

Taking stock

Impact of rising Active Pharmaceutical Ingredients' (APIs) prices on the Indian pharma industry

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Executive summary

The Indian pharmaceutical industry is the largest supplier of generic drugs in the world. The industry accounts for 20% of the global export volume and has been instrumental in shaping the generic drug industry globally. It has also played an important role in bringing down medicine costs, especially in in India, where medicine costs are among the lowest in the world.

With the objective of improving affordability and accessibility of essential medicines, the government decided to implement price control through the Drug Price Control Order (DPCO) in 2013. DPCO 2013 is based on objectives of National Pharmaceutical Pricing Policy (NPPP), 2012, and aims to ensure availability of essential drugs at reasonable prices and make certain there is scope for sufficient innovation and competition for growth of the industry. In 2013, the cost-based pricing mechanism for drugs, implemented as per DPCO 1995 was replaced by market-based pricing, applicable only for formulations. This was considered as a welcome change by most stakeholders. The highlights of the current pricing mechanism are summarised below:

- Average price to the retailer (PTR) is calculated by averaging the prices of all brands of medicines of the same strength and dosage of the scheduled formulations which have a market share of 1% or above.
- Ceiling Price (CP) is worked out as average PTR + 16% (margin to the retailers).
- The yearly revision in the CPs of the scheduled formulations is done as per the annual Wholesale Price Index (WPI) for the preceding calendar year, on or before 1 April of every year.

If we look at the period between 2013 and 2019, the CPs of scheduled formulations have increased modestly between 3% to 10%, much below the theoretical maximum of 18%. This is because the CPs for most formulations listed in the National List of Essential Medicines (NLEM) were fixed twice – once in 2013 after implementation of DPCO 2013 and again in March 2016 after incorporation of NLEM 2015 in Schedule I of DPCO 2013. In certain cases, the CPs have also been reduced. However, during the same period, costs of some of the Active Pharmaceutical Ingredients (APIs) analysed in this paper have increased substantially, in many cases by more than 100%.

Since the current market-based pricing mechanism does not consider the rise of input price to arrive at the CP, changes in input price have a direct impact on the margins of manufacturers. APIs having maximum contribution to cost of goods sold (COGS) for most formulations worsen the pricing scenario.

If there are no immediate interventions taken to address the given situation, it could lead to many direct and indirect implications for the pharma industry and the economy in general. These implications may be short term and long term, ranging from higher costs of medicines for patients due to them switching to the therapeutic equivalent under non-DPCO molecules on the one hand to an impact on some bigger government programmes like Ayushman Bharat on the other hand. This is because in such a situation, several low-cost brands may go out of the market because of financial unviability, as they operate on very low profit margins. Other possible effects are drug shortages and impact on employment, overall health outcome, investment in research and development (R&D) and access to medicines. Because of unsustainable business situations, most pharma companies will find it challenging to invest in healthcare, an area of high importance for the government.

While the market-based methodology of annual revision in CPs is a welcome feature of DPCO 2013 (as compared to the method followed in DPCO 1995), anomalies, as highlighted above, call for swift interventions from the government to allow an appropriate one-time increase in the CPs of affected scheduled formulations so that the government's vision related to domestic manufacturing and universal health coverage become a reality.

We suggest that the government to address the issue of a much higher rise in API prices than the CP increase on a case-to-case basis. Manufacturers should be compensated for rising API prices and hence this should be treated as one-time correction. Thereafter, the current prevailing formula of price revision based on changes in WPI should continue.

We also recommend a sunset clause to this option, wherein the same formula can be used after 3 years to recalibrate the CP. Based on the prevailing API prices in future, the same formula can be applied to revise current prices, upward or downward.



Below is the suggested formula which can be used for one-time correction of CP, on a case-to-case basis:

I_{CP} = $[Q^{API}*(P2013/10^{\wedge 6})]$ *[(P2019/P2013) -(C2019/ C2013)] * [1 + (T/ (100-T)]

I_{CP} = Increase in CP to be allowed

Q_{API} = Quantity of API required per unit (in mg)

P_{2019} = Price of API per kg in 2019

P_{2013} = Price of API per kg in 2013

C_{2019} = CP in 2019

C_{2013} = CP in 2013

T = Trade margin

(As per current industry practice, it is 20% retail + 10% wholesale in line with the National Pharmaceutical Pricing Authority [NPPA] notification dated 27 February 2019. However, as per the current pricing formula 16% retail + 50% of retail margin is considered as the wholesale margin.)

Example:

Let us consider the example of a Ibuprofen 200 mg tablet, where P(c) = 0.38, Q_{API} = 200, P_{2019} = 1045.91, P_{2013} = 504.72, C_{2019} = 0.37, C_{2013} = 0.38 and T=24%.

Based on the suggested formula:

ICP = (200*504.72/10^6) *(2.072-1.027) *(1+(24/76))

= 0.101*1.045*1.316

= 0.139

In the case of DPCO 2013 formulations with a combination of drugs, the same formula can be applied to individual molecules and cumulative ICP can be arrived at by adding the ICP of each molecule.

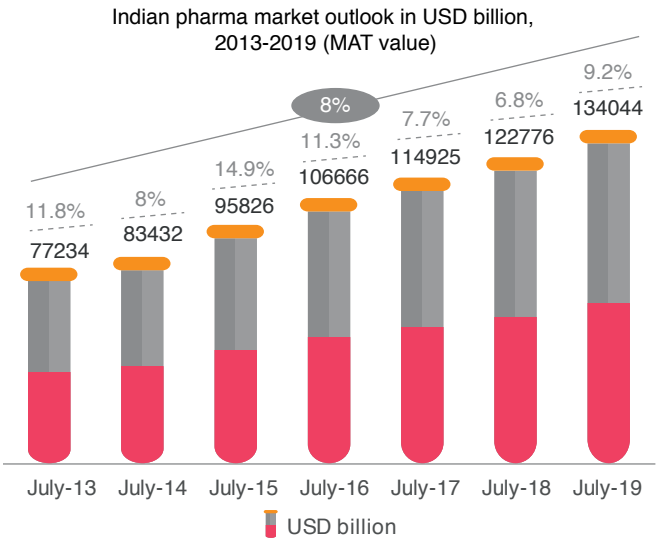
The above recommendations are based on the current thinking and practices of NPPA and Department of Pharmaceuticals (DoP), using statutory provisions currently available and have been utilised in the recent past, with the specific examples. The objective is to ensure accessibility and affordability of medicines to ailing patients and balance growth with competitiveness in the Indian pharma market, thereby resulting in ease of doing business.

Industry overview

The Indian pharmaceutical industry is one of the fastest growing industries in the world. The industry is currently valued at USD 38 billion, out of which exports from India amount to USD 20 billion. India has consistently maintained its supremacy in formulation exports, with over 50% of the total exports constituted by formulations and the balance by APIs.[1]

Governments worldwide are under pressure due to rising healthcare costs, which has brought into focus the importance of generic drugs and their role in making pharmaceutical products affordable to those in need. India's domestic pharmaceutical market accounts for over 3% of the global pharmaceutical industry in terms of value and 10% in terms of volume.[2]

Figure 1: Growth of India's pharma market[3]



The domestic formulation market is expected to reach USD 29 billion by 2021, with a CAGR of around 11%. The growth will be driven by increased diagnosis of chronic and non-chronic diseases, expansion of private hospitals and pharmacy chains, increased expenditure on healthcare by the government and future product launches.

India primarily being a market where people pay themselves for healthcare expenditure, there is a correlation between economic growth and pharmaceutical spending growth.

Composition of Indian pharma market: Key therapeutic areas (TA)[4]

- While anti-infectives (AI) are currently the largest TA, oncology, vaccines and multiple other TAs have registered steady growth.
- More than 10 TAs within the Indian pharma market, with an overall value of more than INR 500 crore.
- TAs such as gastrointestinal, pain, central nervous system, veterinary have registered strong growth recently and are already in the INR 500-1,000 crore range in terms of value.
- Traditionally smaller TAs like vaccines and oncology have also registered high growth, driven by higher accessibility, awareness and mass campaigns.

Changing DNA of Indian pharma companies: Backed by favourable government policies

The industry is moving up the value chain, from manufacturing of generic drugs to inventions and development. Increasingly, Indian pharmaceutical companies are entering into collaborative arrangements such as licensing, co-development, joint distribution and joint venture. Many global pharmaceutical companies have their manufacturing hubs in India. They are looking to get a share of the international generic drug market with high margins. The number of Abbreviated New Drug Applications (ANDA) to the US Food and Drug Administration (FDA) is increasing every year. The industry is also witnessing a healthy inflow of foreign direct investment (FDI).

The government too, has taken several steps to fast-track the growth of the Indian pharmaceutical industry by bringing in measures to curb healthcare costs and surge production levels.

Some of the key measures undertaken by the government are: Rapid approvals for setting up new facilities (including single window clearance mechanism to streamline drug approval process), thereby enabling speedy introduction of generic drugs in the market.

- Relaxation of FDI norms in the pharma sector.
- Providing digital platforms at Central Drugs Standard Control Organisation (CDSCO) and NPPA to regulate and track the sale of quality drugs at affordable prices.

- Reduction in time for issuance of No Objection Certificate (NOC) for export licence from 12 weeks to 2 weeks.
- Reducing dependency on import of raw material by setting up mega bulk drug parks
- Launching the National Health Protection Scheme, also known as Ayushman Bharat, a government-funded healthcare programme which provides annual health coverage of up to INR 5 lakh per family for secondary and tertiary care hospitalisation. The programme is expected to benefit 100 million poor families.[5]
- The government also launched a campaign titled Pradhan Mantri Bharatiya Janaushadhi Yojana, (Generic medicines) to provide, to provide quality medicines at affordable prices through special stores. As of January 2019, more than 4,800 such stores are functional and sell more than 900 types of drugs (including all the formulations under NLEM 2015 and schedule I of DPCO 2013, covering almost all major therapeutic groups and 70% formulations include drugs to tackle chronic diseases).[6]
- With significant measures taken by the government, the healthcare sector has witnessed emergence of innovative drug delivery models and access to better healthcare has become possible not only in metros, but also in smaller towns.

API industry

- API is the most important ingredient in any medicine. As per the industry definition, any substance or mixture of substances, intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, prevention of disease or to affect the structure and function of the body.[7] APIs have also been called bulk actives, bulk pharmaceutical chemicals, bulk chemicals and bulk drugs.
- API is an important segment of the Indian pharma industry, contributing to around 35% of the market. The Indian API industry has been supplying to domestic and international pharma companies. The ongoing global drug patent cliff, where hundreds of billions of brand name drugs – some of which accounted for large percentages of big pharma company sales, will lose patent protection. This is set to further boost revenues of the API market in India.
- The four major elements of quality medicines are API, strength, dosage and delivery system. Normally, the price of API ranges from 40% to 60% of the formulation price. However, in certain cases it can go much higher, based on prevailing API prices.





Dependence on China for sourcing API

Driven by the competitive pricing offered by Chinese suppliers, the Indian API industry has been dependent on APIs and import of advance API intermediates from China for the last few years. It is significant to note that the percentage of API imports from China has spiked from 1% in 1991 to 80% in 2018, primarily backed by large scale manufacturing incentives and state driven subsidies offered in China to promote exports.[8]

Indian API manufacturers lost competitive edge to manufacture lower end of the spectrum for APIs and fermentation technology to countries like China, majorly because of the following factors:

- Stricter implementation of pollution control norms, leading to higher cost of manufacturing API in India.
- Lowering of import duties, leading to cheaper imports from giant plants in China.
- Issues in design and implementation of DPCO 1995.

To cope with skewed policies related to the implementation of DPCO 2013, such as decisions related to scheduled vs non-scheduled formulations, new drugs, and demand notices for overcharging, Indian pharma companies were forced to think of business strategies which would help them move up the value chain and focus on commercially attractive segments, like finished formulations and complex-to-manufacture APIs. India pharma companies thus started sourcing raw materials and simple APIs from cost-competitive locations like China, which has also resulted in huge fluctuations in the API prices.

India is highly dependent on imports of APIs for at least 12 essential drugs, listed within NLEM 2011 and 80% to 90% of these imports are from China, as per Department of Pharmaceuticals.[9] These essential drugs include ranitidine, metronidazole, paracetamol, ibuprofen, metformin, amoxicillin, ciprofloxacin, cefixime, acetyl salicylic acid, ofloxacin, and ampicillin. In-depth analysis of import data of the strategically important intermediates such as ciprofloxacin, ofloxacin, metronidazole, salicylic acid and ampicillin, 6-aminopenicillanic acid (6-APA) indicates that with 98% share of imports, China has achieved near-monopoly in critical intermediates and the API sector in India.[10]

However, in the last 6 to 12 months, the Indian pharma sector has capitalised on the opportunity to re-establish its capability in producing APIs. The increased initiatives by the government are driving small and medium-sized companies to enter the Indian API market and capture the small and niche segments. The market is expected to experience progress, such as a strong focus on the development of high-potency APIs, a preference for generic drugs.

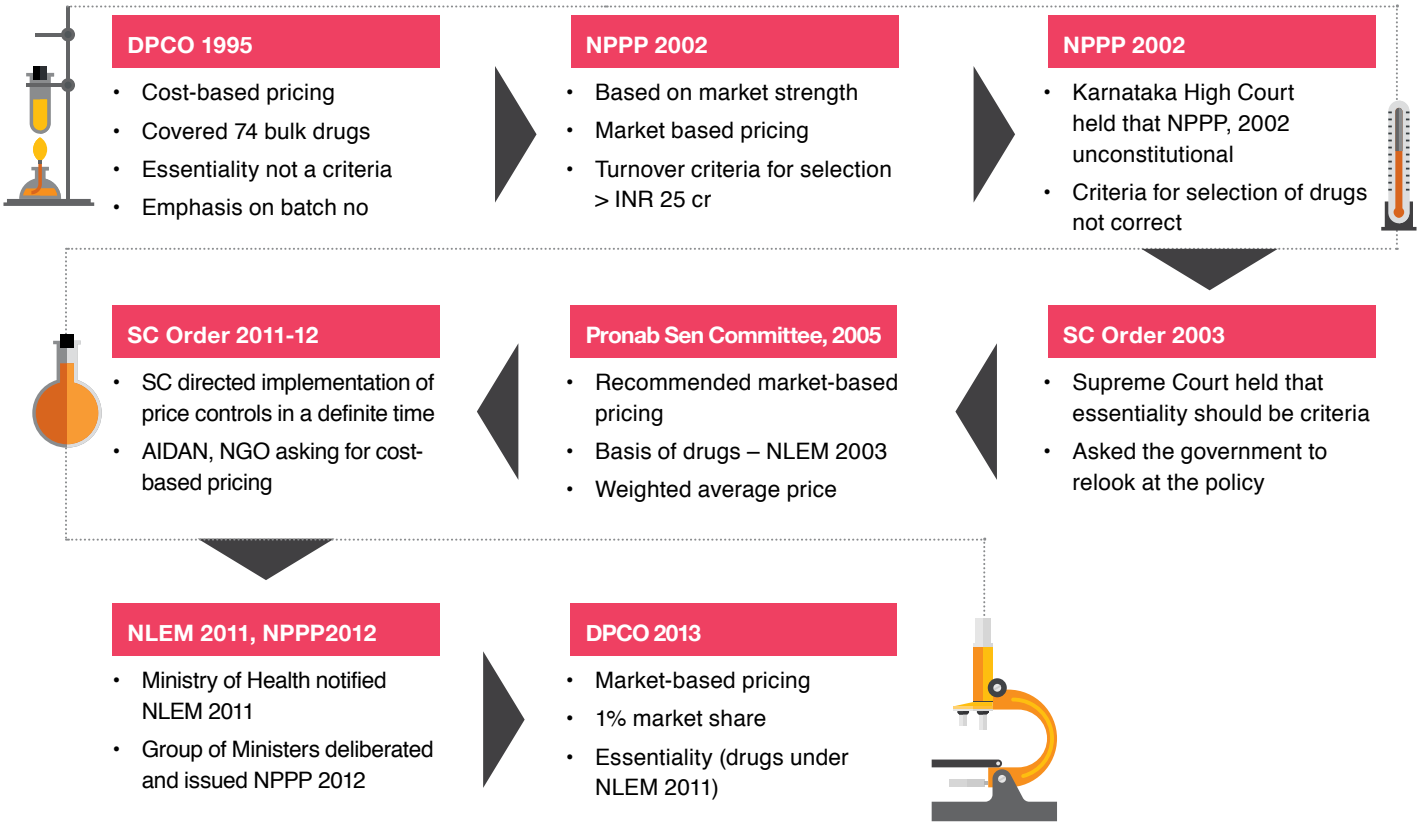
Background on drug price regulation in India

India being a price sensitive market, the government decided to implement price control measures right after independence, to increase the affordability of essential medicines.

The DPCO issued under Section 3 of Essential Commodities Act 1955, aims to ensure that essential drugs are available to all, at affordable prices.

The DPCO order was put in place after the Sino-Indian war of 1962, as it was necessary in public interest to cap drug prices. Over the years, the order has been modified five times.

Figure 2.1: Background of DPCO 2013[11]



Drug Price Control Oder (DPCO) 1995

DPCO 1995 covered 74 bulk drugs and their formulations with a cost-based pricing mechanism.[12]

The 1995 cost-based pricing policy had certain limitations and resulted in negligible impact on patients, but had an adverse impact on the eco-system and the pharma industry. Besides, it created an inconsistent mechanism of price calculation not aligned with requirements of the vibrant economy. The consequences were not quite as hoped, because many drug manufacturers shifted their manufacturing to other countries, mainly China. The result was that the effective price control was hardly on 20% of the drugs.[13]

Drug Price Control Order (DPCO) 2013

DPCO 2013 was notified on 15 May 2013, after a long wait of 18 years, bringing in all 348 medicines, 652 formulations of NLEM 2011, spanning across 27 therapeutic segments under price control and covered approximately 18% of the USD 13.6 billion domestic pharmaceutical market.[14]

DPCO 2013 does not specifically define essential or life-saving drugs, but incorporates the drugs listed in NLEM 2011 in schedule I of the Order, which are defined as scheduled formulations, and those not incorporated in the first schedule are defined as non-scheduled formulations.

The key principles underlying the National Pharmaceutical Pricing Policy 2012 were:

- essentiality of drugs
- control of formulation prices only
- market-based pricing.

National List of Essential Medicines 2011

The NLEM is one of the key instruments to ensure balanced healthcare system of a country to deliver accessible, affordable quality medicines at all the primary, secondary and tertiary levels of healthcare. Realising this, the Ministry of Health and Family Welfare (MoHFW), government of India, decided to have its own list of essential medicines. The first NLEM was released in 1996 and subsequently revised in 2003.

The MoHFW felt the need for updating the NLEM to address the issues of changing disease prevalence, introduce new medicines and treatment modalities and identification of unacceptable risk-benefits as well as therapeutic profiles of some medicines. The NLEM has been revised on the basis of two important national reference documents i.e. Indian Pharmacopeia 2010 and the National Formulary. NLEM 2011, issued by MoHFW, constitutes as a base for the pharma policy pricing.

National List of Essential Medicines 2015

NLEM 2015 came out on 23 December 2015 and was made effective immediately. There were total of 106 additions and 70 deletions in NLEM 2015, from NLEM 2011. NLEM 2011 covered 348 medicines and 652 formulations spanning 27 therapeutic categories, and NLEM 2015 added 4 more therapeutic categories, namely dementia, dialysis solution, ear nose throat (ENT) and neonatal care. This brought the total number of medicines in NLEM 2015 to 376 considering duplication.[15]

After the formation of NLEM 2015, the schedule I to DPCO 2013 had been replaced with NLEM 2015, which is in operation today. The span of control was 18 % of the Indian pharma market, pegged that time to be at INR 95,121 crore.[16]

Currently, NLEM 2015 is also undergoing revision and the standing committee on national medicines has been formed, which had its first preliminary meeting on 25 July 2019.[17]

CPs of the scheduled formulations (medicines under NLEM), as per DPCO 2013

The NPPA follows a methodology for price fixation and price revision of CPs of the scheduled formulations of strengths and dosages specified under the first schedule to DPCO 2013. The methodology is essentially governed by paragraphs 4, 5, 6, 14, 16 and 18 of DPCO 2013.

The above-mentioned paragraphs are summed up below:

- average PTR) is calculated by averaging the prices of all brands of medicines of same strength and dosage of the scheduled formulations, having a market share of 1% or above
- CP is worked out as Average PTR + 16% (margin to the retailers)
- the yearly revision in the CPs of the scheduled formulations is done as per the annual WPI for the preceding calendar year, on or before 1 April of every year
- the revision (re-fixing) of the CP is based on moving annual turnover value and shall be carried out as and when the NLEM is revised by the MoHFW or five years from the date of fixing the CP under DPCO 2013, whichever is earlier.

Thus, in DPCO 2013, market-based pricing has replaced the erstwhile cost-based pricing mechanism. In market-based pricing, simple average price of all brands, with a market share above 1% in their respective segments, has been considered.

Pharma companies selling medicines above the new CPs notified by the NPPA had to slash prices to conform to the new CP level. Those selling the scheduled formulations below the CP were not allowed to raise prices, resulting in significant price reduction for most essential drugs and price increases for none.[18]

Immediate impact of DPCO 2013 on the Indian pharma market

Since the announcement of DPCO 2013, immediate growth had become a challenge for the industry as almost 18% of the market had come under price control, which declined by almost 9% on Moving Annual Turnover (MAT) basis in 2014. The non-DPCO portfolio grew by 11%, which resulted in overall industry growth of 8% on MAT (Sept 2014) basis for the industry. Even after the initial set back following implementation of DPCO 2013, the non-NLEM component of the market continued to outgrow the NLEM one.

Figure 2.2: Value growth of the Indian pharmaceutical market (IPM) – moving annual total (MAT) for July 2014-2019[19]

	Value growth (MAT for July)					
	2014	2015	2016	2017	2018	2019
IPM	8%	15%	11%	8%	7%	9%
NLEM	-9%	10%	5%	-6%	3%	6%
Non NLEM	11%	16%	12%	10%	7%	10%

The market-based pricing control in DPCO 2013 is significantly better than the cost-based approach in DPCO 1995. However, the market trends indicated limited impact on access to medicines. While, in DPCO 2013, the major focus was to improve access to medicines and encourage competition as it was market-based, trends in the past six years clearly indicated that the control measures have had minimal impact in improving access to the medicines, particularly essential drugs in Class II and beyond, as per classification of the town. Hence, price control measures have not resulted in the aimed benefit of reaching out to a broader set of patients across the country.

In-fact, volume share of the molecules covered under schedule I of DPCO 2013 had started declining across therapies. 3% decline was registered within 1.5 years of the implementation of DPCO 2013. Between 2007-2015, contribution of the NLEM formulations to total volume had decreased from 78% to 70%. After implementation of DPCO 2013 by the NPPA, the volume of the NLEM formulations had increased at CAGR of 5%, compared to a CAGR of 8%, before implementation of DPCO 2013. The volume of the NLEM formulations had increased at CAGR of 5% only, compared to 10% for non-NLEM formulations between 2013 and 2015.[20]



Current drug pricing mechanism in the context of rising API prices

Implementation of DPCO 2013 was a welcome change and a positive shift from cost-based approach to market-based pricing mechanism, a move appreciated by most market participants appreciated by most stakeholders. However, as discussed in our earlier sections, in the current pricing mechanism, the cost of API or any other input is not subject to any price control mechanism and the impact of any increase in the price of raw materials must be borne by the pharma manufacturer.

Of all the input materials that goes into making a medicine, API is the largest contributor in terms of overall costs incurred and any changes in API pricing will have a direct impact on the margin of the product. On an average, contribution of API to overall cost is approximately 40%, but in certain cases it may go up to 70-80%, depending on the prevailing API prices.[21]

For example, Diamino Diphenyl Sulfone (DDS), paracetamol formulations, the API cost is around 80%.[22]

Hence, at times, it becomes unviable for manufacturers to market such products if API prices increase beyond control.

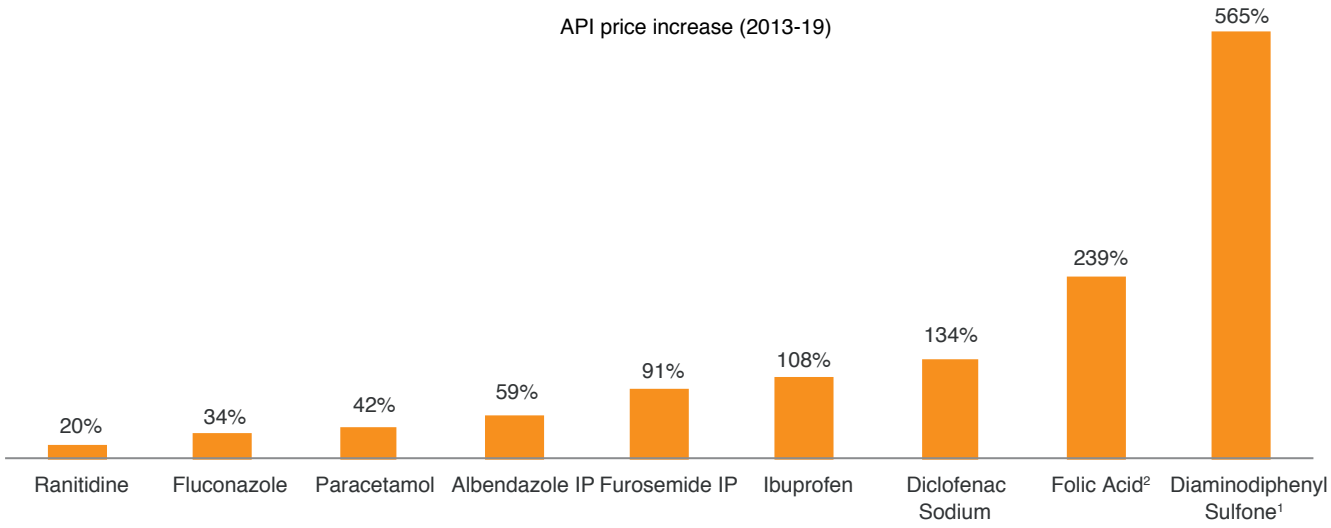
Increase in costs of API

There has been a significant increase in cost of inputs like API, excipients, power, salaries and wages, freight etc. The actual market price of some of the APIs, which are imported from China, have gone up steeply in the last few years. The exchange rates have also gone up from USD 1 = INR 55 in May 2013 to USD 1 = INR 71.78 in September 2019, (a rise of 27.27%), thereby raising the input cost.[23]

We analysed API price movement of select NLEM formulations, most of which are used on a large scale. In most of our examples, we have seen that API prices have gone up multifold and were not in line with the allowed price revision, as per the provisions under DPCO 2013.

Below are the examples analysed for the API price growth (2013-19).

Figure 3.1: API price increase for key molecules[24]



While the CPs were fixed in 2013, pricing data as of August 2012 was used. Hence, the cost increase between 2012 to 2019 would have been even more in many cases.

Rising API prices in relation to changes in WPI

As discussed in our earlier section, the current pricing mechanism uses annual WPI to fix the CP for NLEM formulations every year. The table below lists the changes in CPs due to WPI changes for the period between 2013 to 2019, after implementation of DPCO 2013.

Figure 3.2: WPI movement from 2013-2019[25]

	WPI change	Increase (INR)	Effective CP
CP notified in 2013 (Assumed)			100
CP effective April 2014	6.32%	6.32	106.32
CP effective April 2015	3.85%	4.09	110.41
CP effective April 2016	-2.71%	-2.99	107.42
CP effective April 2017	1.97%	2.21	109.54
CP effective April 2018	3.44%	3.77	113.3
CP effective April 2019	4.27%	4.83	118.14
Maximum increase in CP between 2013-2019			18%

Now, if we look at API price increase in context of WPI changes, API prices have grown far higher in the last six years than the allowed WPI increase. While the maximum price increase allowed as per WPI movement from 2013 to 2019 was just 18%, most APIs for the analysed formulations have increased at a much rapid pace, with some growing in excess of 100%.

Moreover, in most cases, actual increase in CPs is far lower than the permitted maximum. In certain cases, the CPs in 2019 are even lower than those in 2013. The CPs for most the scheduled formulations were fixed twice – once in 2013 after implementation of DPCO 2013 and again in 2016 after the substitution of NLEM 2011 by NLEM 2015 in the schedule I of DPCO 2013 in March 2016. This has resulted in price reductions for such formulations twice during the period between 2013 and 2019. The table below gives the actual CPs of few scheduled formulations for 2013 and 2019.

Figure 3.3: CPs of key scheduled formulations for 2013 and 2019[26]

	Ceiling price		Growth (2013-19)
	2013	2019	
Ibuprofen 200 mg tablet (per 1 tablet)	0.37	0.38	2.70%
Ibuprofen 400 mg tablet (per 1 tablet)	0.63	0.68	7.90%
Acyclovir tablets 400 mg (per 1 tablet)	11.64	12.04	3.40%
Paracetamol tablets 500 mg (per 1 tablet)	0.94	0.89	-5.30%
Cetrizine syrup 5mg/ml (per ml)	0.54	0.58	7.40%
Cetrizine tablets 10 mg (per 1 tablet)	1.81	1.62	-10.50%
Diclofenac injection 25 mg/ml (per ml)	1.53	1.43	-6.50%

Considering the volatility and huge fluctuations in API prices, it is likely that the formulations which are not impacted today can be impacted in future. As we have seen, India is highly dependent on a single source for a majority of its API requirement, and it is unlikely that the situation will change in near future.

A recent study, as per the Department of Pharmaceuticals, showed that India is highly dependent on imports for at least 12 essential drugs such as paracetamol, ibuprofen, ampicillin etc. listed within NLEM 2011 and 80-90% of these imports are from China. Many of them continue to be in NLEM 2015 as well.[27]

So, given the situation, where the significant rise in input price is not considered for fixing the CPs, has resulted in erratic, inadequate supply of the essential medicines in the market for ailing patients, thus making it difficult to access essential medicines.

The main objective of the current pricing policy was to establish a regulatory framework for pricing of drugs. It aims at ensuring essential drugs are available at reasonable prices and at the same time enough opportunity is provided for innovation and competition to support the growth of industry. Thus, meeting the goals of employment, shared economic and wellbeing for all.

While the methodology of annual revision in CPs based on WPI changes is a welcome feature of DPCO 2013, (as compared to method followed in DPCO 1995) anomalies which are highlighted above require quick interventions from the government for one-time modification to the current pricing mechanism.



Implications

In the current scenario, where there is a significant rise in input price for pharma companies, which they are forced to absorb by shrinking margins, we may see many direct and indirect implications for the pharma industry and the economy in general.

Higher costs for patients

If a certain formulation under DPCO 2013 becomes unviable for a manufacturer due to reasons discussed above, chances are that this formulation may go out of market and companies will start focusing more on therapeutic substitutes in the same category, not covered in DPCO 2013. This will ultimately result in higher costs for patients. For example, a physician can prescribe ranitidine for simple gastric related ailments such as hyperacidity, but due to non-availability/low promotion of ranitidine, the physician may start prescribing rabeprazole, plus combination brands, which would cost the patients up to five times the cost of ranitidine. Such consequences defeat the very purpose of having price regulations.

Limited expenditure on improving health outcomes

Many global pharma companies have invested in India to see the opportunities inherent in the country, but also because of the ethical importance of contributing to the economic health of the nation, bringing their treatments to the country and meeting unmet needs.

Pharma companies are taking an integrated approach towards disease management to support patients and improve healthcare outcomes. This is driven by campaigns aimed at creating disease awareness, improving treatment adherence, driving medical innovation and R&D, and training a new generation of healthcare workers on clinical management of diseases. Companies will need to bear limited expenditure towards these programmes.

Impact on Ayushman Bharat (National Health Protection Scheme)

The impact on generic drug manufacturers will be far higher. Because of the low margin profile, any rise in input prices may make their businesses unviable. This can have a negative impact on the current government's agenda of providing low cost healthcare through the Ayushman Bharat programme, as the availability/choice of generic brands can become limited.

Impact on access to medicines

Volume, price and new introductions are the major drivers of the growth in the Indian pharmaceutical market. However, between 2011 and 2015, several brands from the scheduled formulations under DPCO 2013 started exhibiting a declining sales trend, while non-scheduled formulations witnessed an increasing sales trend. Post introduction of DPCO 2013, the number of new introductions in the scheduled formulations under DPCO 2013 had fallen across therapy areas, which indicated diminishing competitive intensity.[28]

In a worst-case scenario, such a situation may result in shortages of essential medicines. For example, in 2015, human serum albumin, an essential drug was brought under the DPCO 2013. The price of a 100 ml albumin vial was reduced from INR 4,000 to INR 1,650, resulting in acute nationwide shortages.[29]



Impact on market players

The Indian pharmaceutical sector has more than 10,000 manufacturers and marketers and for smaller and mid-sized pharma companies, business sustainability became a serious challenge due to erosion in market share.

The implementation of DPCO 2013 had a significant impact on market share and profitability of most of the players, irrespective of their tier.[30]

The net revenue and the overall profitability impact due to price control measures was evident across large and mid-sized companies. For smaller and medium-sized companies, the direct impact on operating margin was much higher due to inability to absorb fixed costs, given already lower volumes of sales.[31]

Low investment in R&D

Drug development is undergoing global transformation. Biologics are increasingly becoming most important. India pharma companies have raised manufacturing standards and the quality of medicines being produced, but significantly lack the ability to master cutting-edge technology.

India pharma companies have stepped up R&D activities. In the year 2000, companies were spending between 1-2% of their annual turnover on R&D, whereas now, many pharma companies' research-related spending ranges between 2-13%, with an average of 8% expenditure. However, with shrinking margins, the companies' commitment towards R&D may decrease.[32]

Impact on economy

The slower growth rate of the pharma industry, post implementation of DPCO 2013 posed economic challenges. Contrary to the historical CAGR of 12-13% between 2011-13, the actual CAGR was a round 11%, resulting in lower revenue generation for the industry. The total revenue loss for the Indian pharma industry was estimated to be INR 18-20 billion, with far bigger impact on the socio-economic bottom-line.[33] The negative investment environment from the unpredictable regulatory changes and pricing pressure led to indifference from internal and external investors, leading to investment erosion.

Impact on employment

Strengthened coverage and increased investments by both public and private players have empowered the Indian healthcare sector, which is expected to generate close to 7.5 million direct employment opportunities by 2022.

According to DV Sadananda Gowda, Union Minister of Chemicals and Fertilizers, the healthcare industry in India has been one of the country's largest economic sectors and is expected to generate 40 million jobs in India by 2020. With regard to both employment and revenue, the healthcare industry in India has been one of the country's largest economic sectors. The sector is expected to record a threefold rise at a CAGR of 22% during 2016-2022 to reach USD 372 billion in 2022 from USD 110 billion in 2016.[34]

Price control can lead to margin pressures, which can impact the job creation potential of the pharma industry.



Recommendations

Various industry analyses conducted over the six years since the implementation of DPCO 2013 demonstrated the deceleration trend in the case of brands under NLEM 2011/2015 category versus progressive growth in the corresponding bands in the non-NLEM category. This is also true with reference to the launches of new products.

Also, looking at the long-term implications of rising input prices on the margins of pharma companies, we suggest that the government look at some interim solution for fixing and revising the CPs of impacted NLEM formulations.

What we recommend:

We propose solution which can be considered by the government to address the scenario where API prices have gone up much higher than WPI, on a case-to-case basis for one-time correction.

The idea behind the suggestion is that the manufacturers should be compensated for the impact they have borne due to rising API prices and hence this should be treated as one-time correction. Thereafter, the current prevailing formula of WPI increase should govern the CP increase.

Manufacturers should be allowed to use this option on a case-to-case basis for one-time correction to the CP.

We also recommend a sunset clause to this option, wherein the same formula can be used after three years to recalibrate the CP. Based on the prevailing API prices in future, the same formula can be applied to revise current price increase upward or downward.

Below is the formula which can be used for one-time correction of CP on a case-to-case basis:

ICP = [QAPI*(P2013/10^6)] *[(P2019/P2013) -(C2019/C2013)] * [1 + (T/ (100-T)]

ICP = Increase in CP to be allowed

QAPI = Quantity of API required per unit (in mg)

P2019 = Price of API per kg in 2019

P2013 = Price of API per kg in 2013

C2019 = CP in 2019

C2013 = CP in 2013

T = Trade margin (As per current industry practice it is (20% retail + 10% wholesale) in line with the NPPA notification dated 27 February 2019. However as per current pricing formula, 16% retail + 50% of retail margin is considered as the wholesale margin)

Example:

Let us consider example of Ibuprofen 200 mg Tablet where P(c) = 0.38, QAPI = 200, P2019 = 1045.91, P2013 = 504.72, C2019 = 0.37, C2013 = 0.38 and T=24%



Based on the suggested formula:

ICP = (200*504.72/10^6) *(2.072-1.027) *(1+(24/76))

= 0.101*1.045*1.316

= 0.139

In case of DPCO 2013 formulations with combination of drugs, same formula can be applied to individual molecules and cumulative ICP can be arrived by adding ICP of each molecule.

Manufacturers who desire for an increase in CP (which is fixed) may make an application giving the average cost of API purchased by them in 2013 and 2019, duly certified by a cost or chartered accountant. If more than one manufacturer submits the cost of API purchased by them, the weighted average of the data submitted by the manufacturers should be considered to arrive at the average cost of API in 2013 and 2019.

For those brands which are being sold at lower than the CP, MRP increase equivalent to increase in CP + GST may be permitted.

After making a one-time correction, future price changes may be based on WPI and in case of any abnormal price increase in API in future, similar interventions may be required.

Basis of recommendation

The premise of our recommendation is well within the framework of current policies mentioned below and can be implemented without changing the basic principle of the 'market-based' pricing approach. The policies on which our recommendations are based on are:

- the National Pharmaceutical Pricing Policy 2012 (NPPP 2012)
- the draft National Pharmaceutical Policy (NPP 2017)
- pricing methodology followed by the NPPA
- invoking DPCO 2013 - para 19
- trade margin rationalisation approach.

Paragraph 19 of DPCO 2013 has been invoked on very few occasions by the NPPA. It was first invoked on 10 July 2014 when the NPPA fixed prices of 108 anti-diabetic and cardiovascular non-scheduled formulations. The second instance was on 27 February 2019 when the government put a cap of 30% on trade margin and directed manufacturers to fix their retail price based on price at first point of sale of product (price to stockist) of the non-scheduled formulations containing any of the 42 cancer drugs.[35]



Conclusion

The Indian pharma industry is on moving towards healthy growth. Given its economic prospects, it's a market that's impossible to ignore by global pharma companies. To propel its growth, the industry will require investments from big pharma companies and favourable government policies. Global pharma companies are ramping up investments in the country, as India's domestic market holds great promise for the launch of new products and has the potential to significantly contribute to their future sales. The country's growing capabilities in contract manufacturing, R&D and clinical trials also make it a preferred partner for the global pharma industry, at every stage of the value chain.

India's value as a globally important destination for the pharma industry will also give an impetus to the government's vision of making quality healthcare affordable and accessible to all. India becoming a globally valuable destination for pharma companies will boost the government's plan of quality healthcare for all as the Government of India will be enhancing the expenditure on healthcare from the current 1% of GDP to 2.5% by 2025.[36]

Most out-of-pocket expenses on healthcare are incurred on medicines purchased from public or private healthcare facilities. The government has already introduced a draft National Pharmaceutical Policy, 2017, with the following main objectives – making essential drugs accessible at affordable prices to common people, providing a sustainable and stable policy environment for the pharmaceutical sector and making India sufficiently self-reliant in end-to-end indigenous drug manufacturing.

Despite the methodical approach to price regulation adapted by the NPPA, there seem to have been some unintended consequences, largely because of volatile API prices in the past and growing dependence on China for API imports. In the past, price regulation led to unavailability and shortage of essential medicines, as many pharma companies stopped the production of drugs which were no longer commercially viable. Many small manufacturers produced medicines by compromising on quality, despite vigilance by drug regulatory authorities.

Since the implementation of DPCO 2013, we have seen a clear deceleration trend in the case of brands under NLEM 2011/2015 categories versus progressive growth in the corresponding bands under the non-NLEM Category, and the same is true with reference to the launches of new products. We have seen that these scenarios may have an impact on some of the key areas like access to essential medicines, increased costs for patients, limited investment on innovation and overall improvement of health outcomes.

Keeping these possible implications in mind, the government will have to take a balanced approach and relook at the pricing mechanism to arrive at a one-time correction of the CPs of NLEM drugs.



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