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Comparative overview of enhancing Drug pricing transparency in India and USA

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Abstract

The United States and other different countries, drug prices are out of control. In that the prescription drug prices increasingly the medical costs and other different healthcare costs. The branded drugs are launched with high prices that increase by double percentage over year. So, many states and countries are focusing on new ways or new approaches to drug pricing problems using different ways and clarity about drug price transparency are mainly that the study about drug transparency and identify the cost key drivers. India is one of the world's developing countries. The ability to obtain health-related services at a reasonable cost is a major worry for them. As a result, medical costs are a determining element for health-care facilities, particularly when it comes to price management of health-care institutions with a greater budget. NPPA (National Pharmaceutical Pricing Authority) and DPCO (Department of Pharmaceutical Pricing and Control) are two Indian regulatory bodies that oversee pharmaceutical pricing (Drug Pricing control order). Despite the establishment of the DPCO, significant price fluctuation is observed between goods containing the same API (Active Pharmaceutical Ingredient), and various reasons are responsible for this. TRIPS (Trade Related Intellectual Property Rights) offers Compulsory Licenses for which drugs have a distinctive function to play in the affordability of medicines to minimize the stated problem and govern the trade practice by patent holder/brand maker. Essential medicine is a basic requirement of the health-care system in order to serve its consumers, and as a result, an effective and overt price restriction on drugs is currently required.

Keywords: Drug price transparency, API, TRIPS, DPCO, NLEM, NPPA

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1. Introduction

An increase in out-of-pocket expenditure mainly accounts for the unaffordability of the medicines that are available in the market. Hence, regulation of drug prices is very important to make the healthcare system in India and United States inclusive and affordable. According to **National Sample Survey Office (NSSO),** approximately 70% total out of pocket expenditure spends only on the purchase of medicines. If the out-of-pocket expenditure significantly comes down, this will have a huge impact on the affordability of healthcare services of a large number of people to the large masses as especially for the poor people. So, the high price of medicines is obviously one huge barrier to healthcare or inclusive healthcare in India. So, to make healthcare affordable and inclusive the drug prices should become down and in this contact make the **Drug Price Control Order (DPCO)** of all essential medicine by fixing the ceiling price. DPCO is made to control the price by fixing the ceiling price or maximum cap. Ceiling price means the company cannot sell their above price that is fixed so; these were set up to the limit to the companies to prices of drugs.

National List of Essential Medicine (NLEM) has drawn to include essential medicine to satisfy the priority health means of population. So, the idea is that the essential medicines listed out, and based on some criteria these essential medicines are put in a category where the prices under control. **Criteria or parameters are decided for essential medicines** will be made with consideration of safety, efficacy, disease prevalence, and comparative cost-effectiveness of medicines. According to these parameters list of medicines set up by an expert panel and these lists were updated periodically to that include those medicines which are important or relevant to the current affairs or contacts and it's done under the **Ministry of Health and Family Welfare (MoHFW).** So, an expert panel set up by MoHFW will be periodically updating the list of essential medicines form the basis of price control under DPCO. So, DPCO is

responsible for fixing ceiling prices of essential medicine are the basis for the DPCO to the fixed ceiling price, in India. (1)

According to **United States** improvement and more enhancing approaches of the drug pricing transparency in the generic medication with higher predictability. The USA has a more enhancing generic market all over the world. US particular focus on decreasing the approval period and increasingly provide higher efficient transparency for entering into the market and take more important decision on how to prices are controlled. Drug pricing transparency it is a debate topic all over the healthcare system because any type of issue regarding the drug pricing or high cost of drugs which cannot be afforded by the peoples so that need for the transparency in a particular area is very important. USFDA has good enhancing approaches for drug pricing transparency ways to cost-reducing and management of problem regarding higher cost. The main goal of USFDA offering a wide range of feasible federal policy action. The USA includes the gap between reflecting net price and list prices of various concessions like discounts and rebates associated with the transactions over the US drug supply chain and also include such entities like as manufacturers, wholesalers, pharmacies, and payers so, basis on drug price transparency the payer goals and payer benefits. (2)

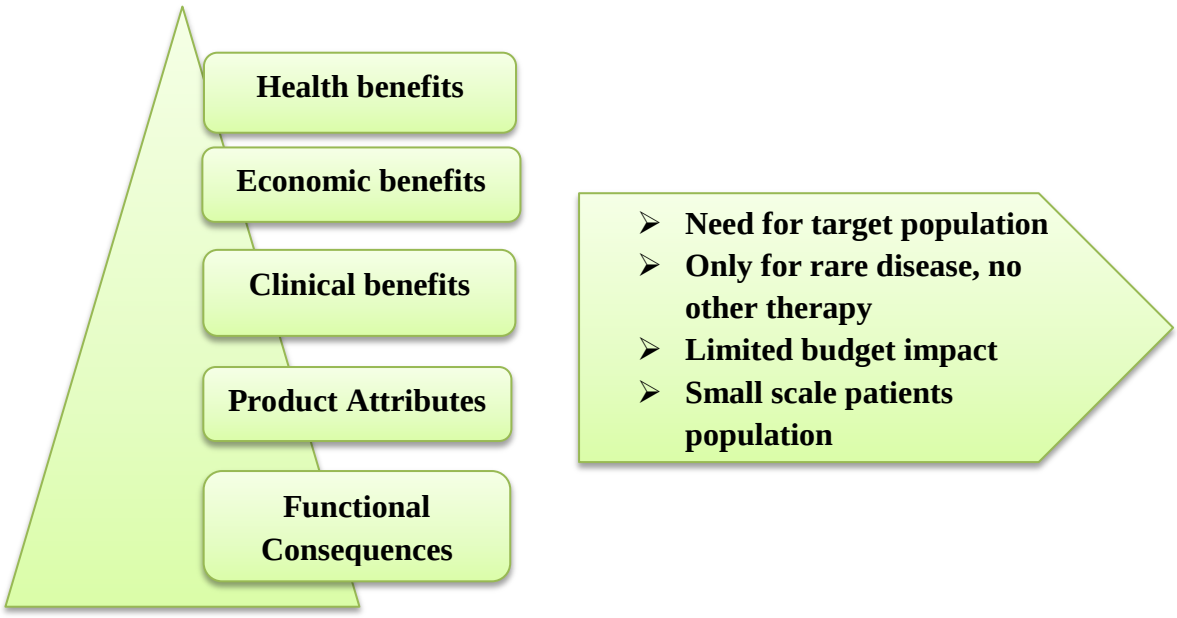

Figure 1. Comparison between payer benefits and payer goals

USFDA mainly focus on different areas like:

- Purchasers are more responsible for enhancing the transparency
- Building efficient bio- similar market to generating an affordable pricing transparency
- Fixing price with supply chain with good and enhance transparently
- Funding of drugs for the developing process (2)

2. Price regulation in current Affairs

In the USA, focus on the efforts which are reducing the risk of medicines for the violation of regulatory obligations. The USA is currently aware of a policy proposal and better affecting the drug pricing transparency. It is covered the **False Claim Act (FCA)** which provides prohibition of false claims-making from the person who is including healthcare cases like hospitals, laboratories, organizations, physicians who followed **government price reporting law.** Reducing the price and higher quality of the medicines is a debate topic for American manufacturers**.**

In the India, NPPA is an organization of the Government of India which was established, inter alia, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the DPCO, 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers.

National Council on Prices and Reimbursement of Medicinal Products (NCPRMP) Approval and registration of medical product pricing, as well as the addition of products to the Positive Drug List. A secondary licensing officer is the National Council. Approves and registers pharmaceutical product prices, as well as adding products to the Positive Drug List. Approves biological and pharmacological guidelines, as well as recommendations for treatment algorithms utilizing medicinal goods. Controls the sale of pharmaceutical products at predetermined prices. NCPRMP Regulation cycle shown in figure: 2 (3)

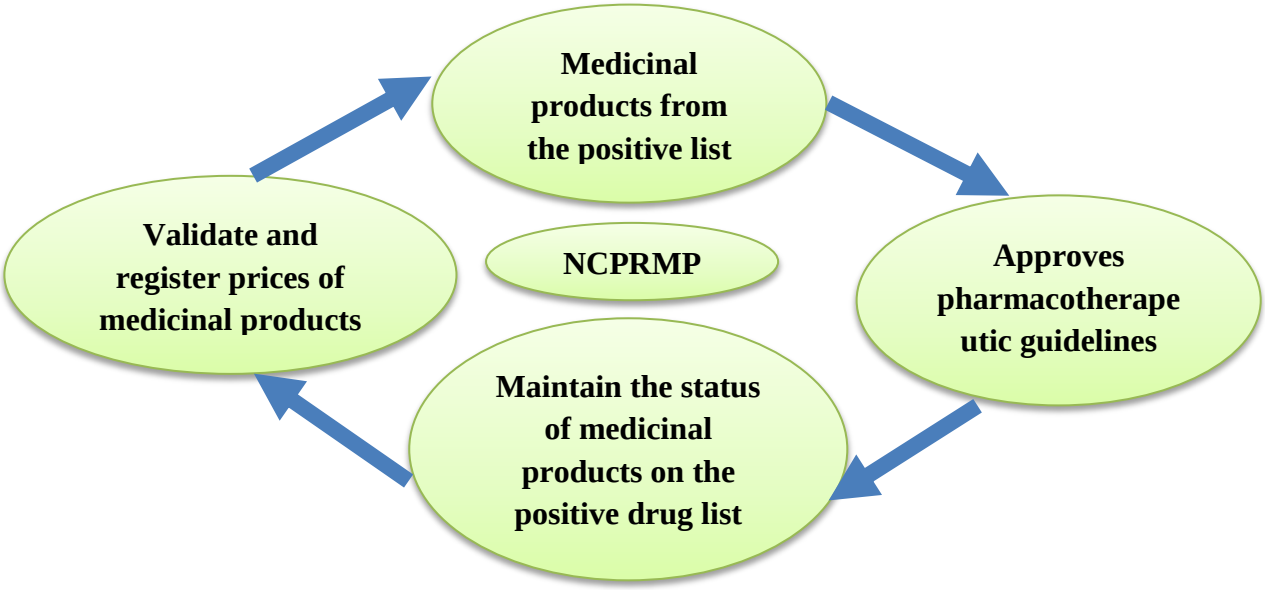

Figure 2. Regulation Cycle of Prices

3. Mechanism for Price Capping

Table 1. Comparison of Drug Price Control Order

DPCO Year	DPCO 1979	DPCO 1987	DPCO 1995	DPCO 2008	DPCO 2013
1. No. of Medicines under Price Control	347	142	76	74	348
2. No. of categories under which the above medicines were categorized	3	2	1	1	3
3. MAPE % allowed on normative/ National ex-factory costs to meet post-manufacturing expenses and provide for margin to the manufacturers.					
Category I	40%	75%	100%	100%	35%
Category II	55%	100%	N.A.	N.A.	60%
Category II (Single ingredient Leader products)	100%	N.A.	N.A.	N.A.	100%

The **National List of Essential Medicine (NLEM)** in 2015 contains around 376 medicines which are based on the list of NLEM the **National Pharmaceutical Pricing Authority (NPPA)** has fixed the prices of over 800 formulations using the provision of DPCO. So, around 800 formulations have been listed or categorized by NPPA to fix the price. (4)

4. Drawbacks of Drug Transparency

According to these 800 formulations cover less than the total pharmaceutical market. So, very little or 1/10 of the total pharmaceutical market has been covered by NPPA and the prices are fixed or the formula of price fixation is recommended by the DPCO. So, DPCO is fixing the prices using a pricing mechanism.

According to the US market higher prices of innovation because USFDA does not direct regulation of pricing mechanism. They are arranged federal program, in this program covered the price fixation of a minimum income of particulars. In the USA greater shares are spent for generating innovation in the world so its price transparency is very complex. In the USA higher government funding programs, If the Americans they do not have insurance for purchasing medicines so, conduction net safety programs or private programs for collecting the funds for access to needed medication. (5)

5. Price fixing schedule

All medications are subject to 100% Maximum Allowable Post Manufacturing Expenses (MAPE) under the 1995 price control regulation.

The Formula for retail price

The retail price of the formulation is calculated based on the following formula:

Retail price= (M.C. +C.C+P.M+P.C.) * (1+MAPE/100) + E.D.

Where, M.C. = material cost
C.C. = conversion cost
P.M. = packaging material cost
P.C. = packing charges
E.D. = excise duty
MAPE = maximum allowable post-manufacturing expenses

6. Recent trends in Drug Transparency (7-9)

In the USA according to HATCH-WAXMAN ACT minimize the drug spending in particular generic

medicines, its low-cost availability of generics because brand drugs are highly expensive so, the current development of newer technologies and justification about high prices or drug transparency is the very important thing. Many states or countries explain the various styles to tackle the price transparency for more expensive drugs.

Every state has conflicts about the transparency requirements and drug price regulation. They give the rapidly increase price transparency and reclaims. Different states prepare own rules and regulation about the drug price transparency, so that different prices of different countries is increasing confusion about price transparency.

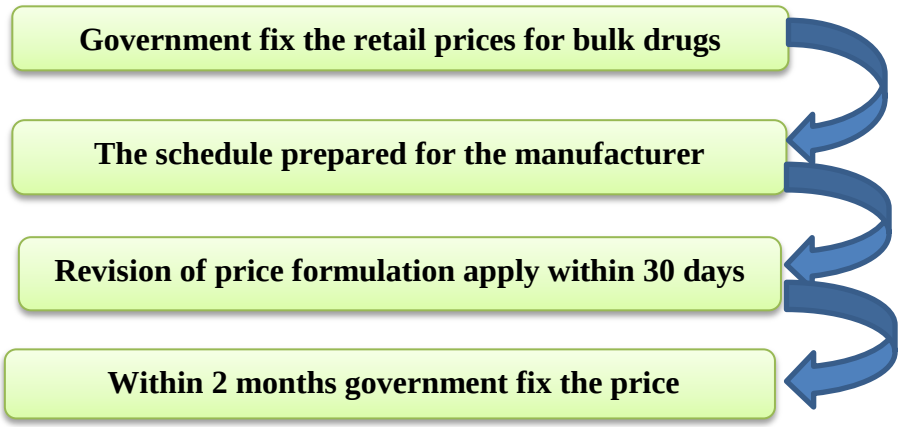

Figure 3. Price fixing schedule (6)

Price transparency follows categories like

- Reporting of new drug
- Notice about new drug application
- Advance reporting of price increase medicines
- Reporting of increased drug price transparency
- Price disclosure is provided for the healthcare team
- These all are followed by every company before the drug has to be marketed.

Drug Transparency: Cancer Drugs *(10)*

Cap Trade Margins

Recently the government plan to keep the trade margin for high drug prices for cancer or rare disease. These were intended to bring out the price of medicines which treats cancer and also rare disease. Now, this was done by the central government. So, patting cap the trade margins was done by the central government and the reason is that recent amendments the DPCO were exempted from fixing the price for patented medicines and rare disease drugs from price control. So, because of this central government has come with a cap on the trade margins.

7. Amendments to DPCO (11,12)

Under these amendments, a drug maker who has a broad and innovator drug will be accepted from the price control deviation for 5 years from the date of marketing.

Orphan Diseases *(13)*

Now, the drugs that are treated for a rare disease or orphan disease will be exempted from the price control the reason is that orphan is a rare diseases. Lesser the prevalence of this disease the company's that procedure the drugs will not be encouraged to procedure or make a treat for an orphan disease. To encourage the company's or pharmaceutical companies to manufacture medicines for rare disease. The government exempted the orphan disease also from the amendment by DPCO. Now, cancer drugs are also increasingly patented which will affect the affordability of cancer drugs to poor people. Now the recent plan of the government kept the trade margin of these cancer drugs and also the rare disease will also not bring down the price to a greater extent so, that is important to the government and policymakers to ensure trade affordability through the implementation of national rare disease policy and also use legal flexibility under patent law.

8. Future Challenges and Outcome (14)

The major challenges are the reform of drug prices and newer approaches needed to the control of too higher prices of drugs or medicines and improvement in patient health. In research and development costs indeed more transparency is needed because better transparency promises good governance, clarity, understanding, and improvements in the thing which controls the price and quality improvements in medicines. Good transparency may expose the unnecessities of innovator because his or her making new innovation is accessible or copiable so that's painful research, innovator invest more time and cost so his or her investing that's the type of investment in future again? So that's why a security system of transparency is also important.

9. Best practices about price transparency (15)

Different states are creating new own laws and regulations its major issue about price transparency so that the laws are consistent and clear guidance about the price transparency is very important. In a rare case the law of drug price transparency across identically in multiple states. Huge challenges as companies decide

own decision about transparency and who need involvement and how the process is optimized.

10. Conclusion

Drug transparency made a decision about the same time undermining differentiate the pricing and access. That debate about drug transparency that has blinded many to deep- lying problems. Complete transparency exposes the unnecessary and makes its invention accessible. The main goal of price transparency initiatives on price control. The majority study about price and purchase the policies that meet own criteria evaluate reference pricing. If any changes in the price which is only based on NDC. Under average NDC method of every drug were good compared and better prices changed by counted as annual prices of the drugs so, better transparency in the prices of the drugs. So, that the greater challenges for the companies to set their price and how to optimize its debate topic. In India, Drug Price Control Order (DPCO) and NPPA (National Pharmaceutical Pricing Authority) acts are more focusing on price control and drug price transparency. The main goal of drug price transparency is healthcare providers and healthcare agencies providing good information about the drug prices and other information about product quality and cost that negotiate good prices. Basis of current data the particular burden of drug price transparency in both healthcare agencies and pharma companies. Some states focuses on how the drug prices are fixed or set by the drug manufacturer and they submit reports related to drug prices to the states for annual costs is greater than $10,000. Another way used to that is if prices are more than 10% in per year so, drug manufacturer needs to description about why those prices and why it necessary to increase.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. Chalkidou, K. & Towse. Can Transparency Lower Prices and Improve Access to Pharmaceuticals? [Internet]. 2019 Mar 29 [cited 2022 Jan 12]. Available from: https://www.ohe.org/news/can-transparency-lower-prices-and-improve-access-pharmaceuticals-five-questions-we-think-matter
2. Fulton D. Perspective: Drug price transparency in the Biden era. USA: New England Journal of Medicine [Internet]. RAPS; 2021 Jan 18 [cited 2022 Jan 12]. Available from: https://www.raps.org/news-and-articles/news-articles/2021/1/perspective-drug-price-transparency-in-the-biden-e
3. Ahmad NS, Makmor-Bakry M, Hatah E. Drug price transparency initiative: A scoping review. Res Social Adm Pharm. 2020 Oct;16(10):1359-1369. doi: 10.1016/j.sapharm.2020.01.002.
4. Motkuri Venkatanarayana and Mishra. R. Pharmaceutical Market and Drug Price Policy in India, SAGE Journal [Internet]. 2020 Jun 01 [cited 2022 Jan 12];25(1):30-53. Available from: https://journals.sagepub.com/doi/10.1177/0972266120929146#:~:text=Pharmaceutical%20Market%20and,org/10.1177/09722661209291
5. Selvaraj S, Farooqui HH, Karan A. Quantifying the financial burden of households' out-of-pocket payments on medicines in India: a repeated cross-sectional analysis of National Sample Survey data, 1994–2014. BMJ Open. 2018;8:e018020. doi:10.1136/bmjopen-2017-018020
6. Parasiya SKR, Balamuralidhara V, T.M PK, Dave A, Gujarati R, Shukla A. NEED FOR DRUG PRICE CONTROL IN INDIA. Int J Drug Reg Affairs [Internet]. 2018Feb.11 [cited 2022 Jan 26];1(4):12-8. Available from: http://www.ijdra.com/index.php/journal/article/view/118
7. Morgan S G, Bathula H S, Moon S. Pricing of pharmaceuticals is becoming a major challenge for health systems. doi:10.1136/bmj.l4627
8. Drug-price-control order (Notified by SO 1221 (E) [internet] (dated 15.05.2013) as amended up to vide SO 1192(E) (dated 22-03-2016) [Internet]. 2013 May 15 [cited 2022 Jan 12]. Available from: https://www.flowsurfv3.net/c.php?cu=https%253A%252F%252Fvibcare.co.in%252F
9. THE DRUGS (PRICES CONTROL) ORDER, 2013 (Notified by SO 1221 (E) [internet] dated 15.05.2013 and as amended up to vide SO 1192(E) dated 22-03-2016). [Internet]. Nppaindia; 2016 Mar 22 [cited 2022 Jan 13]. Available from: https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf
10. WHO India's drug price fix is hurting healthcare cancer drug pricing transparency Measuring medicine prices, availability, affordability and price components 2nd edition. [Internet]. 2013 [cited 2022 Jan 15]. Available from: https://www.livemint.com/politics/policy/india-s-drug-price-fix-is-hurting-healthcare-11572334594083.html
11. WHO drug pricing transparency cancer drugs [Internet]. WHO;2018 [cited 2022 Jan 16]. Available from: https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1
12. Vogler S. Can we achieve affordable cancer medicine prices? Developing a pathway for change. Expert Review of Pharmacoeconomics & Outcomes Research [Internet]. 2021Mar 12 [cited 2022 Jan 14];21:3, 321-325. doi: 10.1080/14737167.2021.1898951
13. Feldman WB, Rome BN, Avorn J, Kesselheim AS. The Future of Drug-Pricing Transparency. N Engl J Med. 2021 Feb 11;384(6):489-491. doi: 10.1056/NEJMp2033734.
14. Dana, K. N., Hertig, J. B., & Weber, R. J. Drug Pricing Transparency: The New Retail Revolution. Hospital pharmacy. 2017;*52*(2):155-159. doi.org/10.1310/hpj5202-155https://pubmed.ncbi.nlm.nih.gov/334400
15. Dana KN, Hertig JB, Weber RJ. Drug Pricing Transparency: The New Retail Revolution. Hosp Pharm. 2017;52(2):155-159. doi:10.1310/hpj5202-155