From the Desk of President

ABLE Association of Biotechnology Led Enterprises

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The e-newsletter for the Indian Biotech industry

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# Let's celebrate ABLE's 19th Anniversary on 22nd March

As the Covid-19 third wave ebbs, it is time to get back to our normal life as it was before March 2020. What better way than meet in person, exchange notes and plan together for the future. With this in mind, we are planning to celebrate the 19th anniversary on ABLE in Bengaluru on 22nd March 22 as a physical event. The event will also mark the resumption of ABLE's 'BioEconomy Conclave' Series where industry leaders will interact with nation's leading policy makers, celebrate the success stories of our innovative companies and prepare to face the challenges that may confront us in the near future.

More details will be shared soon.

Meanwhile, ABLE is proud of the fact that two of our key member companies have been recognized by the nation for their impressive efforts to vaccinate the nation during the Covid-19 pandemic. **Serum Institute** of India's founder chairman **Dr Cyrus Poonawalla** has been bestowed with the '**Padma Bhushan'** award for the stupendous efforts to supply over 150 crore doses of Covishield vaccine against the SARS-CoV-2 virus. Also, **Bharat Biotech's** co-founders **Dr Krishna Ella and Mrs Suchitra Ella** too have been honored with the '**Padma Bhushan'** for their tireless efforts to produce the first home-made Covid vaccine, Covaxin.

Adding to the lustre is the prestigious 2022 **William C Holmberg Award** for Lifetime Achievement in the Advanced Bioeconomy category being given to our member **Praj Industries** Founder and executive chairman **Dr Pramod Chaudhari**. He is the first recipient of this global award from Asia.

Team ABLE has successfully submitted the inputs gathered from our members on the Biological Diversity (Amendment) Bill 2021 to the Joint Parliamentary Committee chaired by Dr Sanjay Jaiswal, MP. We are hopeful that Parliament will approve the various industry suggestions and pave the way for better utilization of our immense biological resources for the greater benefit of humanity.

We are happy to note that the Union Budget for 2022-23 has responded to an issue for greater protection of export/import data privacy raised by an ABLE delegation with the Finance Minister, Mrs Nirmala Sitharaman in July 2021.

This newsletter has details of key changes being made in the various tax laws that will be beneficial to many of our members in 2022-23 and also the accolades won by our members in the recent past

Happy Reading!

G S Krishnan
President, ABLE

## ABLE Governing Body Members

**Non-executive Chairperson**
Dr Kiran Mazumdar-Shaw

**President**
Mr G S Krishnan

**Vice President**
Dr Anand Anandkumar

**General Secretary**
Mr Ravi Bhola

**Treasurer**
Dr Anand Anandkumar

**Governing Body members**

Dr Ezhil Subbian

Dr Kavitha Iyer Rodrigues

Dr Shama Bhat

Dr Shriram Raghavan

Mr Venkat Kamalakar Bundia

COO
Mr Narayanan Suresh

# ABLE MEMBERS GET PRESTIGIOUS NATIONAL, GLOBAL AWARDS

## IN THIS ISSUE



## Dr. Cyrus S. Poonawalla conferred with Padma Bhushan 2022

**ABLE is proud that Dr. Cyrus S. Poonawalla, Dr Krishna Ella, and Dr Suchitra Ella have been awarded the Padma Bhushan Award by the Government of India. This is India's third highest civilian award.**

The Biotech fraternity congratulates Dr. Poonawalla and Dr Krishna & Dr Suchitra Ella and their respective organizations Serum Institute of India and Bharat Biotech International the best in the years ahead.

Dr. Cyrus Poonawalla is the founder chairman of Poonawalla Group which includes the Serum Institute of India. The Serum is India's top biotech company and the world's largest vaccine manufacturer by the number of doses produced and sold globally (more than 1.3 billion doses). Serum partnered with AstraZeneca and the University of Oxford to manufacture the Covishield vaccine. India emerged as a major vaccine provider to the world, thanks to Serum.

After launching Serum in 1966, he contributed to the vaccine production of the world. Serum launched its first therapeutic anti-tetanus serum within two years, and began producing the anti-tetanus vaccines. By 1974, Serum Institute introduced the DTP vaccine to protect children from diphtheria, tetanus and pertussis, followed by an anti-snake-venom serum for snakebites in 1981.

Poonawalla led Serum's journey of innovations. In 1989, Serum began the production of its measles vaccine M-Vac and within a year, it became country's largest vaccine manufacturer; the title holds even today. In the 80s, India was made self-sufficient for tetanus, diphtheria and whooping cough vaccines, thanks to the production from Serum Institute.
In 1994, Serum Institute got accredited by the World Health Organization (WHO) to export vaccines from India and started supplying high quality vaccines to UN Agencies such as UNICEF (United Nations Children's Fund), PAHO (Pan American Health Organization).

Poonawalla's primary concept was not only to make life-saving drugs and vaccines but to see that every child get protection. At that time his dictum was "Health for all by 2000 AD". The resultant effort was the National Program of Immunization, which is largely dependent on the vaccines manufactured by Serum Institute and now that philosophy has proliferated worldwide to International UN Agencies.

His strong belief in “No Compromise with Quality” and willful commitment in “Health for All with affordable Vaccines” has today led Serum Institute to become India’s leading biotech company.

Poonawalla was married to the late Mrs. Villoo Poonawalla and has a son, Adar, who is currently the chief executive officer (CEO) and executive director at the Serum Institute.

**Serum Institute of India managing director Dr Cyrus S Poonawalla, said it was a great privilege for him to be among a prestigious list of illustrious people who have contributed to the growth of the country.**

Mr Adar Poonawalla thanked the Union government for “acknowledging my mentor, my hero, my father”, while NCP chief Sharad Pawar tweeted he was proud of “batchmate Cyrus Poonawala for being awarded Padma Bhushan for the outstanding contribution in the field of medicine”.
My heartiest congratulations to all the deserving individuals who will receive the Padma awards this year. I thank the government of India for acknowledging my mentor, my hero, my father, Dr. Cyrus Poonawalla.
Source: The Hindu

## Bharat Biotech’s Dr. Krishna Ella, Suchitra Ella get Padma Bhushan

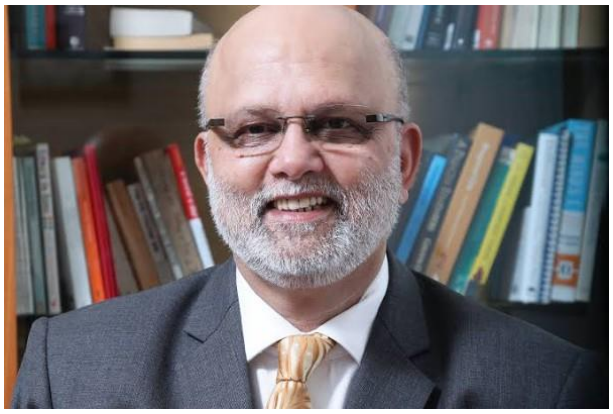
**Bharat Biotech Limited Chairman and Managing Director Dr. Krishna Ella and his wife Suchitra Ella have also been conferred with Padma Bhushan award.**

The duo has been selected for their distinguished service of high order in the category of trade. Under Dr. Ella’s leadership, Bharat Biotech had grown to become a global leader in innovative vaccines, especially with Covaxin, the country’s indigenous COVID-19 vaccine in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

Mr. Ella is the CMD and Ms. Ella, the Joint MD of Bharat Biotech, owns 145 patents and has delivered over 4 billion vaccines doses globally. Though well known for its work, the Hyderabad-based vaccine maker shot to prominence with Covaxin, the indigenous COVID-19 vaccine.

Following the Padma award announcement, Raches Ella, their son, tweeted: “Congratulations to Suchitra Ella / Dr. Krishna Ella & Dr. Cyrus Poonawalla for being awarded the Padma Bhushan! Tremendous recognition to India’s mighty vaccine industry.”

# Praj Industries Executive Chairman Pramod Chaudhari wins the 2022 Holmberg Award for Lifetime Achievement in the Advanced Bioeconomy



**In Florida, The Daily Digest announced that ABLE member, Praj Industries Executive Chairman Pramod Chaudhari will receive the 2022 William C. Holmberg Award for Lifetime Achievement in the Advanced Bioeconomy**, and will give the Holmberg Memorial Address at ABLC 2022, the Advanced Bioeconomy Leadership Conference, on March 17, 2022. Dr. Chaudhari becomes the first recipient of the Award from Asia.

The award recognizes a lifetime of high achievement, courage, and character. It was named in honor of the first recipient, Lt. Colonel William C. Holmberg (USMC), winner of the Navy Cross, an architect of the US renewable fuels program at the Department of Energy and EPA, and a co-founder of the American Council on Renewable Energy.

Previous recipients are:
2014 Lt. Col William C. Holmberg
2015 Guido Ghisolfi, CEO, Beta Renewables (posthumous)
2016 Dr. Robert Graham, CEO, Ensyn
2017 Brian Foody, CEO, Iogen
2018 Vice Admiral Dennis V. McGinn, Assistant Secretary of the Navy
2019 Senator Charles K. Grassley of Iowa
2021 Dr. Jennifer Holmgren

“This Award recognizes the transition of the advanced bioeconomy from the successes of its first-generation of technologies in fuels and chemicals, to a new technology wave that unlocks countless new low-value feedstocks,” said Jim Lane, editor and publisher of The Daily Digest. “These high-value, low-carbon products that will allow so many now, and in years to come to make the transition to a Net Zero Carbon civilization, preserving both the Earth we love and our modern ways of living. This transition requires steadfast leadership, technological prowess, and deep commitment over a long period, and Dr. Chaudhari has shown all those qualities. He was a leader in the first-wave, a leader in the second, and a friend to all who meet him.” Dr. Pramod Chaudhari, is Executive Chairman of Praj Industries Ltd. He founded Praj in 1983, and developed it into a world-class engineering company specialized in agri-processing. As India’s largest bioeconomy technology company, Praj has completed more than 1,000 engagements in over 100 countries, across five continents. Under his leadership, Praj developed technology for conversion of Cellulosic Biomass to 2nd Generation Renewable Fuels, BioGas and Renewable Chemicals & Materials, and Praj is now executing three commercial advanced biofuels projects for Indian OMCs. Globally, Praj is one of the handful of companies to achieve this feat. Praj has also set up first of its kind integrated demo plant of Compressed biogas (CBG). Further, Praj is also engaged in design & deployment of Biojet fuel technology in collaboration with Gevo Inc, USA.

Dr. Chaudhari has been involved since the very inception of the biofuels industry in India, and led the establishment of the Biofuels Cell under the Confederation of Indian Industries to accelerate growth of the biofuel sector. He is also accredited with pioneering contributions in starting the biofuels movement in Colombia and Thailand.

He is an alumnus of Harvard Business School's Advanced Management Program and received an honorary doctorate from the Tilak Maharashtra Vidyapeeth university in Pune, India. He received the 'Distinguished Alumnus Award' and 'Distinguished Service Award' by IIT, Bombay, and the 2020 George Washington Carver Award from the Biotechnology Innovation Organization.

Source: The Daily Digest

# FM Nirmala Sitharaman acts on ABLE suggestion to safeguard export/import data protection

## IN THIS ISSUE



At a meeting with Union Finance Minister, Mrs Nirmala Sitharaman in Bangalore on July 2, 2021, ABLE members had raised the issue of some private agencies extracting commercially sensitive prices etc from routine import/export data published by the Customs department. One of the ABLE members, Mr Ajay Bharadwaj, chairman of Anthem Bio, had then requested the FM to anonymize such crucial date of price, name of exporter/importer, quantity as it provides an opportunity to India's competitors to undercut our company prices.

Now in the Union Budget for 2022-23 presented by the FM on February 1, 2022, this issue has been taken up and Indian companies will be protected from the leakage of commercially sensitive information.
The government has proposed a new section, 135AA, in the Customs Act and added that the provision is aimed at 'bad state actors' and 'hackers' who illicitly mine commercially identifying and sensitive information and are engaged in selling transactional information.

"A number of websites have been identified by the CBIC who are selling data containing the name of exporter/importer, description of goods, quantity, value, classification etc. By selling commercially sensitive information, including the names of importers and exporters, they adversely impact the competitive position of Indian exporters in international trade," Revenue Secretary, Mr Tarun Bajaj, told the Business Standard newspaper. Mr Bajaj was present at the ABLE meeting last July and had taken note of the member's concerns.
As per the new section, which will be brought in with an amendment to the Customs Act through the Finance Bill 2022, if a person publishes any information relating to the value, classification, quantity of goods being exported from or imported into India, or the details of the exporter or importer, he shall be punishable for a jail-term of upto 6 months or a fine upto Rs 50,000 or both.
The new section 135AA will not be applicable if a person or entity is required to publish such information by law or if the government itself releases such data.

**ABLE would like to thank the Union government for removing a major problem faced by biotech exporters.**

**Other Key Budget provisions that help Biotech Industry**
(These are some of the key analyses done by ABLE member company Lakshmikumaran & Sridharan Attorneys, one of India's leading tax experts)

**Extension of Sunset Date for Start-ups**
**Existing Position:** The provisions of Section 80-IAC provide for tax deductions to startups. Eligible startups have to be incorporated on or after 1st April 2016 but before 01st April 2022.
**Proposed Amendment:** Cut-off date for incorporating entity proposed to be extended by a year to 31st March 2022. The amendment will be effective from 01 April 2022.

**Extension of Sunset Date for Manufacturing Companies**
**Existing Provision:** The provisions of section 115BAB provide for a concessional corporate tax rate for companies engaged in the business of manufacturing or production of article of thing. One of the stated provisions is that the company should have been set up and registered on or after 1st October 2019 and has commenced manufacturing or production of an article or thing on or before 31st March 2023.
**Proposed Amendment:** Cut-off date for commencement of manufacturing or production of article of thing to be extended by a year to 31st March 2024. The amendment will be effective from 1st April 2022.

**Phased Manufacturing Program (PMP)**

- The Phased Manufacturing Program (PMP) is being introduced with the object to promote Domestic Manufacturer in line with Make In India and Atmanirbhar Bharat scheme.
- PMP aims to create domestic capacity, provide level playing field to MSME's, easy access to raw materials to curb supply side constraints and enhance ease of doing business in order to promote domestic electronic manufacturing and increase in export of value-added products.
- Presently, the PMP is being introduced for the following three products w.e.f. 01.04.2022:

    - Wrist wearable devices
    - Hearable Devices; and
    - Smart meters

# PHASED MANUFACTURING PROGRAM (PMP) FOR WRIST WEARABLE DEVICES (SMART WATCHES)

| S.No. | Chapter, heading, sub-heading, or tariff item | Commodity | From | To | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2022-2023 | 2023-2024 | 2024-2025 | 2025-2026 |
| PMP for Wrist Wearable Devices (Smart watches) [CN 11/22-Cus. dated 01.02.22 read with CN 15/22-Cus. dated 01.02.22 (S. No. 4(i) ] | | | | | | | |
| Following parts [S. No. 1 to 7] for manufacture of wearable devices falling under Tariff Item 8517 62 90 of the Customs Tariff | | | | | | | |
| 1. | 8517 79 10 | Printed Circuit Board Assembly (PCBA) | NIL | NIL | 10% | 15% | 15% |
| 2. | 8544 | Charging Cable | 10% | NIL | 5% | 10% | 15% |
| 3. | 39, 73, 85 | Specified parts of wearable devices | As per CTH | NIL | 5% | 10% | 15% |
| 4. | 8507 60 00/ 8507 80 00 | Battery | 15% | NIL | 5% | 10% | 15% |
| 5. | 8517 79 90 | Display Assembly | NIL | NIL | NIL | 5% | 10% |
| 6. | 8501 | Vibrator Motor | 10% | 10% | 10% | 10% | 10% |
| 7. | Any Chapter | Parts, sub-parts, and raw materials for use in the manufacture of the S. Nos 1 to 6 above | As per CTH | NIL | NIL | NIL | NIL |

| S.No. | Chapter, heading, sub-heading, or tariff item | Commodity | From | To | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2022-2023 | 2023-2024 | 2024-2025 | 2025-2026 |
| 8. | 8517 62 90 | Wrist Wearable Devices (Commonly known as Smart Watches) | 20% | 20% | 20% | 20% | 20% |
| Note: IGCR conditions shall apply for the items in S. No. 1 to 7 above. | | | | | | | |

# PHASED MANUFACTURING PROGRAM (PMP) FOR HEARABLE DEVICES

| S.No. | Chapter, heading, sub-heading, or tariff item | Commodity | From | To | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2022-2023 | 2023-2024 | 2024-2025 | 2025-2026 |
| PMP for Hearable Devices [CN 12/22-Cus. dated 01.02.22 read with CN 15/22-Cus. dated 01.02.22 (S. No. 4(iv) ] | | | | | | | |
| Following parts [S. No. 1 to 6] for manufacture of hearable devices falling under sub-headings 8518 21, 8518 22, 8518 29 or 8518 30 of the Customs Tariff | | | | | | | |
| 1. | 8518 90 00 | PCBA for Hearable Device | 10% | NIL | 10% | 15% | 15% |
| 2. | 8544 | USB Cable | 10% | 15% | 15% | 15% | 15% |
| 3. | 73, 74, 85 | Specified parts of hearable devices | As per CTH | NIL | 5% | 10% | 15% |
| 4. | 8507 60 00/ 8507 80 00 | Battery | 15% | NIL | 5% | 10% | 15% |
| 5. | 8518 90 00 | Speaker Assembly (Pre-assembled speaker driver with protective mesh, but not including PCBA or battery) | 10% | NIL | NIL | 5% | 10% |

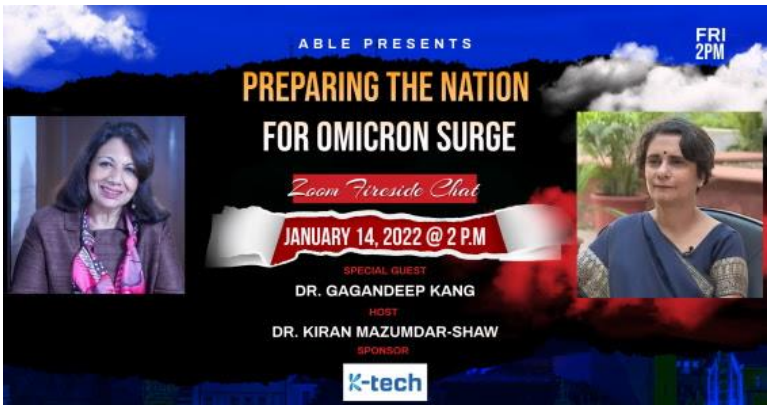
| S.No. | Chapter, heading, sub-heading, or tariff item | Commodity | From | To | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2022-2023 | 2023-2024 | 2024-2025 | 2025-2026 |
| 6. | Any Chapter | Parts, sub-parts, and raw materials for use in the manufacture of the S. Nos 1, 3, 4, and 5 above | As per CTH | NIL | NIL | NIL | NIL |
| Note: IGCR conditions shall apply for the items in S. No. 1 to 6 above.<br>**L&S Comments:** classification indicated in the notification for various items may have to be examined in accordance with customs tariff. | | | | | | | |
| 7. | 8518 21, 8518 22, 8518 29, 8518 30 | Hearable Devices Note – Hearable devices mean: true wireless stereo (TWS), headphones, earphones and similar devices like earbuds, neckbands, headsets, etc., whether or not combined with a microphone, being capable of connecting through a wireless medium; and | 15% | 20% | 20% | 20% | 20% |

| S.No. | Chapter, heading, sub-heading, or tariff item | Commodity | From | To | | | |
|---|---|---|---|---|---|---|---|
| | | | | 2022-2023 | 2023-2024 | 2024-2025 | 2025-2026 |
| | | (ii) portable Bluetooth Speakers comprising of an amplifier and loudspeaker(s) with maximum output power not exceeding 40 Watts, having battery as a source of power and capable of wireless Connectivity through bluetooth. | | | | | |

# ABLE WEBINARS

## Fireside chat with Dr Gagandeep Kang: "Preparing the Nation for Omicron Surge"

January 14, 2022




The fireside chat was held on Jan 14 at 2pm by host Dr Kiran Mazumdar-Shaw, Executive Chairperson, Biocon Ltd & Biocon Biologics Ltd; and non-executive Chairperson ABLE with Dr Gagandeep Kang, eminent virologist & Prof, CMC, Vellore and Fellow, Royal Society. Virologist Dr Gagandeep Kang talks about Omicron severity and tackling strategy

In fireside chat with ABLE Chairperson Dr Kiran Mazumdar-Shaw, Dr Gagandeep Kang, Professor in the Department of Gastrointestinal Sciences at the Christian Medical College, Vellore, India speaks her mind on managing Omicron. She called for isolation days be reduced to five days in the country.

She argued that reducing days of isolation to five is “it will miss about 30 per cent of potentially infectious people, but many of those numbers are based on a virus that had a much longer generation time. Delta variant and others were not as quick as Omicron. With Omicron, we have seen doubling time of two to four days, whereas for other viruses, it was

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four to six days". She said that based on this information, it will not be a problem to shorten isolation to five days.

Dr Kang warned that going by the history of pandemics, many come in wave patterns, and most of these patterns are varied. "With most pandemics, you tend to see an oscillatory pattern, so the first wave may be small, second larger, third may be smaller or larger than the second wave, but as you get to the tail of the pandemic, you see the oscillations beginning to decrease in size and become stretched out over time," she said. However, she warned that it cannot be guaranteed that we will get lucky, like we have with the Omicron variant.

Answering a question on when people could travel freely, she said, "If no new challenging variant comes along, and it continues to be antigenically related to the variants we have seen so far, we can expect to see travel opening up in 2022, and further in 2023."

Speaking on booster doses, Dr Kang said people must now junk the idea that we are going to get permanent protection against infection. She reasons that infection is short-lived, and it won't make sense to keep vaccinating every three months to gain protection against infection. The focus has to be on the severity of the disease and preventing deaths, and double vaccine dose is working.

Appreciating the government's technology-based apps providing real-time data to manage the pandemic, Dr Kang said there is definitely a need to integrate and link databases.

During the chat, Dr Kang appreciated the government's technology-based apps for providing real-time date to manage the pandemic. She suggested that in the next stage, various such databases should be integrated to make it more useful in the future.

Dr Kang emphasized that the Covid-19 will become endemic in the country and people have to learn to live with it. There is no permanent protection against the infections and she did not favor regular booster doses. She advised that frequent lockdown of all economic activities is not the answer to the pandemic and the focus should be on reducing the severity of the disease and prevent deaths.

She mentioned that we learn from the history of various such pandemics that many come in wave patterns, and most of these patterns are varies. "With most pandemics, you tend to see an oscillatory pattern, so the first wave may be small, second larger, third may be smaller or larger than the second wave, but as you get to the tail of the pandemic, you see the oscillations beginning to decrease in size and become stretched out over time." She concurred with the observations of many virologists the world over that the mild Omicron induced third wave as a lucky break in pattern and thanks to this we can expect to see travel opening up in 2022.

Dr Kang fielded a wide range of questions from the audience and the Q&A Session was moderated by Dr P M Murali, President, ABLE Council of Presidents and Mr Narayanan Suresh, COO, ABLE. Mr G S Krishnan, President, ABLE, thanked the speakers for the excellent and informative session on a timely topic.

# ABLE Webinar: Biotech Industry inputs on recent amendments to the Biological Diversity (Amendment) Bill, 2021

January 21, 2022


ABLE conducted this webinar on Jan 21 at 4pm to collect member inputs to be presented to Parliament with the expert speaker **Dr Malathi Lakshmikumaran**, Executive Director and Practice Head, New Delhi with **Dr PM Murali,** President, ABLE Council of Presidents as the moderator for this interactive session.

Our industry has been demanding several amendments to the Biological Diversity Act 2002 to make it biotech industry friendly. The government had introduced many changes in the Act and presented it to Parliament in December 2021 as Biological Diversity (Amendment) Bill, 2021. A Joint Committee of Parliament is reviewing the amendments and has sought further suggestions. The Committee will introduce it for Parliamentary approval in February.

Members participated very actively in presenting their various suggestions during the webinar. Dr B Meenakumari, ex-head of National Biodiversity Authority, highlighted the several steps taken during her tenure to cushion the impact of some of harsh provisions that affected the biotech industry. Mr Shrikumar Suryanarayan, ex-president of ABLE and a member of a technical committee that studied some of the provisions of the original Act, voiced concerns over some issues that may continue to symie innovation in the biotech industry to make best use of our vast biological resources for greater good of the humanity.

ABLE compiled all the suggestions from the members and has presented a detailed memorandum seeking further changes, explanations to some of the provisions of the Biological Diversity (Amendment) Bill 2001, to the Joint Parliamentary Committee chaired by Dr Sanjay Jaiswal, MP, before the deadline on January 31, 2022. The Parliamentary Committee is now gathering further detailed inputs from State Biodiversity Boards before making its final recommendations to Parliament for approval.

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# ABLE EVENTS

## 2nd Annual Women's Biotech Conclave & Awards 2022

March 2022


Golden Jubilee Biotech Park for Women invites Applications from Women Achievers in the field of Life Sciences/ MedTech/ Agri Biotech/ Healthcare/ Marine Biotech for receiving the prestigious awards on the eve of International Women's Day March 2022.

**Last date of application is 20th February 2022**
**Apply to gm@biotechpark.co.in**

On this year's International Women's Day - 8 March 2022, the Park along with the Association of Biotechnology Led Enterprises has decided to take another pioneering step, to set up the country's first National Awards to celebrate women entrepreneurs in Biotechnology. The Awards will be an annual event conducted on International Women's Day. The event will feature a Conclave of women in Biotech. It is proposed to select outstanding women in the life sciences field for the following awards: Lifetime Achievement Award, Biotech Women Scientist of the Year and Innovative Biotech Women Entrepreneur in Tamil Nadu

## BioEconomy Conclave & ABLE 19th Anniversary Celebration

March 2022


ABLE BioEconomy Conclave is scheduled to be held on 22nd March 2022 from 10-6pm. Venue is yet to be announced.

# ABLE MEMBERS IN NEWS

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## ABLE member String Bio shows the way to convert methane into biostimulants for crops, animal feed

A Bengaluru-based firm, String Bio, has built a platform to convert methane into various solutions such as biostimulants for crops, animal feed and alternative protein for human consumption to reduce the release of the greenhouse gas that is 80 times more potent than carbon dioxide.

Since 2014, String Bio, one of the world leaders in gas fermentation, has had a strong IP (intellectual property) protected platform called String Integrated Methane Platform which enables the production of high-quality ingredients from methane via the fermentation process.

Though firms in the US and Europe convert methane, the Bengaluru-based firm differs from them as it converts methane from biogas for fermentation, says Ezhil Subbian, Co-Founder and Chief Executive Officer, String Bio.

It is the only global player with a commercial solution for such a technology. This enables the creation of carbon-friendly products using greenhouse gas as raw material. On the other hand, the global competitors use methane from natural gas for their process.

**Biostimulant products**

The conversion of methane has helped String Bio prepare a pipeline of products for various end markets starting with crop inputs for agriculture, says Subbian. One of them is ImpaKt TM, a peptide-based biostimulant, while another is CleanRise TM, a microbial-based biostimulant - both of which are used for sustainable food production.

"Both products are methane-derived, chemical-free, natural biostimulants that have multiple effects on plant growth including increased vegetative growth, enhanced root development, better soil health, stress tolerance and increased yield. They address the growing need for increased productivity and reduced greenhouse gas emissions from agriculture," she said.

Amino acids and peptides play a critical role in maintaining various plant physiological processes. The application of Impakt improves the plant cell metabolism and signalling processes resulting in enhanced root architecture, enhanced photosynthetic rate, yield, and produce quality, said Ezhilan, who founded the firm with her husband, Vinod Kumar.

**Carbon-friendly**

Impakt is manufactured from methane using a patented fermentation process. "The use of potent greenhouse gas for manufacturing crop inputs makes the products carbon friendly. The use of the products is better for the farmer, consumer, plant and planet. The use of

Impakt has increased yield in groundnut by 25 per cent, in tomato and marigold by 20-30 per cent," the String Bio CEO said.

These products are suitable for both conventional and organic farming systems. The Bengaluru firm has also developed a protein ingredient for animal nutrition - PROfit/PRO-DG, an alternative protein component for animal feed, besides a similar protein ingredient for human nutrition.

Ezhil said her firm has worked with many farmers across 11 States, including Karnataka, Tamil Nadu, Andhra Pradesh, Maharashtra, Uttar Pradesh, Madhya Pradesh and Manipur. These farmers have used String Bio's products in over 30 crops, including paddy, maize, wheat and tomato, potato, marigold, chrysanthemum, horticultural crops, soyabean, red gram and groundnut.

**Catching attention**

Those who have worked with String Bio have been amazed with its platform's ability to convert a gaseous material like methane into a solid such as protein through the fermentation method. The science behind the conversion has caught the attention of people of various ages, she said.

"When we initially started talking about microbial protein, we had to educate our audience - we had a series of questions from 'How is your protein different from paneer?' to 'can you make sushi with this protein?' The overall space has evolved significantly these last five years. Today, the average urban customer is much more aware of alternative proteins and their impact," the String Bio co-founder and CEO said.

**Key milestones**

After the company was set up seven years ago, it initially focused on core technology development. Over the last couple of years, the company has achieved key milestones about technology and product development.

String Bio has now established a patent-protected technology platform for using greenhouse gas as a raw material for manufacturing, besides setting up the first commercial multi-purpose gas fermentation plant in Bengaluru. It has also validated and scaled its gas fermentation process using methane from natural gas and biogas.

It has also developed methane-derived products for multiple end uses, and its development works have earned it quite a few national and global awards, including the Future Food Asia Award.

Source: The Hindu Business Line

## ABLE member Dr Reddy's get DCGI nod for single-shot Sputnik light vaccine

A press release from the drug maker said Dr. Reddy's had submitted its application for approval to the DCGI in December 2021, in addition to data from clinical trial in Russia, following its Phase-III clinical trial of the single-shot Sputnik Light vaccine in India.

Sputnik Light is a single-dose vaccine and the same as the first component — recombinant human adenovirus serotype number 26 (rAd26) — of the two-dose Sputnik V vaccine.

The standalone Sputnik Light vaccine is the latest jab to be approved by the DCGI as part of India's national inoculation effort against COVID-19. Sputnik Light is the second COVID-19 vaccine to be made available in India by Dr. Reddy's, reaffirming the company's commitment to explore every avenue in the fight against the pandemic, it said.

Sputnik Light has been approved in over 30 countries around the world including Argentina, UAE, Philippines and Russia. In September 2020, Dr. Reddy's partnered with the Russian Direct Investment Fund (RDIF) to conduct clinical trials of Sputnik V and distribute the vaccine in India.

In April 2021, the DCGI granted approval to the two-dose Sputnik V vaccine for restricted use in emergency situation in India.

Source: The MSN

## ABLE member Bugworks Research Inc. secures US$18M Series B1 Funding from Reputed Global Investor Syndicate (The EU, UK, Japan, South Africa & India), led by Lightrock India

Bugworks Research, a clinical stage multi-indication therapeutics company, today announced the financing of US$18M Series B1. This round will support the clinical development of BWC0977, a *novel broad spectrum anti-bacterial agent* available in both IV and Oral forms, and the pre-clinical development of its best-in-class *Adenosine immuno-oncology* asset. Bugworks will continue to invest in its proprietary drug discovery platforms GYROX (for AMR) and DARE (for IO), and identify new drugs for serious, underserved indications. Bugworks' lead Antibacterial asset BWC0977 continues to be supported by CARB-X, the global non-profit partnership dedicated to accelerating antibacterial research to tackle the global threat of drug-resistant bacteria.

The Series B1 financing was led by Lightrock India and included existing investors *The University of Tokyo Edge Capital (UTEC) Japan*, *Global Brain Corporation in Japan*, *3ONE4Capital India*, *Acquipharma Holdings S.A*, *I.M Holdings B.V*. and *Featherlite Group India.* **Tejasvi Ravi,** representing LightRock India will join the company's Board of Directors.

The company is also deeply honored to add recognized global thought leaders as investors, including **Lord Jim O'Neill**, the author of *"The Review on Antimicrobial Resistance (AMR) 2016"* and **Dr. Kiran Mazumdar-Shaw,** *Executive Chairperson and Founder, Biocon Limited.*

**Anand Anandkumar, Chief Executive Officer, Bugworks Research** said, "*We are very excited about our lead clinical asset BWC0977 that is potentially the first novel truly broad-spectrum anti-bacterial drug in nearly five decades. We are very honored to welcome a syndicate of world class investors, who join our committed existing-investors in supporting our dual mission of combating AMR and hard to treat cancers."*

*"It is a privilege to partner with Bugworks in solving the problem of antimicrobial resistance (AMR) which is fast becoming one of the most important global public health crises, with the best of Indian talent and technology. Their in-house platform coupled with a truly global execution network, puts Bugworks in a unique position to deliver pathbreaking solutions to combat antimicrobial resistance (AMR*) and cancer," said **Ms Tejasvi Ravi who leads healthcare investments at Lightrock.**

Commenting on the investment in Bugworks, **Mr. Yurimoto, Founder and CEO of Global Brain Corporation, one of Japan's premier investment houses said**, *"We are extremely proud to partner with Bugworks, as the company invents new molecules to treat the worst infections and cancers. Bugworks is a unique company within our portfolio, focusing on innovation in biotech and life sciences, which can change the world forever."*

*"I am very pleased to join this investment round and to stay committed to one of the most innovative and nimble drug discovery startups from India, which is focusing on an issue of global significance, AMR; a silent pandemic with devastating consequences,"* said **Dr. Kiran Mazumdar-Shaw, CMD Biocon.** "*Their new program in the Immuno-Oncology space also validates the promise and potential of early-stage innovation from India to the world!"*

Source: PR Newswire Asia

# ABLE member Bharat Biotech gets permission for intranasal booster dose trials


Drugs Controller General of India (DCGI) gives permission to Bharat Biotech for intranasal booster dose trials. According to the Mint publication, India is expected to get an intranasal booster vaccine in March, after timely conduction of trials.

The Hyderabad-based manufacturer has proposed the booster dose for those who have been already been innoculated against Covid with Covishield and Covaxin vaccines.

Bharat Biotech aims to conduct clinical trials on 5,000 subjects (50 per cent vaccinated with Covishield and 50 per cent vaccinated with Covaxin). The interval between the second dose and booster dose will be six months, sources said.

Earlier in mid-December, the company sought permission to conduct clinical trials for its intranasal booster dose.

Meanwhile, the Drugs Controller General of India (DCGI) granted conditional regular market approval for COVID-19 vaccines Covaxin and Covishield for restricted use in emergency situations in the adult population.

According to Union Health Ministry, the vaccines will not be available in medical stores. The hospitals and clinics can now purchase the vaccines. Vaccination data has to be submitted to DCGI every six months. The data has to be updated on CoWIN app also.

According to Central Drugs Standard Control Organization (CDSCO), the proposals for regular market approval were reviewed by it in consultation with the Subject Expert Committee (SEC) for COVID-19. After a detailed deliberation, the committee recommended updating the status of approval of COVID vaccines -- Covishied and Covaxin from Restricted use in Emergency situation to the New Drug permission as per rules in the adult population with conditions.

The vaccines are for sale or for distribution under New Drugs and Clinical Trials (NDCT) Rules, 2019 in adult population with the conditions that the Firm shall submit data of overseas ongoing clinical trials of the product with due analysis on six monthly basis or as and when available, whichever is earlier.

Secondly, the vaccine shall be supplied for programmatic setting and all vaccinations done within the country to be recorded on CoWIN platform and AEFI, AESI shall continue to be monitored. The firm shall submit the safety data including Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI) with due analysis on six-monthly basis or as and when available. whichever is earlier as per NDCT Rules. 2019.

# ABLE member Serum Institute Gets DGCI Nod to manufacture Covid Vaccine against Omicron Variant for Test, Analysis

The Drugs Controller General of India (DCGI) has approved the Serum Institute of India's proposal to manufacture a vaccine against the omicron variant of coronavirus for examination, test, and analysis. The highly transmissible Omicron variant of COVID-19 was first detected in South Africa in November last year. This variant has over 30 worrisome mutations in its spike protein which makes it easy for it to evade through vaccine immunity.

"With reference to your application, please find herewith the permission to manufacture SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein nanoparticle vaccine (omicron variant) for examination, test, and analysis under the provisions of New Drugs and Clinical Trials Rules, 2019 to manufacture the test batches of the drug/drugs mentioned therein," an approval order issued on February 4 stated.

Director, Government and Regulatory Affairs at the Serum Institute of India (SII), Prakash Kumar Singh had put in an application to the DCGI on January 6 stating the Pune-based firm, in collaboration with Novavax Inc, is working on the development of a vaccine against omicron, an official source said, adding that the SII has obtained permission and licence to manufacture SARS-CoV-2rS drug substance for examination, test, and analysis.

"... the new coronavirus variant 'omicron' has already been reported in more than 100 countries and is spreading very fast worldwide and in our country also. Our CEO, Dr. Adar C Poonawalla is very concerned about the protection of citizens of our country and the world at large against coronavirus and its new variants and we are relentlessly working on the development of SARS-CoV-2 rS Protein (COVID-19) Recombinant Spike Nanoparticle Vaccine (omicron variant). "Development of this vaccine shall be another example of vaccine production strength of our country in line with the clarion call of our prime minister 'Making in India for the World' and shall further keep our country's flag flying high globally," Singh had stated in the application," the source said.

**Cumulative COVID-19 Doses Given In India Crosses 170 Cr**

India's total numbers of cumulative COVID-19 vaccine doses administered crossed the 170 crore landmark on Monday. According to the data, the daily vaccination tally is expected to increase with the compilation of final reports for the day by late night. The countrywide vaccination drive was rolled out on January 16 last year with healthcare workers (HCWs)

getting inoculated in the first phase. The vaccination of frontline workers (FLWs) started on February 2 last year.

Covishield is manufactured by Pune-based Serum Institute of India while Covaxin is manufactured by Hyderabad-based Bharat Biotech.

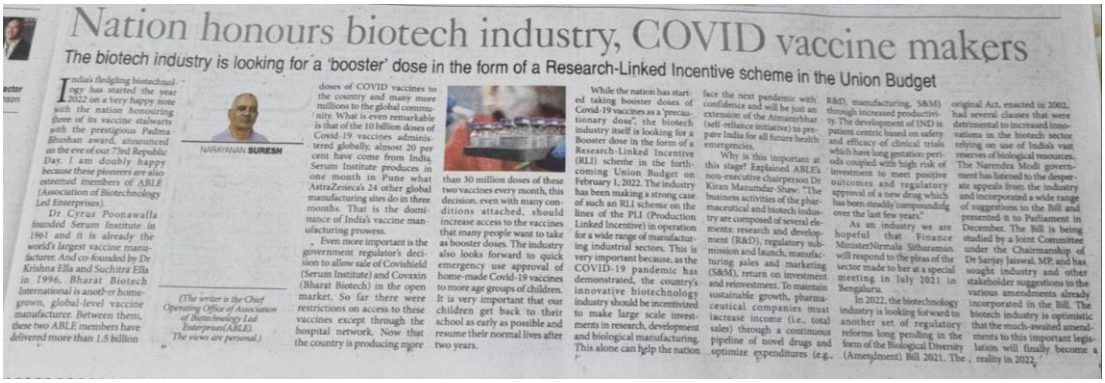
## The Future of Genomics: 10 Bold Predictions


The 2020 NHGRI Strategic Vision culminates with 10 bold predictions for human genomics by 2030, narrated by Pulitzer Prize-winning author, biologist and physician Siddhartha Mukherjee. Crafted to be both inspirational and aspirational, the predictions are intended to provoke thoughtful discussions (and even debate) about what might be possible in the coming decade. 2020 NHGRI Strategic Vision: https://www.genome.gov/2020SV

Article published in the journal Nature: https://www.nature.com/articles/s41586-020-2817-4

Watch here: https://www.youtube.com/watch?v=5kAL11m_fwM

## ABLE in News: The Pioneer, New Delhi



Nation honours biotech industry, COVID vaccine makers

The biotech industry is looking for a 'booster' dose in the form of a Research-Linked Incentive scheme in the Union Budget

India's fledgling biotechnology has started the year 2022 on a very happy note with the nation honouring three of its vaccine stalwarts with the prestigious Padma Bhushan award, announced on the eve of our 73rd Republic Day. I am doubly happy because these pioneers are also esteemed members of ABLE (Association of Biotechnology Led Enterprises).

Dr Cyrus Poonawalla founded Serum Institute in 1961 and it is already the world's largest vaccine manufacturer. And co-founded by Dr Krishna Ella and Suchitra Ella in 1996, Bharat Biotech International is another home-grown, global-level vaccine manufacturer. Between them, these two ABLE members have delivered more than 1.5 billion



NARAYANAN SURESH

(The writer is the Chief Operating Officer of Association of Biotechnology Led Enterprises(ABLE). The views are personal.)

doses of COVID vaccines to the country and many more millions to the global community. What is even remarkable is that of the 10 billion doses of Covid-19 vaccines administered globally, almost 20 per cent have come from India. Serum Institute produces in one month in Pune what AstraZeneca's 24 other global manufacturing sites do in three months. That is the dominance of India's vaccine manufacturing prowess.

Even more important is the government regulator's decision to allow sale of Covishield (Serum Institute) and Covaxin (Bharat Biotech) in the open market. So far there were restrictions on access to these vaccines except through the hospital network. Now that the country is producing more



than 30 million doses of these two vaccines every month, this decision, even with many conditions attached, should increase access to the vaccines that many people want to take as booster doses. The industry also looks forward to quick emergency use approval of home-made Covid-19 vaccines to more age groups of children. It is very important that our children get back to their school as early as possible and resume their normal lives after two years.

While the nation has started taking booster doses of Covid-19 vaccines as a 'precautionary dose', the biotech industry itself is looking for a Booster dose in the form of a Research-Linked Incentive (RLI) scheme in the forthcoming Union Budget on February 1, 2022. The industry has been making a strong case of such an RLI scheme on the lines of the PLI (Production Linked Incentive) in operation for a wide range of manufacturing industrial sectors. This is very important because, as the COVID-19 pandemic has demonstrated, the country's innovative biotechnology industry should be incentivized to make large scale investments in research, development and biological manufacturing. This alone can help the nation face the next pandemic with confidence and will be just an extension of the Atmanirbhar (self-reliance initiative) to prepare India for all future health emergencies.

Why is this important at this stage? Explained ABLE's non-executive chairperson Dr Kiran Mazumdar-Shaw: "The business activities of the pharmaceutical and biotech industry are composed of several elements: research and development (R&D), regulatory submission and launch, manufacturing sales and marketing (S&M), return on investment and reinvestment. To maintain sustainable growth, pharmaceutical companies must increase income (i.e., total sales) through a continuous pipeline of novel drugs and optimize expenditures (e.g., R&D, manufacturing, S&M) through increased productivity. The development of IND is patient centric based on safety and efficacy of clinical trials which have long gestation periods coupled with high risk of investment to meet positive outcomes and regulatory approval of a new drug which has been steadily compounding over the last few years."

As an industry we are hopeful that Finance MinisterNirmala Sitharaman will respond to the pleas of the sector made to her at a special meeting in July 2021 in Bengaluru.

In 2022, the biotechnology industry is looking forward to another set of regulatory reforms long pending in the form of the Biological Diversity (Amendment) Bill 2021. The original Act, enacted in 2002, had several clauses that were detrimental to increased innovations in the biotech sector relying on use of India's vast reserves of biological resources. The Narendra Modi government has listened to the desperate appeals from the industry and incorporated a wide range of suggestions to the Bill and presented it to Parliament in December. The Bill is being studied by a Joint Committee under the Chairmanship of Dr Sanjay Jaiswal, MP, and has sought industry and other stakeholder suggestions to the various amendments already incorporated in the Bill. The biotech industry is optimistic that the much-awaited amendments to this important legislation will finally become a reality in 2022.

## ASSOCIATION OF BIOTECHNOLOGY LED ENTERPRISES (ABLE)

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