India should be the Hub for API and the API schemes are to boost the indigenous manufacturing of API said by Dr. S Eswara Reddy, Joint Drugs Controller, CDSCO

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New Delhi: PHD Chamber of Commerce & Industry organized a Technical Session on Brainstorming the Strategies for Positioning India as a Hub for API- AatmaNirbhar Bharat on the final day of the International (3D Virtual) Health & Wellness Expo & Conferences-2020.

The eminent panellists present were Dr. S Eswara Reddy, Joint Drug Controller, CDSCO, Mr. B R Sikri, Chairman, ABS Mercantile, Mr. Sudarshan Jain, Secretary General, IPA, Mr. V.V. Krishna Reddy, National President, BDMA, Mr. Mahesh Doshi, National President, IDMA and Mr. Srinivas Lanka, Advisor, Pharmaexcil.

The session was graced by the special presence of Mr. Anil Khaitan, Former President, PHD Chamber and Dr. N. Subramanian, Chairman, Health Committee, PHD Chamber and Mr. Vivek Seigell, Principal Director, PHD Chamber.

Dr. Subramanian welcomed all the panelists and Chairman of the session for sparing their valuable time to join us and gave a brief about the 5 days 3D Virtual Health & Wellness Expo & Conferences organized by PHD Chamber. Dr. Subramanian mentioned that the Indian pharmaceutical industry is the world's third largest by volume and thirteen largest in terms of value. The industry generates over USD11 billion of trade surplus every year and is amongst the top five sectors contributing to the reduction of India's trade deficit.

The backbone of Indian pharmaceutical industry is the bulk drugs industry and is ranked the third largest in the world, and the country contributes approximately 57% of APIs to prequalified list of the WHO. However, over the past two decades, India's reliance has grown for imports of low-cost intermediates and APIs. India imported around INR 249 billion worth of bulk drugs in FY19 as compared to INR193 billion in FY18. Imports from China have been on a steady rise over the years (from 62% in FY12 to 68% in FY19) as India imported INR169 billion worth of intermediates and APIs from China. High import dependency on a single nation is of concern to all stakeholders, including the Government for – health security, industry in terms of – raw material shortage, price hike, and lower margins and the end consumers regarding – drug shortage and spurious drugs.

While moderating the session, Mr. B. R. Sikri congratulated Government of India for the PLI Scheme on API and told that we need analytical analysis of this AatmaNirbhar Scheme. Mr. Sikri told that the Pharma Industry has created more than 2.7 million employment and we are leader in vaccine manufacturing & the first country to eradicate polio too; our motive should be to strengthen our position on global market.

Mr. Sikri also touch upon various industry issues and challenges with the scheme which includes some points like..

· Applicant should have 30% of net worth

· Removal of 6-APA from the scheme

· Not allowance of brownfield category in the scheme

· The scheme should also allow existing manufacturers to manufacture these products with some incentive

· 65% of Sale price marking in the scheme

· The threshold investment should not be treated as double and this needs to get reconsideration

· Excipient is another area where Govt is silent.

· Protection of industry investment

· Maximum Incentive per eligible product and per selected applicant, need justification on Investment versus return

· Functioning of CDSCO, where the capacity needs to be increased with the manpower and digital approvals to be implemented.

Mr. Sikri also mentioned that the linkage should be created between the Central and State regulatory authorities are missing and the regulations should be India centric.

In response to the issues asked by Mr. Sikri, Dr. Eswara Reddy gave a point wise clarification on all the points. Where he mentioned that India should be the Hub for API and the schemes are to boost the indigenous manufacturing of API. He further

mentioned that we are heavily dependent on other countries for API / KSM and until and unless we have the complete eco-system, we cannot become leader.

Dr. Reddy gave a brief on two promotional schemes. First to develop 3 Bulk drug Parks, where total 3000 cr investment will be made by Government of India and second is the Promotion Linked Incentive scheme for the bulk drug where around 7160cr has been sanctioned, which measures the total investment of 10,000 crores.

Dr. Reddy further mentioned that India has an advantage of huge costal area and the main aim is to have a complete background integration. While giving clarification of Mr. Sikri's first point, Dr. Reddy mentioned that Government do not want players who are not interested and still make the application without any financial back up, which is the reason to set up the minimum investment threshold else the scheme will fail.

Mentioning about the removal of 6-APA, Dr. Reddy said that if we keep both the molecules i.e. Penicillin G and 6-APA in one category, it will create a confusion on selection of application as 6-APA made from Penicillin G only.

Regarding not allowing brown field category, Dr. Reddy mentioned that Department of Expenditure not agreed on this point, though we have made some points on that as even the existing manufacturer in their current facility can be eligible for the production of these compounds by adding some additional facilities and some additional modification.

Talking about the annual product capacity point, Dr. Reddy mentioned that the Government is seriously looking for another alternative scheme and it is in pipeline.

While mentioning about the sales price specification issue, Dr. Reddy gave an example that if the sales price specified is INR 100 / kg than the incentive will be made on this only whereas the manufacturers can sale it at INR 110 or 120 per kg. he further said that if the it is not fixed the applicant can say that the sales price may vary time to time which will again create the confusion.

Dr. Reddy also mentioned that the incentive scheme will be applicable to excipient also and in the new scheme, we have the products of excipient also.

Regarding protection from Government, Dr. Reddy mentioned that Department of Pharmaceutical initiated the steps to increase the custom duty to some identified molecules and I am sure that the Government will take necessary action to protect our industry.

Regarding specific molecules, Dr. Reddy said that we need to sit with the industry and workout the same and need to see all 41 molecules one by one for any errors.

Mentioning about the CDSCO functioning, Dr. Reddy appreciated the DCGI for their tremendous work support and said that the Clinical Trial protocol approval time has now been reduced to almost 3-4 days. He further said that we have granted more than 200 import & manufacturing licenses for invitro diagnostic in this Covid situation. He further told that we will definitely institutionalise this mechanism what we are following during the Covid times.

Dr. Reddy also mentioned that we are restructuring the whole CDSCO including its nomenclature and also working on with the old 1940 D&C act. He further mentioned that we are also coming up with the Version 2 of SUGAM portal and to give the priority to innovation and research, CDSCO has come up with a public relation office also.

Dr. Reddy mentioned that we are making a list of Government facilities for R&D and innovation and make that list available on the CDSCO website so any innovator can use the Government facility for R&D.

Mr. Sudarshan Jain mentioned API policy as the landmark policy to make India a global hub for API. Talking about the India vision 2030 report, Mr. Jain said that India can move from $41 bn to $120 bn by 2030 with not only with the goal of make in India but with the foal of Make for World and also move our Foreign exchange from $14 bn to $40 bn.

Mentioned about the China, Mr. Jain said that China has gain tremendous importance now with more than 70% share in API which has been only possible with their Government support.

Mr Jain said that we have talent & technology and with the Government support, we can also make the difference. Mr. Jain further mentioned that out of 53 molecules 23 are make in India and 12 molecules have less than 60% production in India though we have the capacity and while for 27 molecules we have a reliability on single source. Which shows that we really need to start the scheme early and allow the production to get self-sufficiency in these.

Mr. Jain also mentioned that economy of strategic scale is very important and we need to talk, create and act very quick. He further mentioned about the environmental clearances support from the Government and to have a same enthusiasm with the Environmental Ministry also to support the industry. Mr. Jain also mentioned to have a bilateral trade with different countries and to encourage foreign partners to invest in India to make India an API hub with a global trade alliance.

Mr Jain said that this is a great opportunity for India right now and industry is committed to work together for the growth of the industry and for the growth of the country.

Mr. VV Krishna Reddy, in his remarks thanked the Government of India for having BDMA as a part of the Production linked incentive scheme.

He appreciated that it is well balanced scheme in which the aspect for the Chemical synthesis part is good. He mentioned about some apprehensions towards fermentation part, highlighting that there is less no. of companies that are involved in fermentation in India.

He emphasized that there is one major hindrance that stands before the effective implementation of this scheme is the low enthusiasm of the Environment Ministry. He stated that DOP and the Environment should increase Liasoning among them. He said that the Environment Ministry’s response has always been lukewarm. Hence, before the scheme is implemented there should be a couple of meetings that should be arranged so that the confidence of the investors can be boosted.

He further said that other than pharma parks, there are lot of issues to open an industrial unit.

He mentioned that the time frame to forward the application is 120 days & the government will take 90 days to give the letter of intent to the companies which have been selected. The scheme is from 2022 onwards, and the letters of intent shall be given probably in the first quarter of 2021, hence the companies will only be left with 9 months-1 year to set up the factory and start producing. Therefore, approximately the first year would lapse for the company to avail the incentive. To take care of this in the future, he suggested that the time calculation should be done starting from the day the production begins. It is very unlikely that the company will get the EC clearance in such a short time and one cannot even start the construction before they get the clearance.

Mr. Mahesh Doshi commenced his remarks by throwing some light on the history of the import and manufacturing of APIs in India. He suggested that if the Government of India is striving to enhance the domestic capacity of production of APIs quickly, then the requirement of the minimum investment should be flexible and the already existing brown field manufacturers with ideal capacity should be welcomed and encouraged to fully utilize their capacities. He stated that the Indian API industry is very much capable as far as the Global market is concerned.

He said that today we say that India is the Pharmacy of the world in the context of formulations, but it is possible that at a later stage this will be true in case of bulk drugs as well. He added that the Indian API industry will need a clear roadmap with a defined action plan, set priorities and milestones along with a favourable environment to grow, sustain and achieve the desirable goal of self-sufficiency. He mentioned that this is the time to have a plan with a clear definition of roles and responsibilities. The Government, Industry and Academia need to collaborate with a common vision of reviving this industry. He finally mentioned that we need to think global and produce local.

Mr. Srinivas Lanka, Advisor, Pharmexcil thanked Govt. of India for launching a very transparent scheme for the first time for the Industry. Mr. Lanka raised some issues about the schemes. He said there’s a need for a National R&D mission for small scale Industry. He also highlighted about the requirement of finance for growing of the green field Industry and this will certainly boost the entire Pharma Industry. Mr. Srinivas mentioned that the Indian Pharma Industry is not totally dependent on China, As the overall industry is of $60 Billion dollars, and we import only $3 Billion dollars and 80% is also manufactured in India only. He said we are actually dependent on Intermediate and KSM.

He said clusters are required and Govt. of India should consider for at-least 6 API’s Parks for more opportunities as there’s a lot of demand in the future and this will also give opportunities to other states as well. He said these R&D programme should be incorporated and the MSME sector should also to be considered by the Government, as this is a very crucial for the API Industry. Also, the Govt. of India should also support in research and development. He said financial support is also required from the banks to support the Industry. There’s a need for Industry and academia collaborate to work together for the growth of the Industry. He also highlighted the Issues about the Royalty and certain cost Issues and higher Incentive for exports for the Industry.

Mr. Anil Khaitan gave a formal vote of thanks and said that we need to call API as Accelerated Project Implementation and requested the Government to Consider the

Pharma industry as the IT industry. He also said that the Government should support the industry at an extent of giving export incentives that event these schemes can't provide to encourage them.

With the gracious presence of the Chairman of the Session, Dr. S. Eswara Reddy and Mr. Anil Khaitan, Former President, PHD Chamber, Health & AYUSH Committee, PHD Chamber launched E-Market Place- the online Market place for Health & AYUSH products and the session was attended by more than 250 delegates through Zoom, You tube and online exhibition platform.