INDIA PHARMA 2021

(25-26th Feb 2021 & 1-2nd Mar 2021)

Report and Recommendations

(A). PHARMA CONFERENCE SESSION RECOMMENDATIONS

SESSION 1 – MANUFACTURING AND SUPPLY CHAIN
1ST MARCH 2021 (10:00-11:30 PM)

Chair: Ms S Aparna, Secretary, Department of Pharmaceuticals, GoI

Moderator: Mr Ashit Saxena, Leader- Manufacturing, Life Sciences, EY

Co-Moderator: Mr Sudarshan Jain, Secretary general, IPA

Government Participants:

- Dr VG Somani, Drug Controller General (India), MoH&FW, GoI
- Mr M. K. Das IAS, Additional Chief Secretary (Industries & Mines), Govt of Gujarat
- Dr. P Anbalagan (IAS), CEO, Maharashtra Industrial Development Corporation, Govt of Maharashtra
- Mr Hans Raj Sharma, IAS, Director of Industries, Govt of Himachal Pradesh
- Mr Ravi Uday Bhaskar, DG Pharmexcil
- Dr Kiran Kalia, Director, NIPER Ahmedabad

Panellists:

- Mr Ajit Singh, Chairman, ACG Capsules
- Mr Kirti Ganorkar, CEO India Business, Sun Pharma - COVID Learning
- Mr Sanjiv Navangul, Managing Director and CEO, Bharat Serum - COVID Learning
- Mr Prasad Deshpande, Global Head of Supply Chain, Biocon - Supply Chain
- Mr Rajendra B Chunodkar, President- Manufacturing, Lupin - Manufacturing
- Mr Girish Dixit, President, Eisai Pharmaceuticals - Quality
- Mr Madan Mohan Reddy, Director, Aurobindo Pharma – API & reliability
- Dr Dinesh Dua, Executive Director, Nectar Lifesciences - EXPORTS
- Mr Mahesh H Doshi, Partner & Managing Director, DY-MACH PHARMA
- Mr. Vinay Jathar, Director – Technical, Otsuka Pharma

Key Discussion Points:

Ms. S Aparna, Secretary, DoP:

- To take this industry to the next level, Look at different aspects of the sector. 3-4 issues need to be addressed

  1. Even though 8 Indian pharma companies are in the top 100 pharma companies globally, but the largest Indian company in size about 4 bn dollars whereas the largest global player is 82 bn dollars. So will have to talk about scale and how we can bridge this gap

  2. Should we focus on doing "more of the same", or we should do "more and different". Our strength is currently in Generics. What will more and different look like? How do we go about doing this?

  3. We are known for our Cost effective product with high emphasis on quality. However, with increase in the scale the quality needs to be kept on a close watch. What is it that will be required from the Industry, Quality regulating authorities, etc. in terms of technology upgradation, technology support, testing capability and infrastructure, test [sic. Track] and trace and manpower requirements (with respect to skills) to give assured quality

  4. General ecosystem: 1. Ease of doing business, Supporting infrastructure, incentives, etc. What are the elements of the ecosystems that will be critical for strengthening the base in domestic and global markets? How can we as a country strengthen the manufacturing base – at a time when everyone is trying to diversify their supply base.

Covid 19 learnings:

Mr. Sanjiv Navangul:

- Main learning form COVID 19 has been to build "good habits"
  - Safety and security of employees, business continuity
  - Better working capital management and tighter supply chains
  - We cannot be thin on inventory (shift from "Just in Time" to "Just in case" inventory)
  - Technology to be included in every sphere of manufacturing and supply chain – including audits and certifications going online
  - R&D has to be part of the decision making body – we have to go up the value chain and this is where we need to focus
  - Regulatory body interactions increased – our communications and data understanding has improved

  Risk taking ability increased. Since growth will only come through risk-taking, this will be critical. Our focus should be to keep these "good habits" continuing and not becoming complacent as our industry was earlier

Mr. Kirti Ganorkar:

- Unprecedented collaboration between Industry, academic and govt. has been a great thing that has happened and should continue
- Digital Adoptions has gone up significantly
- Social media platform usage for patient awareness has improved
- Interaction with Govt. agency has increased – this has led to shortening product launch times
- Large number of e-platforms have been launched and these should be taken forward

- In March and April high variability in supply chain. 2 digital initiatives were taken during this time of high variability- Dashboard for stockist to manufacturing level which was updated on a weekly basis instead of monthly basis; Launched Pragati portal to understand which stock is available within his area. Hence these have helped us manage inventory . We would like to keep this going forward

Mr. Ajit Singh:

- We should be answering this question: cure a situation like covid or avoid covid?
- The answer for the same is in the field of nutraceuticals. These help the body remain healthy. In America over half the dosage forms are nutraceuticals. In China – about 60% (Traditional medicine). It is time that India looks into this important field as well.
- More importance given to health, preventive medicine to be taken all throughout the year

Mr. Rajendra Chunodkar:

Following improved during pandemic and needs to be kept intact:

- Collaboration between industries with the Govt. bodies, regulatory bodies
- Acceleration of digitization with introduction of paperless and contactless/touchless systems. These were introduced the safety but have also increased efficiencies and effectiveness.
- Changes in packaging configuration – to avoid close proximity of workers – and to ensure certain manual processes could be automated
- Virtual platform is the new reality – inspections, audits, maintenance etc. have been happening on virtual platform – this has reduced time and cost. We should keep doing this going forward
- Need for alternate vendor for each and every material. The regulatory approvals also came through in a timely manner to on-board these vendors.
- Shift management also improved

Mr. Prasad Deshpande:

- Biocon is the leading manufacturer of biosimilars and APIs as well.
- To have a sustained supply chain, we don't only have to focus on our vendors but their suppliers as well
- The supply disruption of 2019 due to environmental issues in China gave us early warning signals to work on this and make ourselves independent in china. We have started monitoring a metric - % revenue independent of china. We have reduced this significantly having developed vendors within India. . However basic chemical materials are still manufactured in China and needs to be moved to India – this is what we are currently working on.
- We have a huge potential to build scale in India. Our attitude is right but what we also need is global scale infrastructure to help us compete in capturing the volume as well as value of the global pharma trade

Mr. MK Das

- Gov of Gujarat started a control room to make sure continuity of production without disruption. We made sure the supply continued not only in Gujarat but also to other countries as well

- In Gujarat, during covid year FDI recorded 550% growth, coupled with 240% growth in last year.16 times growth in FDI in 2 years. Companies had trust in us. This established the state as a favourable destination. Policies are also consistent and there is good infrastructure too.
- Power consumption had increased by 12%. Govt gave tremendous support to the industry.
- We are going to set up of one pharma park. Medical device park already exists. We are planning to also have one much bigger medical devices park.
- We are increasing focus on ease of doing business. Need to have everything digitally like Singapore and New Zealand. There is a need to reduce the burden on compliance.
- More incentives are going to be given to the pharma industry and also allocate land at 6% annual rental on lease plus 12 % incentive that is capital expenditure which is independent of SGST
- Many companies are setting up global R&D facilities in Gujarat
- Close coordination is required between Govt and industry

Dr. P Anbalagam

- Government of Maharashtra faced challenge with respect to maintaining supply side and permissions
- MIDC came up with a portal for self certifications, and with hologram to download the vehicle passes
- Plug and play infra was planned in 40000 acres with 5000 acres only for the vendors
- Introduction of the investor first program where hand holding of the investor is done from pre establishment to pre commencement is done
- Bulk drug park initiative by gov of India will change the entire scenario

Mr. Hansraj Sharma:

- Biggest pharma Hub in Himachal
- Hydroxychloroquine supplied to USA through Himachal
- Implementation of SDGs
- Innovation index rank improved from 16 to 7 in 2020

<u>API, PLI Scheme</u>

Mr. Mahesh Doshi:

- Biggest hurdles for bulk drugs -1) Environmental issues and 2) Incentives for which gov of India has come up with the PLI Scheme
- Treating API and DI as a single category ; removal of cap on production quantity and quality of the effluent - Some environmental problems that are being faced
- PLI Scheme 1: majority units' given. It will run smoothly shortly and PLI Scheme 2: notified, categorized in A,B,C . More details on this will be very helpful for the industry. PLI 1 and 2 are commendable steps to achieve self sufficiency in supply chain and manufacturing
- PLI will lead to incentivize at MSME and academia level and is important to grow.
- We need to achieve complete self-reliance to fulfil domestic demand and one additional capability for manufactures is to scale up production capacity for meeting global requirement
- To a bulk drug industry, infrastructure should be a grant so this will be helpful to borrow money from insurance companies, international lenders with long tenures and pension fund

- All government, central and state procurement should give the preparation treatment for the finished formulations from API manufactured by India
- Raise money through external commercial borrowing routes at competitive rates
- The problem is that there is no security to business and manufactures against dumping of Chinese products apart from imposing anti-dumping duty
- We must also establish an agency to monitor Chinese prices periodically and to give support to the industry

Mr. Madan Mohan Reddy

- Domestically we have lot of flexibility, however for export there are various challenges:
  - KSM dependability, most of the markets are depending on KSMs from China or any other manufacturers from other countries . If we don't have API, no formulations as a result our exports will be affected
  - Especially in the regulatory market, If we don't deliver product on time, there are huge penalties industry has to suffer
  - Regulatory exports: GNP compliance. We are having very good compliance, due to changes in stringent specifications, regulatory expectations, if there is a noncompliance, it is going to cause stoppage of business
  - Environmental failure is also a damage to the industry
  - Human resources must be strengthened
  - Any critical KSMs must have an alternate source otherwise any change in the export market, we need to take approval

Prof. Kiran Kalia:

- We need use Green chemistry which will address the environmental issues and will also allow us to reduce the cost of API
- Industries should collaborate with NIPERS , as it is capable of giving suitable solution

<u>Quality</u>

Mr. Girish Dixit:

- We belong to the Japanese pharma.
- stringent regulatory plays an important role
- Packaging plays a key role and is extremely important in Japan, Japan market has some unique requirements in pharma industry.
- Quality by design and analytical tools have replaced root cause analysis for quality frameworks
- Technology transfer has been replaced by Knowledge transfer and knowledge transfer of any manufacturing process for commercial activities from R&D is not acceptable unless it has strong scientific rationale and proven equipment mapping from lab to kilo lab to pilot plant to commercial plant
- For Japanese customer, appearance is the representative of quality

Mr. Vinay Jathar:

- We have to keep investing in quality to meet global standards
- Our primary focus should be on the customers i.e. the patients' health

- Investment does not necessarily mean capital expenditure; it could be in quality culture as well E.g.: JIM (Japanese institute of manufacturing) is a joint initiative of India and Japan to train the Indian youth in pharma manufacturing in Japanese way. This will be a win-win situation as it will create talent and help us achieve Japanese quality
- Quality is not only about meeting specifications; it is about entire value chain starting from procurement of raw materials till the product reaches the patient there fore we need to meet global standards.
- However the investment should be incentivised to encourage the companies
- We should be part of PICS or ICH to help us meet the global standards and increase exports

Dr. V G Somani:

- Quality by design required across the system and that is throughout Product life cycle: If we can build quality of the life cycle from RM till the pharmacovigilance, it will require some time.
- Quality of materials, methods used and monitoring and machine is important
- Aim is to build quality products to meet unmet needs of the world

Dr. Dinesh Dua:

- We have achieved the highest ever growth in the history of pharma industry exports (25%)
- Target is to achieve: 50 billion dollars share in exports
- We should pursue China, South east Asia and Latin America
- We must promote brand India. IBEF had done a great job. We must do lobbying like US along with Indian embassy
- Challenges we face are MEIS and RODTEP. China is offering 6% incentive. On RODTEP we must get 6%.
- We have achieved IP recognition, Nigeria, Ghana, Ethiopia, Kenya have taken steps to ensure that IP IS RECOGNISED. We must continue to get the recognition
- India must become member of PICS and through pharmexil we must galvanise Africa.

Mr. Ravi Uday Bhaskar

- There should be more focus on innovations in R&D. Govt needs to rethink about weighted reductions given to R&D expenditure and also introduce new R&D incentives and allow 200% weighted reduction
- Bangladesh is one of India's competitors. They have a strong manufacturing base. To compete with China and European countries we must move beyond generics manufacturing formulations for better future

<u>Talent</u>

Prof. Kiran Kalia

- Our NIPERS department is performing well with talented faculty. Industry should make use of this faculty and join hands with national institutes to find solutions for any problems that are being faced
- The government has created an ATAL innovation program to fund new innovations and new R&D schemes
- Industry should leverage the R&D system that is supported by Indian Government

- We should have incentives for the industry if they collaborate with NIPERS
- We must adopt parallelly next generation pharmaceutics focusing on cell and gene therapy and other next gen therapies (siRNA) as well
- With the availability of electronic notebook system at NIPER, we can have skill development program for people already working in the industry to support quality.

Value Added Products

Dr. V G Somani

- People want highest quality and most affordable price whether it is API or formulations. We have to prepare a gap analysis. How to make what is already existing more efficient and affordable
- To meet the unmet need of the globe, only that can make the value addition

Summary

Ms. S Aparna:

- The states should recognize the opportunity in the availability of infrastructure in the form of parks
- Promote digitization in terms of automating manufacturing e.g. use of AI, etc.
- Our PLI is fairly successful, however out of 41 APIs, 7 APIs did not receive any application hence certain introspection is required
- New PLI can also look at KSM if it is important
- In the applications of PLI, there is great variation in price and investment level for the same product and volume – This needs to be looked into
- Atmanirbhar Bharat is 3 pronged – 1) PLI; 2) Phased manufacturing; 3) FDAs

SESSION 2: ECOSYSTEM FOR R&D AND INNOVATION: MOVING UP THE VALUE CHAIN
1ST MARCH 2021 (11:45-13:15 PM)

Chair:

- Prof. K. Vijay Raghavan, Principal Scientific Adviser to the Government of India
- Dr. Renu Swarup, Secretary, DBT

Moderator:

- Mr Sriram Shrinivasan, National Health Sciences Leader, EY
- Ms Smriti Mishra, Advisor, Health Sciences, EY

Co-Moderator:

- KG Ananthakrishnan, Secretary General, OPPI

Government Participants:

- Mr Jayesh Ranjan, IAS, Principal Secretary (Industries), Government of Telangana
- Mr Rajnish Tingal, Joint Secretary, Department of Pharmaceuticals
- Dr. R K Goyal, Vice-Chancellor, Delhi Pharmaceuticals Science & Research University
- Dr. Arvind Bansal, NIPER, Chandigarh

Panellists:

- Mr Pankaj Patel, Chairman, Zydus Cadila Healthcare
- Mr Glenn Saldanha, Managing Director, Glenmark
- Mr Manoj Saxena, Managing Director, Bayer Zydus Pharma Pvt. Ltd.
- Dr. Abhijit Deshmukh, Head- Global OSD & API Scientific Affairs, Mylan (A Viatris Company)
- Dr Mahesh Bhalgat, Chief Operating Officer, Syngene International Ltd
- Dr Anil Kukreja, VP - Medical Affairs & Regulatory, Astra Zeneca

Key Discussion Points:

Establishing Innovation Ecosystem

Prof. K Vijay Raghavan –

- Need to learn what the pandemic has pointed out and how we need to restructure our systems in new ways. 3 things needed going forward – daring, content and mechanism.
- 1. Importance to be given to investment in early stage research, e.g. mRNA vaccines. The early investment done in this area 5-10 years earlier is the reason why it is working well today.
- 2. Thoughtful regulation – Conflate precision with accuracy. Pandemic has highlighted how things can happen faster without compromising quality (this is a global issue) and also keeping public interest in mind. Regulatory needs dramatic transformation – and this is a continuous process. Regulators need to be at gold standard.
- 3. Risk mitigation needs to take place – our industry doesn't have risk mitigation. We must connect our huge R&D infrastructure DBT, ICMR, CSIR, universities – this should be available to industry so that this dark fibre can be lit.
- Also, we need to get into international collaborations
- The biggest difference between this industry and aircraft manufacturing (for example) – is our capability and ability to do cutting edge research at high speed. This requires training of people and expanding the footprint of science.

Dr Renu Swarup

- We have realised the value of the sector during the pandemic.
- The sector responded so quickly during the pandemic not only within India but globally as well because of the robust ecosystem. This has to be taken forward exponentially.
- We can't wait for pandemics to deliver. Collaboration and convergence happened between interdisciplinary groups to deliver during the pandemic – we need to take this forward
- The key component has been building capacities for both human resources and infrastructure
- Policy enablers also helped through the pandemic – industry-academia partnerships, funding through BIRAC,
- During the pandemic – start-ups came forward and delivered
- Area of genomics came up because of interdisciplinary groups coming together
- The ecosystem today is robust – HR, infra, regulation, policy – now it is imp to go ahead as a group.
- What we need now is risk investment. We have ~5000 biotech start-ups today. But Risk investment is still something we are trying to get. We are setting up clusters, trying to get everyone together, but the gaps need to be deliberated in the session to take it to the next level.

Mr. Jayesh Ranjan –

- Life Sciences ecosystem has developed over the last few decades in and around Hyderabad.
- IDPL was setup in Hyderabad when the country became independent and the PM chose a decentralized model of pharma PSU
- Hyderabad is the epicentre for indigenous innovation
- 3 things to create the ecosystem – 1) Government seriousness should reflect in the policy to get the buy-in. Our intent has always been to have the policy translated to action. No one

taking ownership – reason for lack of translation into action. Development of institutions to bring the policies to action, e.g. RICH – it is a one of kind institution which was started 4 years ago. RICH platform brings together all R&D start-ups, industry, govt and private institution, etc. for collaboration and synergies. A molecule in the COVAXIN vaccine was developed by such a collaboration between IICT and a couple of start-ups. 2) In Telangana, we believe the talent and wisdom is available even outside the government. Talent in RICH has been recruited from the private sector based on merit.

Mr. Pankaj Patel

- There are 5 important parameters – 1) Seamless, efficient regulatory system; 2) Funding support – Risk capital comes from innovative ways to get VC to India. How do we ensure high rate of returns for such investment? Best practices in other countries like China should be studied for the same; 3) Academia Industry collaboration – All the gov labs should be involved to get into healthcare research work in time bound manner; 4) Policy landscape – policies should also be implemented with the same spirit with which it is made; 5) High quality infrastructure – Hubs already exist, we need to work together to get more output. Need for specialised hubs.
- Bottom Line – Need to create a national pharmaceutical research council which will have industry reps, labs and all other Lifesciences stakeholders. This is the need of the hour.

Mr. Glenn Saldanha

- Glenmark is the biggest believer of innovation. Innovation is the heart of what they do. Innovations done in both small molecules and biologicals. We did a lot of partnerships till 2012-2013. Now most of it is self-funded and driven internally.
- The need is the demonstration of intent of the government to fund innovation.
- It will be great to have VC, but VCs are indifferent in the way they look at innovation. So before VC funding, we need to move to world class innovation over the next decade. China has done the same – provision of incentives which helps them grow their innovation)
- The entire ecosystem has to go through major transformation. There are a lot of smart minds, eager minds, start-ups to create something that is globally competitive. All it needs is nurturing and incentivization.

<u>Enhance Talent Base</u>

Dr. RK Goyal

- There is a need for breakthrough research. For the same, it is needed to have stronger tie ups between the industry and academia. Most research is coming out of industry whereas the R&D at academics is relatively poorer.
- The national council of research should be a cluster of pharmacy, biotechnology, medical colleges, basic sciences, veterinary colleges, AYUSH, Agriculture, Industry, etc. It should include all disciplines related to drug discovery under it and not working in silos. PCR is also not being taught – students learn this in industry. For breakthrough research students must get the opportunity to work on the latest technologies.
- There is a need to strengthen the existing R&D system. There should deregulation of the education system. Accordingly the finances can be redefined.

Dr. Arvind Bansal

- Skillset is a moving target. Each year, new types of skillsets are required.

- Academics need to be industry relevant. For the same the faculty should be able to teach industry relevant coursework – most of the academicians have low interaction with the industry.
- Industry should be involved in making of the courses and also delivering the same to students – as adjunct faculty.
- In Europe, it is mandatory for PG students to have 3 to 6 months internship. Even for NIPER students, CSIR labs, we should make it mandatory that research projects be done in the industry. This will make our pool of manpower industry ready.

Mr. Mahesh Bhalgat

- There are 5 major components of the ecosystem – 1) Risk sharing framework needed; 2) Human resources and talent – recognise that within India we can have data scientists and cross collaboration across industries; pharma industry is poor implementor of IT 3) Regulatory framework - There is need of more focus. 4) Govt emphasis and visibility on R&D – an R&D barometer. KPIs should be tracked and progress should be ensured in - i. Funding, ii. No. of Scientists, iii. Industry – academia projects, iv. No. of relevant patents, v. Amount of MECE funding and vi. No. of Sq. ft put into R&D.
- Building an ecosystem through leveraging experience 5) Human resource and talent – need to incentivize talent movement – bringing in projects even from worldwide partner network.

Prof. Vijay – Govt funding will never be enough – we need to look at other avenues in banking, etc. to fund R&D

Mr. Glenn Saldanha

- Needs from Academia (why industry collaborates with them worldwide – new drug targets, technologies, setting up filing patents, setting up incubators, etc. Improvement of the quality of research coming out of academia is needed to facilitate these collaborations. This will attract the industry to collaborate.
- Also, speed is very important. Speed of innovation in academia needs to be hastened for it to drive industry to partner with academia.

Mr. Rajnish Tingal

- Govt research is also spread among various departments, ministries. We have set up a motion and coordination council. To ensure duplication of efforts, overlapping of funds. The focus should shift from generics to next higher level of drug discovery, R&D should be the prime focus to move up the value chain. A high-level secretary level committee with representation from NITI aayog, the core committee was headed by Dr. Pankaj Patel. Recommendations are being used to form policy based on these with stakeholder consultations soon.
- Course curriculum in the NIPERs should be revised – this is being done. Industry should work in collaboration with NIPERs and NIPERs should also focus in specific areas.

Mr. Pankaj Patel

- Pharma training and development has been focussed on manufacturing and not complete innovative research in a big way.
- There is a need to create specialised programs for specific areas for example in silico development, in silico testing, use of AI, PKPD, ADAB, Biological areas including

pharmacology, rDNA, product developments, clinical developments, etc., Statistical analysis – all post graduate programs

- Industry can collaborate by building incubation centres in NIPER campus and use NIPER infra
- NIPERS can work with the industry. One NIPER can work on animal modelling, one can work on toxicity, etc.
- NIPER should be given accountability so that results are given in time bound manner. This way there can be timely data generation.
- BADOL act (US) – we should have a version of this too - Scientists working in the universities can start their own companies when doing a specific research. The university will have some equity so that they can get awarded later. This is already happening in the US. Funding support for same will be needed.

<u>COVID Learnings</u>

Dr. Anil Kukreja

- There have been a lot of learnings from the pandemic. The same needs to be nurtured. There can be a concept paper on the learnings we want to carry forward.
- Multiple companies and academia coming together to develop a diagnostic methodology (Cambridge and other industries as well). Example – AstraZeneca and Oxford collaboration, Serum Institute.
- Industry and academia need to collaborate to meet the unmet needs in different geographies
- There is a need for this kind of collaboration for the other diseases as well which are also causing fatalities
- During the pandemic, even regulators came together, there were real time reviews, rolling reviews, e-submissions. All of these activities should be continued.
- There is a need of collaboration even within academia for example between clinical department with para clinical department.

Manoj Saxena

- Incentivising R&D can bring a lot of FDIs and a lot of investments.
- We have to harmonize policies globally
- Need of investment in specialized courses -
- Focus on technology and data science
- Incentivization to ensure continuous investment in clinical trials

Mr. Abhijit Deshmukh

- Importance of collaboration of multi- disciplines and importance of drug repurposing
- The future of innovation will be led by collaboration
- The technologies to expedite would be – 1) AI for drug discovery; 2) Optimization to optimize processes; 3) Big data and analytics; 4) Integrated continuous manufacturing – This will change the paradigm of how we manufacture the pharma products. Will bring in agility, high throughput, etc.; 5) IOT – to provide real time data of machines

<u>Financing</u>

Mr. Pankaj Patel

- Globally, governments are providing incentivization. In India, there is no special tax rates, there is no financial funding available. There is a need to create the environment for VCs to fund here. we need to give them returns similar to what they will get from larger market.

Dr. Anil Kukreja

- Need to explore all available funding options. BARDA was one, gov funding is there. Procurement should be incentivizing the researchers and manufacturers.

Mr. Mahesh Bhalgat

- Example that can be referred to is what Korea had as Tesla policy in 2017 which incentivised biostartups (allowed to IPO even without generating revenue) and saw an increase by 75% in sizes of the companies. Similar innovative ways of funding need to be incorporated for India.

Mr. Glenn Saldanha

- Reinstate the R&D incentives, need to go up to 200% which should be bare minimum. This is important to fund research companies. For MSMEs, start-ups, there are multiple models like partnerships, capital funds, VC funding, etc.

SESSION 3- HEALTHCARE DELIVERY AND MARKET ACCESS
1ST MARCH 2021 (2:00 PM TO 3:30 PM)

Chair:

- **Ms Shubhra Singh,** Chairman, NPPA
- **Dr Praveen Gedam**, Additional CEO, National Health Authority

Moderators:

- **Prof Arvind Sahay**, IIM Ahmedabad
- **Dr Viranchi Shah**, Senior Vice President, IDMA

Government Participants

- **Prof. Randeep Guleria**, Director, AIIMS
- **Lt. Gen. Nardeep Naithani**, Director & Commandant, Armed Forces Medical College
- **Mr Navdeep Rinwa,** Joint Secretary, Department of Pharmaceuticals
- **Dr S Eswara Reddy,** Joint Drugs Controller (India), MoHF&W

Panellists:

- **Dr Sangita Reddy,** Managing Director, Apollo Healthcare
- **Dr Ashutosh Raghuvanshi**, MD and CEO, Fortis Healthcare
- **Mr S Sridhar,** Managing Director, Pfizer India Ltd
- **Mr Rajaram,** Managing Director, Sanofi Ltd
- **Mr Sanjay Murdeshwar,** Country President & Managing Director, Novartis India
- **Mr V Simpson Emmanuel,** General Manager**,** Roche India
- **Mr Vishwanath Swarup**, COO, Bharat Serum
- **Mr Kaivaan Movdawalla,** Healthcare Leader, EY

Key Discussion Points:

Ms. Shubra Singh

- Access to essential medicines has been construed by the Indian judiciary and WHO as a fundamental right to health.
- Any pharma policy will serve multiple, often competing, objectives outlining the area of access and balancing industry demands. It is important to have inherent trade-offs between static efficiency and dynamic efficiency. In other words, consumer welfare maximization v/s trade-off for investment in R&D for potential drugs.
- Of the total expenditure on health (2014-15 report), almost 70% was out-of-pocket (OOP) and was a major constituent for dragging families below poverty line. And a key component of OOP was medicines. Therefore the important need of balancing the needs of the consumer with that of the industry.
- Hence, there is a need for appropriate policy mix. We need to discuss what are the policy options for expanding access, expanding the scope under Ayushman Bharat, policy with respect to patented drugs and how the same can reach the consumers, opportunities that can be availed in e pharmacy and tele consulting, scope for adult vaccination.
- Major areas of discussion – what are the policy options for expanding access, we are also talking of trade marginalization for non-scheduled segment of drugs, NLEM is round the corner, the expanding scope under Ayushman Bharat. Policy with respect to patented drugs, opportunities for consumers to access while addressing the concerns of the industry on R&D spends on these, opportunities unveiled by e-pharmacies and telemedicine and adult vaccination.

Dr. Praveen Gedam

- We are in the middle of the revolution in healthcare delivery in India
- Affordable and accessible healthcare is being provided via Ayushman Bharat and wellness centres
- There is also a chain of Jan Aushadhi stores in the country
- The country is moving towards digital healthcare. The prime minister announced that every citizen will get a health ID which will link all health records and create a longitudinal medical history of the patient.
- Intention is to bring all healthcare professionals on a single platform. Patients can connect with doctors on this platform without bothering about KYC of doctor. Pilot for same has been launched in the 6 UTs.
- How can we make even pharmacy more approachable and accessible to people in the country

How can access be improved? For essential as well as for patented products

Mr. S Sridhar

- Pfizer purpose is “breakthroughs that change patient’s lives”. And that every person at every income level in the country should have access to quality medication.
- Ayushman bharat is a step in the right direction. We should ensure that this program covers not just the BPL patients but also enhance that to middle class patients. We will be very happy to offer to offer differential pricing to patients under Ayushman Bharat. We can also have innovative outcome-based pricing so we can have most innovative products into Ayushman Bharat.

- We should focus on preventive healthcare with the penetration of awareness of vaccination, differential pricing, innovative outcome-based pricing and partner with the government to get more innovative medicines to the common therapy.

Mr. Arvind Sahay

- In the UK, Gilenya (Novartis product) is sold on basis of outcome – what is the improvement of Quality of Life for cancer patients. That requires a certain knowledge of being able to run some tests, especially new drugs. So the question is if we are at a place in the country where we can increase market access through outcomes-based pricing that has been talked about?

<u>View on outcome-based pricing</u>

Mr. V Simpson Emmanuel

- Outcome-based pricing is the way to go.
- Access is a systemic problem and pricing is just a part of it.
- There is a need for unified outcome-based objective rather than treating pharma companies as just a vendor.
- Everyone needs to come together and think about this instead of thinking in silos
- Example – Roche has a patient support program which is not based on the pricing alone. India is not very far away from implementing this.
- Roche can participate in the patient journey by helping by just sharing knowledge. It is a program of awareness, diagnosis, reach and how can we share the knowledge to help the patients in their journey and hence lead to better outcomes.

Mr. Arvind Sahay

- DPCO has had differential impact – 52 out of 108 – access/uptake declined. Some form of price control exists across the globe, and for a sector like this we expect it, but how do we decide which one is suitable form in the Indian context? Given that on one hand 70% of healthcare expenses is OOP and on the other hand prices are already amongst the lowest in the world?

Mr. Sanjay Murdeshwar

- One of the advantages we have is that Ayushman Bharat Scheme has covered large number of people and hospitals – 100 million patients, ~20,000 empanelled hospitals, 2500 different procedures; hence we are sitting on pools and lakes of data. This data needs to be leveraged for outcome-based pricing methodology. Just throwing more money at healthcare is not going to help.
- Another area of knowledge we can build is private insurance – it prices its premiums based on certain actuarial values. Fundamental knowledge already exists in the system. We just need to harness it and bring it into a more disciplined way of taking decision.

Dr. Sangita Reddy

- It is very important to us to segregate and highlight that fact that we need to work across primary, secondary, tertiary and quaternary healthcare.
- We do that in a framework of universal health coverage. And then we look at the universal access which is 1) financing mechanism; 2) the availability of the providers and our ability to spread them where we need them; 3) innovation and design and how do we streamline, one of the methodologies being outcome based pricing that empowers the benefit for the

patient – and hence is extremely critical. But there are multiple steps in the process that need to be parallelly looked at – e.g. ramping up of infrastructure.

- One very important aspect of outcome-based pricing is that it is driven in the western world because the system evolved in a certain manner which was not that effective. It was a reset mechanism for people to focus on outcomes. In our context, it will enable us to focus on primary healthcare interventions. Indian is one of the only countries, where health insurance while being set up – it sits in life insurance, general and in health. But its positioning in life insurance is not being pushed as much as it could. Preventive diagnostics can help save lives as well as high costs in insurance.
- There is a need to capture data in an understandable way and decipherable format. Currently we are not capturing outcome data currently.
- Using the current IT, we need to move very aggressively in the tele health model. Example – 350 primary health care centres are being managed as they are all e-enabled. A lot of studies are possible using the data collected

Mr Navdeep Rinwa – (33rd minute to 37th minute)

- Developments in the last few years… 2017 – National health policy - increasing spend on healthcare
- Ayushman Bharat – insurance to over 50 crore people
- Department also working on various schemes on bulk drugs and many other categories of drugs are incentivized
- …Other historical updates
- Currently working on Trade margin rationalization based on cancer drugs analysis
- Working with industry on making drugs available and affordable

Prof. Randeep Guleria

- Outcomes are multi-factorial especially in a country like India which is very diverse – healthcare, a state subject, is very diverse across states and from public to private sector.
- It is a complex issue as health services differ state to state depending on the investment, role of the pharma companies, etc.
- There is a need of a good insurance model. Involvement of middle class by paying a small amount in Ayushman Bharat could be done to cover a larger part of the population
- Telehealth needs to become user-friendly as there are multiple challenges with respect to rural India where people don't have the smartphones or are not comfortable using that interface.

General Nardeep Naithani

- We need to have a granular anonymized data so we can plan and prioritize procurement better. India is a unique position for differential pricing because large public sector caters to volumes and commands lower prices and we also have a population that basically depends on private institutions and can pay higher. There are hardly any companies that are GEM marketplace registered from whom we can procure medicines. HTA provides for a robust procedure for assessing outcome-based results, we do it for vaccines in the armed forces, and also for adult immunization also and that can be used for pricing purposes.
- Regarding common generics – there is less confidence due to lack of perceived quality control
- IT enabled services: we need to have clinical decision support systems that can enforce protocolised treatment at least in the public sector and even in insurance there is a lot of

scope to ensure authentic treatment. We have done it for the country, and we can use IT to better enable and also make it more scientific.

Imperatives to achieve Universal Health Care

Mr. Ashutosh Raghuvanshi

- Design is important to achieve universal health care and that private healthcare can only complement and not replace public healthcare system. There are large gaps in the system and to achieve Outcome based pricing or universal healthcare, all building blocks need to be put in first. Some of the initiatives being taken up where the existing data can be leveraged
- Need for adequate degree of regulation – technology can play a major part in imparting primary and preventive care.
- There are certain elements that can be taken over by telemedicine. Already existing patients with chronic diseases who are in the system can be managed better with technology. However over-dependence on technology might not solve the issue due to cultural issues and regional imbalances.
- Physical infra is the third part that can fill up the inequalities. Here public sector plays a major role.
- Both the public and private sector need to provide care and be viable
- Health ID is the most important component in going forward with UHC

Dr. Eswara Reddy

- Access to essential medicines or technologies is the right to health. Govt has a constitutional obligation to ensure universal healthcare.
- Medicines contribute maximum to the OOP in India. It is almost 52% of the OOP.
- The government has constituted a standing national committee on medicines to review NLEM, other healthcare products from time to time
- The medicines that are approved by the authorities are standard quality and the quality is proven in India as well as globally. Our >50% of exports to highly regulated markets are a testament to this.
- Regulations have been also brought in to ensure quality of generic medicines while ensuring accessibility.
- We need to balance innovation and accessibility. Govt is considering a proposal for innovation promotion council to bring down the cost of innovation. One of the methods is voluntary licensing. This will make drugs accessible and affordable globally.
- Health technology assessment board (HTA) board has been constituted in ICMR to assess health outcomes compared with the medicines. So to conclude, the medicines are not high cost but high priced.

Innovative Financing

Kaivaan Movdawalla

- India can be a stellar example in achieving UHC through coming together of 1) political will, 2) private sector capacity and capability 3) public demand for accountable
- There are 2-3 points about UHC
    - Capacity creation: it is not about just generating capacity but equitable distribution of capacity. There is a need of innovative models such as targeted incentives and

viability gap funding. How in specific underserved areas, government commits to sponsoring patients.

- We have also spoken about the role of insurance – it is a necessary condition but not a sufficient one as evidenced by global examples. So there has to focus on primary health care and focus on lifetime cost of care, rather than transaction cost to make UHC a reality

Mr. Rajaram Narayanan –

- Pricing and insurance are very interconnected
- The pricing experience in India is very encouraging
- There is a need to fix the extremes. Need to make sure that innovative medicines are accessible, 80-90% of innovative medicines are under a framework.
- There is a need to cover the large middle-class population by Ayushman Bharat

<u>Self-care and prevention</u>:

Mr. Vishwanath Swaroop

- We have illness insurance and not health insurance – as most of our insurance plans cover only illness and not wellness.
- We take pride in providing the lowest cost medicines but let us take a step back. the NCD is longer duration, so pricing is one piece, and another is the awareness and diagnosis. Along with being the pharmacy of the world, we are also the IT of the world.
- E - pharmacy and tele consult - there is a huge opportunity to make this normal practice going forward.
- The awareness of adult vaccination was very limited, but now suddenly everyone knows about it. Government enables awareness and diagnosis.
- Innovative pricing techniques are also equally important

Mr. S. Sridhar:

- Segmentation of the population is required, basis which adult vaccination guidelines can be prepared.
- Segment population into affording and not affording class
- Govt. should take on responsibility, gov should partner with private companies to get in at differential pricing of multi – dose vials for high risk patients and leverage the technology and infrastructure created for covid vaccine and make private companies take care of private population.

<u>How do we leverage Tech</u>

Dr. Ashutosh:

- Tech can play an important role in both preventive and primary care – however a proper regulation is required around it and limitations need to be accepted. Acute care, procedure related care can't happen remotely.
- If they have to happen, we need to have proper tech – e.g. we discussed the example of rural patients who don't have smart phones. So one way could be kiosks, wellness centres that could be linked through tech with larger hospitals, and that may be great way to expand into rural and more inaccessible areas.

- Even the urban areas where people can't afford – those also need support. We can utilize our infrastructure much better. That is one of the major usage of tech. the health IT will play an important role to make it reality – as long as the system is not integrated, there will be wastages as people will go to one hospital and the other hospital and the data also can't be shared

Kaivaan:

- The biggest role of tech is shaping healthy behaviours. Globally studies show that 40-50% outcome improvement happens by shaping behavioural changes and that is the root cause where tech with its innovative advancement on products, has a significant role to catalyse this part of behavioural change.
- Second, the patient being at the core – traditionally, unless it is deliberately controlled, it has advanced the cause of democracy by providing power and consolidating the voice of the powerless masses and traditionally we have had this power imbalance between the providers and public, now we are seeing the emergence of this active consumer, demanding consumer from being docile in the lack of information age, technology has a real role to consolidate the voice of patient and this trend is very strong where we are putting power in hands of the patient, where the patient to be treated right, with honesty, dignity, care, this is going to be the core. Tech will play a role in both these things.

INDIA PHARMA 2021SESSION 4- NEXT FRONTIERS
1ST MARCH 2021 (3:45-5:15 PM)

Chair:

- **Dr V K Paul,** Member, NITI Aayog
- **Ms S Aparna,** Secretary, Department of Pharmaceuticals, GoI

Moderators:

- **Mr Sriram Shrinivasan,** National Health Sciences Leader, EY
- **Mr Pramod Sudhindra**, Digital & Innovation Leader, EY

Government Participants:

- **Dr YK Gupta,** President, AIIMS Bhopal; Vice Chairman- Standing National Committee on Medicines and Healthcare Products, GoI
- **Dr V G Somani,** DCGI, MoH&FW, GoI

Panellists:

- **Mr Satish Reddy**, Chairman, Dr Reddy's Laboratories
- **Mr Prashant Tandon**, CEO, 1 mg
- **Mr V Simpson Emmanuel,** Managing Director, Roche India
- **Mr Subrata Bhattacharyya**, Health Economist, Founding Director, PharmaQuant
- **Dr Balagopal Nair**, Medical Director- India Region, Abbott
- **Mr Saumil Mody**, General Manager, Novartis Oncology
- **Mr. Anil Raina**, General Manager India- Sanofi Genzyme
- **Mr Harish Jain**, Secretary, KDPMA
- **Mr Rajesh Madan,** General Secretary, FOPE

Key Discussion Points:

Ms. S Aparna

- Prioritization – We should look at development of a personalised healthcare experience which is increasingly becoming necessary, how will pharma contribute to the same catering to the treatment of 700-odd rare diseases
- The regulatory system – is needed for a public good imperative. But this should not stop it from being predictable, innovative, simple to navigate, transparent, responsive to the needs of the industry, healthcare providers and the patients, etc.
- Digitalization – Digital tools are making individuals got to be more in control of their own health. This information overload from personal health tracking tools creates a greater challenge for healthcare providers as well as pharma and medical product providers to counter the plethora of info with something that provides a basis for insight, trust, empathy with the patient. It is not an unadulterated benefit but also a benefit only if we are able to address the associated risks and challenges

Dr. V K Paul

- The importance of this sector was experienced during COVID 19.
- 3 broad facets –
    - Improved paradigm of regulation, that is how can we expedite without compromising quality/rigour of the established scientific system
    - New frontiers have to be opened up that is cell-based therapies, gene-based therapies, etc. There is a need of specific, comprehensive guidelines for treatment on some of these aspects. There is a huge vacuum in this space. We need to be more specific, comprehensive in this paradigm. We have to emerge as leaders in these areas. Within 12 weeks, India made 96 new diagnostic kits – two using cutting edge technologies. It is possible for our regulatory, scientific and industry enterprise to rise to the occasion and be able to provide affordable solutions to these rare diseases.
    - Novel Delivery platforms – e-pharmacy and tele medicine need detailed guidelines as the regulations still have gaps.

Mr. Satish Reddy

- Patient centricity: one of the things is, Pharma has always been about medicine – chasing doctor's prescriptions, making them at affordable cost. But that was past. But we made a switch long back – what can be done in the interest of the patient, through doctor's prescriptions. E.g. for the cancer treatment, it is not just the Rx by doctor, but there are lot of side effects of therapy and a lot of mental trauma, so a lot needs to be done. So for the patient, there is only so much that doctor can do. Pharma can play a huge role in the entire disease management cycle - getting the patient to recover faster and get back to the normal life in a much faster way.
- Another part is lot of ancillary needs of the patient– there is a dialysis product, darbepoetin – this also requires additional services, and also assisting the doctor. If there is a way by which we can assist the doctor for necessary counselling to the patient. Pharmaceutical companies could play a role in the same.
- From patient centric POV as well, there is overload of information at this point of time, but it has to be credible information, it has to be dealt with experts, it also has to enable the patient to take care of the issue themselves. This whole thing is a process and who can play

the role in this, the role that the doctor plays, pharma company can play a role but more importantly the patient can take the responsibility on themselves

Dr. Y K Gupta

- During COVID, there was too much attention given to COVID and we succeeded too, but there is a need of a concerted effort to develop drugs for anti-microbial agents at affordable cost and make it accessible. This will require investment by the industry and by funding agencies.
- There is need to empower patients. The drug immunoglobin was required and was available by Rs. 17,000 if through insurance, and patient was getting it for 7,000 from market, but was asked to buy Rs. 17,000 immunoglobulins forcefully. Industry has to ensure that the cost of their product is reflected into the benefit of the patient.
- Everyone has to work together for neglected diseases. Academic institutes, labs and industry have to work together.
- E.g. KYP – Know Your Prescription has been started by me. The issue is that patients cannot read their prescription. It can only be read by the chemist. So this platform helps to prevent medication error. This is another area where corporates should put in more effort.
- Drug disposal – Every house and hospital dispose drugs in open drains which is leading to havoc. This is another reason for anti-microbial resistance apart from irrational drug prescribing. There is a need for guideline particularly in hospitals for the same.
- Any ideas coming up in academia should be channelized by industry through an industry-academia-regulatory triangle

<u>How should India tackle rare and neglected diseases?</u>

Mr. V Simpson Emmanuel

- We need to look at it from an ecosystem point of view. One single stakeholder like gov or industry can't solve it – It has to be together. Industry, gov, patient groups have to come together. When it comes to rare diseases, it is limited population, so very less companies are in the rare disease space.
- There is a need to incentivise industry to invest in rare diseases
- In a country like India, expenditure is majorly OOP so there is a need of a solution like funding stack where government pays some amount. There is a need to bring innovative pricing mechanisms for India. E.g. Singapore has a rare disease fund where donations come into the fund and the gov matches that, similar to Scotland. One point – strongly increase the concept of funding stack.
- There could be option of layering funds on top of it through CSR, private insurance, etc.? to add to the existing funds. For e.g. we have Ayushman Bharat, but no provision for patients to put some funds on top of it. This could be useful to address the problems of affordability and rare diseases.

Mr. Anil Raina

- For rare diseases, number of patients that are eligible for treatment is very small. There is a need for an access mechanism. Insurance in India cannot take care of such a large population for the cost involved, which is extremely high and beyond the reach of any individual. E.g. for the disease Haemophilia, a PIP funding model is used. The funding is either shared equally or a 60:40 ratio between the centre and the state.

- For India, there could be a mandatory CSR or cess which could be levied. This should take care of the funding towards rare diseases

Dr. V K Paul

- There are 3 issues that we are facing in rare diseases space –
    - Somebody is making these products somewhere, why are we not making it in India?
    - Children in other countries are receiving these medicines though some mechanism, they are accessible to them but why children of my country are not able to get it
    - We can do it, but why are we not coming forth on how to do it. We can make it better and cheaper for the world. Can we pick priorities and work towards at least a few?

Mr. Satish Reddy

- Our mission - as an industry - has been to provide generics competitively. Cost of development and low volumes makes it difficult for the industry to do it alone. The government needs to be a part of this too.

Mr. Anil Raina

- Volumes are very low in India as well as across the globe and hence it is very difficult to have multiple manufacturing locations – whether they are in India or abroad.

<u>Overarching regulatory body</u>

Mr. Saumil Mody

- We have experienced that in the last 12-18 months, approvals have been expedited from a CDSCO perspective.
- One of the suggestions is how do we get provision of data protection to support innovation. There is no linkage between IP part (IP appellate board) whereas product approvals happen from DCGI office – something to regulate that, it will be a welcome move
- Need to have a central procurement body for all the innovative drugs as it will help in terms of access.

Mr. V Simpson Emmanuel

- We are looking at accelerated approvals and I want to compliment the department. Couple of suggestions:
    - Products that are already approved globally, have USFDA and Europe approval, can we accelerate the timelines. We may want to insist on certain phase 3 trials. But as there is already a lot of data, can we look at phase IV commitment instead.
    - Need to strengthen IPR as well. There should be monitoring of the outcomes and the impact on Indian patients.

Mr. Satish Reddy

- If we look at what happened during the pandemic, it gives us some answers on what needs to be done. The industry has had good experience– we are extremely happy with the regulatory approvals
- So three things:
    - India can improve timelines as compared to benchmarks from other countries like US, Europe – there is still more work to be done though a lot has already been done

- Tracking system: industry also at this point of time, the submission is online, and we are able to track, but more in terms of tracking the outcome. There is a need to track the performance metrics for the approvals which will bring transparency. We could also have checklists for the approvals required.
- Capabilities within the regulatory system: There is a requirement for the predictability, transparency and the capability. This will take industry to the next level. We need to look into how we can get phase 1 trials back to India

Dr. Somani

- We don't need to duplicate what has been already done – here or globally.
- We should also learn to get experience and innovative with real world data and situations. That is where we need to develop a more patient centric and life cycle-based approach.
- We are working towards transparency, to minimize duplication, to get a predictable timeline.
- If we are able to accurately prioritize our focus areas, we can succeed in a similar way to Cuba – as they've done in the field of biosimilars.

Overarching body –

- I, being a vested party cannot say that I can do it/own it – though that is what generally happens in the rest of the world.

<u>Use of digital to empower patients</u>

Dr. Balagopal Nair

- Self-medication is a common practice in India. The time to look at OTC medicines is here. This is the appropriate time to bring regulations for OTC drugs. The same will release a lot of time for healthcare workers. Regulations will help in self-care and improve well-being.
- The widened access to OTC has to be monitored stringently.
- There is need for tools that will help information reach the patients and will break the boundaries of reach and address the rationale use of medicines and give better access

Dr. Y K Gupta

- There is a need to develop the regulatory science in India. For example, we introduced the compensation mechanism for clinical trials.
- Alternative animal models should be developed and included in regulatory
- Regulatory science needs to bring in new models
- Digital and Patient care – Why can't we have QR on packaging of drugs so that patient can get all the information of the drug when scanned. This can help avoid medication error.
- We have to do quality check without increasing the cost. There is need for introspection and self correction. All medicines that were approved by mistake or are irrational need to be deleted.

Mr. Subrata Bhattacharya

- The procurement being done currently is very scattered. This needs to change by a concerted effort. If you look at international experience, e.g. in Washington, they have put

up new procurement approach where they are looking at cost of procurement and what is direct and direct cost. They are trying to optimize the current portfolio

- Another opportunity for India is where we need to look for diseases where evidence is very strong that we know that making the right reimbursement decisions can lead to future savings or can have cost avoided. From perspective of economist this is good.

Views on evidence-based drug procurement

Dr. Somani

- It is very important idea and necessary for health care delivery. Various countries, including WHO, have adopted these models. In certain points of time we will also have to consider that instead of just looking at the L1.
- The second part, the entire digital ecosystem and instant data generated should drive it along with the health technology assessment which has recently started

How can we complement the e-pharmacy with the brick and mortar?

Mr. Prashant Tandon

- Digital healthcare has become imperative. China came up with concept like Internet hospitals where doctors were available digitally, etc.
- In India also, e pharmacy was started in 2015. There is very clear adoption from the consumer side. Consumers are seeking information, access and a platform they can trust to get information.
- The physical pharmacy operates under the drugs and cosmetics act, the digital part operates under the IT act, how the marketplaces work. The drug inspector does not understand IT act and vice versa.
- In 2018, drug ministry came up with a draft on e-pharmacy, in 2019 the same was approved after which it has remained in cold storage.
- In the lock down, e pharmacy became essential service
- The regulatory clarifications for e pharmacy have still not moved forward which is being awaited
- Given the population of India and the scale, India can be the leader in digital healthcare in the world

Summary

Ms. S Aparna:

- It will be useful for us to approach a kind of roadmap, rather than try to solve everything in one go. If we know where we want to reach and we identify the procedural, legislative changes, that will probably be something where people can agree and take it forward. For e.g. we have CDSCO here, we have ICMR here, and they actually work very closely where there is need. What is probably required is better coordination.

- Digitization: whether it is telemedicine or e-pharmacy – there is a need to understand, the Indian context, which is little different from the framework that is in the US and other advanced economies.

Dr. V K Paul:

- Do we know what are the illnesses for which we don't have the choice of medicines? Yes, we should examine that as we are superpower in pharma. We can then systematically develop capacities in those priorities that are currently unaddressed
- Idea of working on orphan drugs – let us try and come together. All easy things have been done, now let us try to do the difficult things. I heard a lot of reasons on why not to do it, but let us now find reasons to do it. Somebody has to bring solutions; can we not do it? We respect and accept that gov participation is required – let us all work in this direction, let us try to create an ecosystem. Let us make a beginning here, maybe one drug, 3 drugs
- Digital health paradigm: not to forget one basic principle of health and medicine as we understand today – health and medicine is ultimately a matter of trust between physician and patient. I will not like to see that paradigm of, let us say digital health or any distortion, that kills that trust.

(B). **Joint Session**: **International Drug Regulatory Session with Pharmaceutical & Medical Device Industry**

DAY 1, 25th Feb 2021 | 5PM – 7PM (IST)

Chair:

- **Dr. V. G. Somani**, Drugs Controller General of India
- **Ms. Vinod Kotwal,** Member Secretary National Pharmaceutical Pricing Authority (NPPA)

Session Panelists

- **Dr. Sarah McMullen,** Deputy Country Director, US Food and Drug Administration
- **H.E. Dr. Amin Hussain Al Ameeri,** Asst. Undersecretary of Health Policy & License, Ministry of Health & Prevention, UAE
- **Ms Emer Cooke,** Executive Director, The European Medicines Agency's (EMA)
- **Dr Jane Cook** First Assistant Secretary Medicines Regulation Division, TGA Australia
- **Mrs. Togi J Hutadjulu,** National Agency of Drug and Food Control of Indonesia
- **Dr June Raine** CBE, Chief Executive, Medicine and Healthcare Product Regulatory Agency

Moderator

- **Mr. Pankaj Bhandari,** Compliance and Regulatory Leader, EY

Context Setting by Mr. Pankaj:

- Structural Metric Changes impact on Pharma and Medical Devices industry at International Level
- Spotlight on the whole global Healthcare system
- Enabling availability of affordable qualitative medicine at International level
- Regulatory framework of different countries and regulatory harmonization between various countries
- Streamline the regulatory environment system at International level.
- Departmental issues and building bilateral collaboration to strengthening the pharma industry while focusing on the centric approach for the same.

I. Drug Regulatory Updates in India by Dr. V. G. Somani, Drugs Controller General of India

Drug Regulatory Updates in India

- Drug Fall under the Concurrent list of the Constitution
- The Act is a central act Enforced by the central and State Govt. through the system of licensing.
- Extended to Whole India

Central Responsibilities

- New drug (New Drug, FDCs, Vaccine, LVPs, r-DNA, Stem Cell derived products) Medical devices/ in Vitro Diagnostic drug Approval.
- Import of drugs/Cosmetics/Medical Devices.
- Clinical Trial, Ethics Committee, BABE studies and site approvals
- Standards of drugs
- Making the regulations
- Pharmacovigilance

State Responsibilities

- Licensing of the manufacturers, sale and distributions of the cosmetics
- Monitoring quality of drugs and cosmetics by sampling and testing
- Investigation and Prosecution

Legal Provision

Drug and Cosmetic act 1940

- Drugs and Cosmetic Act 1945
- Medical Devices Rules,2017
- New Drugs and Clinical trial Rules, 2019
- The cosmetic Rules, 2020

Medical Devices Rules, 2017

- The Medical Device Rules, 2017 were notified on 30/01/2017 which are effective from 01/01/2018.
- These rules have been framed in the conformity with Global Harmonization task force framework and conform to best international practices.
- Quality Management system in line with ISO 13485 has been adopted.
- New online system for the Medical Devices is functional for uploading the application for import License and Manufacturing License
- Classification for Medical devices and IVDs has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.

Road map for the regulation of Medical Devices

- All medical devices are notified as drugs under the drugs and Cosmetics act, 1940 w.e.f 1ST April 2020.
- Registration of these devices under Drugs and Cosmetics Act, 1940 shell be done in an phase wise manner

New Drugs and Clinical Trial (NDCT) Rule 2019

The drugs and Clinical Trials Rules, 2019

- These rules apply to NDs, for human use
- Definition of new drugs includes Vaccines, Novel drug delivery system (NDDS),living modified organism, monoclonal antibody stem cell derived products, gene therapeutic products and xenograft
- The Rules contains various provisions for improving transparency.

Timelines for the applications of the Act

A. In case of CT, as part of discovery, Research, Marketing and Manufacturing in India.
   - Permission/ Resection/ Query in 30 working days
   - Deemed approval if no reply in 30 working days.
     (However, the applicant needs to inform CLA for the about the initiation)

B. For other applications for CT
   - Permission/ Resection/ Query in 90 working days
   - No Deemed approval provision

Timelines for the approval of New Drugs

- Disposal of new drug application within period of 90 working days
- Provision of accelerated approval with condition of requirement of post marketing trial
- Provision for application by sponsor for Expedited review.
- In case of modified or new claims and NDDS the non-clinical and clinical data requirements may be relaxed omitted under certain conditions
- Permission/ rejection / Query in 90 working days

Fast – Tracking approval of New Drugs in Special Situations

- Provisions under ND & CT rules, 2019 for relaxation abbreviation, omission or deferment of data including local clinical trial data for approval of a new drug.

Accelerated Approval

1. Accelerated approval process may be allowed to a new drug for
- Serious/ Life threatening disease
- Rare Diseases

- Diseases of special relevance to Indian Health Scenario
- For disease for which there is unmet medical need
- Disaster or special defence use

Accelerated Approval Process

1. Accelerated approval may be allowed for a new drug for a disease taking into account.
- Severity, rarity or prevalence of the disease
- Availability or lack of alternative treatments

There is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment.

- Surrogate endpoints may be considered rather than standard outcome measures such as survival or disease progression, which are reasonably likely to predict clinical benefit.
- In case of remarkable efficacy, marketing approval may be based on Phase II clinical trial data.
- Accelerated Approval may also be granted to a new drug integrated for serious life threatening disease, disease of special relevance to India and Unmet medical need.
- Phase IV CT may be required to validate the anticipated clinical trial.

Expeditious review Process

- Application for a situation where the evidence for clinical safety and efficiency have been established even if the drug has not completed the all or normal clinical trial phase
- In such case following conditions need to satisfy
  a. Serious or life threatening or rare disease or conditions
  b. If approved, the drug would provide a significant advantage in terms of safety and efficacy
  c. There is substantial reduction of a treatment- limiting adverse reaction and enhancement of patient compliance that is expected to lead to an improvement in serious outcomes

- It is also applicable for new drug development for disaster or defense use where new intervention has been developed and where real-life clinical trial may not be possible
- It is also applicable for approval of an orphan drug.

<u>The Cosmetics Rules 2020</u>

Regulation for Cosmetic

- Provision for smooth export of cosmetic
- Provision for voluntary recall of cosmetics in case of / equality safety issues
- Concept of Good laboratory Practice has been introduced for laboratory.
- Debarment of applicant in case of submission of misleading, or fake , or fabricated documents for registration / License

Major Regulatory interventions during COVID-19 pandemic

- Allowed the door step delivery of medicines to the needy patients
- Stock pilling of vaccines, while under clinical trials is permitted under section 26B of the act.
- Exemption of requirement of sales license for hand sanitizers
- Published draft Guidelines for development of COVID-19 vaccines in considerations of WHO,USFDA,EMA.
- In coordination with state drug controllers all proactive step has been taken to ensure the availability of essential drug including Medical Oxygen.

New Drug and Vaccine Approval for COVID-19

Approved for restricted use under emergency situation

Drugs:

- Remdesivir Injection
- Favipiravir tables
- Itolizumab injection

Vaccines

- COVISHIELD: Recombinant Chimpanzee Adenovirus vector vaccine encoding the SARS- CoV Spike (S) glycoprotein with technology transfer from AstraZeneca/ Oxford University.
- COVAX: a whole Virion Inactivated corona Virus Vaccine (Covaxin) in collaboration with ICMR.

<u>International Collaboration</u>

Broad areas of co-operation are as below

- Medical devices regulations
- Pharmacovigilance
- Regulation of biological product
- Medicines and Active pharma Ingredients regulation
- Training
- Recognition of Indian Pharmacopoeia
- Visit to Pharmaceutical industry for training
- Cooperation in multilateral for a
- Any other areas of common interest

(The areas of cooperation in MoUs may differ from country to country based on mutual interest)

II. U.S. FDA Update Including COVID-19 Activities

Sarah McMullen, PhD. Deputy Country Director, India

FDA AT A GLANCE

- FDA is responsible for assuring the safety, effectiveness, quality and security of food, medical products, cosmetics, tobacco, vaccines and other biological products, and veterinary drugs in the U.S.
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers, or approximately $2.8 trillion.
- The FDA budget includes 17,686 full time equivalents (FTEs).
- FY 2020 budget is $5.9 billion

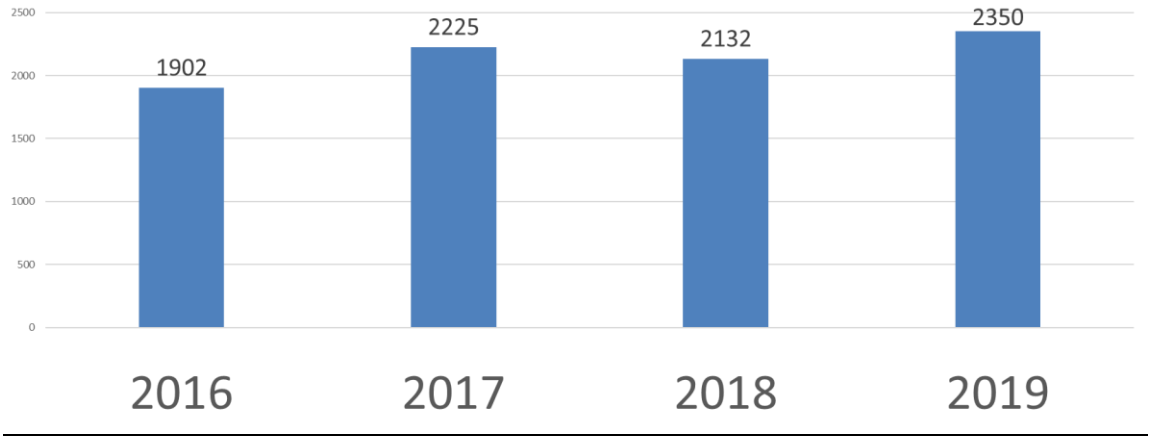
Globalization…By the Numbers

- Production of FDA-regulated goods and materials outside of the U.S. has exploded over the last decade.
- FDA-regulated products originate from more than:
- 150 countries
- 87 percent of biologics sales are imports
- About 57 percent of fresh fruit, 31 percent of vegetables, and 93 percent of seafood consumption by volume are imports.
- About 39 percent of medical devices used in the U.S. are imports

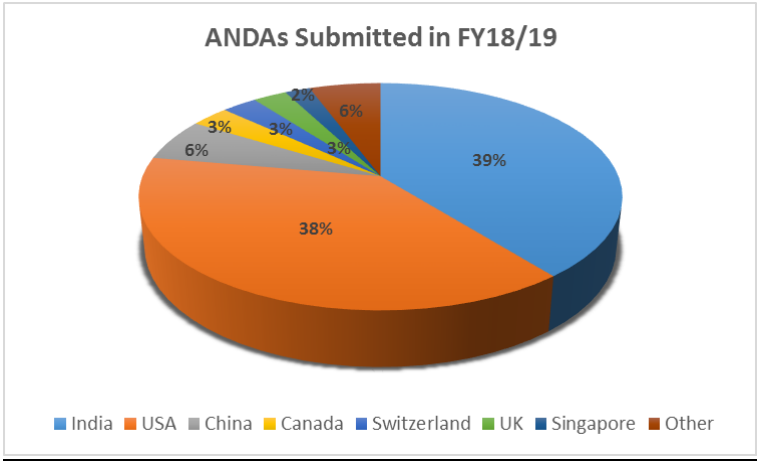
Themes Within Globalization

- Information and ideas
- Manufacturing
- Safety of imports
- Emerging threats
- Greater cooperation with regulators
- Economic competitiveness
- Clinical trials

FDA Pharmaceutical Updates



ANDA's submitted in FY 18/19 by Country



Approvals-Drugs & Biologicals

Date of approval	Product	Authorized Use
Oct 22, 2020	Remdesivir for Certain Hospitalized COVID-19 Patients	U.S. Food and Drug Administration approved the antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval. On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Veklury® (remdesivir) for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19)3

Emergency Use Authorization-Drugs & Biologicals

Date of first EUA Issuance	Product	Authorized Use
NA	Janssen Biotech Inc. COVID-19 Vaccine	The FDA has scheduled a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) for Feb. 26, 2021, to discuss the request for emergency use authorization (EUA) for a COVID-19 vaccine from Janssen Biotech Inc.
Dec 18, 2020	Moderna COVID-19 Vaccine	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older
Dec 11, 2020	Pfizer-BioNTech COVID-19 Vaccine	For the prevention of 2019 coronavirus disease (COVID-19) for individuals 16 years of age and older
Varies	Multiple Monoclonal antibodies	mAbs to be administered together for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
Aug 23, 2020	COVID-19 convalescent plasma	For the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19)

Emergency Use Authorization-Drugs & Biologicals

Date of first EUA Issuance	Product	Authorized Use
Nov 11, 2020	Bamlanivimab	For the treatment of mild-to-moderate COVID-19 in adult and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
Aug 23, 2020	COVID-19 convalescent plasma	For the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19)
August 13, 2020	REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit	To be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting
May 8, 2020	Fresenius Kabi Propoven 2%	To maintain sedation via continuous infusion in patients older than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting
April 30, 2020	Fresenius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions	To provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.

FTC – USFDA WARNING LETTERS TO INDIAN FIRMS

- US FDA has been issuing warning letters regarding COVID-19 since the beginning of March 2020. Besides fighting false advertising, the US FDA is also trying to control the usage of drugs that are dangerous for human consumption.
- As of this date, four (4) Indian firms have been warned by USFDA for posting claims relating to prevention of COVID-19 and advertisements on Facebook / Company's webpage claiming that their products will prevent and/or cure COVID-19.
- The Warning Letters were shared with AYUSH Secretary for appropriate regulatory action as per GOI's Drugs and Cosmetics Act.

FDA Medical Devices Update

FDA Medical Device EUAs

Device	*FDA EUA Link*
PPE	***https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas***
Wearable Devices	***https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas***
Infusion Pumps	***https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas***
Ventilators	***https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas***

COVID-19 Inspection Updates

In-person inspections are not being conducted unless they are mission critical or prioritized by the agency and not in a location under domestic Indian travel restrictions.

Remote assessments:

- Are NOT inspections and do not replace an inspection
- No written observations (FDA 483) issued on remote assessments
- Do not result in a final agency classification (NAI, VAI, or OAI)

FDA is working to resume routine surveillance inspections for foreign and domestic establishments as COVID-related restrictions and personnel availability allow.

Remote Drug reviews: 704(a)(4)

- "704(a)(4) records request" is in advance of or in lieu of an inspection.
- Under the authority of section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374(a)) and FDA Safety and Innovation Act (FDASIA), Section 706
- 704(a)(4) records requests are occurring via email for preapproval inspections (PAIs) and surveillance inspections of manufacturers.
- Records are received via email or electronic drop-box system.
- Firms receive a confirmation email that records were received

Outcomes vary based:

- On the type of inspection
- If all requested records were submitted

III. Update on Drug Pricing by Ms .Vinod Kotwal, Member Secretary, NPPA

Drug pricing Mechanism in India

NPPA-2012

- Essentiality of The Drugs
- Controls only the price of the formulation Price
- Market Based

Essentiality of The Drugs

The standing committee draws up the list of the essential medicine in the country, which should be available at any time and that should be affordable for the society. This list became part of the schedule of the drug price control order which governs the prices of these medicine under this schedule.

Controls only the price of the formulation Price

Prices decided by the Manufacturers according to their business proposition. The price of these drugs gets monitored under one provision of the price control where the manufacturer cannot increase t6he price beyond 10 %

Market Based

Manufacturer can launch new drugs with the retail price given by the NPPA.

IV. Updates by Dr Jane Cook, First Assistant Secretary, Medicines Regulation Division, TGA Australia

Regulation of therapeutic goods in Australia to ensure ongoing flexibility

Regulatory reforms

Review of Medicines and Medical Devices Regulation (MMDR)

- **Provisional approval** pathway for medicines
- **Priority review** pathway for medicines and medical devices
- Notification process for minor variations to registered medicines
- **Comparable overseas regulators**
- **Permitted indications** for listed complementary medicines
- **Assessed listed** medicines pathway – "claimer"
- **Pharmacovigilance Inspection Program**
- Adverse event reporting – **Black Triangle Scheme**

Other regulatory reforms

- Changes to regulation of **personalised medical devices**
- New classifications for **software-based medical devices**
- Establishment of a **Unique Device Identification** (UDI) system
- **Patient information leaflets** for implantable or active implantable medical devices
- Regulatory framework for **Faecal Microbiota Transplant** (FMT)
- **Opioids** – warnings and indications, smaller pack sizes, communication
- Publication of new medicines under evaluation – **Transparency**

Other improvement

- **Digital Transformation Project** - streamline our business systems and modernise IT infrastructure
- Standards for 2d bar codes – track and trace

COVID-19 unprecedented times

New challenges

- **Facilitating patient access to approved medicines and vaccines** as soon as deemed safe and effective
- **Continuation of clinical trials** under social distancing and travel constraints
- **Increased demand** for medicines due to stockpiling and flight cancellations
- Concerns for supplies of medicines for ventilated **intensive care unit patients**
- Development of specifications for **locally manufactured ventilators** to meet potential demand
- **Flood of enquiries** mostly from potential new sponsors
- Greatly enhanced **focus on cleaning and use of disinfectants** with antiviral activity
- **Inappropriate advertising and illegal importation** of COVID-19 products

Changes in response to COVID-19

Medicines

- **Prioritise regulatory review** of potential therapies and vaccines for COVID-19
- **Emergency exemptions** enabled certain unapproved medicines to be procured for National Medical Stockpile
- **Rolling submissions, simultaneous reviews** by teams, very rapid review (e.g. remdesivir)
- **Earlier and ongoing engagement with industry** on trial design, manufacturing requirements especially those developing COVID-19 vaccines
- **Enhanced international collaboration** for COVID-19 therapies and vaccines e.g. frequent meetings & dedicated working groups in ICMRA, WHO, ACCESS
- **Commitment by governments** to purchase vaccines before they receive regulatory approval
- **Management of medicine shortages** e.g. Medicine Shortages Working Party, facilitating substitution, mandatory notification, communication
- **Excluded Goods determination** for specified hand sanitisers
- **Expedited applications** for relevant products
- **TGA COVID-19 Enforcement Taskforce** established

Manufacturing

- **Remote 'virtual' inspection programme**
- **All international GMP inspections** postponed
- **Overseas GMP clearance process** where sponsors can provide a recently expired inspection report from a recognised regulator, and complete a GMP Clearance questionnaire
- **Regulatory amendments** made to enable hospitals to manufacture radiopharmaceuticals for the treatment of a patient in another State or Territory

Medical devices

- **Prioritise regulatory review** of COVID-19 diagnostic tests and medical devices
- Applied **time limited exemptions** to certain medical devices, including PPE, COVID-19 tests and domestically manufactured ventilators to ensure adequate access to necessary products
- Established **specific advisory groups** to focus on products of interest, e.g. COVID tests, masks, ventilators
- **Increased collaboration and information sharing** with international regulators to discuss COVID-19 related issues
- **Increased support and guidance** to manufacturers and sponsors - especially those new to regulation
- New processes developed for **virtual and alternative inspections** processes for manufacturing quality assurance requirements

Regulation in the future

The new normal - ensuring flexibility

- Increased **regulatory alignment and harmonisation** including evidence and safety requirements

- Enhanced **international collaboration** for therapies and vaccines for COVID-19
- Expand and evolve **work-sharing**

product evaluations, e.g. new active substances, oncology medicines through Project Orbis,

- Greater utilisation of **comparable overseas regulator reports** to bring products to market faster
- Regular sharing of information with international regulators on regulatory flexibilities and policies
- **Nimbleness** in approach to meet context and situation – risk appetite
- **Patient engagement** – transparency and role in decision-making considerations

V. Drug Regulatory System in the United Arab Emirates by Dr Amin Hussain Al Amiri, M.Sc., Ph.D., Asst. Undersecretary of Public Health Policy and Licensing Sector

Health Systems are not a Drain on Resources but an investment in **HEALTH** and **WEALTH**

Population Health

MOHAP's mission is to enhance community health by:

- Providing comprehensive, innovative, and fair healthcare services as per international standards,
- And performing its role as a regulator and supervisor of the healthcare sector through a modern and integrated health legislative system.

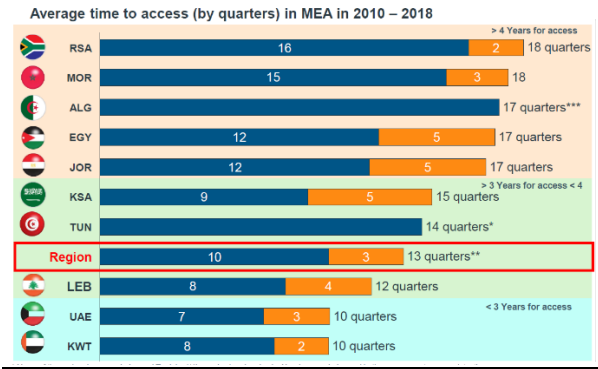
Economic

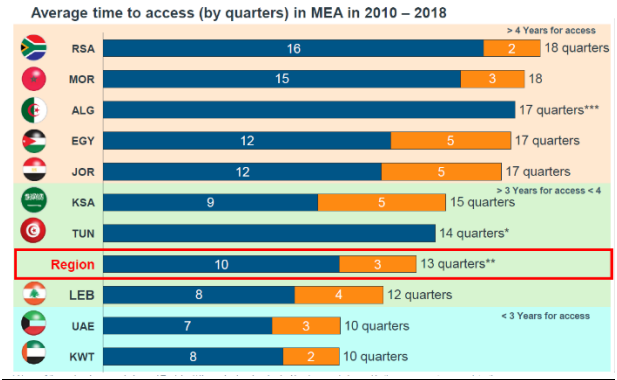
- Health has a significant impact on economic Productivity.
- A healthy population offers clear value to society at large: it can retain a high socioeconomic status and be more socially and economically productive.

Innovative medical solutions for better patients' outcome

Assessment of Access to Medicines in Selected Countries in the Middle East and Africa

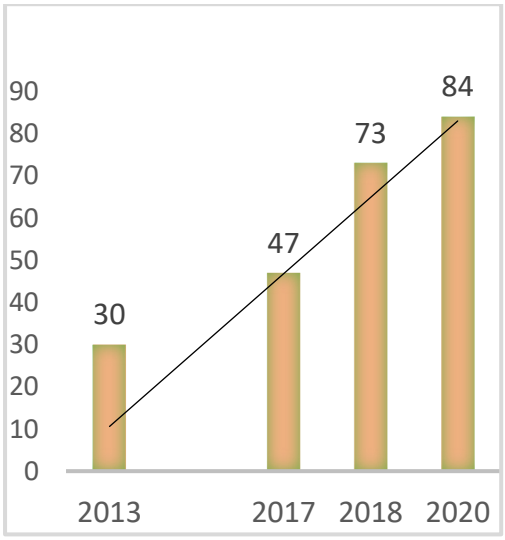
Final report



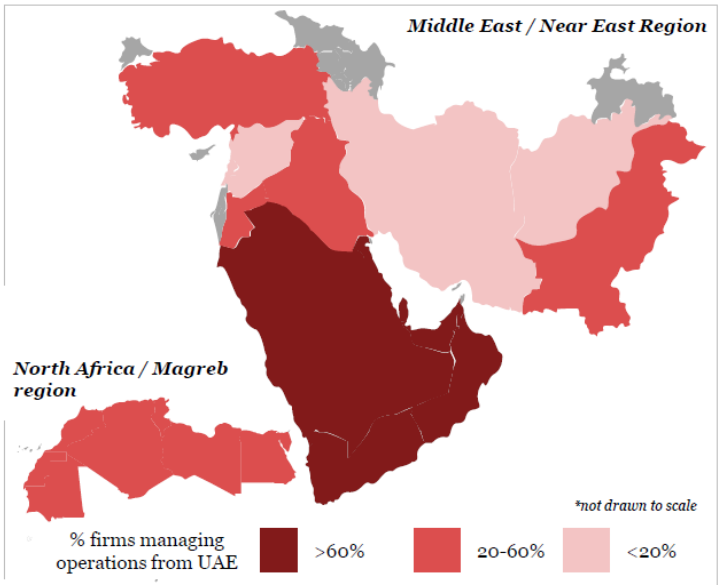


Presence of international pharmaceutical companies

Number of Scientific Offices based in the UAE

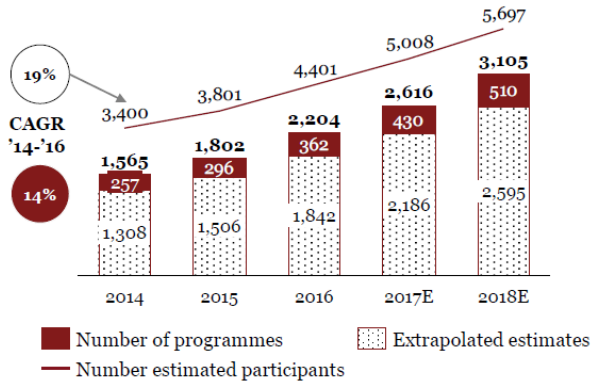


Countries managed from regional hubs in the UAE*

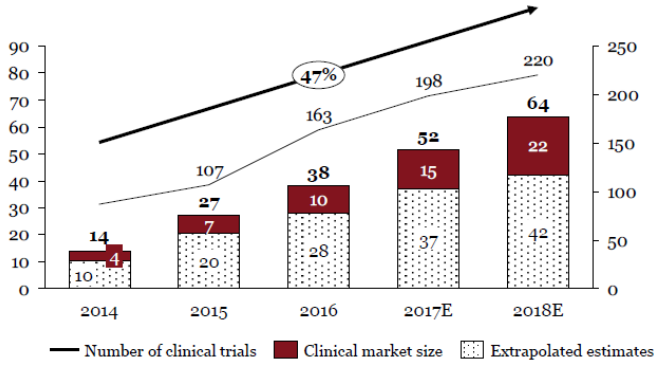


Industry's role in healthcare education and clinical research: for the UAE and the region

Healthcare programmes* conducted from the UAE, targeting other countries, 2014-2018E

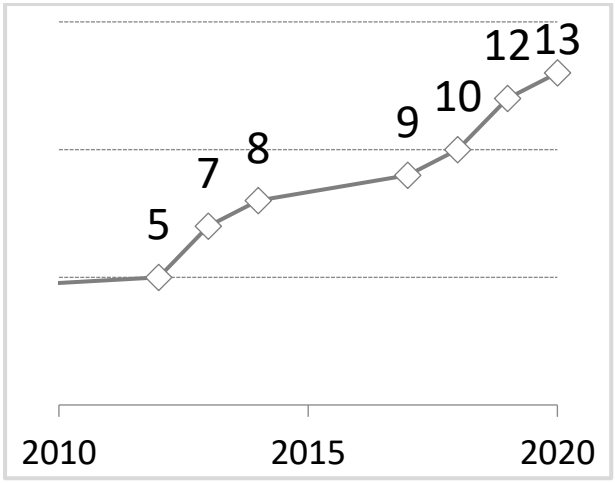


Clinical trial market size*, 2014-2018E*
AED million

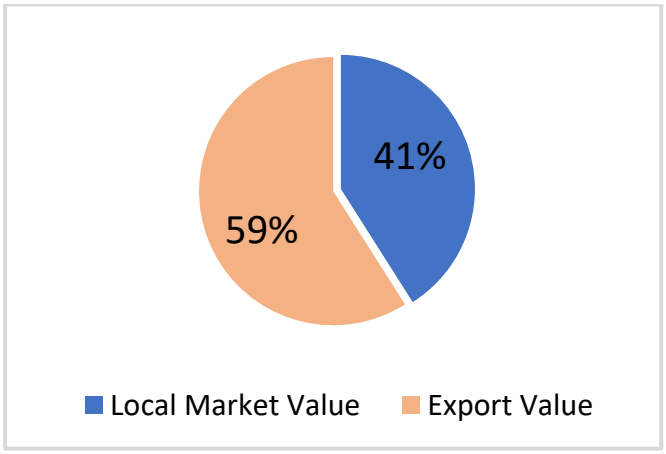


Development of local factories offering quality generics to the UAE and the region

*Number of licensed pharmaceutical factories in the **UAE***



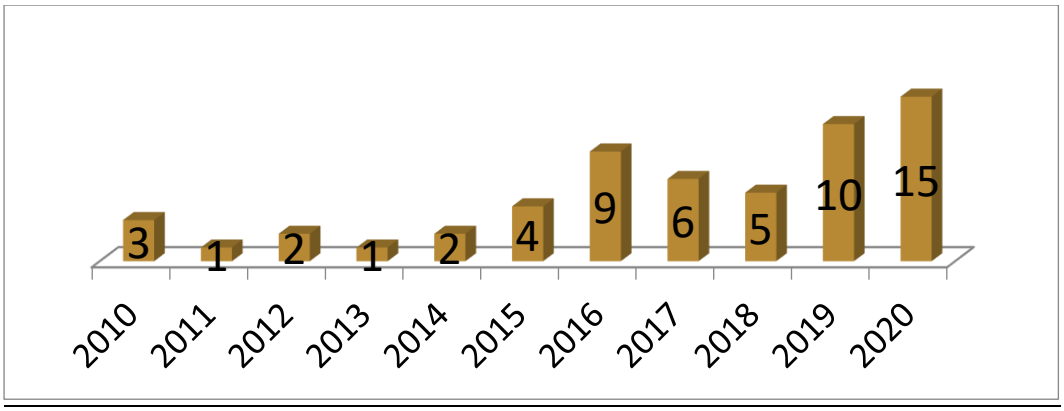
Distribution of the UAE made Medicines.



Safety Monitoring A development in collaboration with MHRA

- Directly connected to the WHO system (Vigiflow)
- Enhanced quality and quantity of ADR reports
- Allowing more proactive and preventive actions by the Ministry
- User-friendly mobile application
- Allows reporting of ADRs by consumers and healthcare professionals
- Grants user access to ADRs cases reported globally

Healthcare Legislations updates



Number of new & updated health legislations

Recent legislations relevant to the pharmaceutical sector

- Federal Law No.8 of 2019 regarding medical products, pharmaceutical professions and facilities.
- Cabinet Decree No. 59 for 2020 regarding medicines tracking and tracing.
- Ministerial Decree No. 730 for 2018 regarding the clinical research guidelines
- Ministerial Decree No 379 for 2019 regarding the Unified Platform for prescribing and dispensing narcotics, controlled and semi-controlled medicines.
- Ministerial Decree No 677 for 2019 regarding control measures related to travelers carrying narcotics or controlled medicines.
- Ministerial Decree No 253 for 2020 regarding controlling prescription and dispensing of controlled medicines.
- Ministerial Decree No 321 for 2020 regarding the use of innovators' regulatory data.

VI. Updates by Ms Emer Cooke, Executive Director, The European Medicines Agency's (EMA)

European Medical Agency

Initiative by EMA for the International collaboration with Indian Pharma Industry

- Annual Bilateral meetings with Indian Govt and Industry to identify the area to cooperation.
- Fulfill the medicine requirements at affordable price
- White listing concept for Indian company to increase the Export
- Proactive communication to protect the Patients
- Acknowledge the collaboration of the International Regulatory agencies during COVID-19.

- Collaboration with Indian industry for the Innovation and development with the association of WHO

Initiative by EMA to increase the supply of Indian Pharmaceutical Products to EU

UK has officially left the EU on 31 Dec 2021, to ensure the smooth functioning EMA has initiate an Agreement with UK, which allow the access and inspection from the UK under risk based approach, it includes the voluntary inspection by the UK for EU and by the EU for the UK.

VII. Updates by Dr June Raine CBE, Chief Executive, Medicine and Healthcare Product Regulatory Agency

MHRA has three main centres

- Safeguarding public health through regulatory innovation in vaccines and biologics
- Improvements in public health using innovative, world leading surveillance & research via RWE
- Robust regulatory action, innovative, collaborative systems, patient and public involvement & IT advances

Transforming regulation

- Establishing MHRA as a proactive, innovative agile regulator
- Focus on enabling healthcare access – aligning medicines and medical devices
- Collaborating with medicines producers and regulatory partners nationally & internationally

MHRA's response to COVID-19

- Clinical trial approval time reduced from c19 to 8 days
- Delivered rolling review of vaccines in shortest time
- Supported developers with novel technologies
- Desk-based not on-site inspections
- Approvals of medical devices

Three pillars of transformation

Innovative products

- Biologicals, biosimilars and advanced therapies
- Vaccines – development, manufacture, post market surveillance
- In vitro diagnostics, genomics
- Artificial Intelligence algorithms and analytics

New regulatory processes and system join-up

- Innovative licensing pathway

- Real-world evidence maximised
- Optimised clinical trials
- Patients engaged in all activities and impact in all decisions

Strengthened evidence base and regulatory simplification

- Removing overlaps, full digitisation
- Horizon scanning, regulatory science

New Regulatory Pathway for Innovative Products

VIII. Updates by Mrs. Togi J Hutadjulu, National Agency of Drug and Food Control of Indonesia

Mrs. Togi J Hutadjulu highlighted the following points during her talk.

- Collaboration between Govt. of India and Govt. of Indonesia for the ease of access of Medicine for the Global health
- Indonesian Govt. has implemented online drug registration to make the registration process more effective and less consuming.
- New licensing policies for Ease of Doing Business.
- New policies to encourage pharma ingredient manufacturer to invest in Indonesia.
- Export drug product from India to Indonesia
  2018: 33 Drug products imported from India to Indonesia.
  2020: 102 Drug products imported from India to Indonesia.