

Government to devise suitable criteria to make sure that essential, lifesaving drugs remained under price control.<sup>58</sup> It also directed the Government to review these drugs until May, 2003.<sup>59</sup> Therefore, the Drug Policy of 1994 remained in effect.

The All India Drug Action Network (AIDAN)<sup>60</sup>, along with other NGOs, filed a Public Interest Litigation in 2003 before the Supreme Court, challenging the Government's drug pricing policy.<sup>61</sup> The main plea of this public interest litigation was to ensure that the prices of essential drugs remain within the reach of the common man.<sup>62</sup> The Government set up a Committee in November 2004 to investigate the options and alternatives of price control and related issues and accordingly make suggestions to ensure the availability of essential, lifesaving drugs at affordable prices.<sup>63</sup> This Committee offered its suggestions in September 2005. In the meanwhile, the Ministry of Health and Family Welfare revised the list of drugs and notified the new National List of Essential Medicine (NLEM), 2011.<sup>64</sup> Due to concerns raised by various stakeholders and difference between Ministries, the 2011 list was replaced by the new National List of Essential Medicines, 2015.<sup>65</sup>

### Present Law relating to Drug Price Control in India

Price is one of the important marketing mix elements along with product, physical distribution, and promotion. It is obvious that price fetches revenue to organizations. When organizations fix prices for its product they have to keep their pricing objectives in their mind.<sup>66</sup> While setting the price for any product factors such as cost of production, cost of distribution, offering of the competitor, positioning strategy,

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> All India Drug Action Network (AIDAN) is an independent network of several non- government organizations working to increase access and improve the rational use of essential medicines. It is working towards a world where all people, especially the poor and disadvantaged are able to exercise their human right to health, which requires equitable access to affordable quality health care and essential medicines.

<sup>61</sup> S Srinivasan, *A network for the rational and ethical use of drugs*, INDIAN JOUR. OF MEDICAL ETHICS (Nov. 6, 2017, 07:45 AM), <http://www.issuesinmedicaethics.org/121di013.html>

<sup>62</sup> *Medicine Prices shouldn't rise: Supreme Court*, IBNLIVE (Nov. 4, 2017 12:41 AM), <http://ibnlive.in.com/news/medicine-prices-shouldnt-rise-supreme-court/203413-17.html>

<sup>63</sup> *Id.*

<sup>64</sup> National List of Essential Medicines (NLEM) 2011- India, DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA (Nov. 5, 2017, 08:45 AM), <http://pharmaceuticals.gov.in/sites/default/files/NLEM.pdf>

<sup>65</sup> National List of Essential Medicines (NLEM) 2015- India, WORLD HEALTH ORGANIZATION (Nov.5, 2017, 09:04 AM), <http://apps.who.int/medicinedocs/documents/s23088en/s23088en.pdf>

<sup>66</sup> Renganathan R, et al, *Pharmaceutical Pricing Policy and Control: Indian Perspective*, 9(6) Asian Jour. Of Pharm. and Clinical Res. 305, 305-308 (2016).

and target customer have to be considered.<sup>67</sup> According to Scangos, prices of the medicines will be fixed as per the value they fetch to patients and innovative drugs which make a difference in the lives of patients continue to acquire good pricing.<sup>68</sup> In India, healthcare is one of the major sectors from the perspective of revenue and employment which includes hospitals, medical devices, clinical trials, telemedicine, medical equipment, health insurance, medical tourism, and outsourcing.<sup>69</sup>

The policy interventions undertaken by the Government of India have resulted in the Indian pharmaceutical industry becoming self-reliant in the production of the entire range of formulations and about 70 per cent of bulk drugs.<sup>70</sup> The present Drug Pricing Control legislation in India can be enumerated in the following points:

- i. In 2012, the National Pharmaceutical Pricing Policy, 2012 was set up and it was entrusted with the regulation of prices of drugs on the basis of their essentiality as specified under the NLEM, 2012. The Government enunciated the National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012) which replaced the Drug Policy enunciated in September, 1994 as 'Modifications in Drug Policy, 1986' (Drug Policy 1994). The policy is in continuation of the Policy announced earlier in 1994. Drug prices are thus, monitored and controlled by the National Pharmaceutical Pricing Authority. All the powers of Government of pricing according to Essential Commodities Act have been delegated to it. The salient features<sup>71</sup> of National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) are as under:
  - a. The regulation of prices of drugs is on the basis of essentiality of drugs as specified under National List of Essential Medicines (NLEM)-2011.
  - b. The regulation of prices of drugs is on the basis of regulating the prices of formulations<sup>72</sup> only.
  - c. The regulation of prices of drugs is on the basis of fixing the ceiling price<sup>73</sup> of formulations through Market Based Pricing (MBP).

<sup>67</sup> April Maguire, *6 Different Pricing Strategies: Which is Right for Your Business?* (2015), COURSE HERO (Nov. 7, 2017, 10:28 AM), <https://www.coursehero.com/file/18810609/Pricing/>

<sup>68</sup> Fry E., *Big Pharma won't stay silent in drug pricing debate for long* (2015), FORTUNE (Nov. 7, 2017, 10:30 AM), <http://fortune.com/2015/10/22/big-pharma-wont-stay-silent-in-drug-pricing-debate-for-long/>

<sup>69</sup> Renganathan, *supra* note 66.

<sup>70</sup> DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA (July, 12, 2017, 09:25 AM), <http://pharmaceuticals.gov.in/html>

<sup>71</sup> *Id.*

<sup>72</sup> Section 2(1) (b) of the Drug (Prices Control) Order, 2013.

- ii. Based on this policy, a new Drugs Price Control Order was notified in May, 2013. The Drug Price Control Order, 2013 was, issued by the Government, in exercise of the powers conferred under Section 3 of the Essential Commodities Act, 1955,<sup>74</sup> for enabling the Government to declare a ceiling price for essential and lifesaving medicines so as to ensure that these medicines are available at a reasonable price to the general public. In the Drug Price Control Order, 2013 the term “Act”<sup>75</sup> refers to the Essential Commodities Act, 1955 and the definition of the drug is the same as laid down under the said Act.<sup>76</sup>
- iii. Drug prices are monitored and controlled by the National Pharmaceutical Pricing Authority (NPPA). All the powers of Government of pricing according to Essential Commodities Act have been delegated to it. Under Drug Prices Control Order, 2013 the powers to review are vested with the Government. Hence, the Department of Pharmaceuticals is the reviewing authority whenever pharmaceutical companies file review petitions against any price fixation done by NPPA. Policy related matters are also dealt by the Department of Pharmaceuticals. Thus, the primary aim of the authority is to ensure adequate availability of essential and lifesaving drugs at affordable prices and in doing so, it carefully balances the interests of both the producers and the consumers the organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.<sup>77</sup>
- iv. Recently, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers through an order dated 6<sup>th</sup> April, 2017 has issued a Draft Pharmaceutical Policy 2017 which is the result of various requests and representations received from the NPPA, the Pharma Industry Associations and other stake holders suggesting improvements in the provisions of DPCO-2013

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<sup>73</sup> Section 2(d) of the Drug (Prices Control) Order, 2013 provides that, “*Ceiling price*” means a price fixed by the Government for Scheduled formulations in accordance with the provisions of the Order.

<sup>74</sup> On 16th May, 1970, a comprehensive order was promulgated under Section 3 of the Essential Commodities Act, 1955 and in supersession of all the earlier orders on the subject. This order was called The Drugs (Prices Control) Order, 1970.

<sup>75</sup> Section 2(1) (a) of the Drug (Prices Control) Order, 2013.

<sup>76</sup> Section 3(b) of the Drugs and Cosmetics Act, 1940.

<sup>77</sup> NATIONAL PHARMACEUTICAL PRICING AUTHORITY (July 15, 2017, 02:56 AM), <http://www.nppaindia.nic.in/>

based on the experience gained during its implementation.<sup>78</sup> The Draft Policy aims at improving the availability and accessibility of drugs and a group consisting of six members shall be set up to recommend the Government on the further steps to be undertaken.

The Pharmaceutical Industry in India is thus, robust and thriving. India's drug policies over the years have created an environment of duality. The country not only produces enough drugs to meet domestic consumption, but as one of the largest exporters of generic and branded drugs is known as the 'global pharmacy of the south'.<sup>79</sup> The annual turnover of the Pharmaceutical Industry in India in 2015-16 was reported as Rs. 2, 04,627.15 crores.<sup>80</sup> However, despite this seemingly commendable performance, millions of Indian households do not have access to drugs. This results from both financial and physical barriers.

The paper shall now discuss the lacunas in the present Drug Pricing Policy and the suggestions for a better policy so as to meet these challenges

### Lacunas in the Present Drug Pricing law in India and Recommendations

It is the state responsibility to ensure right balance between health and the pricing of drugs. Moreover, the Right to health should supersede all other rights. Thus, we desperately need to battle India's dismal conditions of drug pricing policy if human rights are to be, maintained and provide essential medicines at affordable prices and to provide to all the human beings a life which is dignified, healthy and safe.<sup>81</sup> In 2009, 'Human Rights Watch' documented the poor availability of pain treatment and palliative care in India<sup>82</sup>, and its report claimed that hundreds of patients with advanced cancer suffer from severe pain without access to morphine or other strong pain relievers.

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<sup>78</sup> Draft Pharmaceutical Policy, 2017, MINISTRY OF CHEMICALS AND FERTILIZERS, DEPARTMENT OF PHARMACEUTICALS (Oct. 15, 2017, 18:09 PM), <http://www.indiaenvironmentportal.org.in/files/file/draft%20pharmaceutical%20policy%202017.pdf>

<sup>79</sup> High Level Expert Group Report on Universal Health Coverage for India, *Access to Medicine, Vaccines and Technology*, UNIVERSAL HEALTH COVERAGE FOR INDIA (Oct.12, 2017, 12:43 PM), [http://uhc-india.org/reports/hleg\\_report\\_chapter\\_3.pdf](http://uhc-india.org/reports/hleg_report_chapter_3.pdf)

<sup>80</sup> *Supra* note 78.

<sup>81</sup> Akram Ahmad et al, *Drug pricing policies in one of the largest drug manufacturing nations in the world: Are affordability and access a cause for concern?* 4 Jour. Res. in Pharm. Prac. 1, 1-3 (2015).

<sup>82</sup> Human Right Watch report titled, *Unbearable Pain: India's Obligation to Ensure Palliative Care*, HUMAN RIGHTS WATCH, (June 7, 2017, 12:30 PM), <https://www.hrw.org/report/2009/10/28/unbearable-pain/indias-obligation-ensure-palliative-care.html>

According to a recent report,<sup>83</sup> Cancer patients in Punjab, who are undergoing treatment at the Post Graduate Institute of Medical Education and Research, (PGI) are facing a tough situation, because price of life saving cancer drugs supplied by the institute in lieu of private grants provided by Punjab Government is higher than that of drugs available in other pharmacies.<sup>84</sup>

Due to a crumbling and dilapidated public health care system, most of the drugs in India are either out of stock or the system simply does not have the adequate resources to buy them.<sup>85</sup> This has largely resulted in private sector takeover of health care system in the country.<sup>86</sup> The provision of affordable, high quality and appropriate essential medicines is a vital component of a well-functioning health system. It has been rightly stated:

How did the drug industry with its life saving innovations, manage to earn a public image that is much worse than the industries with products that kill, such as gun and tobacco industries? How will stricter controls over pricing and patient access to drugs evolve as a new generation of expensive biotech drugs threatens to bankrupt pharmaceutical budgets?<sup>87</sup>

Nevertheless, the Government of India has undertaken various steps in order to make the lifesaving and essential medicines available at affordable prices. Some of these efforts are:

- i. The Pharma Advisory Forum in its meeting held on 23rd April, 2008 under the Chairmanship of Shri Ram Vilas Paswan, Honorable Union Minister of Chemicals & Fertilizers and Steel, Decided to launch a *Jan Aushadhi Campaign*.<sup>88</sup> The Jan Aushadhi initiative makes available quality drugs at affordable prices through dedicated stores selling generic medicines which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs.<sup>89</sup> It is being run

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<sup>83</sup> Punjab State Report on *Cancer Awareness & Symptom Based Early Detection Campaign*, INDIA ENVIRONMENT PORTAL (Oct. 30, 2017, 06:20 AM), <http://www.indiaenvironmentportal.org.in/files/file/Campaign-on-cancer.pdf>

<sup>84</sup> *Id.*

<sup>85</sup> SAKTHIVEL SELVARAJ, *HOW EFFECTIVE IS INDIA'S DRUG PRICE CONTROL REGIME?* (Harvard Publications, 2007).

<sup>86</sup> *Id.*

<sup>87</sup> ED SCHOONVELD, *THE PRICE OF GLOBAL HEALTH DRUG PRICING STRATEGIES TO BALANCE PATIENT ACCESS AND THE FUNDING OF INNOVATION 1* (Gower Publishing Limited, Surrey, England, 2011).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

in a Campaign Mission Mode on the principle of *Not for Profits but with Minimal Profits*.<sup>90</sup>

- ii. During the 12th Five Year Plan<sup>91</sup>, Ministry of Health and Family Welfare proposed to start an initiative for free supply of essential medicines in public health facilities in the country aiming to provide affordable health care to the people by reducing out of pocket expenses on medicine.
- iii. The National Pharmaceutical Pricing Authority has also launched an online platform Integrated Pharmaceutical Database Management System (IPDMS) which enables online submission of mandatory forms prescribed. Moreover, *The Pharma Jan Samandhan (PJS)*<sup>92</sup>, a public grievance portal was also launched, to facilitate the submission of grievances by the public.
- iv. In May, 2014, another amendment was made in Drug Price Control Order, which authorized the National Pharmaceutical Pricing Authority to control prices of other 108 life-saving drugs which were not originally included in the National List of Essential Medicines. This patient friendly policy significantly reduced the prices of some important life-saving drugs for disease conditions such as cancer, HIV/AIDS, tuberculosis, cardiovascular diseases, diabetes, etc.
- v. In September, 2016 the authority also reduced the prices of another 33 essential medicines including the antibiotics and drugs used to treat ulcerative colitis, anti-allergic used for common cold and cough, etc.
- vi. The Draft Policy of 2017, also aims at taking measures for making the pricing policy more in favor of poor patient's affordable Medicare and Health Security. Moreover, suggestions will be made to make the DPCO-2013 more comprehensive in the light of past experience of implementing the order.

As we know the Pharmaceutical market in India exports medicines to many countries worldwide and is also considered to be one of the leading market in the world. In spite of that, more than half of its population has no access to essential medicines in

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<sup>90</sup> *Id.*

<sup>91</sup> RAMESHWARI PANDYA, HEALTH, FAMILY PLANNING AND NUTRITION IN INDIA, FIRST FIVE YEAR PLAN (1951-56) TO ELEVENTH FIVE YEAR PLAN (2007-12), (New Century Publications, 2009).

<sup>92</sup> The Pharma Jan Samadhan (PJS) initiative is part of Government of India's Digital India initiative, which aims at empowering the citizen through a transparent, accountable and responsive governance system. It provides the consumer with an effective and time bound grievance redressal system to effectively deal with complaints related to pricing, shortage and non-availability of medicines. Apart from the internet- based online facility, there is a consumer Help Line also, which can be used to lodge complaints.

the government hospitals due to heavy dependence of a majority of patients on the private sector. A significant proportion of the Indian population pays for their health care expenditures by shelling money out of their pockets. Pharmaceutical industry in India is thus favoring the industry rather than the public.

According to a World Health Organization (WHO) report, almost 68 % of the people in India have limited or no access to essential medicines.<sup>93</sup> Poor availability of medicines in the public sector has pushed up household out-of-pocket (OOP) expenditure, making them the largest household expenditure item after food.<sup>94</sup> Nearly 80 per cent of India's health care expenditure is borne by patients OOP, of which medicines constitute 70%.<sup>95</sup> Another study in the three North Indian states of Haryana, Punjab and Chandigarh also reported that medicines constituted 19-47 % of hospitalization expenditure and 59 to 86 per cent outpatient department (OPD) expenditure borne out-of-pocket by households in public sector.<sup>96</sup> Poor financial risk protection of households in India, resulting from gross underinvestment in the health sector, especially on medicines, has led to a scenario where access to essential medicines has become extremely difficult.<sup>97</sup>

Some of the reasons for the non-availability of drugs are:

- i. Inefficient and Iniquitous Financing Mechanisms,
- ii. Unreliable Medicine Supply systems,
- iii. Poor Quality of Medicines,
- iv. High Drug Prices,
- v. Unaffordable Drug Pricing,
- vi. Unfair Health Financing Mechanisms,
- vii. Inadequate Funding for Research in neglected diseases,
- viii. Widespread use of Irrational Medicines,

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<sup>93</sup>Cameron A, et al, *Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis*, LANCENT.COM (Nov. 10, 2017, 09:49 AM), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.178.8108&rep=rep1&type=pdf>

<sup>94</sup>S. Oberoi and A Oberoi, *Pharmacoeconomics guidelines: The need of hour for India*, 4 Int. Jour. Of Pharma. Investigation 109-111 (2014).

<sup>95</sup> Data compiled from the National Health Accounts India (2004–2005), MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA (July, 20, 2016, 16:20 PM), [http://planningcommission.nic.in/reports/genrep/health/National\\_Health\\_Account\\_04\\_05.pdf](http://planningcommission.nic.in/reports/genrep/health/National_Health_Account_04_05.pdf)

<sup>96</sup>Prinja S, et al, *Health care inequities in north India: role of public sector in universalizing health care*, 136 Indian Jour. Of Med. Res. 421-431 (2012).

<sup>97</sup>Sakthivel Selvaraj, et al, *Universal access to medicines: evidence from Rajasthan, India*, 3 WHO South East Asian Jour. Of Pub. Health, 3-4 (2014).

- ix. Lack of Regulation of Drugs and Diagnostics,
- x. Stringent Product Patent Regime.

In order to meet all these challenges, the following recommendations are made by the author:

- i. There should be a proper enforcement of the price regulation and the Drug Price Control order, 2013 should apply to all the formulations laid down in the Essential List of Medicines issued by the World Health Organization.
- ii. The Central and the State regulatory authorities should more effectively perform the price control mechanisms.
- iii. The Department of Pharmaceuticals should be transferred to the Ministry of Health, since it is not only responsible for ensuring the quality, safety and efficacy of drugs but is also accountable for the unhindered availability of the essential drugs.<sup>98</sup>
- iv. The existing mechanisms for the collection of market-based data on prices of medicines should be made more robust and stream-lined. Moreover, the existing pharmaceutical database management system should be more strengthened.<sup>99</sup>
- v. The number of *Jan Aushadhi* centers should be increased and the poor people from the rural areas should be given requisite knowledge about these centers with the help of government officials and media.
- vi. Strengthening the public sector availability of medicines is a long-term, sustainable way to reduce private expenditure on healthcare. Increased allocation of funds on medicines is of paramount importance.<sup>100</sup>
- vii. Robust IT systems should be used for scientific warehousing and inventory management, real-time stock monitoring and transparent centralised procurement and decentralised distribution mechanism. State governments should evaluate their procurement systems to ensure efficiencies and make necessary reforms to improve availability.<sup>101</sup>

However, these recommendations will inherently be limited in enhancing access to treatment because the successful implementation of each depends on several legal,

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<sup>98</sup> *Supra* note 79.

<sup>99</sup> *Supra* note 78.

<sup>100</sup> Prinja et al, *Availability of medicines in public sector health facilities of two North Indian States*, 16 BMC Pharmacology & Toxicology, 43 (2015).

<sup>101</sup> *Id.*

administrative and political factors.<sup>102</sup> The litigation with Novartis<sup>103</sup> is an example of such limitations that further delay or deny access to affordable lifesaving drugs. Hence, the Government of India should review and ensure the proper implementation of the Drug Policy at present and consider the pricing strategy which affects the society at large and makes healthcare accessible and affordable to the citizens.

## Conclusion

Health care in India remains heavily skewed for the poor and access to affordable medicines remains a significant concern. The National Pharmaceutical Policy, 2012 along with the Drug Price Control Order, 2013 is not effectively implemented and regulated under the legal framework. In order to make drugs more affordable and accessible to patients, National Pharmaceutical Pricing Authority (NPPA) needs to cap the price of the essential drugs in accordance with the National List of Essential Medicines (NLEM).

Hence, a stricter regulatory regime, which not only brings down drug market prices but also continuously expands span of price control, is cited as the main reason why drug manufacturers are losing their India focus. Industry officials also blame looming uncertainty in policy as another reason for companies to delay product launches. Apart from pricing, the pharmacy industry has been facing hiccups in foreign investment, new drug approvals, as well as clinical trials. Government and regulators, however, brush aside such concerns.

The drug policy is to be reviewed with a strong base to consider the pricing strategy for the society at large and make healthcare accessible and affordable to the citizens. In revising its drug policies, the Government of India needs to balance its core responsibility to protect the health and welfare of the Indian people and the nation's interest in sustaining the continued development of a world class Indian life sciences capability.

Change is the need of the hour.

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<sup>102</sup> Jain, *supra* note 30.

<sup>103</sup> Novartis AG v. Union of India (2007) 4 MLJ 1153.