IDMA 61st Annual Day Celebrations 2023: A Report

IDMA celebrated its 61st Annual Day on Saturday, 11th February 2023 at Hotel Four Seasons, Worli, Mumbai. Earlier in the day, the 61st IDMA Annual General Meeting was held at the same venue with the active participation of a large number of members.

Prior to the AGM, the Membership Committee of IDMA had an interesting meeting where the deliberations were about increasing the IDMA Membership and most importantly focused on retaining the IDMA Members. The Membership Committee along with the State Boards were given the responsibility to retain their members. Another important decision taken was that every new member would be presented an IDMA Pin along with the welcome kit.

The 61st IDMA Annual General Meeting was chaired by Dr Viranchi Shah, National President along with Shri. Bharat Shah, Sr. Vice President, Shri. Mehul Shah, Hon. General Secretary and Shri. Daara B Patel, Secretary – General.

Shri. Daara B Patel began the proceedings by reading the Notice convening the meeting. The Annual Report for the year 2021-22 and the audited statement of accounts for the year ended 31st March 2022 was adopted by the members. CA Chetan Doshi & Associates was appointed as appointed Auditors for the year 2023-2024.

Dr Viranchi Shah began his address informing the members that IDMA had actively participated in 139 meetings last year that is at an average of a meeting every 3 days. This proved the activeness as well as the importance of IDMA as an Association. He also addressed the members about the latest happenings in the Pharma Industry. He informed the members about the earlier held Membership Committee meeting wherein it was decided to have EC meetings in the State Boards to boost the State Boards and also attract new members for IDMA. Madhya Pradesh State Board would be having the EC Meeting on 17th March 2023, Gujarat State Board in June, Tamil Nadu, Kerala & Puducherry State Board in August and West Bengal State Board in November 2023. Shri. S V Veeramani, Past National President was congratulated on assuming the post of the Chairman of Pharmexcil. The members had active deliberations about the latest

happenings specially the QR Code wherein the National President answered all their queries amicably. Dr Shrenik Shah, Chairman, IDMA GSB invited all the members to attend the 1st Pharma Live Expo & Summit to be held from 1st to 3rd March 2023 at Bombay Exhibition Centre, Mumbai. Shri. Hari from ICEXPO made a PowerPoint presentation to all the members and requested them to attend in large numbers. The 61st IDMA Annual General Meeting ended with a vote of thanks by Shri. Mehul Shah, Hon. General Secretary, IDMA.

The 61st Annual Day celebrations was graced by Chief Guest, Dr. (Ms.) Vinod Kotwal, Member Secretary, NPPA and Special Guests of Honour: Dr. N. Yuvaraj, IAS, Joint Secretary, Department of Pharmaceuticals, Shri Abhimanyu Kale IAS, Commissioner, Food & Drug Administration, Maharashtra and Guest of Honour: Shri Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries and Keynote Speakers: Shri. Rehan Khan, Managing Director, MSD India and Shri. Parijat Ghosh, Partner, Bain & Company. The celebrations were graced by Madam Jyoti Sardesai, Director, FDA, Goa and Dr H G Koshia, Commissioner, FDA, Gujarat along with the cream of Indian Pharma Leaders gathered together at this event which had a presence of 225+ participants.



Shri. Daara B Patel, Secretary General, IDMA welcomed the august gathering to the 61st IDMA Annual Day Celebrations and mentioned that the Indian Pharma Industry has done well for itself and specially with greater Government support in last few years we are doing much

better. He said that the pharma industry this year was marked by a greater degree of collaboration between the Government and Industry, with both playing a pivotal role in helping the pharma sector further strengthen its position in the global market keeping the patient in mind. He said that the Centre's recent decision to make the QR code mandatory on the packaging label of the top 300 drug formulations is a much-needed and well-thought-out step by the Government which would likely curb the sale of spurious and counterfeit drugs in India. (Excerpts from Shri. Daara Patel's welcome address & opening remarks is published in the following pages).



Dr Viranchi Shah, National President, IDMA in his Presidential Address stated that we have realized that during the last three years when there was a total disruption globally the Indian Pharmaceutical Industry, the Regulators, the Government and all the Stakeholders had come

together when there was a severe disruption due to the surge in COVID and it was during this difficult phase that we all worked together and created an impact as a Nation globally ensuring that when we say we are the pharmacy of the world we ensure that all the pharmacies across the globe had enough stock and despite all the disruptions that we had on the API front and on several other fronts we could successfully do it ensuring that the essential medicines are available at every single place where we used to cater and that was a major achievement. He further added that in the coming years, we have a wonderful opportunity and this opportunity in terms of the visioning exercise that we have done with the Government is likely to happen in the next 25 years. He mentioned about our Honourable Prime Minister vision with regards to Amrit Kaal (2047) wherein our Pharma industry has a growth potential to reach from 50 to 500 billion and this is a big opportunity for the industry. He said that in this journey, he thinks that three "I"s would be very important -

I for Individuals,

I for Industry and

I for India.

(Excerpts from Dr Viranchi Shah's Presidential address is published in the following pages).

Released of the 61st IDMA Annual Publication 2023

Dr Gopakumar G Nair, Editor was invited on stage and along with all the Dignitaries on the dais, released the 61st IDMA Annual Publication 2023.

Felicitation of Madam Jyoti Sardesai, Director, FDA Goa

Madam Jyoti Sardesai, the Director of Food & Drug Administration at Goa was felicitated at IDMA 61st Annual Day Celebrations in Appreciation of her being bestowed the Neha Shoree Award for Best Woman Drugs Control Officer for the year 2022 by All India Drugs Control Officers' Confederation (AIDCOC).



Interview with Padma Shri Dilip Bhai Shanghvi Shri. Mehul Shah, Honorary General Secretary of IDMA and the Promoter & Managing Director, Encube Ethicals introduced Padma Shri Dilip Shanghvi, Promoter and Managing Director of Sun Pharmaceutical Industries.

He said that Shri Dilip Bhai has played a vital role in the globalization of the Indian pharmaceutical industry and continues to inspire generations of entrepreneurs in their journey of success. He further added that Shri Dilip Bhai is a committed and generous patron of the IDMA and has attended numerous meetings and events amidst his busy schedule. He said that we all at IDMA are grateful to him for his exemplary contributions to the industry and IDMA.

Padma Shri Dilip Shanghvi thanked Shri. Mehul Shah for his introduction & nice words. He said that he thinks this interview idea is, to kind of share whatever Shri. Mehul asks him with a view to help the august gathering understand what they would have gone through when they were faced with an issue. He stated that he strongly believes that Indian Pharmaceutical industry has enormous potential both in India as well as outside of India. He further added that one simple factor that somebody like him with very little background in business as well as science could achieve what he has achieved with his team in Sun pharma, He thinks that all of us have also the same potential, same capability and if all of us work along with the Government then he thinks nothing is impossible.

Shri Dilip Bhai Shanghvi shared his thoughts on current state of the Indian pharmaceutical industry and how is it expected to evolve in the next 10-years. He gave us insights on how Sun pharma builds and nurtures great brands? He mentioned that in times of greater regulatory scrutiny, how Sun pharma is investing to meet ever-growing quality and compliance expectations of regulators. He briefed the august gathering on fostering an ecosystem in India which would be like the formidable partnerships between academia and companies in the US and Europe for R&D.

Shri Dilip Bhai Shanghvi candidly shared his experience and words of advice for all of us on introducing the next generation in business which often poses a challenge for the founder promoter with regards to the former's role fitment, entry timing, and acceptance by stakeholders. Lastly he talked about what keeps him motivated to work hard every day and remain excited about the future?

(Excerpts from Shri Dilip Bhai Shanghvi's Interview in a questions & answers format is published in the following pages).

IDMA - N I Gandhi Chief Mentor Award:

Shri. Daara B Patel briefed the august gathering about the IDMA – N I Gandhi Chief Mentor Award. He said that this year we have decided to present the IDMA – NI Gandhi Chief Mentor Award to our Immediate Past National President, Shri Mahesh Doshi. Shri. Patel informed that Shri. Mahesh Doshi has been indisposed for some time and he has regretted his presence due to ill health. Shri. Patel requested his son, Shri. Niraj Doshi to accept the Award. He then requested, Shri. Kunal Gandhi of Lyka Labs who are the sponsors of this Award and Shri. C I Gandhi to join in, to present the Award.

Shri. Patel announced that the IDMA – N I Gandhi Chief Mentor Award is proudly bestowed upon Shri. Mahesh Doshi in appreciation of his outstanding contribution to IDMA and the Indian Pharma Industry and also, for his consistent & unstinted support in meeting the objectives of the association.

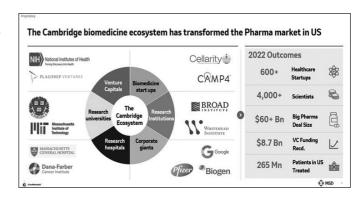
Shri. C I Gandhi mentioned that IDMA was always very close to his brother Late Shri. N I Gandhi's heart and Shri. N I Gandhi worked selflessly for IDMA till his last breath. Thus, the value, importance & significance of this Award increases tremendously. He said that Shri. Mahesh Doshi is the rightful person for this Award and deserves this award as he performed his best as the National President of IDMA during the two years of covid-19 pandemic.



Keynote Address by Shri. Rehan Khan, Managing Director of MSD India

Shri. Daara B Patel introduced Shri. Rehan Khan, Managing Director of MSD India, and requested him to deliver the keynote speech. Shri.

Rehan Khan began by expressing his gratitude to IDMA for inviting him to the event and stated that his goal was to spend 15 minutes discussing three stories: the pharmaceutical industry in India, MSD and its impact, and the biomedicine ecosystem in Cambridge.



Shri. Rehan began with a Chinese proverb, "May you live in interesting times." "If we look at the pharmaceutical industry, we certainly are living in interesting times," he mentioned. He then highlighted the significant progress made by the Indian pharmaceutical industry in the last 20 years, which has grown ten times to \$50 billion (including exports), with the majority of the market share held by Indian companies. He praised Sun Pharma as a hugely impressive company and lauded their growth story. Additionally, he discussed the contribution of India to vaccines and API markets globally. He spoke about how India is a talent hub in manufacturing, development, analytics etc. for international countries and how developing this talent is crucial for India.

He then proceeded to his second story on MSD and its important role in the pharma industry. MSD operates in 100 countries, is one of the largest pharma companies globally, employs almost 70,000 individuals, and has generated \$60 billion in sales. MSD is a research intensive biopharmaceutical company that is focused on science led strategy. Within MSD India, 85% of products are locally manufactured, which is unique for a multinational company. India is one of the largest API sourcing hubs for MSD products all over the world. Rehan stated that MSD has a strategic focus on Asia, particularly India, and is looking to serve more patients in India.

Shri. Rehan emphasized that what sets MSD apart is its passion and energy, as well as the company's philanthropic initiatives, such as MSD for Mothers and the Mectizan Donation Program. MSD for Mothers focuses on teaching doctors and patients about maternal health and creating a world where no woman has to die while giving life, while the Mectizan Donation Program helps to prevent blindness and is one of the oldest drug donation programs in the world, with over 300 million people and 4.4 billion doses.

Shri. Rehan then proposed taking a journey from Mumbai to Boston's Kendall Square, dubbed the most innovative square mile in the world. He spoke about the development of the biomedicine ecosystem in Boston's Kendall Square. Boston is a hub for science, with approximately 100 research hospitals and universities. The astonishing aspect of this infrastructure is that professors are more focused on research than teaching as their full-time jobs. Harvard Medical School alone has 12,000 professors, of which ~11,000 conduct research in disease areas of interest. This ecosystem leads to an emerging hub of startups funded by hundreds of VCs in the area. In 2022. Biopharma firms in Massachusetts attracted almost \$9 billion in venture capital investment. Corporate giants from the pharma, IT, and biotech industries, such as Pfizer, Biogen, and Google, often collaborate with startups and research institutions to develop novel treatments and bring new products to market. Total deal size from big pharma in Massachusetts was more than \$60 Bn in 2022. Massachusetts is now home to over 600 health care startups. Through this ecosystem, they have been able to treat 265 Mn patients in the US.

Shri. Rehan believes that the Indian pharma industry should not necessarily copy this model, but rather focus on learning from it. He spoke about emphasizing real collaboration through incentives to develop new ideas and to take risks. This is in contrast to a winner-take-all culture, where only a few individuals are successful. In this model, many people can succeed, and this feeds itself through upfront investments. Additionally, he noted that talent already exists in India and should be nurtured with investments in science. He ended his speech discussing India's potential to become the world's largest player in the biomedicine industry, and he encouraged that Indian pharma industry take advantage of all available opportunities.

Felicitation of Dr. H G Koshia, Commissioner, FDA, Gujarat

IDMA felicitated Dr. H G Koshia, Commissioner, Food & Drugs Control Administration, Government of Gujarat in appreciation of his Meritorious Service as the Longest Serving Commissioner, FDA – Gujarat and for his continued support to the Indian Pharma Industry.

Address by Special Guest of Honour Dr N Yuvaraj, Joint Secretary, Department of Pharmaceuticals

Dr N Yuvaraj in his address heaped praises on IDMA for inviting the Government Officials and also,



for felicitating them in front of the esteemed members of IDMA. He began his speech by mentioning the Pharma Industry in India is a self-made Industry and the support of the Government other than the Regulatory guidance and Regulatory parameters were minimal till recent

times. He said even than the Industry has done very well -50% is Domestic & 50% is Exports by value. He said that the Indian Pharma Industry specially the domestic market is huge as we have the largest population in the world.

Dr Yuvaraj mentioned that from the Government perspective, the Pharma Industry has a huge responsibility with regards to quality, pricing, R & D, etc. He mentioned that the DoP was founded in 2008 under the Ministry of Chemicals & Fertilizer. He said that under the guidance of our Hon'ble Minister Dr Mansukh Mandaviya Ji, NPPA & DoP were constantly & regularly having interaction with the Pharma Industry and also had major consultations with the Industry for their suggestions & inputs with regards to policies, issues, R & D, etc. He added that the Industry is very open with their ideas regards policy & other issues. He said that the Government has released many Bulk Drug Park schemes & PLI Schemes and other schemes for the benefit of the industry after consultation with the stakeholders. He said that India has ageing population, the Government health expenditure of Rs.86,000 crores is increasing, focus on terminally ill diseases like cancer, more awareness of the public and the young population focus on health only projects that we have a huge domestic market for our pharma industry. He added that the next 25 years would have a lot of scope for the Industry and the focus would be on Quality and mainly on innovative products.

Dr Yuvaraj mentioned about the 22 Committees of IDMA focused on different topics and said that he was currently involved with the NDPS Committee of IDMA. He thanked IDMA for the support to the Government across India.

IDMA Outstanding Value Creator of the Year Award

Shri. Daara B Patel announced that the first recipient of this new award titled "IDMA Outstanding Value Creator of the Year Award" is Dr Dushyant Patel.

Dr Dushyant Patel received the award in appreciation of his remarkable contribution to the Indian Pharma Industry specially for the Impressive Value Creation of his Organization. IDMA is proud to bestow on him the IDMA Outstanding Value Creator of the Year Award.

Shri. Jay Patel the son of Dr Dushyant Patel received the award on his behalf and he said that his Dad is very passionate about IDMA and truly values the contribution made by IDMA in his journey specifically the mentorship and guidance he has received from Sr IDMA Members and the network he has established. He said that IDMA has been a catalyst in building Astral. Shri. Jay Patel said that IDMA & Dr Dushyant Patel's mindset was essential in getting this milestone. He thanked everyone for the Award.



Address by Shri Parijat Ghosh, Partner, Bain & Company

Shri Parijat Ghosh, the Partner of Bain & Co. made an excellent presentation on "Recent Trends in Merger & Acquisitions in the Pharma Industry"

Shri. Parijat Ghosh said that merger & acquisitions is the red hot topic for the past few years. Although the merger & acquisition have been steady globally, in India, Merger & Acquisitions is on a high and there are a few points to be noted in regards to it:

- India is bucking the global trend in M&A: Global M&A is down yet India remains a M&A hotspot; Strategic deal value and volume are at all-time highs; Healthcare is a material contributor
- 2. Strong liquidity in the market: Democratization of M&A (first time buyers, smaller deal sizes), insurgents shopping, companies partnering with financial investors for big bets (e.g. Piramal-Carlyle, Encube-Quadria, etc.)
- 3. Positive sentiments for India pharma growth: Investors are confident on the India growth story, benefits from the China+1 trends; Boards are "leaningin" to make BOLD moves
- 4. Companies are seeking to disrupt the statusquo: Focus on new value creation pools, M&A for transformation not just growth; Big bets on higher P/E themes (category leadership, new segments, CHC, Engine 2, API platforms)

- Deal environment is qualitatively different: Rich multiples along with larger pipeline, quality assets with high revenue growth potential, multiple buy-out opportunities
- 6. However, healthcare deals are expensive, imperative to find additional sources of value and have a clear playbook: Clear deal thesis, rigorous diligence/pre close planning to underwrite revenue synergies, ensuring leadership alignment and talent retention are key to drive deal success
- 7. M&A momentum expected to remain strong:
 Despite some risks on the horizon, Critical to not sit it out; "serial bolt-ons" have almost 2x the annual total shareholder returns (TSR) of "inactives"; M&A during turbulence



Address by Shri Abhimanyu Kale, IAS, Commissioner, FDA Maharashtra

Shri Abhimanyu Kale said that he is pleased to be present in such an august gathering. He added that he is close to IDMA as IDMA Headquarters is in Mumbai and is

working closely with IDMA to bring back the glory of the Pharma Industry in Maharashtra.

Shri Kale mentioned that no regulator can be a friend of the manufacturer but he said that he believes in trying as the Glory of Maharashtra & India is enhanced due to the pharma industry and most importantly the manufacturers. He said that we regulators & administrators should remain the same. Shri Kale requested that he wanted feedback regarding approvals on WHO-GMP compliance and the Certificate of Pharmaceutical Product (CoPP). He thanked Dr Yuvaraj for the various schemes given by the Department of Pharmaceuticals to the industry. He also thanked Madam Dr Vinod Kotwal and NPPA for their support. He requested IDMA to organize training programs / workshops for FDA Officials and to educate them with regards to the recent trends in quality, technical & regulatory affairs.

Felicitation of Shri. S V Veeramani, Past National President and Chairman, Pharmexcil

IDMA felicitated Shri S V Veeramani, Chairman, Pharmaceuticals Export Promotion Council of India (Pharmexcil) and Past National President, IDMA in

appreciation of his continued support and contribution to the Indian Pharma Industry and for being elevated as Chairman, Pharmaceuticals Export Promotion Council of India (Pharmexcil).



Address by Chief Guest, Madam Dr Vinod Kotwal, Member Secretary, National Pharmaceuticals Pricing Authority (NPPA)

Dr. Viranchi Shah, Dr. Yuvaraj, Shri Abhimanyu Kale, Shri Mehul Shah, Shri Daara Patel and Ladies

& Gentlemen. It's a pleasure for me to be present here today at the 61st Annual Celebrations which have been organized by IDMA. I would also like to acknowledge the close association that I've had with the two Drug Regulators who got felicitated today which is Madam Jyoti Sardesai and Dr Koshia. You would be happy to know that my PhD which is on food regulation and under the umbrella of food regulation we had something called street food and the case studies from their states which is Goa and Gujarat appeared in my PhD thesis. My dual comparison was with international countries like Bangladesh, Singapore and so on. I wanted to highlight this point to say that these two are not only good regulators in their area but they do equally well in food. So as they say if you're good in something you good across. Congratulations to both of you and I would also like to acknowledge the company which got the award for value creation and it was a pleasure hearing Mr Jay Patel, the young son and I'm sure he must have taken messages from Shri. Dilip Shanghvi's address where he said what the young generation must have to do and actions speak louder than words. I once again say that it is my pleasure to be here.

After listening to the galaxy of speakers who have touched upon multiple things, I would like to share a few things. I have to compliment IDMA for having put up such an interesting session here today. I noticed the presence of OPPI & IDMA at this celebrations, it was wonderful to see all the three major Associations together with the Industry, it was a kind of "Manthan" as you say, you hear what is happening, good combination of industry experts, a Dion from the Industry, Regulators also speaking and therefore my congratulations to you for a wonderful program.

I thought that IDMA is the biggest drug manufacturers association in India but I think I was

corrected and I was told that it's not only in India but also the largest in the world. One of the members proudly told me that we're not the largest in India only but largest globally.

It is wonderful to see and know that the Association having members who are drawn from large medium and small companies and you are ready to address the different issues all of them may be facing and I see that the sessions that you have organized as a step in that direction only because you are through these inspirational leaders like Shri Dilip Shanghvi trying to tell you what is possible and nothing is impossible and then you also have the examples where you are felicitating the companies for value creation so again it's like you know telling them that you think big and we can create value. So it's wonderful for me to be here today and I was also happy to know that IDMA members I think export 75% of India's total drugs & pharma exports. It is really appropriate that the theme for your annual celebrations is Indian Pharma Global Health Care so it ties up very well with the strength of the Indian Pharma sector and how we can cater to the global health care needs.

All of you are aware that the Indian pharma sector has the triple advantage of cost, quality and scale so that's what has made us the leaders and we contribute to 22% of the global generic production by volume and we are the 3rd largest exporter of pharma by volume and 11th largest manufacturer by value. So the contribution of Indian Pharmaceutical industry has become more prominent. Everybody has started talking about pharma and everybody knows about certain drugs which have become part of the local Hexagon thanks to the Covid pandemic.

I must also put on record the appreciation for the role played by the Indian pharma sector in ensuring and assuring us that we will take each and every step to make available that the essential drugs which were needed for Covid pandemic and here I would like to tell Shri. Kale that most of the drugs used in COVID are under control and are scheduled drugs so the Government does that delicate balance of availability and affordability.

But the industry played a tremendous role in supporting us. I remember those days in the second wave of COVID, where the regulators present here used to sit till 2-3 o'clock in the night. We would be all be working to see to it that the supplies are reaching to the patients who are entirely in need of those drugs and the industry stood behind us

like a solid rock. So my compliments and my appreciation to all of you.

We would not have been able to serve the people of this country, if we did not have that kind of support from you it was wonderful. And during those times I remember the messages on the WhatsApp groups used to just go haywire, the messages that were being sent across and everybody was responding to it promptly. It is a really a great lesson for us and we take great pride in saying that we not only do this for India but also for the world.

Recently I was reading a book by Ms Debra McKenzie she's a writer who writes on new Scientist and this is a book that she has written which has a very long title and it says "The pandemic that never should have happened and how to stop the next one" it is a very insightful book. The lady has written on how the Covid pandemic unfolded and what was needed to be done, what could have prevented it from becoming what it did. There are lot of points that she has mentioned, two points which really made a lot of sense to me were one was that we have to learn for the future and second that we have to be prepared for similar new infectious diseases.

We cannot say that COVID pandemic is the end, as we have seen since the 90s, we had the SARS, Ebola, Zika, Swine so all these flu and then we had the COVID. She makes it a point that we have to be vigilant and be prepared to see how the future will unfold. Why I am raising this point is because pharmaceutical is a key player in our overall preparedness and therefore it is desirable that we have a systemic approach. How we approach it and this ties with the discussion that we have been having on R&D, innovations. One doesn't do the R&D and innovation only for the present but you also do it for the future.

As Shri Sanghavi brought out so well when he was answering the questions that you were asking him, when he said that the GDP of Pharma will be far more than the overall percentage. I agree to him because it is not only the ageing population but it is also the rise of noncommunicable diseases in the country which is making us become more dependent on pharma.

We have to be in that space where we can give good quality and affordable drugs to people, that is what we need to do and here we have crossed the so-called Rubicon of being the generic producer it is important for us to move up the value chain. I would like tell you about two points one that Dr. Yuvaraj made where he said that Pharma is self-made industry, that grew on its own and I would like to tie this up with what Shri. Rehan Khan said when he talked about and gave us the example of Cambridge square where you have the ecosystem, where you have the players of the pharma companies, the research institutions, so it is not something that has been done by the U.S. Government, it is something which has come up on its own.

And this reminded me that I had the opportunity to attend Jaipur literature festival last month which was in Jaipur. There I had the good fortune to listen to Dr. Siddhartha Mukherjee. There he was talking about his new book "The song of cell" Dr. Mukherjee is a researcher and an Oncologist and he is also an entrepreneur. He was basically talking about his research which is into the area of immunity and he was talking about having these weaponized T cells. He has set up a company which is based out of Bangalore and he has collaborated with some Indian entrepreneurs. That is the kind ecosystem we need to have in this country. If you really want to make a mark, then you have to look at the future say maybe the next ten, fifteen, twenty years. We need to be on the top where we can say that these drugs came out of India.

When I was listening to Shri. Rehan Khan talking about the Cambridge square it all tied up very well with what Dr. Siddhartha Mukhrajee was saying, here is a man who can crossover from being a researcher to an Oncologist to Entrepreneur. Maybe that kind of quantum will help us to grow in this sector.

The other speakers have touched upon so many other points and I think I would like to take this opportunity to explain or tell you about what NPPA has done. I would like to tell about two points one is the IPDMS 2.0 we have implemented it and there were a lot of issues when we started rolling it. And I am so happy to tell that we got very positive and constructive feedback from the industry. We took it very seriously and we are trying to address as many issues as we can so that we have a robust system which is useful not only to the industry but also to the Government. As Dr. Yuvaraj in his talk said, that is we do not have quality data. So I urge all the members of IDMA who are present here and those who have not yet registered, that it would be really great if you can start registering in IPDMS.

Already we have around 1150 companies who have registered out of which 1058 are pharma companies and we have around 4900 plants which have been brought to

the IPDMS, also some 5579 companies have filed Form V. I am giving these statistics to tell you that we have been making steady progress in companies getting registered on IPDMS and to see that more and more companies are slowly helping us to get that data.

We need good quality data for making decisions, sometimes we are accused as a regulator of not making proper decisions. For doing evidence based decisions we need data. So I take this forum as an opportunity and I want to urge all the IDMA members that please start using IPDMS you will find value in it and we'll also find greater value in it and we can work together.

The second point that I wanted to tell is that we have started revising the ceiling prices, so the revised schedule of the DPCO was notified by the Department of Pharmaceuticals on 11th November 2022, and we have revised ceiling prices of around 400 scheduled drugs, so if you look at how the drug regulatory system has evolved in this country you would see that we have been having a cost based system till DPCO 1995. And then we moved on to the market based system in 2013, the overall principle which has guided all these drug policies or drug price control orders has been through the principle of essentiality. We need to make essential drugs available to the consumers at an affordable price that is the philosophy behind it. But at the same time while fixing the ceiling prices we have tried to have the utmost transparency in how ceiling prices are fixed. The calculation sheets are uploaded on the NPPA website, we get many representations on the draft calculation sheets and let me assure all the members that each and every representation that we receive in NPPA is looked into and we examine it and if there are certain inherent flaws in what we have done, we revise it, also we go back to authority we revise and upload the corrected calculation sheets wherever it is required.

It is an alternative process which we have been following with transparency, all the minutes of the meetings of the authority are on the website, what is the pricing methodology apart from DPCO, that we have followed is also uploaded on website for everyone to see. So that industry comes to knows how the prices are being fixed and they come to know how the regulator is going to fix the prices.

We are doing brainstorming on lot of issues wherein we have touched upon the important aspects like Quality, Investing in R&D Innovation and looking ahead. We have achieved certain things, we have reached a certain stage, but we have to start looking and moving ahead and as all of us know that knowledge should be at the forefront of the convergence of drugs devices and data and move forward. The words like artificial intelligence, machine learning these are not simply buzzwords these are certain things which all of you must be already implementing in the work that you're doing so we need to be aware of what's happening and all these cutting edge IT techniques also need to be brought into our practices.

So that we become more efficient because equitable availability of health interventions can be provided through various interventions including the use of IT techniques. It is a matter of greatness to us that our sector today is a mature, robust, resilient and responsive sector. I have no problems and saying that and again I would like to place on appreciation to the sector which mitigated the challenges which arose out of the COVID pandemic in the country.

I congratulate IDMA on completing 61 years of existence and look forward to further consolidation and IDMA taking far more active role in making your members look beyond what they're doing and I'm sure you'll be able to do with this kind of program that you have put together it was great learning for me also.

We embark upon the Amrit Kaal which provides us a golden opportunity to fulfill the dreams and goals of this aspirational society. I would like to quote our Hon. Prime Minister what he said in his address to the nation on the 75th Independence Day, it is I urge the countrymen to start the Amril Kaal today by nurturing new possibilities realizing new resolutions and moving ahead with confidence and I would say that these words echo not only for us as a nation but to the Pharma sector as well and I wish you all the best and much more power as they say to you.

Felicitation of the Sponsors & Exhibitors

Shri. Daara B Patel thanked the below mentioned members who were the main sponsors at IDMA 61st Annual Day Celebrations for their continued support towards IDMA initiatives & activities:

- 1. Micro Labs Ltd.
- 2. Elysium Pharmaceuticals Ltd.
- 3. Gufic Biosciences Ltd.
- 4. Naxpar Pharma Pvt Ltd.

Shri. Daara B Patel thanked the below mentioned exhibitors who had taken an table space to exhibit their products at IDMA 61st Annual Day Celebrations for their support towards IDMA initiatives & activities:

- 1. ICEXPO Consults
- 2. Marsh India Insurance Brokers Pvt Ltd.
- 3. Onspot Solutions Pvt Ltd.
- 4. Tata AIA Life Insurance Company Ltd.

Release of Biomedical Waste Publication

Shri. Sacheen Gandhi, Founder & CEO and Dr. Artiben R Thakkar, Editor-in-Chief, Healthcopeia Outreach released their periodic supplement for public awareness titled "Biomedical Waste" at the hands of the Chief Guest, Dr Vinod Kotwal and our National President, Dr Viranchi Shah at IDMA 61st Annual Day Celebrations. The publication was distributed to all the dignitaries present on the stage and also to the august gathering at the celebrations.



Vote of Thanks by Shri Mehul Shah, Hon. General Secretary, IDMA

Shri Mehul Shah, Honorary General Secretary of IDMA, proposed a vote of thanks at IDMA 61st Annual Day Celebrations. He conveyed gratitude to all dignitaries

and participants for their presence at the annual celebrations. He specially thanked outstation members for attendance. He added that as India celebrated its 75th anniversary of Independence and IDMA celebrated its 60th year diamond jubilee in 2022, the growth projections for the Indian economy are the highest for any large economy over the coming decades. He concurred with Shri Dilip Shanghvi on something extraordinary is expected and it is indeed the beginning of Amrit kaal for India. India@100 in 2047 will be a much prosperous and inclusive India wherein the fruits of development would reach to everyone. He mentioned that the IDMA 61st year celebrations is in furtherance of the association's earnest efforts to bring all the stakeholders together for the mission of serving mankind with high-quality efficacious affordable medicines. Beyond celebrations, these milestones are an opportunity to envisage a vision for the country and the pharmaceutical industry. He enthused about the prospects of today's US\$50B Indian Pharmaceutical industry becoming US\$130B by 2030 and US\$600B by 2047. He

reinforced Dr. Kotwal's perspective that everyone has to come together to realize aspirations and spur innovation in the industry.

He thanked Government of India under the astute leadership of Shri Narendra Modi, our Honorable Prime Minister, for developing a new policy to cater to all range of therapies from gene therapy to precision medicines. He further informed that Smt. Nirmala Sitharaman, our Honorable Minister of Finance and Corporate Affairs in the budget 2023 announced launch of a new program to promote research and innovation in pharmaceuticals through Centers of Excellence. He thanked Dr. Mansukh Mandaviya, Honorable Minister of Health and Family Welfare and Chemicals and Fertilizers; Shri Bhagwanth Khuba, Honorable Minister of State for Chemicals and Fertilizers; Madam S Aparna Honorable Secretary, Department of Pharmaceuticals, Government of India and all other Government Officers and Departments for policy clarity and direction to the industry.

He recognized noble presence of many distinguished Regulators and policymakers at 61st Annual Day Celebrations: Madam Jyoti Sardesai, Director, Goa FDA; Dr. H G Koshia, Commissioner, Gujarat FDA; Dr. N Yuvraj, Joint Secretary, Department of Pharmaceuticals; Shri Abhimanyu Kale, Commissioner, FDA Maharashtra; and Madam Dr. Vinod Kotwal, Member Secretary, NPPA, Government of India. He thanked them for taking out precious time from their busy schedule and to grace our occasion and he further added that IDMA is humbled to be recipient of their direction and support.

He informed IDMA was blessed to have Shri Dilip Shanghvi (MD, Sun Pharmaceutical Industries); Shri Rehan Khan (MD, MSD India); and Shri Parijat Ghosh (Senior Partner, Bain & Company). He thanked gentlemen for sharing their perspective with everyone. He recognized Shri Sudarshan Jain's (Secretary General, IPA) presence for gracing occasion.

He congratulated all the awardees for their accomplishments and success and for being an inspiration for others to emulate. He thanked sponsors for their continued support and presence at IDMA 61st Annual Day Celebrations: Micro Labs, Elysium Pharmaceuticals, Gufic Biosciences, and Naxpar Pharma.

He thanked Dr. Viranchi Shah (National President, IDMA), Shri Daara Patel, Shri Ashok Madan, and the office bearers and IDMA Staff for their excellent

leadership and administration. He reiterated IDMA's commitment for the seva for Sampurna swastha to the entire world. He reinforced that in this noble endeavor, IDMA is working with the Union Government, various State Governments, Regulators and also, fellow Industry Associations like IPA.

Mr Mehul Shah thanked everyone present at the IDMA 61st Annual Celebrations and for being a part of this really great occasion. He requested everyone to join for dinner.

Thank you

IDMA 61st ANNUAL DAY CELEBRATIONS 2023 AWARDS

- IDMA N I Gandhi Chief Mentor Award: Shri Mahesh H Doshi, IDMA Immediate Past National President and Partner & Managing Director, Dy-Mach Pharma
- IDMA Outstanding Value Creator of the Year Award: Dr Dushyant Patel, Chairman Emeritus, Astral Steritech Private Limited

Welcome Address & Opening Remarks by Shri Daara B Patel, Secretary- General



On Behalf of our National President Dr. Viranchi Shah, members of our Executive committee I welcome you all to our 61st Annual day Celebrations.

It gives me great pleasure to welcome our Dignitaries:

- Hon'ble Chief Guest Dr. (Mrs.) Vinod Kotwal, Member Secretary NPPA,
- Special Guest of Honour Dr. N. Yuvaraj, IAS, Joint Secretary, Department of Pharmaceuticals,
- Guest of Honour Shri Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries,
- Keynote Speaker Mr. Rehan Khan, Managing Director, MSD India,
- Keynote Speaker- Mr. Parijat Ghosh, Partner, Bain & Company,
- Special Guest of Honour- Shri Abhimanyu Kale IAS Hon. Commissioner, Food & Drug Administration, Maharashtra.
- Our National President Dr. Viranchi Shah, Promoter
 & Director, Saga Laboratories, Saga Lifesciences
 I td
- Our Hon. General Secretary Mr. Mehul Shah, Managing Director, Encube Ethicals Pvt Ltd.

Our former National Presidents and distinguished Guests & Invitees.

Chairmen and Hon. Secretaries of our State boards and our dear members who are still continuing to contribute to the growth of IDMA without whose support the celebrations would not have been possible.

Before we go further we would like to welcome our Dignitaries on the Dias & in the audience with Flowers.

The Indian Pharma industry had done well for itself, however with greater Government support in last few years we are doing much better. You will agree that with this pace of growth and recognition, we now become own competitors. We need to better our Best.

The pharmaceutical industry witnessed the normalization of trends that emerged in the last three years. Remaining cautious of the simmering issues from different fronts globally, we must prepare ourselves to move up to find new means and ways to increase our volumes go up the value chain by scaling up the country's R&D investments, we need to work towards harmonizing our regulatory requirements with global standards.

The pharma industry this year was marked by a greater degree of collaboration between the government and industry, with both playing a pivotal role in helping the

pharma sector further strengthen its position in the global market keeping the patient in mind.

India's pharmaceutical market value is about US\$ 44 billion and we are slated to reach US\$ 130 billion by 2030.

Various factors which will contribute to the pharma market growth in India are govt, initiatives such as Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana and Ayushman Bharat Yojana under National Health Protection Scheme (NHPS).

The government has a role in boosting research and manufacturing capacities, as well as expanding the PLI scheme so that more local manufacturers can access incentives and support needed to promote the API sector. Additionally, the centre's recent decision to make the QR code mandatory on the packaging label of the top 300 drug formulations is a much-needed and well-thought-out step by the government. It will likely curb the sale of spurious and counterfeit drugs in India. Though figures show very marginal percentage of such drugs in the country.

One of the most notable measures taken so far was the introduction of the PLI Scheme in a bid to promote local manufacturing of APIs, Key Starting Materials (KSMs), and Drug Intermediates in India.

The few set of key avenues which would feed the growth engine of the pharma industry in which IDMA has given humongous contributions.

Modification of certain clauses of the PTUAS Sub-scheme of the Scheme 'Strengthening of Pharmaceuticals Industry' IDMA along with DoP and SIDBI had organized awareness programs in Gujarat & Maharashtra for our MSME members to avail the benefit of this scheme. This initiative was led by Dr. N. Yuvaraj.

➢ RoDTEP

It may be noted that Government is leaving no stone unturned to support domestic industry and make it more competitive in the International markets. Export centric industries are being reformed and introduced to better mechanisms so as to increase their competitiveness, boost exports, generate employment and contribute to the overall economy. This will go a long way in achieving our vision of building an Aatmanirbhar Bharat. RoDTEP Scheme got extended to Chemicals, Pharmaceuticals from 15.12.2022.

- U.S. Food and Drug Administration (USFDA) India Office and the Drug Information Association's (DIA) India Office organized a 2 - day workshop (VIRTUAL) on regulatory policies, guidance and support for the adoption of advanced manufacturing technologies. IDMA supported the Workshop.
- U.S. Food and Drug Administration (USFDA) in collaboration with IDMA and IPA is conducting a 'FDA Quality Summit 2023' on Monday, 27 February 2023 at Novotel, Juhu Beach, Mumbai.

The Summit will cover important topics such as:

- Best practices in Aseptic manufacturing and smoke studies.
- Regulatory expectations for OOS & failure investigations.
- Best practices to respond to FDA 483 after inspection.

NPPA brings in changes in IPDMS 2.0 to improve ease of filing

The new version of IPDMS was launched by the minister of chemical and fertilizers, Dr Mansukh Mandaviya in the end of August, this year. IPDMS 2.0 is an integrated responsive cloud based application developed by NPPA. IDMA had several discussions with the NPPA and we are glad that NPPA is conducting a training session for facilitating the implementation of the IPDMS version 2.0. This is scheduled on the 15th February 2023. We are thankful to Madam Dr. Vinod Kotwal for this initiative.

I would like to congratulate our Presidents, Office Bearers & Members of IDMA for their unstinted efforts in working together with the Government and all Stakeholders to keep the flag of Indian Pharma Industry flying high. Whether it is local sales, exports, R&D & Innovation, support for MSMEs, etc. IDMA has always been on the fore front.

We will be organizing our flagship event the 22^{nd} PAC on the 24^{th} & 25^{th} February 2023 at the same venue.

We are also hosting a Pharma Live Expo & Summit 2023 at the Bombay Exhibition Centre, Mumbai from 1st to 3rd March 2023. This is an initiative of our G.S.B jointly with ICEXPO Consults.

Thank you for joining us in the Celebrations and a warm welcome once again to all our Dignitaries, Invitees and everyone present.

Enjoy the Deliberations and Celebrations.

May I now call upon our very popular & Dynamic National President Dr. Viranchi Shah to deliver his presidential address. He gave us a very excellent theme & goal at the beginning of his term namely:

RITE =

R stands for Regulatory Reforms
I stands for Innovation
T stands for Team building and
E stands for Entrepreneurship.

Address by National President Dr Viranchi Shah



Respected Dr. Madam Vinod Kotwal, Member Secretary, NPPA, Respected Dr. N Yuvaraj, Joint Secretary DoP, Respected Shri Kale, Commissioner FDA Maharashtra, Respected Shri Dilip Bhai Shanghvi, the Industry Stalwart, the person whom we all follow and vision

ourselves to be in his place someday and our Dream Man, Mr. Parijat Ghosh from Bain & Company, Dr. H G Koshia, Madam Jyoti Sardesai and Ladies and Gentlemen.

On this very important day, I would like to stress some points where IDMA has been able to create a mark in the Industry. When we say Indian Pharma Global Health Care, as an Industry we mean it and we almost have realized it during the last three years when there was a total disruption globally and the Indian Pharmaceutical Industry, the Regulators, the Government and all the Stakeholders had come together.

In fact, it was just one year back when we were supposed to have the 60th year celebration in last January which we had to postpone to April because there was a severe disruption owing to the surge in COVID and it was during this difficult phase that we all worked together and created an impact as a Nation, globally, ensuring that when we say we are the pharmacy of the world we ensured that all the pharmacies across the globe had enough stock and despite all the disruption that we had on the API front and on several other fronts, we could successfully do it ensuring that the essential medicines are available at every single place where we used to cater. I think there is a major achievement that we all have done together.

Going forward, we understand that the bad days are over, the firefighting is over and therefore, in the coming years, we have a wonderful opportunity at hand. And

this opportunity in terms of the visioning exercise that we have done with the Government, is that likely in the next 25 years, when our Honourable Prime Minister talks about the Amrit Kaal that is up to 2047, this industry has a growth potential to reach 500 billion from 50 b to 500 b and this is a big opportunity at hand.

The industry itself has the capability to do a lot and the good thing is that the Government and the Regulators today are with the Industry, hand holding us, helping us, showing us the right way forward. I think with this wonderful confluence of various Stakeholders, it is very much possible that we would be able to even surpass the 500 billion mark that we all had envisioned to reach by 2047 and in this journey, I think three **Is** are going to be very important where we all have to focus.

The first I - being the Individual

The second I - being the Industry

The third I - being the India

The Individual by which I mean in terms of the unmet patient needs, in terms of continuing our efforts to provide affordable quality healthcare to the world. Reinforcing our strength as the world's most preferred manufacturer of off-patent drugs and this is going to be our strength and will have to continue to focus on it. But at the same time, we'll also have to work on value added products and I think in that context the Government has been working closely with the industry. In fact, IDMA & IPA they are working together on many of the things including on the research links support and value added products are going to be very important for all of us.

The second I being the Industry and everything can be achieved if we build an industry that has sustainable competitive advantage and when I mean sustainable

(Contd. on Pg. No. 29)

Glimpses of IDMA 61st Annual General Meeting (AGM) 2023



61st Annual General Meeting 2023 in progress(From Left to Right) Shri Bharat N Shah, Sr Vice President, IDMA; Shri Mehul M Shah, Hon. General Secretary, IDMA; Dr. Viranchi Shah, National President, IDMA and Shri Daara B. Patel, Secretary General – IDMA addressing the members

Glimpses of IDMA 61st Annual Day Celebrations 2023





Lighting of Lamp



Welcome Address and Opening Remarks by Shri. Daara B. Patel, Secretary General – IDMA



Address by Dr. Viranchi Shah, National President, IDMA



Interactive session with Guest of Honour Shri Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries Ltd.



Address by Keynote Speaker - Shri. Rehan Khan, Managing Director, MSD India



Address by Special Guest of Honour Dr. N. Yuvaraj, IAS, Joint Secretary, Department of Pharmaceuticals, Government of India



Presentation by Shri. Parijat Ghosh, Partner, Bain & Company on "Recent Trends in Merger & Acquisitions"



Address by Special Guest of Honour Shri Abhimanyu Kale IAS, Hon. Commissioner, Food & Drug Administration, Maharashtra



Address by Chief Guest - Dr. (Ms) Vinod Kotwal Member Secretary, National Pharmaceuticals Pricing Authority (NPPA), Government of India



Felicitation of Madam Jyoti Sardesai, Director, FDA Goa



Felicitation of Dr H G Koshia, Commissioner, FDA Gujarat



Shri Mehul M Shah, Hon. General Secretary, IDMA welcomes Shri A Senkathir, Deputy Drugs Controller, West Zone(Mumbai)



Shri Mehul M Shah, Hon. General Secretary, IDMA welcomes Shri Sudarshan Jain, Secretary- General, IPA



Felicitation of Shri S V Veeramani, Past National President, IDMA on being elevated as Chairman of Pharmexcil



Felicitation of Guest of Honour Shri Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries Ltd.



Felicitaton of Dr. N. Yuvaraj, IAS, Joint Secretary, Department of Pharmaceuticals, Government of India



Felicitaton of Shri Abhimanyu Kale IAS Hon. Commissioner, Food & Drug Administration, Maharashtra



Felicitation of Dr. (Ms) Vinod Kotwal, Member Secretary, National Pharmaceuticals Pricing Authority (NPPA), Government of India



Shri Bharat N Shah, Sr Vice President, IDMA joining the dignitaries



IDMA Outstanding Value Creator of the Year Award bestowed to Dr. Dushyant Patel, Chairman Emeritus, Astral Steritech Private Limited. Shri. Jay Patel receiving the award on his behalf

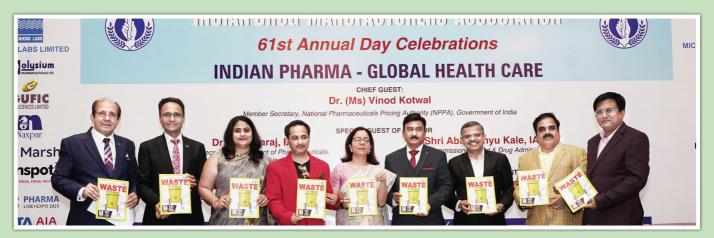




IDMA N I Gandhi Chief Mentor Award bestowed to Shri Mahesh H Doshi, Immediate Past National President. Shri. Niraj Doshi receiving the award on his behalf



Release of 61st IDMA Annual Publication 2023



Release of Biomedical Waste of Healthcopeia Foundation



Audience View



Vote of Thanks by Shri. Mehul Shah, Hon. General Secretary, IDMA



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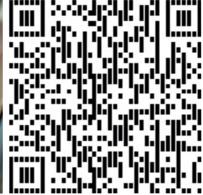
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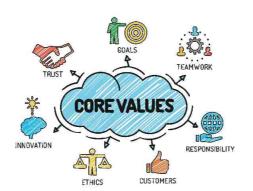
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competitive advantage it is both in terms of costs and in terms of quality because we have seen in some recent past there have been certain instances where it is time for us to also do a good introspection and make sure that we continue to build an industry that is competitive and continues to perform par excellence.

And the third I that we will have to focus in the coming years is India. Pandemic has taught us a very important lesson that supply chain, the dynamics of supply chain can be disastrous and therefore we will have to build an India, where we have the entire supply chain at least the important elements of the supply chain located within our control. And therefore we'll have to focus also on the API, on the complex generics, on the areas, on the biologics, those elements of the healthcare system where we still are dependent on technology or otherwise for some of the players outside India.

So I think these are three very important areas and it is IDMA's endeavour to ensure that our members are abreast of these developments.

In the Annual General Meeting (AGM), we had very good long discussions on various facets, the purpose of bringing the Industry and the Government Stalwarts here was again to sensitize all our members on the trends that we are going forward towards and keeping ourselves ready to reach those heights that we aspire to be in the next 25 years.

We tried to bring our Honourable Minister Dr. Mansukh Bhai Mandaviya here today but he was committed to an event with the UP Government, so he has sent his greetings and wishes to all of us. Under his leadership and the leadership of industry stalwarts we will continue to work forward for the betterment of the industry.

I wish you a good engagement today and at the end of the day with the views and inputs from all the stalwarts I hope that we will have some meaningful lessons to take home. Once again most welcome to all of you and thank you for being here.

Interview with Guest of Honour, Padma Shri Dilip Bhai Shanghvi, Promoter and Managing Director of Sun Pharmaceutical Industries



Shri Dilip Bhai Shanghavi was interviewed by Shri Mehul Shah during IDMA 61st Annual Day Celebrations. Shri Dilip Bhai candidly answered all the questions and his detailed interview is published for the benefit of our members / readers:

Question 1: What are your thoughts on current state of the Indian pharmaceutical industry and how is it expected to evolve in the next 10-years?

Generally, I find it difficult to predict long into future but if you look at macroeconomic data, then we have a young population but a part of that population is aging because of improvement in healthcare. I think life expectancy is increasing so I expect the overall pharma consumption in India to continue to grow at least a few percentage points higher than the GDP growth and Indian GDP growth economists tell us that it's likely to continue

to grow at one of the fastest rate globally. So that's a very significant positive. The other important positive is that income level in the country is increasing, awareness is increasing, importance of health and maintenance of health is increasing, so per capita consumption of drug also is going to increase. Some of the other dynamics which we need to keep in mind is that a large number of products which patients in India consume are already off patent and if I see in next 10 years not many very large products are going off patent so competition for existing products is going to increase so that's one that we need to keep in mind the second important issue we have to keep in mind is that the dynamics of trade and distribution is changing. In today's newspaper you would have seen that almost 11% of the market is with either organized retail or with mail order of pharmacy and the rate of growth of both of these modalities significantly higher than individual pharmacies so like what we see in Europe, US and other developed market today there will be a shift towards increasing concentration

of procurement and at purchasing with limited number of customers so we need to navigate this at the same point of time I think I see Indian companies investing in research and hopefully some of these products will come to market globally and my own expectation is that when one or two Indian companies are successful in launching their own research product globally that will create a virtuous positive cycle encouraging it what do you call making other industrial groups focused on developing similar products so I think in next 10 years we will see investment in innovation increasing in research so very long answer to a small question but I'm quite optimistic but I hope that that optimism is shared by all of you.

Question 2: In times of greater regulatory scrutiny, how is Sun investing to meet ever-growing quality and compliance expectations of regulators?

I think it's an important question for all of us and over time I think maybe with experience we realized that good manufacturing practice is not a constant standard, it's a constantly evolving and constantly changing standards. We have regulators present here and they would understand but I think as a company or as an industry we need to ensure that we keep abreast of all the new developments and keep on upgrading both our processes, practices and infrastructure so that we can meet with the expectations of the regulators. At the same point of time, Audit is only a snapshot. Say like Audit will be there for two, three or four days and they will see a few things when happening in front of them or they would have some what you call market complaints which they will investigate. So they look at only a small part of your investment and capability, GMP and manufacturing. So I think every company needs to focus on ensuring that every product that they develop is robust because I think if you see the current regulatory requirement, robustness of the product processes starts from R & D, analytical methods, validation and when you have a problem, regulators expect you to not only investigate that problem but then apply that same lens across your product group so that not only that product but all other product which can have potentially the same problem will be addressed based on your new learning. So it's a journey and I think it's important for the whole industry to work together so that we can collectively increase and improve our capability and help with each other. Within IPA I think we have groups working on different challenges in quality and we transparently share our processes and share the final outcome as a paper every year. I think it's

important to share more than whatever we are sharing so that collectively we can improve. I think since regulators are present, I wish that as a country I think our challenge is that we are judged by the worst of our player. So when one or two bad apples create a problem, the whole industry gets a bad name and it's not possible for the industry to weed out the bad apples it's only possible for the regulators to weed out the bad apples. I think we've been working with the regulators to see that they recognize this as an important issue and find a way to fix it. We have many suggestions and many thoughts but ultimately that will require some changes in the law. Hopefully, I see a lot of interaction with this challenge that we are facing in the industry.

Question 3: How have you institutionalized your values and business acumen at Sun? How has management scale-up been done to cater to Sun's growing size and ambitions?

So one I think is how you manage the business and how you manage the team. How you reward and how you recognize. I mean if business our size, it is not possible for us to grow only if I pull the engine, it is not possible because we have become too big and we are distributed across many locations. We need a large number of people taking decisions at the same point of time. So first of all philosophically aligning everybody's interest and priorities so that everybody works towards the same direction. Also, recognize that when people take decisions they make mistakes I am yet to meet anybody who says that he is not made a mistake in life if I look at myself I've made more mistakes than most of you. Fortunately for me or for us as a company I think some of the good decisions which I took helped overcome the mistakes and also helped us to grow. So we don't generally evaluate a person for what he fails to do but what he contributes. One challenge which I see is that as we are becoming bigger and structured I think bureaucracy is seeping in and risk taking ability within the company is going down but I think we have to remain entrepreneur. I think when I heard Viranchi Bhai mention that Entrepreneurship, I think that applies to us as much as it applies to you all.

Question 4: Introducing next generation in business often poses a challenge for the founder promoter on the former's role fitment, entry timing, and acceptance by stakeholders. Please share your experience on

inducting Aalok and Vidhi at Sun and words of advice for all of us here?

I think and say that this is not for children it's for everybody that worked with you, is that people see what you do people will not follow what you see. So if you want something to happen, I think you have to do it. You expect that I will drink but I don't want my children to drink that's not going to work. So from young age I think my focus was that children are grounded and are focused on hard work, diligence and also are not impatient. Fortunately, God has been kind. My children overtime have taken over functions that at one point of time I was managing and what I recognize is that I can appoint bosses but if they have to become leader they have to earn their leadership themselves because people will respect you only if you deserve the respect. So fortunately for us I think they have done well and they are respected by their colleagues. But some broad suggestions one is that at least in case of both Aalok and Vidhi and also in case of Khyati (Sudhir Bhai's Daughter), they did not report to me, they reported to somebody who I thought had the right value system and would treat them like a normal employee and also teach them how to become a better Managers. I don't think that they were treated very differentially when they joined. Expectations out of them was no different than anybody else who was joining Sun as an employee and the same rigor in terms of review process and same rigor in terms of what you call greater responsibility if you are successful. Fortunately for me I think their own self-assessment is far more rigorous than our organizational assessment so they learn from what doesn't work for them but that I think is pure luck. But there is a lot of things that we can do to see that our children are successful. Don't make them entitled because they are your children. They are not entitled to anything. I think they need to earn what they think they need to get.

Question 5: Your reticent nature makes you a man of mystery. What keeps you motivated to work hard every day and remain excited about the future?

I think the first part is that maybe when I was young, my father always used to say that let your work speak for you. So I think that's kind of drilled into me so I don't talk too much. The other question is an important question which I think all of you also must be grappling with many times is that many of the problems that you work on, don't have short term solutions. Say like we had a problem in Halol, Gujarat right now suppose it is not going to go away tomorrow, so we need to ensure that what happened at Halol, we are able to ensure that it doesn't happen anywhere. So have timeline for success of whatever that you are working on long, instant gratification will not work for people like us. So everything that I work on has response time of a few years. So I have learned over time to take happiness out of progress that I'm making and long term outcome. So that keeps me motivated and focused on what I am trying to achieve.

Question 6: Any last words of wisdom to all of us?

I think we are fortunate because technology enables us to do things which say like when I started the business, it honestly took me 3 months to get one patent that I was looking for because they were no method by which I could access the patent nor I didn't know of a method by which I could access. So technology is more rapidly so we are all blessed. So use this opportunity to constantly upgrade whatever that you're doing so that we can continue to compete in marketplaces as a more capable organization. I mean in our case, I think aim long term but set up measurable short term milestones so that you know that you are on the path to whatever that you wish to achieve.

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