NPPA
AFFORDABLE MEDICINES FOR ALL
सभी के लिए वहनीय दवाईयाँ

सत्यमेव जयते

राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
औषध विभाग
रसायन एवं उर्वरक मंत्रालय
भारत सरकार

आज़ादी का अमृत महोत्सव

AUSHADH SANDESH

Vol.-II | DECEMBER, 2021

A Bi-monthly e-Newsletter

Committed Towards Accessibility, Availability & Affordability of Medicines for All

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About NPPA...

The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals was constituted by the Government of India vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, inter-alia, includes fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to affordability, availability and accessibility of medicines.

The Authority is a multi-member body consisting of a Chairperson, a Member Secretary and three ex-officio members. Two of the three ex-officio members are from Department of Economic Affairs and Department of Expenditure respectively and third member is Drug Controller General of India.

The Drugs (Prices Control) Order, 2013(DPCO, 2013) was notified on 15.05.2013 under the Essential Commodities Act, 1955(EC Act, 1955) and is based on the broad guidelines of the National Pharmaceutical Pricing Policy (NPPP), 2012. The three key principles of the NPPP-2012 are as below:

a. **Essentiality of Drugs:** The regulation of prices of drugs is on the basis of essentiality of drugs as per the medicines under NLEM-2011, NLEM-2015 as amended vide S.O. th 701(E) dated 10 March, 2016 has been incorporated as the First Schedule of DPCO 2013.

b. **Control of Formulations prices only:** The prices of formulations only are to be regulated and not the prices of the Bulk Drugs and the resulting formulations as adopted in the Drug Policy 1994.

c. **Market Based Pricing:** The ceiling prices of medicines are fixed on Market Based Pricing (MBP) methodology.

You can also give your suggestions/ feedback at: **monitoring-nppa@gov.in**

From CHAIRMAN'S DESK

सत्यमेव जयते

Shri Kamlesh Kumar Pant, IAS
Chairman
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

I am happy to bring to you the second issue of the NPPA bi-monthly e-Newsletter.

NPPA organized a webinar on "Affordability and Innovation: Ensuring Quality Drugs for All" on 29th October 2021 that was chaired by Prof. K. VijayRaghavan, Principal Scientific Adviser to the Government of India. This issue highlights the brief summary of the webinar along with various other initiatives of NPPA during "Azadi ka Amrit Mahotsav" celebrations.

Carrying forward the theme of Innovation & Affordability, Dr. U.S.N. Murthy, Director, NIPER, Guwahati has written an article on "India's contribution to Affordable Healthcare Innovations". He very lucidly explains the linkages between accessibility, affordability and innovation.

This time, the editorial team has included some insights on the revenue share of various drug classes, according to which "Anti-infective drugs" today has the highest share.

I am also happy to share that NPPA has expanded its reach in two more States/UTs i.e. West Bengal and Puducherry in the last two months by setting up Price Monitoring and Resource Units (PMRUs), taking the total tally of PMRUs to 21 States/UTs.

As has been said necessity is the mother of invention and in these challenging times of COVID pandemic we look forward to pharmaceutical sector deploying innovative solutions that make healthcare accessible and affordable.

NPPA wishes good health to all its readers; stay safe, stay healthy and follow all COVID appropriate behavior.

With best wishes

(Kamlesh Kumar Pant)

INDIA'S CONTRIBUTION TO AFFORDABLE HEALTHCARE INNOVATIONS

Upadhyayula Suryanarayana Murty

Director, National Institute of Pharmaceutical Education & Research (NIPER)-Guwahati, Changsari-781101, Kamrup (Rural), Assam & Chairman, BioNEST Incubation Centre (Funded by BIRAC, DBT, Govt. of India), NIPER-Guwahati, Assam, India

At the outset, I would like to quote the remarkable statement drafted by Ministry of Health and Family Welfare in its National Health Policy-2015 draft "India has a great tradition and capacity for innovation in most areas, but despite having the technical capacity to manufacture any drug, its role in new drug discovery and drug innovation including in biopharmaceuticals and biosimilar, even for its own health priorities is limited,""Drug innovation and new drug discovery are important aspects of access," adding, "Government policy would be to both stimulate innovation and new drug discovery as required to meet health needs as well as ensure that new drugs discovered and brought into the market are affordable to those who need them most."

Therefore, to meet the unmet healthcare needs I firmly believe "affordability" is the key to success for accessibility. However, it requires creativity, intellect, out-of-the-box concept, concrete thought process, etc. To deliver "affordability" in healthcare settings, we require innovative concepts in discovering drugs, delivering drugs, developing therapeutics, biologicals etc. This can be achieved only by creating innovation in Science & Technology, strategies, practices, and policies that we can take on local and global healthcare challenges. India's contribution to affordable healthcare efforts goes much beyond being a pharmacy of the world, as mentioned by Kiran Mazumdar-Shaw, Biocon Limited, Bangalore, India. It extends to affordable innovation which goes to the core of ensuring a global right to healthcare helped by a significantly lower cost base that supports a large talent pool of scientists and engineers. India's research engine is now driving a new model of innovation that draws on the philosophy of affordable access.

There is also emergence of several start-ups in the country that can offer affordable healthcare solutions for paving the pathway of innovations and accessibility, say for example:

1. UE Life Sciences, OncoStem Diagnostics and Mapmygenome are leveraging "affordable innovation" to come up with business models that can make early cancer detection available and accessible.

2. UE Lifesciences portable devices i.e., iBreastExamfor early detection of breast cancer. This device is a huge benefit over traditional mammography and other detection techniques involving radiography that are harmful as well as expensive, and hence unaffordable in the Indian context.

3. Mapmygenome, a molecular diagnostics and predictive health analytics company that offers a full range of tests to identify an individual's genetic predisposition to lifestyle, metabolic, cardiovascular, ocular, skin, and hair, orthopaedic, and gender-specific conditions.

4. Navya Network has developed an online platform that allows patients and their families to consult leading oncologists from top institutes such as the Tata Memorial Hospital for a nominal fee.

5. Perfint Healthcare, has developed advanced robotic technology for image-guided cancer therapy, enabling doctors to perform quick, accurate and cost-effective interventional procedures such as biopsy and drug delivery.

Affordable innovation is the only way forward, and India has a unique opportunity to deliver it to global markets by building excellence across the innovation chain from discovery to product development. For this kind of innovation to happen in India, linkages need to be established between health research and national health programmes to ensure research findings are leveraged in decision making in public health.

Today, India's biopharmaceutical sector is a world leader in vaccines, producing 60% of the world's supply. India is supplying more than half of all the vaccines to international organisations, such as the WHO and the UNICEF.

India has managed to fill this gap by creating a successful, cost-effective generic pharma industry by first reverse engineering patented drugs and adopting disruptively innovative process engineering to deliver affordable pricing. A strategy of delivering the highest quality at the lowest cost has enabled the Indian pharma industry to bring affordable medicines to patients in the country and other developing ones at price points that made them affordable and thus accessible. Generic producers in India drastically brought down the prices of vaccines and life-saving drugs used to treat diseases such as HIV, TB, and diabetes over the last couple of decades. India is therefore proving its mettle as a "laboratory for the world" that can deliver affordable innovation.

ARTICLE BY PHARMA EXPERTS

The Indian industry has successfully obtained the first-ever WHO approval for rectal artesunate suppositories (RAS) for the pre-referral management of severe malaria in children. The innovations by the Indian industry have also contributed to bring down the treatment costs of life-threatening diseases such as Chronic Myeloid Leukaemia and viral hepatits C, to less than five percent of the original cost. The prices for Hepatits B vaccines have also been brought down due to these innovations.

Pharma manufacturers in India can produce bulk drugs that cost 60% less than those in the West and can open a production plant in India 40% cheaper than in developed countries. This has helped India emerge as a hub for pharmaceutical research and development and clinical trials for many leading foreign pharmaceutical companies. A lower cost base combined with a robust and ethical regulatory environment has enabled India to emerge as a vital producer of affordable medicines and the world's largest supplier of affordable generic drugs. India's pharmaceutical industry exports to more than 200 countries and is the second largest supplier of over-the-counter and prescription drugs to the US market.

Affordable innovation, which presents ways to innovate, be flexible, and do more with less, can lead to breakthrough growth in a complex and resource-scarce world. At the same time, I believe that innovation should go together with affordability- it is only when the benefit of research reaches the person on the lowest rung of the economic ladder that it can be considered as delivering true value. India thus needs to invest in affordable innovation and embrace entrepreneurship as an economic model of growth. By backing innovative start-ups, we wish to create an "ideas economy" that generates perpetual value accretion and thereby economic and employment growth.

BioNEST Incubation Centre with state-of-the-art infrastructure at NIPER Guwahati was established in 2019 with the ambition of nurturing entrepreneurship culture in the entire North Eastern States (NER) of the country by means of affordable innovations. BioNEST was setup with a goal to nurture an environment of innovation and entrepreneurship in schools, research institutes, educational organizations and industries. BioNEST connects industry and academia and enables interactions for exchange of knowledge and facilitate technical and business mentorship. It provides enabling services and mentorship for IP and Technology management, Legal and Contract, Resource mobilization and Networking platform with the following operational model:

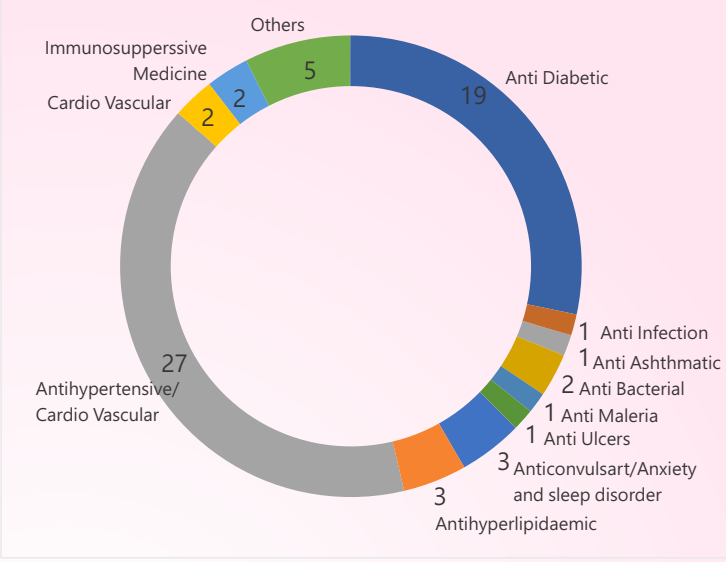
- BioNEST core team members for regular functioning
- Governing Committee consists of external experts for over all advisory
- Technical committee of external experts for Monitoring and mentoring the incubate.

Bio-NEST has entered into MoU with 04 innovators from NE-India to roll-out their NER projects and very shortly they will be able to commercialize their product/prototype through affordable innovations.

Reference: Kiran Mazumdar-Shaw. Leveraging affordable innovation to tackle India's healthcare challenge Author links open overlay panel. IIMB Management Review. 30 (1), 2018, 37-50.

News related to pricing of drugs

- Ceiling prices for 884 scheduled formulations (National List of Essential Medicines, 2015) and Retail prices for 1770 non-scheduled formulations have been fixed under DPCO, 2013 till 20th December 2021.
- As on 20.12.2021, over all 225 Authority meetings have been conducted and out of which 93 are under DPCO 2013.
- Ceiling prices of 2 scheduled formulations and Retail prices of 67 new drugs for various Pharmaceutical companies were fixed in the 93rd meeting of the Authority under DPCO 2013 which was held on 15.11.2011.
- Details of ceiling prices fixed in 93rd Authority Meetings are as follows



Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Category
(1)	(2)	(3)	(4)	(5)	(6)
1	Methylthioninium chloride (Methylene blue)	Injection 10mg/ml	1 ML	21.85	Antidotes and other substances used in Poisonings
2	Hydroxocobalamin	Injection 1 mg/ml	1 ML	9.91	Anti- anemic

- Details of retail prices fixed for various formulations in 93rd Authority Meetings are as follows:

S. No.	Therapeutic group	Total Number	Type of formulation	Retail Price fixed (Rs. Per unit)	Range (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1	Anti Diabetic	19	Tablet		6.25-11.07
2	Anti infection	1	Cream	5.2	
3	Anti Ashthmatic medicines	1	Capsule	7.1	
4	Anti bacterial	1	Tablet	5.99	
		1	Gel	3.48	
5	Anti Malaria	1	Tablet	12.55	
6	Anti Ulcers	1	Capsule	8.53	
7	Anticonvulsant/Anxiety and sleep disorder	3	Tablet		7.9-19.92
8	Antihyperlipidaemic	3	Capsule		2.68-19.64
9	Antihypertensive/ Cardio vascular	27	Tablet		8.6-17.74
10	Cardio vascular	2	Tablet		2.76-3.11
11	Immunosuppressive medicine	2	Ointment		16.41-35.44
12	Others	5	Tablet		2.9-12.64

REGULATORY NEWS

NEWS RELATED TO PRICING OF MEDICAL DEVICES

- NPPA vide Office Memorandum dated 3rd December 2021 has allowed the manufacturers and importers of Medical Devices namely (i) Bare Metal Stents (ii) Drug Eluting Stent (iii) Orthopaedic Knee Implants (iv) Oxygen Concentrators to report the information relating to stock details on quarterly basis instead of monthly in the prescribed format. The same has been published in the website of NPPA **www.nppaindia.nic.in**

- NPPA vide S.O. 2161 dated 3rd June 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of Oxygen Concentrators at first point of sale (price to distributor) for fixation of Maximum Retail Price of the product upto 30th Nov 2021. This has been further extended upto 31st May 2022 vide S.O. 4909(E) dated 30th Nov 2021.

OTHER RELATED NEWS

Global Innovation Summit 2021 of the Pharmaceuticals sector

Prime Minister Narendra Modi inaugurated the 'Global Innovation Summit-2021', organized by Indian Pharmaceutical Alliance (IPA) and its partners to bring together world leaders from across different stakeholder groups including government, industry, academia, investors, and researchers to discuss and strategize priorities to foster a thriving innovation ecosystem that will enable Indian pharmaceutical industry to further consolidate its position as a global leader and become an innovation hub for the world.

Read More

US FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals

As per press release dated 8th December 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms [about 88 pounds]).

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UK MHRA approves Xevudy (sotrovimab), a COVID-19 treatment found to cut hospitalisation and death by 79%- This monoclonal antibody – the second to be authorised by the Medicines and Healthcare products Regulatory Agency – is for people with mild to moderate COVID-19 who are at high risk of developing severe disease.

As per press release dated 2nd December 2021, another COVID-19 treatment, Xevudy (sotrovimab), has today been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) after it was found to be safe and effective at reducing the risk of hospitalisation and death in people with mild to moderate COVID-19 infection who are at an increased risk of developing severe disease.

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WHO Update on Omicron

On 26 November 2021, WHO designated the variant B.1.1.529 a variant of concern, named Omicron, on the advice of WHO's Technical Advisory Group on Virus Evolution (TAG-VE). This decision was based on the evidence presented to the TAG-VE that Omicron has several mutations that may have an impact on how it behaves, for example, on how easily it spreads or the severity of illness it causes. Here is a summary of what is currently known.

Read More

US FDA Approves First Treatment for Common Type of Post-Transplant Infection that is Resistant to Other Drugs-Approval is for Cytomegalovirus, a Type of Herpes Virus

As per press release dated 23rd November 2021, the U.S. Food and Drug Administration approved Livtencity (maribavir) as the first drug for treating adults and pediatric patients (12 years of age and older and weighing at least 35 kilograms) with post-transplant cytomegalovirus (CMV) infection/disease that does not respond (with or without genetic mutations that cause resistance) to available antiviral treatment for CMV. Livtencity works by preventing the activity of human cytomegalovirus enzyme pUL97, thus blocking virus replication.

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INTERNATIONAL NEWS

US FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age

As per press release dated 29th October 2021, the U.S. Food and Drug Administration authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age. The authorization was based on the FDA's thorough and transparent evaluation of the data that included input from independent advisory committee experts who overwhelmingly voted in favor of making the vaccine available to children in this age group.

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US FDA, NIH, and 15 private organizations join forces to increase effective gene therapies for rare diseases

As per press release dated 27th October 2021, the U.S. Food and Drug Administration, the National Institutes of Health, 10 pharmaceutical companies and five non-profit organizations have partnered to accelerate development of gene therapies for the 30 million Americans who suffer from a rare disease. While there are approximately 7,000 rare diseases, only two heritable diseases currently have FDA-approved gene therapies. The newly launched Bespoke Gene Therapy Consortium (BGTC), part of the NIH Accelerating Medicines Partnership (AMP) program and project-managed by the Foundation for the National Institutes of Health (FNIH), aims to optimize and streamline the gene therapy development process to help fill the unmet medical needs of people with rare diseases.

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Celebration of Azadi Ka Amrit Mahotsav

NPPA celebrated "AzadikaAmritMahotsav" from 24.10.2021 to 31.10.2021 on "Affordability of Essential Drugs". During this week long celebration, awareness campaign was organised on social media platforms.

As part of activities to commemorate the occasion of 75th anniversary of India's independence during the year long 'Azadi Ka Amrit Mahotsav', the National Pharmaceutical Pricing Authority under the Department of Pharmaceutical organized a webinar on **"Affordability and Innovation: Ensuring Quality Drugs for All"** on 29th October, 2021 through video conferencing. The webinar was chaired by Prof. K. VijayRaghavan, Principal Scientific Adviser to the Government of India and was graced by Ms. S. Aparna, Secretary, Department of Pharmaceuticals. Around 350 Participants from industry, academia, Central and State governments, Price Monitoring Resource Units (PMRUs), civil society, patient advocacy groups from all over the country joined the Webinar.

Activities undertaken by PMRU's

- Price Monitoring and Resource Units (PMRUs) set up under the CAPPM scheme of NPPA undertook a special campaign from 24th to 31st October, 2021 with the theme of "'Affordability and Availability of Essential Drugs". During this special campaign PMRUs conducted Paricharcha on the topic, reached out to various stakeholders through electronic/print media, conducted awareness campaign in pharmacy colleges, panchayats etc.

- All these events organized by the PMRUs had active participation from the various stakeholders i.e., manufacturers, chemists, industry associations, patient advocacy groups, etc. Some of the State Drug Controllers also reached out to a larger audience by giving interviews on television and radio. Some PMRUs also organised outdoor campaigns and publicity material in the form of brochures was also circulated by some PMRUs. The week long special campaign will prove to be a useful exercise in reaching out to various stakeholders and most importantly the consumers to make them aware about the various activities being undertaken by NPPA, and provisions of DPCO.

KNOWLEDGE SHARING: SUMMARY OF WEBINAR

Brief Summary of the Webinar

Prof. K. VijayRaghavan, in his address, emphasized that we need to move from a situation where we have grasped opportunities and markets to a situation where we can be leaders in development of new kinds of approaches, which serve a large number of people. Government, industry and the scientific community need to work together in a holistic manner. We need to create agencies that facilitate communication and coordination across research institutes. The feasibility for exponential growth is there and can be grasped and there is feasibility for the extraordinary risk mitigation for the industry, because of this connect. Facing us, facing the planet are problems of climate change, biodiversity and environment. These are dramatically changing health from both the perspectives of our lifestyles, new diseases, and these will happen on sudden timescales as well as on huge volume. The history of medicine has been to search, whether it is through traditional wisdom or through modern chemistry approaches, it is the search for medicines that worked. Today, we can design medicines that work while we understand how they work but we can also do large scale work through a combination of various kinds of searches, theoretical, computational and experimental, for medicines which work in different context. New kinds of drug discovery now allow to explore this combinatorial space to get specificity in cells.

Prof. VijayRaghavan emphasized that this approach, both computational and experimental, needs to be scaled up enormously. This capacity is there in India and risk to industry can be mitigated. Labs like the IICT in Hyderabad and other industries in Hyderabad can be anchored on chemistry in a big way and try this approach rather substantially. A similar push with biology, with biologics, vaccines, large proteins which can be used as drugs can be done on scale that comes from a better understanding of biology. The critical challenge here as also in chemistry is site specific delivery. So along with understanding of biology get better with the delivery of treatment.

There is better and more access to diagnostics and this necessitates the need for making affordable drugs. It is now time for our industry to come together with our academia to deliver on this.

Speaking on the occasion, **Ms. S. Aparna, Secretary, Department of Pharmaceuticals,** noted that it was relevant that as the nation commemorate the occasion of 75th anniversary of Indian independence during the year long 'Azadi Ka Amrit Mahotsav', a stocking taking is done of the work done and what needs to be done in future. She highlighted the fact that NPPA has been at the forefront of commitment of government to ensure affordable medicines to patients. She pointed to the fact that innovation in medical products has become essential to ensure drug security of the country which can be and will be supported by streamlining regulatory processes and stronger collaboration between research institutions and industry. In this sector the goal of research institutes should be to provide better therapeutic outcomes and greater safety to the patients. Innovation should target improved affordability of the treatment and access to all. Since innovation by industry requires deployment of risk capital, policies and mechanisms must find a balance at fulcrum that incentivizes investment in innovation, research and development, while maintaining the affordability at the same time.

She also informed that government is providing support to industry through PLI scheme to innovate the capacities in biologics, gene cell therapy, complex generics, and medicines of the future. As innovation by industry requires deployment of risk capital, policies and mechanisms must find a balance at fulcrum that incentivizes investment in innovation, research and development, while maintaining the affordability at the same time.

In his welcome address, **Shri Kamlesh Kumar Pant, Chairman, NPPA** while welcoming the participants to the webinar, highlighted the relevance of conducting the Webinar on the

important topic of "Affordability and Innovation: Ensuring Quality Drugs for All" as affordability is the key to accessibility. In the economic reality of a developing country, cheaper drugs and low-priced healthcare infrastructure models can work wonders. To deliver affordability, one requires innovation - in discovering drugs, in developing therapeutics and delivering healthcare. It is only by creating innovation in technology, strategies, practices and policies that the local and global healthcare challenges can be met.

He also emphasized the need of pricing as an instrument to ensure continued availability and affordability of essential life saving drugs with improved access to consumers. NPPA fixes the ceiling prices for scheduled drugs and monitors the prices for other drugs as per the provisions of the Drug Price Control Order. It was informed that NPPA supports incremental innovations that could increase the therapeutic value and effectiveness of a drug and also provide incentives for the same. Incentivizing innovation would provide stimulus for further affordability as two cannot be decoupled.

The panel discussion organized during the webinar, moderated by **Prof. Javed Iqbal,** had experts drawn from various fields i.e., Dr. Y.K. Gupta, Vice-Chair SNCM & Member, SCAMHP; Shri Pankaj Patel, Chairman of Zydus Cadila; Dr. S. Chandrasekhar, Director, CSIR-IICT; Shri Manoj Jhalani, Director, Department of UHC/Health Systems & Life Course, Regional Office for South-East Asia, World Health Organization (WHO); Shri Deepak Bagla, Managing Director & CEO, Invest India; and Dr. Ratna Devi, Chair of the International Alliance of patient Organisation (IAPO).

During the panel discussion, panelists highlighted the various facets that touch upon this important area of affordability and innovation. **Dr. Y.K. Gupta** spoke on the philosophy and the methodology for drawing up the National List of Essential Medicine (NLEM). The basic philosophy of NLEM is that it is primarily drawn for the resource limited countries so that the budget can be optimized to reach the maximum possible health care in the widest possible corner and reach every corner of the country. NLEM is based on the epidemiology and the disease burden of the country. One important criterion for inclusion of drugs is that that they have to be approved and licensed by the drug regulator (CDSCO) and the other is that these medicines must have a proven efficacy and safety based on the evidence.

Shri Pankaj Patel emphasized upon the need to optimize costs by the pharma industry to stay ahead of the curve. It was highlighted that Pharma industry is doing a lot in terms of working on process improvements and it has been able to continuously work to improve the cost of production of different APIs etc. The industry is also working towards leveraging digital technology, automation, artificial intelligence etc. to bring in more automated processes, optimize the kind of conditions under which the reaction should be conducted, how to achieve the maximum, how to maximise the yields at each stage of operation. It was informed that innovation has two kind of costs. One is the development cost at early stage and the clinical development cost. The significant cost is the clinical development though there is also 20% cost involved in the early development area. Also, there is risk involved as only one or two per cent or ten per cent of the drugs will ultimately hit the market. Since then risk is high; the issue of the pricing comes in the picture. Thus, it is important that a collaborative effort between the Government and the industry can definitely help in terms of optimizing the cost and thereby ensuring that cost effective research can also help in providing medicines at a reasonable prices. He also emphasized the point that Government needs to think on supporting indigenous research and create market for them. A collaborative effort can actually create something which will be the model the whole world is looking forward to.

Dr. S. Chandrasekhar while taking on the industry – academia linkages, stated that building trust between them is very important. It is not possible

KNOWLEDGE SHARING: SUMMARY OF WEBINAR

for academia to solve every problem of the industry, and what is more important is to provide skilled manpower to the industry. It is important to impart proper training so that from day one they are ready to be deployed at bench to deliver what is required for the industry. He also noted that there is need to prioritize our research activities for short term, medium term, long term needs so that research done has some application in industry. At the same time, industry also needs to change the manufacturing processes like changing from batch process to continuous process and some good work has already been started in flow chemistry by academic institutes like NCL, Pune; IICT, Hyderabad; UDCT, Mumbai; IIT-Bombay. He also noted that a lot of work has already been done on small molecules and we can have large quantity of small molecule at very affordable price. However, in case of large molecules like large peptide, large nucleosides, biologics, there are large number of patents that are going to expire in coming 20-30 years and industry has not been able to work on these large molecules. Thus, it is timely industry should work to make these large molecules also affordable.

Shri Manoj Jhalani informed about four areas of WHO framework that focuses on equitable access to affordable medicine and role of WHO in encouraging innovations. The four major components are rational selection, affordable prices, sustainable financing, and reliable health and supply system. As far as rational selection is concerned, WHO updates its model list of essential medicines every two years. Health Technology Assessment (HTA) has become important for rational selection of essential medicines and medical products. Ireland is good example of HTA practices. The Health Intervention and Technology Assessment Program (HITAP), Thailand, and the National Institute for Health and Care Excellence (NICE), UK, are national HTA organizations providing technical support to governments in LMICs to build up their priority setting capacity.

In the area of affordable prices, prices are important factor to determine the essential medicine list. Affordable prices can be pursued through various mechanisms viz. Price information exchange, price competition, promotion of generic product, bulk procurement, price monitoring, price control etc., and India is pursuing several of these measures. CROs (contract research organisation) are planning to establish a global platform for medicine's price information exchange and currently undertaking a baseline survey with the member states. Within health expenditure, medicines are the biggest component of the household's out of pocket expenditure. Now, with the increasing burden of the non communicable diseases, there would be a challenge to sustainable financing. With cost of medicines getting higher, this would really affect the poor. Best practices from the States of Rajasthan and Tamil Nadu should be replicated in other states also. PMBJP is working in the direction to provide access to affordable medicines.

In terms of reliable health and supply system, WHO has deployed many norms and standards so that countries worldwide can adopt these best practices. WHO- SEARN (South-East Asia Regulatory Network) has Information Sharing Platform to develop and strengthen regulatory collaboration, convergence and reliance in the South-East Asia Region over shared regulatory issues and challenges that will build capacity and enable national regulatory authorities to fulfil their mandate. As far as innovation are concerned WHO has WHO Health Innovation Group, and it is also working on neglected diseases, rare diseases,etc. It is working with WIPO and WTO for promoting research and development.

Shri Deepak Bagla informed that 2360 business requests received by Invest India from 85 countries are in the area – healthcare and pharmaceuticals including medical devices. Of all the 63 sectors that received FDI last year, the one which has the widest global interest where India is concerned is pharmaceutical. COVID pandemic has brought healthcare to the forefront and thus, the pace at which R&D is undertaken will have to be increased.

Prof. VijayRaghavan is playing a big role there and running a programme called Agni. They accelerated the growth of new India innovation by joining the dots very quickly. India has three unicorns every month this year. Till now, a large number of these unicorns were focusing on the customer side consumer products or digitisation. Now, they are coming from healthcare, pharmaceuticals, and a significant amount of global VC capital is seeking out these initiatives very fast. Some interesting elements are being seen there, for example, uberisation of healthcare delivery, better utilisation of capital etc. riding on the process of digitisation and its decreasing cost significantly.

It was also informed that in the past 70 months, over a thousand R&D centres of global multinationals in India, not just pharma and healthcare, but even others have been opened and India is the number one destination in the world for R&D centres outside of their head office. Shri Bagla also informed that PLI schemes of DoP are one of the most well received and one of the most well structured schemes globally as a policy initiative which is being acknowledged, not just in India, but globally too. These will firmly establish the eco system which will bring in the entire strength of frugal innovation, which is what was seen during the pandemic, viz., hosiery makers pivoting their business models and coming up with world class PPEs, start-ups manufacturing ventilators and all other types of things at price points which were less than half of the global price points at equal quality.

Quoting the WHO report, "Nothing about us without us", **Dr Ratna Devi** emphasized that every platform, every dialogue, every innovation, every process needs to involve the patient's voice and take their input so that what their lived experiences are and whatever they bring to the table, shapes the dialogue and policy. In India, the process has started long time back with HIV, going on to Oncology Patients group and very recently with rare disease patient group. The ability to embrace the patient's voice is happening but at a slower pace. Patient expectation is simple with regard to access to affordable medicines- all they want is effective, safe, affordable, accessible good quality medicines. Patients want healthy life, free of pain, so that he/she can go back to work, useful to his/her family and not be a burden.

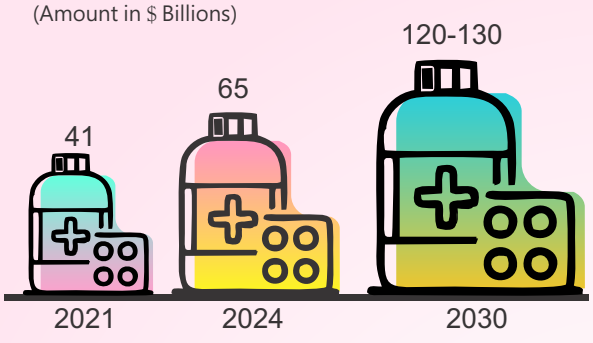
Innovative solutions are being provided that are affordable as well as accessible. For e.g. in HIV sector, landscape has changed how ART (Anti Retroviral Drug) is made available in India and across the world. Recent example is of how vaccines are made available in this pandemic scenario. However, more needs to be done in specialty therapeutics, whether it is cardiovascular, neurosciences, rare disease, etc. In newer areas like gene therapy, bio-similars, large molecules, etc., we are still dependant on companies from other part of the world.

Dr. Vinod Kotwal, Member Secretary, NPPA thanked Prof. K. VijayRaghavan for chairing the Webinar, sharing his thoughts and also releasing the inaugural issue of NPPA bi-monthly Newsletter-Aushadh Sandesh. Secretary, DoP, all eminent panelists, and all the stakeholders were thanked for their participation in the Webinar. It was noted that the discussions in the panel were testimony to the fact that viewpoints of various stakeholders were heard and these discussions will continue.

KNOW YOUR REGULATOR/SECTOR

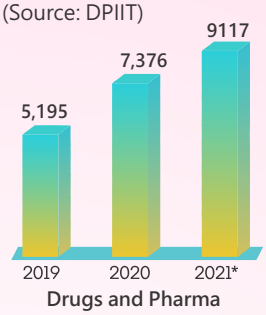
Size of Pharma Industry

(Source: Economic Survey 2020-21)
(Amount in $ Billions)



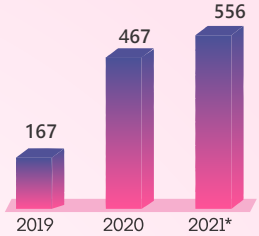
Investment Intentions in Terms of IEMs Filed

(Source: DPIIT)



Drugs and Pharma

(Amount in Rs. crore)

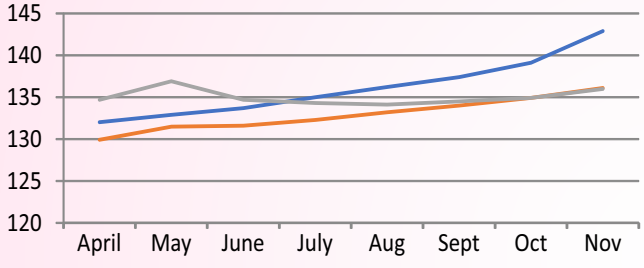


(*Till October, 2021)

Medical & Surgical Instruments

Wholesale Price Index (WPI)

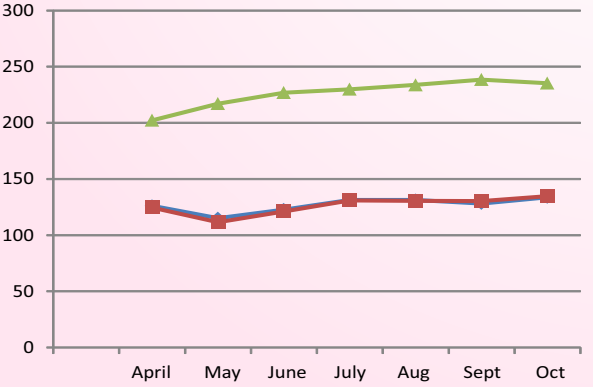
(Source: DPIIT)



	April	May	June	July	August	September	October	November
All commodities	132	132.9	133.7	135	136.2	137.4	139.1	142.9
Manufacturing	129.9	131.5	131.6	132.3	133.2	134	134.9	136.1
Manufacture of pharmaceuticals, medicinal chemical and botanical products	134.7	136.9	134.7	134.3	134.1	134.5	134.9	136

Index of Industrial Production (IIP)

(Source: MoSPI)



	April	May	June	July	August	September	October
General	126.1	115.1	122.8	131.4	131.3	128.2	133.7
Manufacturing	124.6	111.5	121.2	130.9	130.5	130.3	134.7
Manufacture of pharmaceuticals, medicinal chemical and botanical products	202.3	217.1	226.9	229.9	233.8	238.5	235.3

Therapeutic Group wise Total Sales of Drugs

(Amount in Rs. crore)

Group Name	12 months period ending 30.11.20	12 months period ending 30.11.21	% of Change
ANTI-INFECTIVES	18,836	23,804	26%
CARDIAC	19,732	21,616	10%
GASTRO INTESTINAL	15,924	19,349	22%
ANTI DIABETIC	14,689	15,695	7%
VITAMINS / MINERALS / NUTRIENTS	12,796	14,963	17%
RESPIRATORY	10,781	12,593	17%
PAIN / ANALGESICS	9,330	11,383	22%
DERMA	9,605	10,688	11%
NEURO / CNS	8,879	9,752	10%
GYNAECOLOGICAL	6,818	7,923	16%
HORMONES	2,647	3,064	16%
ANTI-NEOPLASTICS	2,863	3,011	5%
OPHTHAL / OTOLOGICALS	2,353	2,611	11%
UROLOGY	2,043	2,363	16%
VACCINES	2,211	1,934	-13%
BLOOD RELATED	1,627	1,822	12%
OTHERS	1,268	1,416	12%
STOMATOLOGICALS	827	986	19%
SEX STIMULANTS / REJUVENATORS	737	873	18%
ANTI MALARIALS	533	564	6%
Grand Total	**1,44,499**	**1,66,409**	**15%**

Source: Pharmatrac database

FREQUENTLY ASKED QUESTIONS

Question: What is the "Drugs (Prices Control) Order, 2013 (DPCO, 2013)"?

Answer: The Drugs (Prices Control) Order, 2013 is an order issued by the Government of India under Section 3 of Essential Commodities Act, 1955 to, inter-alia, ensure maintaining supplies of drugs or for securing their equitable distribution and availability at fair prices. The Order, inter-alia, provides the list of Scheduled (controlled) drugs, procedures for fixation of prices of drugs, control on increase in MRP of all drugs, method of implementation of prices fixed by Government, recovery of overcharged amount with interest and penalty in case of contravention of provisions etc.

Question: Are all the drugs marketed in the country under price control?

Answer: NPPA fixes the ceiling price of formulation listed in Schedule I of DPCO, 2013 as per Para 4 of DPCO, 2013. NLEM 2015 which was notified as Schedule I of DPCO, 2013 contains 966 scheduled drug formulations (including formulations as per explanation 1 to Schedule – I of DPCO 2013) spread across 31 therapeutic groups. NPPA also fixes the ceiling prices of formulations listed under Explanation-I to Schedule – I of DPCO 2013.

NPPA fixes the retail price of medicine based on the Form-I application received from the manufacturing/ marketing companies. The notified retail prices are applicable only to the applicant manufacturing/ marketing companies.

Further, Companies also cannot sell non-scheduled formulation (other than those appearing in Schedule I of DPCO, 2013) at a price which is more than 10% higher than the MRP of the preceding twelve months.

Question: What happens if a manufacturer sells a drug with MRP above the price allowed under DPCO, 2013?

Answer: Selling a medicine at an MRP which is higher than the notified ceiling price/retail price plus applicable local taxes is a violation of DPCO, 2013 and the manufacturers are, inter- alia, liable to deposit the overcharged amount along with interest and penalty thereon. In case of non-deposit, the amount can be recovered as arrears of land revenue.

Similar action is taken whenever companies are found selling non-scheduled formulations having an MRP which is more than 10% higher than the MRP of the preceding twelve months.

Feedback and Complaint Redressal

Grievance Redressal

Pharma Jan Samadhan: A web enabled system for grievance redressal – catering to consumers, distributors, dealers, retailers.

Information Dissemination

Pharma Sahi Daam: One can easily search brand name, composition, ceiling price and MRP of the formulation – available to public.

Seminars and Workshops conducted by NPPA and by PMRUs

Collaboration with State Governments

PMRU: To help NPPA to monitor notified prices and ensure availability of medicines.

To spread awareness regarding the pricing of drugs, etc.

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