat Biotech and Thomas Jefferson University of Philadelphia have signed an exclusive deal to develop a new vaccine candidate for covid-19 invented at Jefferson. The novel vaccine has been developed using an existing deactivated rabies vaccine as a vehicle for coronavirus proteins. Biological E and Cadila healthcare is also developing a vaccine which is in pre clinical trial phase.

There are also some Indian vaccines that are in the Phase 1/ 2 clinical trial phases. UK based SpyBiotech, a company with a novel vaccine platform to target infectious diseases, cancer and chronic diseases in partnership with the Serum Institute of India (SIIPL) that is manufacturing covishield has a vaccine in Phase I/II trial. SII and US based Codagenix Inc. are conducting Phase 1 Trials.

The department of Biotechnology (DBT), ministry of science and technology is supporting the vaccine development. "DBT is backing many covid-19 vaccines' development programs such as Mission COVID Suraksha program. We are fostering technological innovation in biotechnology in India. The department is also providing

support towards scale-up and clinical studies," said Dr. Renu Swarup, Secretary, DBT.

Source: Neetu Chandra Sharma, Mint, 19.10.2021

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Mix-and-match vaccines highly effective against COVID-19: Lancet study

Past studies have demonstrated that mix-and-match vaccine schedules generate a robust immune response

A health worker prepares a dose of the Covishield vaccine against the Covid-19 coronavirus, at a vaccination centre in Rajawadi Hospital in Mumbai.

London: People who received a first dose of the Oxford-AstraZeneca COVID-19 vaccine followed by an mRNA vaccine shot had a lower risk of infection compared to those immunised with both doses of the AstraZeneca preventive, according to a nationwide study in Sweden.

Since the use of AstraZeneca's vector-based vaccine against COVID-19 was halted for people younger than 65 years of age due to safety concerns, all individuals in Sweden who had already received their first dose of this vaccine were recommended an mRNA vaccine as their second dose.

"Having received any of the approved vaccines is better compared to no vaccine, and two doses are better than one," said Peter Nordstrom, a professor at Umea University, Sweden.

"However, our study shows a greater risk reduction for people who received an mRNA vaccine after having received a first dose of a vector-based, as compared to people having received the vector-based vaccine for both doses," Nordstrom said.

The study, published in The Lancet Regional Health - Europe journal on Monday, is based on nationwide registry data from the Public Health Agency of Sweden, the National Board of Health and Welfare, and Statistics Sweden.

In the main analysis, about 700,000 individuals were included.

During a 2.5-month average follow-up period after the second dose, the study showed a 67 per cent lower risk of infection for the combination of AstraZeneca and Pfizer vaccine shots. There was a 79 per cent lower risk of infection for AstraZeneca and Moderna vaccine shots, compared to unvaccinated individuals, the researchers said.

For people having received two doses of the AstraZeneca vaccine, known as Covishield in India, the risk reduction was 50, they said.

These risk estimates were observed after accounting for differences regarding date of vaccination, age of the participants, socioeconomic status, and other risk factors for COVID-19.

The researchers noted that the study estimates of effectiveness apply to infection with the Delta variant, which was dominating the confirmed cases during the follow-up period. "The results of the study may have implications for vaccination strategies in different countries," said Marcel Ballin, doctoral student at Umea University, and co-author of the study.

"The World Health Organization has stated that despite the promising results from previous studies regarding immune response from mix-and-match vaccination, there is a need for larger studies to investigate their safety and effectiveness against clinical outcomes. Here we now have one such study," Ballin said.

There was a very low incidence of adverse thromboembolic events, or formation of blood clots in blood vessels, for all vaccine schedules, according to the researchers. The number of COVID-19 cases severe enough to result in inpatient hospitalisation was too low for the researchers to be able to calculate the effectiveness against this outcome.

Past studies have demonstrated that mix-and-match vaccine schedules generate a robust immune response. However, it has been unclear to which extent these schedules may reduce the risk of clinical infection, the researchers said, adding that their study aimed to fill that knowledge gap.

Source: PTI, 18.10.2021

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Q2 corporate results: These sectors will report good quarterly numbers

The second-quarter numbers will look fabulous due to a low base effect. Now the most important question: how much of this positive news is already factored into the price?

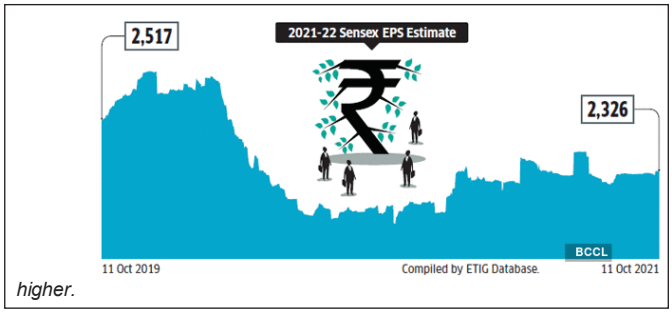
Investors should note that despite the fall in PE, the valuations are still at elevated levels.

Despite the second wave-induced disturbances, India Inc was able to report a solid set of numbers for the first quarter of 2021-22. Now that the **covid** situation has improved significantly and economic activity has picked up in the second quarter, market participants are looking forward to this results season with a lot of hope. "Economic growth is back on track and the same should get reflected in quarterly numbers now," says G. Pradeep Kumar, CEO, Union Mutual Fund.

"In addition to improving economic situation, the second-quarter numbers will also look fabulous due to a low base effect —very low numbers during the same period last year due to covid disturbances," says Hemant Kanawala, Head of Equity, Kotak Life Insurance. Due to some restrictions in the previous quarter triggered by the second wave of covid, the low base effect will be apparent even in the q-o-q analysis.

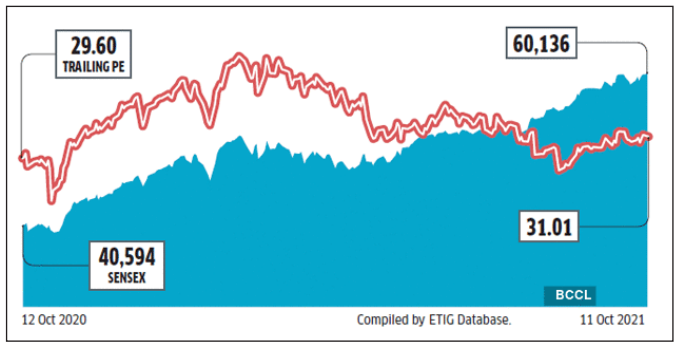
Now the most important question: how much of this positive news is already factored into the price? Analysts have already started factoring in the better quarterly numbers and that explains why the expected Sensex **EPS** for 2021-22 is going up on a regular basis for the last few quarters. Marketwide valuations were already up because the market had been discounting this expected earnings jump. Once that started happening, Sensex **PE** started coming down even as the Sensex went up. Since the earnings jump will continue in the second quarter, the trailing PE multiples may come down further.

Expected 2021-22 EPS has gone up due to better quarterly numbers *Positive surprises and more upgrades required to push the market higher.*



higher.

Despite market rally, PE is coming down due to better earnings
The PE is still way above the historical average of 19 times.



However, investors should note that despite the fall in PE, the valuations are still at elevated levels. For instance, Sensex's current trailing PE of 31 is way above its historical average of 19 times. "Market valuation is expensive compared to the intrinsic fair value. While the growth is good, that may not be enough to sustain current high valuations," says Kumar.

Thus the high expectations are like a Damocles' sword hanging on the market and the market may punish any company even for a small earnings miss. For example, most market participants believed that the IT sector will continue to report good numbers and TCS tanked by more than 6% on its results day due to a small negative surprise.

Now, let us take a closer look at what is expected from different sectors.

Auto

Though the aggregate auto sector numbers looks disastrous, it is mostly because of Tata Motors. In the second quarter, Tata Motors is expected to reduce its net loss to Rs 1,600 crore from Rs 4,450 crore in the previous quarter and this should help the aggregate sector to report net profit versus net loss sequentially. However, the auto sector performed poorly even after excluding Tata Motors. While the sector was able to report low revenue growth, it is still under severe margin pressure.

"The auto sector is now facing two problems. While the chips shortage is restricting volumes, jump in commodity prices is putting pressure on margins," says Kanawala. At the aggregate sector level, excluding Tata Motors, net profit fell by 20% q-o-q.

Banks & NBFCs

With the improvement in collection efficiency, banks continue to do well and are expected to report decent numbers, both y-o-y and q-o-q. Their revenues will

show modest growth because of the improvement in new disbursements. Reduction in cost of funds and fall in NPAs are other factors that will help the sector to report 20% plus net profit growth. Leading banks like SBI, which is expected to report 50% y-o-y jump in net profit, are expected to continue with their strong performances. Due to strong performance by companies like HDFC and Bajaj Finance, the NBFC space is also expected to report good numbers.

Another set of fabulous numbers

Due to improvement in economic situation, several sectors will report good q-o-q numbers also.

	Revenue Growth (%)		Net profit Growth (%)	
Sector	y-o-y	q-o-q	y-o-y	q-o-q
Auto & ancillaries	8.20	0.57	-84.80	NA
Banks	6.09	2.44	24.23	20.01
Capital goods	11.27	-7.54	12.62	-14.07
Cement	8.95	-3.20	-2.30	-25.95
FMCG	14.87	13.55	6.17	29.70
Hotels	135.40	85.48	NA	NA
Infra	29.51	2.34	26.63	-1.21
Metals & mining	52.84	11.56	254.44	9.64
NBFCs	15.50	30.86	29.61	15.50
Pharma	6.50	0.50	11.50	22.00
Real estate	37.00	48.14	51.21	355.24

Source: Research reports. **NA:** It was a net loss in previous quarter.

Capital Goods

While this segment will report decent y-o-y numbers, the pressure is building up due to spiralling commodity prices and the same will drag down margins. However, from this segment, market participants will be keener on new deal wins in the second quarter than the absolute net profit growth. Government's Atmanirbhar Bharat push continues and the ministry of defence has recently announced a new negative list for import and this will benefit the companies with domestic manufacturing base in this space.

Cement

Most commodity sector companies should report good numbers in the second quarter, but there are exceptions. "Among commodity companies, cement may report weak numbers. While demand will be low due to monsoon, coal prices will hit their margins," says Kanawala.

FMCG

Ever since the second covid wave ended in the first quarter, discretionary consumer demand has jumped in the second quarter. While the aggregate numbers look good, there will be margin pressure on some segments – especially on paints. While industrial segment is expected to deliver steady growth, automotive paint segment will be negatively impacted by the woes of the automobile sector. The decorative paints segment is expected to report faster revenue growth due to pent up demand — revenue fell in the first quarter due to covid disturbances. However, net profit growth will be muted. "Though decorative paints companies have taken price hikes to protect profitability they will not be sufficient enough to cover the rising raw material cost inflation," says Naveen Kulkarni, CIO, Axis Securities. For instance, Asian Paints is expected to report a y-o-y revenue and net profit growth of 30% and 5% respectively. Consumer staples space have almost inelastic demand and therefore, are expected to report stable numbers in the second quarter as well.

Hotels

Though the fall in covid cases has resulted in a jump in demand, the sector is yet to come out of the losses. However, hotel companies have taken several steps to reduce their fixed and variable costs and therefore, were able to bring down their losses. The weakness in the sector is also resulting in consolidation and helping companies with strong parentage, like Indian Hotels, EIH, etc. to gain further market share.

Infra

Infrastructure companies were not much impacted during the same period last year and therefore, are not going to benefit from the base effect. However, this space is a wide basket and their results are expected to be mixed. "Infrastructure space will be very interesting during this results season and some of them can give positive surprises," says Kulkarni. Among them, road construction companies will remain on the forefront due to lower base and pick up in execution due to increased availability of labour.

Metals

Metal companies reported fabulous numbers during the first quarter and a similar trend is expected in the second quarter as well. "Since metal prices are still at elevated levels compared to the same period last year, metal companies should report good numbers in the second quarter," says Kanawala. Due to the low base, some of them may even report fabulous numbers.

For example, Steel Authority's net profit is expected to grow 2,500% y-o-y, Tata Steel (600%), Hindalco,

JSW Steel and Jindal Stainless (300% each), etc. Metal companies are also expected to show good q-o-q growth because of volume improvement compared to the previous quarter. Since steel companies maintain 2-3 months of coking coal inventory, the impact of jump in its price will be negligible in the second quarter. Though it may impact in coming quarters, fall in iron ore prices should neutralise a part of the coking coal price jump.

Mining

While all metal companies are expected to report a good set of numbers, the mining sector is a mixed bag. The sudden jump in coal prices and fall in iron ore prices are the main reasons for this. Since Coal India won't be in a position to increase production to benefit from the present coal shortage, the improvement in numbers will be restricted realisation improvement. Though NMDC will report decent y-o-y growth, its net profit is expected to fall by 30% q-o-q.

Pharma

After reporting solid numbers during the last several quarters, growth rate at pharma sector is expected to moderate. "Increased competitive pressure on the US base business, coupled with the reduced pace of launches and lower covid related off-take, is expected to drag down the overall sector performance in second quarter," says Kulkarni. However, the aggregate q-o-q numbers will look good due to bumper profit expected from Sun Pharma.

Real estate

The outlook for real estate sector improved significantly after the fall in covid numbers from the second wave. Several factors like improvement in sentiments, very low home loan rates, etc are increasing demand. Builders are also utilising this positivity to come up with new launches during the festive season. The y-o-y numbers of real estate companies will look fabulous due to last year's very low base. With more and more companies looking to restart their offices, activities have picked up in the commercial real estate segment as well.

Source: Narendra Nathan, ET Bureau, 19.10.2021

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Govt will decide on COVID vaccination of children, adolescents on 'scientific rationale', supply situation

Paul, who has been playing a key role in the government's efforts in the fight against the coronavirus pandemic, also cautioned that even though infections are coming down and the second wave is subsiding, it will not be fair now to say that the worst is over since many countries have seen more than two waves.

The government will take a final decision on vaccinating children and adolescents against coronavirus on the basis of overall scientific rationale as well as the supply situation of vaccines available for those below 18 years old, COVID Task Force chief V K Paul said on Sunday.

Paul, who has been playing a key role in the government's efforts in the fight against the coronavirus pandemic, also cautioned that even though infections are coming down and the second wave is subsiding, it will not be fair now to say that the worst is over since many countries have seen more than two waves.

Currently, three vaccines -- Covishield, Covaxin and Sputnik V -- being administered in the country are only for those above 18 years of age. All of them are two-dose vaccines.

Zydus Cadila's indigenously developed needle-free COVID-19 vaccine ZyCoVD is set to become the first vaccine that will be available in India for those in the age group of 12-18 years. It has received Emergency Use Authorisation (EUA). "We do know that several countries have introduced vaccination for adolescents (people) and children. We will take a final decision based on the overall scientific rationale and the supply situation of the child licenced vaccines, going forward," Paul told PTI in an interview.

An expert panel of India's central drug authority has recommended granting EUA to Bharat Biotech's Covaxin for children and adolescents in the 2-18 years age group with certain conditions.

If approved by the Drugs Controller General of India (DCGI), it will be the second vaccine after ZyCoV-D to get EUA for use among those below 18 years.

The National Technical Advisory Group on Immunisation (NTAGI) is looking at how ZyCov-D should be positioned for most optimum use.

According to Paul, Covaxin is a part of the adult vaccination programme and how to provision the vaccine, if at all for children, has to be also examined in the totality of the requirements of the vaccination programme. "A pragmatic decision (on vaccination of children and adolescents) can be taken (only) by balancing the supply and the potential eligibility," he said.

While noting it will not be possible now to give a particular timeline on when COVID vaccination will start for children, Paul said, "The preparation for incorporation of Zydus Cadila's vaccine into the vaccination programme is proceeding well, training is already being held. NTAGI advice for the best use of the vaccine is explored. So soon, this will be rolled out".

According to Paul, children are part and parcel of the chains of COVID transmission and are infected in large numbers. At the same time, COVID infections in children are very mild or asymptomatic, and that is one side of the story.

On the other side, he said that once there is enough vaccine available that can be used in children, "so why not protect them".

Schools have reopened in many states, mainly for higher classes.

When asked whether the worst of the pandemic is over, Paul said, "It is reassuring that the number of COVID cases are now on the decline and the second wave is now subsiding but to say that the worst is over will not be fair because we have seen in other nations, there have been more than two waves". Cautioning that the country is passing through a phase when there are festivals and potential gatherings, he said this is a critical phase as the virus can spread again.

"We have seen that even in other countries where vaccine coverage is good, the escalation in the pandemic can happen and has happened.

"Therefore, certainly we should not assume that this situation of the declining trend will continue and definitely we should not think that the worst is over, we have to be ever watchful," he emphasised.

While stressing that the vaccination programme has picked up huge speed, Paul also said that states which are for whatever reasons lagging behind must work hard and must push vaccination.

"Given the present generous vaccine supply situation and the performance of the vaccine implementation programme, it is well within our grasp to accomplish universal vaccination of the adult population," he asserted.

On some reports that India simply will not have enough syringes for COVID vaccines if every single adult is to be fully vaccinated by the end of the year, Paul said, "there is no problem of syringe availability, we are in a good shape".

The country recorded 14,146 fresh COVID infections in a day while active cases declined to 1,95,846, the lowest in 220 days, according to the Union Health Ministry's data released on Sunday.

Source: ET Bureau, 21.10.2021

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Pfizer seeks green light for COVID jab for children aged 5-11 in Canada

Pfizer-BioNTech submitted an authorization request to Health Canada on Monday for the use of its COVID-19 vaccine in children aged 5-11, the companies and the Canadian government said.

"This is the first submission Health Canada has received for the use of a COVID-19 vaccine in this younger age group," it said in a statement.

The authorization request is based on data from trials conducted on 2,268 children in this age group for whom the dosage was lowered to 10 micrograms per injection —three times less than the standard dose—which the company says is "the preferred dose" for 5-11 year olds.

This same Pfizer-BioNTech vaccine is approved in Canada for ages 12 and up. Health Canada said that it will only authorize the use of the vaccine if the independent and thorough scientific review of all data submitted confirms that the benefits outweigh the risks with this group. The Canadian ministry also indicated that other manufacturers also were testing their vaccines on children of different age groups.

Earlier this month, Pfizer and BioNTech laboratories made the same request for 5-11 year olds in the United States. Childhood immunizations are raising questions around the world. Many countries vaccinate adolescents from the age of 12, but very few do so below that age. In recent months, the World Health Organization (WHO) has insisted that the urgent issue was to immunize the population of poor countries before children and adolescents in rich countries

Source: Medical Press, 19.10.2021

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India set to achieve exports target of $400 bn this year, but its impact on GDP may be muted

While noting it will not be possible now to give a particular timeline on when COVID vaccination will start for children, Paul said, "The preparation for incorporation of Zydus Cadila's vaccine into the vaccination programme is proceeding well, training is already being held. NTAGI advice for the best use of the vaccine is explored. So soon, this will be rolled out".

While robust exports have been a silver lining, the impact on India's GDP growth could only be marginal. Synopsis Between April and September 2021, India clocked merchandise exports worth $197 billion, 57% more than the same period last year.

As India's half-yearly export figure is published, it can be safely forecast that GoI's ambitious target of $400 billion merchandise exports for the year is likely to be met without a hitch. With the Covid pandemic seemingly on the wane, Indian exporters have been riding the momentum of global economic recovery and a surge in commodity prices worldwide.

Between April and September 2021, India clocked merchandise exports worth $197 billion, 57% more than the same period last year and a decent 24% rise over the corresponding period in the pre-pandemic 2019-20. The sectors that are leading the pack include engineering goods, gems and jewellery, petroleum products, pharmaceuticals, chemicals — in that order, according to data available with the ministry of commerce and industry.

An internal assessment of the ministry that analysed data till the end of September suggests that several commodities surpassed 50% export target in the first six months, according to an officer privy to the document. These include engineering goods (51%), petroleum products (52%) and chemicals (57%), giving hope that India will be able to meet the $400 bn target — which was reckoned as far too ambitious when minister Piyush Goyal announced it three and a half months ago.

The target, after all, was much more than the $313 bn in 2019-20. In 2020-21, total exports slipped to $292 bn. India achieved the highest ever merchandise exports — $330 bn — in 2018-19. While robust exports have been a silver lining, the impact on India's gross domestic product (GDP) growth could only be marginal.

The positives from an enormous export growth would be offset if consumption and investment — two bigger determinants for calculating output — remain fragile. The rising imports in April-September — 11% more than the corresponding period in 2019-20 — will also have an adverse impact on the GDP.

INDIA'S MERCHANDISE EXPORTS (in $ bn)

Month	2019	2020	2021
April	26	10	31
May	30	19	32
June	25	22	33
July	26	24	35
August	26	23	33
September	26	27	33
Total (Apr-Sep)	**159**	**125**	**197**

Source: Department of Commerce

"In GDP calculation, the positive impact of faster than expected export growth will be partly offset by higher prices of oil imports. Taken together, the impact of higher exports net of import bill will merely offset the weak recovery in private consumption so far," says Arvind Virmani, former chief economic adviser and chairman EGROW, a Delhi-based economic foundation.

The GDP is calculated by adding the expenditures by three broad groups — households, business and the government. If one adds up consumption, investments, government spending and net export, the total output can be arrived at.

Pronab Sen who, as the chief statistician of India in 2007-10, got a first-hand experience of calculating the GDP, says exports contribute only about 14% of India's output, far too low compared with other two drivers — domestic consumption, which powers about 62% of GDP, and investment, which contributes about 28%. The amount spent on imports is deducted from the total output. "Faster export growth does help the GDP to grow rapidly. But if consumption and investments are badly hit, as it is seen now, export by itself can't help the economy much," Sen tells ET.

So, while healthy export is a good sign for the economy, the government must immediately bring in policy interventions to boost consumption and investments, which in turn will power a faster GDP growth.

"Many countries have shifted their sourcing bases from China and are preferring India. They want to reduce their dependence on one country. That is a big opportunity for us." - Rajiv Kumar, Vice-Chairman, Niti Aayog

Virmani argues that states and the Centre must no longer be obsessed with short-term revenue maximisation via rate increases. "With private consumption recovery getting slower and consumer confidence being weak, GST Council must go for short-term revenue negative and long-term buoyancy raising tax reform," he says, adding that the move must be complemented in the next Union budget by reforms on direct tax code and customs tariffs so as to reduce MSME costs and increase their exports and revenues, thereby stimulating jobs and incomes of the lower 60% of workers.

There is no ready data available to measure private consumption mid-year but most economists seem to be on the same page that the level of consumption in the country is still pretty low. Also, the private sector is reluctant to pump in money for building new projects. "Low private investment has been a weak spot in the economy," says Montek Singh Ahluwalia, who was deputy chairman of the erstwhile Planning Commission in 2004 -14. "It is difficult to imagine an acceleration in GDP growth to the high levels we enjoyed earlier without a significant revival of investment," he adds.

While the economic survey in January predicted an 11% GDP growth for FY2022, RBI forecasts 9.5%. Ahluwalia says 9.5% is also unrealistic. "I fear the actual growth rate will be lower," he says, adding that there has been rampant under-employment, which is why consumption demand is still depressed.

In GDP calculation, the positive impact of faster-than-expected export growth will be partly offset by higher prices of oil imports. Taken together, the impact of higher exports net of import bill will merely offset the weak recovery in private consumption so far"

"In GDP calculation, the positive impact of faster-than-expected export growth will be partly offset by higher prices of oil imports." - Arvind Virmani, Chairman, EGROW

All these arguments make it clear that exports alone can't power a robust GDP growth and sustain it in the coming years. Yet, the story of an upsurge in exports bodes well for the economy, particularly when the pandemic is not yet over and the likelihood of a third wave is hanging like a sword of Damocles. The question is whether $400 bn-plus exports can be sustained.

NITI Aayog Vice-Chairman Rajiv Kumar says the upswing will continue as many countries are shifting their sourcing bases from China as they want to reduce their dependence on one country. Also, the global trade as a whole is increasing, and so is the share of trade in global GDP, he says. "Our government has also undertaken a number of reforms to address supply constraints. That's why Indian exporters today are far more competitive to take advantage of this global scenario. Yes, $400 bn merchandise export is eminently sustainable," he adds. He also says that the government's recent Production-Linked Incentive Scheme, which incentivises companies to undertake incremental sales of products manufactured in India, will be helpful in this regard.

"The items that comprise 70% of global trade occupy only 30% of our export basket. We have a long way to go in manufacturing and exporting electronics" - Anup Wadhawan, Former Commerce Secy

In fact, sustainability of high exports will depend on India's ability to enlarge its and explore new geographies. Deepak Bagla, CEO of Invest India, says the government has recently emphasised a lot on "one district, one product" policy. "The idea is to create a new base of products which will find global interest. It will help broaden the nation's bucket of exports," he says. Invest India, which promotes investments into the country, is an arm of the ministry of commerce and industry.

Former commerce secretary, Anup Wadhawan, says there is enough elbowroom for Indian exporters to explore. "The items that comprise 70% of global trade occupy only 30% of our export basket. We have a long way to go in manufacturing and exporting electronics, sophisticated machinery etc.," he says. Clearly, India needs to promote export diversification to accrue long-term dividends. But in the short run, the focus should remain on boosting domestic consumption and investments — the key engines to drive economic growth on a sustained basis, which export alone will fail to accomplish.

Source: Shantanu Nandan Sharma, ET Bureau, 18.10.2021

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In the spotlights, API sector sees frenzied M&A action

Valuation of companies surge as global biggies step up investments

Fuelled by an 'Atmanirbhar' push and growing preference for India-made pharmaceutical raw materials over Chinese, the Active Pharmaceutical Ingredient (API) sector is in the spotlight for mergers and acquisitions (M&A). Attractive valuations, bright future prospects and certified plants make the Indian API sector attractive for Indian and global investors.

Sector observers revealed that several API players are planning a complete exit by stake sale. Two such Hyderabad and Chennai-based API makers are scouting for investors with valuations of approximately ₹1,500-2,000 crore each. The interested investors include Private Equity (PE) groups, chemical players and integrated pharmaceutical companies who look for APIs that are crucial in their formulations. Global majors such as True North Capital, Carlyle, Advent International have already spiced up the pan.

For instance, Bengalurubased RL Fine Chem is said to be in talks with investors, including the Asia-focussed PE Fund, PAG to sell its 100 per cent equity and monetise API capabilities.

Its three manufacturing facilities — two with USFDA certification — with annual turnover of ₹350 crore, makes it an attractive buy for those interested in tapping regulated markets like the US. The company eyes 10-12 times the EBITDA valuations. A company source told BusinessLine, that the investors prefer entire holding in the company, hence the promoters will make a complete exit post deal, which is estimated at ₹1,000-1,200 crore.

Rising valuations

The valuations for API, M&A have gone up from what was earlier at 6-8 times the EBITDA value to about 10-12 times. Formulations valuations ranges between 15 and 18 times the EBITDA. "The valuations have gone up as investors are getting competitive to pick stakes in API companies. Second, structural issues such as Chinese supply-chain disruptions and geopolitical tensions have prompted global pharma players to consider India to hedge their operations. Also, major pharma players are trying to be self-sufficient in critical API for manufacturing," said Ashesh Shah of TransContinental Venture Fund (TCVF), adding that return-oncapital in API wasn't very attractive due to the low-margin commodity products. But now the margins have improved.

Government push

Apart from market and the structural factors, a government push for the sector has further lifted the prospects. "Government schemes for healthcare covering the bottom-of-the-pyramid has yielded a composite impact on the pharmaceutical sector. Earlier, API was considered the poor cousin of Indian formulations industry. But the last 12-18 months has seen a sudden reversal of fortunes for API entrepreneurs," said Sanjeev Shah, a chartered accountant and valuation expert.

The API companies get about half of their revenue from exports. Acquiring an API company that has plants with certifications such as WHO-GMP, USFDA, Health Canada and European Medicines Agency gives immediate access to regulated markets. "Setting up an API facility is a complex procedure requiring multiple environmental clearances, approvals and public hearings (if set up outside demarcated industrial estate). Time required to start a new plant is two to three years. But looking at the current demand scenario, no investor would want to let go of this period," said Bhavesh Upadhyay, a pharma sector expert, adding that the next 15 years appear promising for API players in India.

Source: The Hindu Business Line, Rutam Vora 20.10.2021

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AstraZeneca sets up clinical data insights division in Bengaluru

Highlights Drug firm AstraZeneca on Wednesday said it launched a clinical data and insights division in India for data-related management of its clinical trials

The Bengaluru-based clinical data and insights (CDI) division is a critical advancement to support a growing global portfolio and build on internal data expertise, the drug firm said in a statement.

The CDI division works across therapy areas and portfolios, supporting early and late-stage clinical programmes from Phase 1 to Phase 3, with an integrated end-to-end approach for clinical data, analytics, insights and risk management, it added. Currently, a 30-member team, the division is expected to grow to over 100 members

by 2022, the drug firm said. "India has seen a constant uptick in investment in areas such as business services, engineering, digital, IT, R&D and product development from global Fortune-500 companies.

"AstraZeneca in India is no different – since its inception, AstraZeneca India has supported the global organisation with various services spanning IT, business services and R&D from our centres in Chennai and Bengaluru, on transformative projects," AstraZeneca India Managing Director Siva Padmanabhan said.

AstraZeneca's decision to set up the CDI division in India is only a natural progression of this to further capitalise on the extensive talent pool in the country, he added. At present, the drug maker's CDI footprint includes over 400 employees and around 700 data management professionals in vendor partnerships across six countries. "Clinical data and insight solutions enable pharmaceutical organisations such as ours to gain in-depth visibility into the patient's journey by extracting actionable insights from disparate data sources.

"The establishment of the CDI division in India is key to our strategic vision of being industry leaders in this space," AstraZeneca Vice President, Global Head of Clinical Data & Insights Natalie Fishburn said.

Source: The Hans India, 21.10.2021

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European firms keen to expand footprint in Telangana: KTR

Hyderabad: Telangana IT and Industries minister KT Rama Rao interacted with the members of European Business Group (EBG) in a webinar on Wednesday and asserted that there is a growing interest among European companies to expand their footprint in the State.

He further appealed to the EBG members to consider Telangana when they are looking for new projects in India. The minister said, "Among the global investments that we have received, it is a fact that the largest chunk has come from US-based companies. We also have sizeable investments from Japan, Korea, China, Taiwan etc. European investments were a few to begin with seven years ago, but of late their numbers are rising significantly. I have interacted with many of the European companies who have a footprint in Telangana, and I can share this with you that all of them are extremely satisfied with their locational choice and are planning to do much more in our State."

"I do hope that EBG members will spread the good word about us and will consider Telangana as a very appropriate location when they are looking for new projects in India," he added.

Policy push

Talking about TS-iPASS, the minister said that this policy brings about a number of path breaking reforms that have never been thought of in India before. "There are many salient features in this law relating to self-certification and time-bound guaranteed approvals," KTR added.

He said that the State government has been according top priority to sectors such as IT, electronics, life sciences (including pharmaceuticals, biotech, and medical devices), defence and aerospace, food processing, textiles, automotive (including electric vehicles), plastics and chemicals, gems and jewellery, retail, and logistics. Telangana also has the highest industrial land bank in the country, and in that sense, it becomes very easy for the government to identify a suitable land parcel for allotment to the industries, without going through the complexities of a land acquisition process.

KTR further highlighted that the State is power surplus with high-quality power. He also mentioned that high-quality skilled manpower is available for the industries. Telangana also offers multiple non-financial advantages. Being located in the centre of the country, the State offers the best bet for logistics. "Because of all these reasons, Telangana has become a go-to destination for some of the most marquee names from across the world as well as domestically. I also feel proud to share that more than 24 per cent of our investments come from our existing investors, meaning that these are repeat investments.

This obviously shows that our existing investors have found the going to be so good that they are prepared to bring more and more investments into the same State of Telangana instead of looking elsewhere," said the minister.

Source: Telangana Today, 20.10.2021

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India is close to turning the pandemic tide: Poonawalla

Adar Poonawalla, CEO of Serum Institute of India (SII), expects the world to go back to the pre-Covid times by this time next year

The country had administered 87.60 crore doses of SII's Covishield Covid-19 vaccine till Wednesday.

Adar Poonawalla, CEO of Serum Institute of India (SII), expects the world to go back to the pre-Covid times by this time next year. At a global level, he said it would take a year to reach a stage of normality where no testing or precautions were required. In comparison, India was in a good position as it had made huge strides in vaccinating a large population in such a small amount of time. "We are now very close to turning the tide on the pandemic," Poonawalla said. However, he cautioned against early celebrations. Poonawalla was speaking at the 'FICCI HEAL 2021' organised jointly with the ministry of health and family welfare and the NITI Aayog, after winning the Healthcare Personality of the Year award at the FICCI Healthcare Excellence Awards on Wednesday.

The award was a validation of all the risks and decisions taken in 2020 in building capacity, finding the right partner and scaling up, Poonawalla said. This takes a lot of time and very few companies in the world were able to scale up fast and that was because of the calculated risks and decisions taken at the start of the pandemic, he added. The country had administered 87.60 crore doses of SII's Covishield Covid-19 vaccine till Wednesday.

Source: Financial Express, 21.10.2021

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Long wait: Vaccine makers queue up for WHO approval, shows data

Industry insiders say typically a WHO EUL takes between two months and a year

As public interest piques around when a final nod from the World Health Organisation (WHO) would come for Bharat Biotech's Covaxin, data shows that several other Covid-19 vaccines from around the globe are also waiting for WHO Emergency Use Listing (EUL). Industry insiders say typically a WHO EUL takes between two months and a year. "During the pandemic, however, this audit process

has been expedited. Even then, the Chinese vaccines took five months before they got a final nod from the WHO," said a senior official at a vaccine firm.

France's Sanofi, US major Novavax (along with its Indian partner Serum Institute of India), and China's CanSinoBio, etc., are also awaiting WHO EUL (see chart). These makers have also submitted data around the same time as India's Bharat Biotech. Another industry source pointed out that for G-20 nations, the process of review is usually stringent. For countries that have stringent regulators such as the US, UK, Japan, EU, the process is usually faster.

VACCINES WAITING FOR EUL NOD FROM WHO

Covid-19 vaccine	Company	WHO EUL status	Decision Date
Sputnik V	The Gamalaya National Center	"Rolling" submission incomplete. On hold, awaiting completion of rolling submission	Anticipated date will be set once all data is submitted and follow-up of inspection observations completed
Covaxin	Bharat Biotech	Rolling data started on July 6, 2021	October 2021
Inactivated SARS-CoV-2Vaccine (Vero Cell)	Sinopharm (2)	Rolling data started on July 23, 2021	To be confirmed
Ad5-nCoV	CanSinoBio	Rolling data started August 9, 2021	To be confirmed
NVX-CoV2373/Covovax	Novavax	Rolling data starting in August 2021	To be confirmed
CoV2 preS dTM-AS03 vaccine	Sanofi	Rolling data started on July 30, 2021	To be confirmed
NVX-CoV2373/Covovax	Serum Institute of India	Rolling data starting in August 2021	To be confirmed
SCB-2019	Clover Biopharmaceuticals	Rolling data starting 20 September	To be confirmed

(2) Wuhan Institute of Biological Products

VACCINES WITH WHO EULs

Covid-19 vaccine	Company	WHO EUL
BNT162b2/COMIRNATY Tozinameran	Pfizer-BioNTech	Dec 31, 2020
AZD1222 Vaxzevria	AstraZeneca	Feb 15, 2021 *
Covishield (ChAdOx1_nCoV-19)	Serum Institute of India	Feb 15, 2021*
Ad26.COV2.S	Janssen	Mar 12, 2021
mRNA-1273	Moderna	Apr 30, 2021
SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	Sinopharm (1)	May 7, 2021
COVID-19 Vaccine (Vero Cell), Inactivated/ CoronavacTM	Sinovac	Jun 1, 2021

* manufactured by AstraZeneca-SKBio (Republic of Korea)
(1) Beijing Institute of Biological Products

TO-DO LIST FOR MANUFACTURER

- Manufacturing quality data
- Non-clinical data and clinical data
- A plan to monitor quality, safety and efficacy in the field and an undertaking to submit any new data to WHO as soon as the new data are available
- Labelling details

On Monday, the WHO clarified that the timeframe for EUL procedure is dependent on how quickly the company producing the vaccine is able to provide the data required for WHO to evaluate the vaccine's quality, safety, efficacy and its suitability for low- and middle-income countries. It added that it cannot "cut corners" before recommending a product for emergency use. Bharat Biotech has submitted "one last piece of information" on Monday. "If the information provided addresses all questions raised, WHO and the Technical Advisory Group (TAG) will complete the assessment and come to a final recommendation on the EUL," WHO said.

Source: Sohini Das, Business Standard, 20.10.2021

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TNIE Expressions: 'Pharma sector needs Government push', says Secretary General of IDMA

It has taken more than 40 years to come to the position we are in today, so it will certainly take us more time, but we are going in the right direction.

Government support is needed on various tax benefits for innovation and research in the pharma manufacturing space, says Daara B Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA), during an interaction with the Editorial Director of *The New Indian Express* Prabhu Chawla and noted journalist Kaveree Bamzai in *TNIE Expressions* on Thursday.

On the question of how far India is from becoming a global manufacturing hub, Patel said, It has taken more than 40 years to come to the position we are in today, so it will certainly take us more time, but we are going in the right direction. He said, "We are the third largest manufacturer of formulations because of what we used to do till 2005 owing to the facilities that were available."

He emphasised on the need "to shift from cost arbitrage to intellectual arbitrage", explaining, "We need to spend more time on research and development. We need to have more thorough interactions among the industry academia and we need government support on various taxes on R&D."

Patel informed that earlier, there was a 200% special tax benefit on R&D spend, which was reduced to 150%, and which is now only 100%. "If we have to do more R&D and come up in the value chain with more patented products, then we need the support from the government."

He called India the pharmacy for the world, noting that we supply to over 200 countries in the world.

Patel said the various issues the pharma industry is grappling with include product prices, the industry not being the preferred choice of employment, OTC policy for guidelines on products that can be sold over the counter and harmonisation.

Harmonisation, he added, is very crucial to get approvals from countries across the globe. "Even our companies which have USFDA approval are not put on fast-track by other countries," he said, adding, "we also need readymade people in pharma, for which, the curriculum has to be updated. "We are working with government bodies, and in a year or two, you should see solid support coming from the government of India to fuel our R&D," Patel said in the conversation.

Source: Express News Service, 15.10.2021

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