

Self Reliance & Way forward

PLI Schemes

Srinivas Lanka

MBA (IIMA), FCMA

Helped building 5 mega corporates

Mentored PMBJP

Advisor/ Mentor of Pharmexcil,

Select Nipers, CSIR institutes

Acknowledgements



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- Late Shri PK Kakodkar, Late Shri Labdi Bhandari, Mr Orsinger, Mr Mike Sundman, Mr Borkar, Mr Ramesh Seth and mentors who taught me the essentials
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- Support from Sri Shyamal Misra, Sri Nagi Reddy, Shraddha Lanka and DG Uday Bhaskar in shaping up the roadmap

Why

Health of 1.3 Bio people

GDP & Forex earnings

Skill & Knowledge Economy

Huge Opportunity for health
improvement & Economy



Why Concern ?

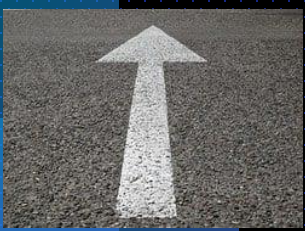
- Post independence – completely dependent on imports
- Abolition of Patent Act – NCL, RRL, PSUs rised to occasion
- Diffusion of knowledge from Govt and PSUs – Rise of Private Sector
- Great leaders like Dr Parminder Singh, Dr Hamied, Dr Anji Reddy, DB Gupta and top class leaders made us self reliant

India developed capabilities both in chemistry and biology in this era



Why Concern ?

- Capex , Infra & Flow of R&D Issues – Migration to Offshore
- Drug Intermediates, API dependence from Offshore
- 1.3 billion people health can't be outsourced to Offshore
- Knowledge economy growth is vital
- For every import dependence of one \$, We lose six \$ global opportunity due to competitive disadvantage
- An estimated US 165 billion \$ loss - next 15 years



My perception of Govt Intentions

- ❖ Rajeev Kher committee , JS Deepak Committee, Dr Surendra Singh Committee, Katoch Committee, Group of Secretaries Discussions , Niti Aayog Discussions, DoP Secretaries Committees, Committees chaired by Dr Somani, Dr Eswar Reddy
- ❖ All bureaucrats are concerned always about this and most recommendations have harmony

My perception of Govt Intentions



The Challenge – Technology has not emerged for real time surveillance and monitoring of effluents of clusters and industry

Dependence vs Pollution Risk for the Nation

At the nation level it is hardly US \$ 5 billion, Trivial.

It is not money. It is health security risk of nation.

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After 2014, greater attention to health

- Generics Project, PMBJP
- DCGI, CDSCO Expansion
- CSIR initiatives to develop technologies for nation
- Cluster schemes, Coop Programmes
- Studies by various ministries to develop road map



The Turning Point – The Roadmap

- A large study for self reliance and develop the roadmap was assigned to Pharmexcil
- Prof Govardhan Mehta, Prof Javed Iqbal, Dr Chandra Sekhar , Dr Oruganti, and around 150 scientists from CSIR, IITs, IISc, Universities and industry; over 100 leaders from industry, marketing and supply chain across the nation participated with whole heart
- Over 20 years data of thousands of chemicals and apis, pricing patterns, the emerging monopoly power of offshore, and the next 15 years estimates were done with help of Artificial Intelligence.



The Turning Point – The Roadmap

- Self reliance – Is it a slogan? - Can it ever happen? – has the opportunity moved forever?
- The exporting country chemical industry size is 8 times larger
- The Ebidta in the exporting country is so low that we can't source funding to raise the industry
- The gestation period is so long that none will fund the industry

The Turning Point – The Roadmap

- Studied models in EU, US. How they survived and thrived
- Smart nations moved to clusters for competitive advantage like Netherlands
- Smart companies moved from c2, c3, c4, to c5 and c6 specialities
- Smart companies focused on applications, reactions and value addition
- Smart companies left low ebidta, large capex to east and invested in IP , Technology , Applications and succeeded

The Turning Point – The Roadmap

1. The roadmap became clear
2. Identify what cant be done financially or technologically or due to economies of scale
3. Identify what can be done with amalgamation of local talent, local finance ability, and local demand
4. Select platforms that will disrupt the industry and give disproportionate competitive advantage
5. Amalgamate chemistry, chemical engineering, biology, electronics and AI to do things smartly – A new collaborative life is needed. Luckily we have such institutions already in place
6. Reach out to large, medium, small industry; convince the investment opportunity to funds and investors; convince the government to roll out a structured plan

The Final Impetus – The Roadmap

Studied required various chemistry backbones, emergence of novel technologies, and filtered what can be done in the nation in mid term

18 platforms were identified, and various drug molecules in the platforms were identified

How to develop the new chemistry platforms, How to mitigate the infrastructure costs through clusters, How to reward the industry for investments into these drug molecules were discussed

The Final Impetus – The Roadmap

Detailed financial models for next 15 years were forecasted with estimated break even point and the pay back time for the nation

Awareness created in industry and capital markets & financial institutions

Awareness created at state , centre and various govt departments

Drafted various implementation schemes for R&D, Manufacturing and Clusters with help of eminent persons



The Persuasion

- ✓ Knowing the problem often solves the problem. Problem for a MSME is an opportunity for a Fund which can mitigate the constraints.
- ✓ Private Sector, Venture Capitalists, Private Equity, Stock Markets took interest in Pharma and saw the way forward in drug intermediates and API industry.
- ✓ API companies have surfaced like Solara. PE funds with focus on API have emerged.
- ✓ Scientists have started developing technologies and industrialists are getting funds
- ✓ Industrialists were made aware of their involvement to solve the challenge
- ✓ Govt Schemes are announced. Ahead of announcements Industry is also ready

Quick look at PLI

Rome is not built in a day: We thought a 25% import substitution is a good initial target.

First Step : identify drug molecules with significant dependence from outside and announced remedies for cost mitigation

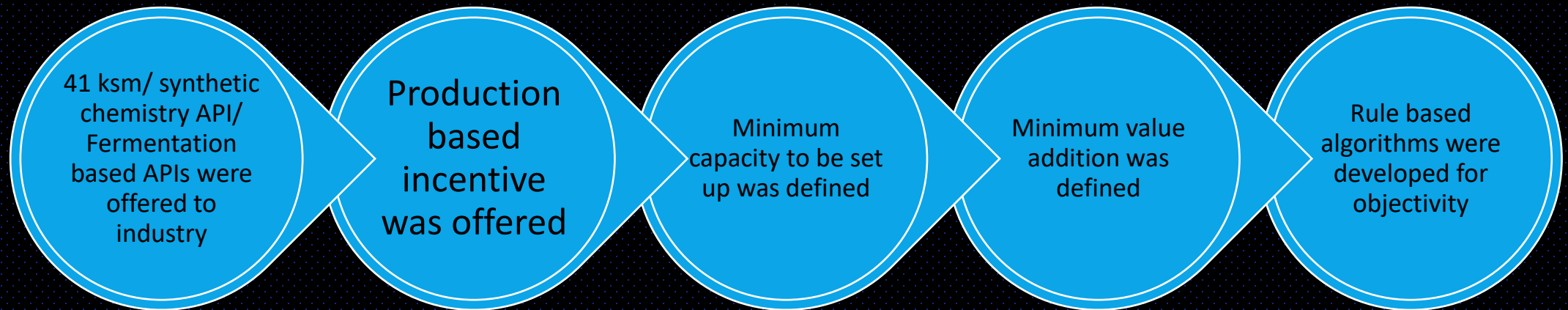
Second Step: The Platforms required for future like Biopharmaceuticals, New Drugs that will expire in future, Complex Excipients, Critical Diagnostics, Phytopharmaceuticals, Complex Formulations are encouraged.

Markets understood clearly the growth areas. Current Industrialists could channelize the efforts with some remedies for cost mitigation

Substantial interest and applications from companies who cared to grow and solve these challenges.

Over Rs 17000 crores is earmarked and the products and companies are identified. All on rule based, objective scoring. Clean and Neat

PLI 1 – Focus Drug Intermediates, APIs - Rs 6000 crs



PLI 2 – Thrust into Future is the focus

Biopharmaceuticals

Gene Therapy

Products whose
patents will expire in
future

Complex drugs

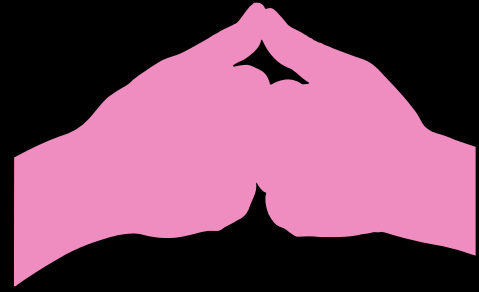
Phytopharmaceuticals

API/ Drug
Intermediates

Key therapeutics from
oncology,
immunology,
cardiology , neurology

Invitro Diagnostics

Pli 2



Invest for expansions (1000 crores to 50 crores based on a b c categories) and msme commitments

Develop technologies or obtain technology transfer

Applicants with commitment to expansion and producing these categories are approved .
Objective parameters like sales, dmfs/andas/patents, accreditations, r&d investments.

Scheme Successful Eligible applicants are announced

Country will see the advantage over next few years

Rs. 15000 crores earmarked

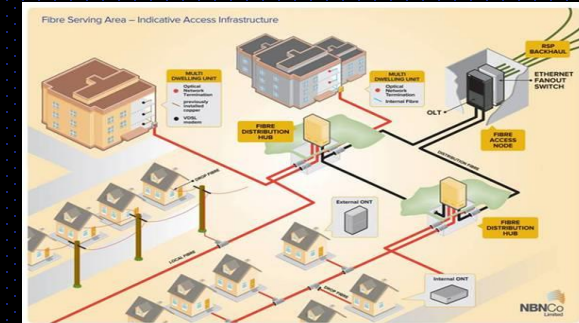


Current Status

- ❖ A lot of water has flown in the last five years
- ❖ API dependence is replaced with only intermediates dependence
- ❖ For example: our pharma market is approx. US \$ 50 Bil. API consumption is estimated around 16 to 18 US \$ Bil. API Exports around US \$ 4 Bil. Out of the required US \$ 20 to 22 Bil, our imports are just around US \$ 3 Bil. Say 15%
- ❖ The market opportunity, awareness, govt interventions have mitigated the risk significantly in APIs
- ❖ However, we depend on offshore for Drug intermediates. Now this has become a significant challenge.
- ❖ The drug intermediates manufacturing is a key ingredient in PLI
- ❖ Hence a lot more will get mitigated in a few years

Direction for the future – Chemistry

- ✓ 6 major and 12 mini platforms were identified
- ✓ Each platform requires a center of excellence to support msme and even large pharma, and a cluster to integrate the efforts
- ✓ Example, isolated efforts in Flow chemistry could be very expensive. We need a national effort . Similarly Fluorination chemistry or Biocatalysis etc
- ✓ Chemistry, route of synthesis, can help only a few percentages in cost in old drugs. But the infrastructure and Quality Laboratories cost is prohibitive for msme.



Direction for the future – Chemistry

- ✓ We need shared infrastructures for msme. We need CoE for MSMEs. Each state should look at developing such parks for MSMEs with or without center support. Industry needs to work with governments on lease models, pay per use models, getting international agencies funds.
- ✓ MSMEs need these technologies. They can't develop these on their own. Scheme for innovation, to be funded on milestone basis involving universities, Govt institutes and Private Sector is urgently required
- ✓ MSMEs are the backbone of either pharma or biology and attention is needed to nurture this.

Direction for the future - Biology

50 % of the Global pharma shall be from biology in the next five years

Biopharmaceutials shall drive the future of the world

An urgent initiative to visualize the opportunity and create shared infrastructure for biologists to do research, to take scale up batches, to produce commercial batches and support in the testing is urgently required.

Bioreactors, various instruments in manufacturing depend on imports. Domestic manufacturing of these is vital. Biotech devices parks are critical for success

Biology is expensive and time taking. But we have the capability. We can aim to be a significant player in the world.

DBT is building biotech. However this has to be multiplied by manyfold for pharma

MSME in Biology , I guess is the future

Drug Discovery - Direction



Thousands of scientists , perhaps running into lakhs are working in the drug discovery system in our country

Ofcourse, these people are doing research for MNCs in CROs and obviously the patents shall belong to West.

Visionaries in basic research, finding targets, and the evaluation framework are key and can migrate subject to capital investments

Guess this will develop on a adoptive and opportunistic model



Goals, speed, accuracy and monitoring - The hall marks of our nation today

India shall become the real Pharmacy Hub of the World

Health is an important Agenda for Honorable PM

Our entrepreneurs, scientists, professionals are driving the world in the competence areas required to make India as health capital of world

Integrating modern medicines with our multi dimensional ancient knowledge shall make it happen.

Thank You

Jai Hind

Srinivas Lanka