

IS THE NATIONAL PHARMACEUTICAL POLICY, 2012 REALLY CHEERING THE PHARMA?

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The National Pharmaceutical Policy was approved by the Cabinet and notified in 2012. Based on this policy, a new Drugs Price Control Order was notified in May, 2013. As a result, several drugs will come within the ambit of price control under the National list of Essential Medicines (NLEM). The primary purpose of NLEM is to facilitate the rational use of medicines which will allow for cost effective, safe and drugs with efficacy. This paper critically evaluates the provision on exclusion of patented drugs in the recent National Pharmaceutical Policy, 2012 from the Drug Pricing Policy for five years. The policy states "Drugs patented under the Indian Patents Act, 1970 and which have been made as a result of indigenous products or process have been exempted from price control for a period of five years." Further, a formulation involving a new delivery system developed through indigenous R&D would be eligible for exemption from price control for a period of five years from the date of its market approval in India. While this exclusion may have been designed keeping the opportunity for innovation for pharmaceutical companies, however, given the critical situation of HIV/AIDS medication, cancer drugs, tuberculosis etc., it is pertinent to have these drugs under price control well before the prescribed period of five years. This paper argues that this provision of the NLEM, 2012 contravenes the main objective of this policy and in turn violates the Constitutional right to life and health of millions of people who need these patented lifesaving drugs, especially the people living with HIV/AIDS (PHLAs).

Introduction

Access to essential drugs is a pressing concern in India today. This concern was in part exacerbated by India's transition from a process patent regime to a product patent one in 2005.¹ Essential drugs like the antiretroviral ('ARV') medicines for HIV/AIDS treatment and anti-cancer drugs are likely to become unaffordable due to implementation of the product patent in the Indian Patent Act, 2005.² The changes are likely to result in grave shortage in supplying ARV drugs to people in poor countries³ and may encourage pharmaceutical company to prioritize revenues above the genuine needs of public health.⁴ There are a few flexibilities available within Trade Related Intellectual

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² Ministry of Health and Family Welfare Government of India, REPORT OF NATIONAL COMMISSION ON MACRO ECONOMICS AND HEALTH (2005), page 6, available at <http://www.who.int/macrohealth/action/Report%20of%20the%20National%20Commission.pdf>

³ Sorcha O'Carroll, *Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya*, available at http://www.mcmillan.ca/Files/SOCarroll_ImportingIndianGenericDrugs.pdf

⁴ See Cecilia Oh, *TRIPS and Pharmaceuticals: A Case of Corporate Profits over Public Health*, THIRD WORLD NETWORK, Aug.-Sept. 2000, available at www.twinside.org.sg/title/twr120a.htm.

Property Rights Agreement under the WTO regime (TRIPS). Beyond the patent regulations and other available flexibilities in the national and international legislations, drug pricing is another available ex post remedy to regulate access essential drugs by ensuring affordability.

Drug pricing is crucial towards making drugs affordable to ordinary citizens. Many price control policies have been introduced in India from time to time.⁵ These policies were driven by the twin objective of controlling the prices of essential (and later, bulk) drugs but also sought to simultaneously ensure the availability of these drugs and to meet the requirements of the industry for cost effective production, invention and capacity building.⁶

However, post-liberalization in 2002, a new pricing policy for pharmaceuticals was presented which sought to liberalize the prices control further.⁷ This 2002 Policy was challenged in the High Court at Karnataka and the Court issued a stay on the implementation of the policy on 12.11.2002.⁸ The Government challenged this order in the Supreme Court. The Apex Court vacated the stay but directed the Government to devise suitable criteria to make sure that essential, lifesaving drugs remained under price control.⁹ It also directed the Government to review these drugs until May, 2003.¹⁰ Therefore, the Drug Policy of 1994 remained in effect.

The All India Drug Action Network (AIDAN), along with other NGOs, filed a PIL in 2003 before the Supreme Court, challenging the Government's drug pricing policy.¹¹ The main plea of this public interest litigation was to ensure that the prices of essential drugs remain within the reach of

⁵ *Id.* In India, the first drug pricing policy was implemented in 1963 under the Defence of India Act. The other are-the Drugs (Prices Control) Order of 1966, the Drugs (Prices Control) Order of 1970, issued under the "Essential Commodities Act 1955 by declaring drugs to be essential commodities under the EC Act, 1955; the Drugs (Prices Control) Order of 1979 and Drugs (Prices Control) Order, 1987 were issued following the declaration of Drug Policy, 1978 and Drug Policy 1986.

⁶ *Supra* note 4.

⁷ *Supra* note 4.

⁸ NATIONAL PHARMACEUTICALS PRICING POLICY, 2012 (7th December, 2012), available at <http://www.pharmaceuticals.gov.in/NPPP2012.pdf>

⁹ *Supra* note 8.

¹⁰ *Supra* note 8.

¹¹ S Srinivasan, A network for the rational and ethical use of drugs, Indian Journal of Medical Ethics, 11 January 2013, available at <http://www.issuesinmedicalethics.org/121di013.html>

See also *Medicine Prices shouldn't rise: Supreme Court*, THE ECONOMIC TIMES, Nov 17, 2011 available at http://articles.economictimes.indiatimes.com/2011-11-17/news/30410046_1_drug-pricing-policy-essential-medicines-prices-control

the common man.¹² 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.¹³ This Committee offered its suggestions in September 2005.¹⁴

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), 2011.¹⁵ Due to concerns raised by various stakeholders and difference between Ministries, the 2011 list was replaced by the new NLEM, 2012. This list consists of “those medicines that satisfy the priority healthcare needs of majority of the population.”¹⁶

The National Pharmaceutical Policy, 2012

The National Pharmaceutical Policy was approved by the Cabinet and notified in 2012.¹⁷ Based on this policy, a new Drugs Price Control Order was notified in May, 2013. A list of several drugs will come within the ambit of price control called the National list of Essential Medicines (NLEM). The primary purpose of NLEM is to facilitate the rational use of medicines which will allow for cost effective, safe and drugs with efficacy.¹⁸ This paper critically evaluates the provision on exclusion of patented drugs in the recent National Pharmaceutical Policy, 2012 from the Drug Pricing Policy for five years. The policy states “*Drugs patented under the Indian Patents Act, 1970 and which have been made as a result of indigenous products or process have been exempted from price control for a period of five years.*” Further, a formulation involving a new delivery system developed through indigenous R&D would be eligible for exemption from price control for a period of 5 years from the date of

¹² *Medicine Prices shouldn't rise: Supreme Court*, IBNLIVE, 18 November 2011, available at <http://ibnlive.in.com/news/medicine-prices-shouldnt-rise-supreme-court/203413-17.html>

¹³ *Id.*

¹⁴ *Supra* note 12.

¹⁵ *Supra* note 12.

¹⁶ NATIONAL LIST OF ESSENTIAL MEDICINES OF INDIA 2011, available at <http://mohfw.nic.in/WriteReadData/1892s/4767463099list.pdf>

¹⁷ *Government notifies new drug pricing policy, cheaper drugs on way*, FINANCIAL EXPRESS, 13 December, 2012, available at <http://www.financialexpress.com/news/government-notifies-new-drug-pricing-policy-cheaper-drugs-on-way/1044845>

¹⁸ *Supra* note 17.

its market approval in India. While this exclusion may have been designed keeping the opportunity for innovation for pharmaceutical companies, however, given the critical situation of HIV/AIDS medication, cancer drugs, tuberculosis etc., it is pertinent to have these drugs under price control much before five years. Exception of 5 years will make accessibility to drugs extremely difficult.

This paper argues that this provision of the NLEM, 2012 contravenes the main objective of this policy and in turn violates the Constitutional right to life and health of millions of people who need these patented lifesaving drugs, especially the people living with HIV/AIDS (PHLAs). While most of the Drug Pricing Policies in the past have been implemented in light of various objectives, the 2012 National Pharmaceutical Policy is aimed mainly at making drugs affordable. The main objective of the 2012 policy is to put in place a regulatory framework to ensure the availability of essential drugs listed in the NLEM at affordable prices.¹⁹ Other measures for encouraging the growth of the Pharmaceutical Industry and the development of new medicines, etc. will be adopted by the Government at a later time.²⁰

It is apparent from this provision that the Government has once again failed to address the most pressing concerns relating to patented drugs in India. Patented drugs, especially the essential and lifesaving drugs must be bought under price control. Many essential and lifesaving and ARV drugs introduced in India after 2005 will be patent protected.²¹ Although patents are provisional and will eventually expire, since ARV is a relatively new invention and will take some time before these come off patent, many people living with HIV/AIDS will not be able to afford these drugs and may die for lack of access to these antiretroviral drugs.²² People living with HIV/AIDS are likely to develop resistance to first generation drugs and will need second-generation drugs soon. The second and third generation drugs are mostly patented.²³ The civil society has been filing patent

¹⁹ *Supra* note 17; *supra* note 2.

²⁰ *Supra* note 2.

²¹ Harriet Gliddon, *The end of the line for affordable HIV drugs?*, available at http://aglobalvillage.org/journal/issue3/global_health_and_development/hiv-drugs/ and Rachel Rizal, *Patents versus people: The battle over generic antiretroviral drugs in India*, 8 INT. J. HEALTH ETHICS & POL'Y 1, 15 (2008) available at <http://ase.tufts.edu/tuftsscope>

²² Edwin Cameron, *Patents and public health: principle, politics and paradox*, 19 October, 2004 available at <http://www.law.ed.ac.uk/ahrc/script-ed/docs/cameron.asp#Causes>

²³ WHO HIV DRUG RESISTANCE REPORT, 2012 available at <http://www.who.int/hiv/pub/drugresistance/report2012/en/index.html>; Eben Harrel, *New Study Raises Concerns About HIV-Drug Resistance*, TIME, 14 January 2010, available at <http://www.time.com/time/health/article/0,8599,1953718,00.html>

oppositions²⁴ to block patenting of these lifesaving drugs. While some of these patent opposition petitions were successful²⁵ others were not.²⁶

In this scenario, if these patented drugs remain outside price control mechanism, it defeats the purpose of this policy. It is pertinent to note that effective treatment for PLHA involves use of multiple drugs in a process called “combination therapy.” The use of multiple drug therapies is mostly considered better because it decreases the chance of developing drug-resistant strains of HIV by cancelling out mutations against other drugs.²⁷ Lack of access to one drug in a combination therapy can impede effective treatment. According to Médecins Sans Frontières (MSF), the fixed-dose combination of d4T/3TC/NVP, a generic triple combination therapy costs 26 times less than using the originator’s triple therapy.²⁸ Though NVP and d4T were off-patent, Glaxo-Smith-Kline’s (GSK) patent on the ARV 3TC obstructed the availability of this drug.²⁹

Further, the lack of availability of one patented drug in multiple combination therapy can encourage the government to roll out drugs that may exclude the patented component. For instance, the ARV 3TC was under patent protection, hence inaccessible in China. Therefore, the government advocated a therapeutic regime which excluded 3TC.³⁰

²⁴ On 30 March 2006, the Manipur Network of Positive People (MNP), and the Lawyers' Collective HIV/AIDS Unit filed an application opposing the patent application filed in the Kolkata patent office by Glaxo Group Limited for Combivir, a fixed-dose combination of two AIDS drugs (zidovudine/lamivudine, or AZT/3TC), Brazilian Interdisciplinary AIDS Association (ABIA) and the Indian NGO SAHARA submitted a joint pre-grant opposition to the patent application of Tenofovir Disoproxil Fumarate in India, The Indian Network for People Living with HIV/AIDS (INP+) and the Delhi Network of Positive People filed an opposition to the patent application on the AIDS drug tenofovir disoproxil fumarate (TDF), see also, Sangeeta Shashikant, *Indian opposition to drug patents*, TWN INFO SERVICE ON HEALTH ISSUES, 23 May, 2006, available at <http://www.twinside.org.sg/title2/health.info/twninfohealth018.htm>

²⁵ India’s first post grant opposition was successful, the Intellectual Property Appellate Board (IPAB) has revoked the patent on Roche’s pegylated interferon alfa-2a in 2012, see <http://www.thehindubusinessline.com/companies/patent-on-roche-hepatitis-c-drug-revoked/article4057999.ece?homepage=true&css=print#>> and the Cipla’s patent opposition application was successfully against Pfizer in 2012, see http://www.business-standard.com/article/companies/cipla-wins-patent-opposition-against-pfizer-s-cancer-drug-112100400199_1.html

²⁶ See also Geeta Anand, *Drug Makers Decry Indian Patent Law*, WALL STREET JOURNAL, February 11, 2010, available at <http://online.wsj.com/article/SB10001424052748703455804575057621354459804.html>

²⁷ King JR, Acosta EP, Chadwick E, et al, *Evaluation of multiple drug therapy in human immunodeficiency virus-infected pediatric patients*, 22 PEDIATR. INFECT. DIS. J. 3 (2003), available at <http://www.ncbi.nlm.nih.gov/pubmed/12634585>

²⁸ Cheri Grace, *A Briefing Paper for DFID: Update on China and India and Access to Medicines*, DFID HEALTH RESOURCE CENTRE, 19 (November, 2005).

²⁹ *Ibid.*, at 4

³⁰ *Supra* note 29, at 18

It is clear that access to proper antiretroviral treatment is limited due to the high costs associated with patented ARV drugs. With new waves of ARV drugs being produced to combat resistance, access to proper treatment will only worsen as these new drugs are subject to patent protection. Price control on patented drugs is essential because a medicine market is not a perfect market and lack of price control will lead to exorbitant pricing.³¹ Increasingly, drugs in India are purchased through private, out of the pocket expenditure (79% according to a WHO study)³². Exemption from price control for a period of five years is extremely unreasonable and is likely to adversely impact the availability of lifesaving drugs. Even provisions like compulsory licensing, allow for only a three year lock-in period which is under considerable criticism. One of the main reasons for the three year lock-in period for compulsory licensing and the 5 year exemption for price control is imposed mainly because there is an argument that patents represent one of the most important incentives for commercial enterprises to undertake research and development.³³ The proponents of TRIPS argued that the 2005 amendments will encourage foreign investment, transfer of technology and increase investment in research and development of neglected diseases. However, the evidence has shown otherwise. There is also evidence to show that a strong patent regime does not necessarily guarantee increased investment in Research and Development (R&D).³⁴ Overall, evidence shows that the implementation of stringent patent rights in developing countries has had a negative impact on access to treatment, especially for PLHAs.³⁵ These time lags may result in prolonged delay in accessing essential medications.

Constitutional Right to Health

The exemption on patented drugs under the NPP is in violation of the right to life under Constitution of India. By recognizing that the fundamental right to life in Article 21 of the

³¹ REPORT OF THE COMMITTEE ON PRICE NEGOTIATIONS FOR PATENTED DRUGS, Page 1 (Para1.1), available at <http://www.elsevierbi.com/~media/Supporting%20Documents/Pharmasia%20News/2012/August/India%20Patent%20Drug%20Pricing%20Report.pdf>

³² *Id.*

³³ See, e.g., Jorge A. Goldstein & Elina Golod, *Human Gene Patents*, 77 ACAD. MED 12, 1315, 1323–24 (2002).

³⁴ *Why today's R&D model doesn't work for the needs of developing countries*, MÉDECINS SANS FRONTIÈRES (May, 2012) available at http://www.msfacecess.org/sites/default/files/MSF_assets/Innovation/Docs/MedInno_Briefing_GlobalConventionRD_ENG_2012Update.pdf

³⁵ Dipika Jain and Rachel Stephens, *The Struggle for Access to Treatment for HIV/AIDS in India*, COMBAT LAW PUBLICATION, 113 – 114 (2008).

Constitution emphasizes the value of human dignity, the Supreme Court began to address the importance of health as a fundamental right for Indian citizens. In addition to Article 47, the right to health also has its genesis in Articles 38³⁶, 39(e)³⁷, 41³⁸ and 48A³⁹ of the Directive Principles. In a series of cases, the Supreme Court⁴⁰ has addressed the issue of healthcare as a fundamental right and has imposed an obligation upon the state to take all steps to create conditions necessary for good health, including facilities for basic curative and preventive health service. Lack of access to essential and lifesaving drugs constitutes a violation of their right to the highest attainable standard of health and therefore, the right to life.⁴¹ Courts around the world have relied on the rights to life and health to ensure their respective Governments provide HIV/AIDS treatment to those in need.⁴² In 2001, the Supreme Court of El Salvador in *Jorge Odir Miranda Cortez v. Director of the Salvadoran Institute of Social Security*⁴³ held that the El Salvadorian Government must provide ARV therapy and other medications that prevent the death and improve the quality of life of persons

³⁶ State to secure a social order for the promotion of welfare of the people.- (1) The State shall strive to promote the welfare of the people by securing and protecting as effectively as it may a social order in which justice, social, economic and political, shall inform all the institutions of the national life. (2) The state shall, in particular, strive to minimise the inequalities in income, and endeavour to eliminate inequalities in status, facilities and opportunities, not only amongst individuals but also amongst groups of people residing in different areas or engaged in different vocations

³⁷ Certain principles of policy to be followed by the State: - The State shall, in particular, direct its policy towards securing. (e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;

³⁸ Right to work, to education and to public assistance in certain cases.- The state shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to education and to public assistance in cases of unemployment, old age, sickness and disablement, and in other cases of undeserved want

³⁹ Article 48A: Protection and improvement of environment and safeguarding of forests and wild life - The State shall endeavour to protect and improve the environment and to safeguard the forests and wild life of the country

⁴⁰ In *Consumer Education and Research Centres & Others. v. Union of India*, (1995) 3 SCC 42, the Supreme Court held that the right to health and medical aid to protect health is a fundamental right and that health implies more than an absence of sickness. The Supreme Court in another case, *State of Punjab and Others v. Mohinder Singh Chamala*, (1997) 2 SCC 83, reiterated that the right to health is integral to the right to life and that the Government has a constitutional obligation to provide healthcare facilities.

⁴¹ Hans V Hogerzeil, *Essential medicines and human rights: what can they learn from each other?*, 84(3) BULLETIN OF THE WORLD HEALTH ORGANIZATION, 371-375 (2006), available at <http://www.who.int/bulletin/volumes/84/5/371.pdf>

⁴² See *Diego Serna Gómez v. Hospital Universitario del Valle*; *XXX v. Instituto de Seguros Sociales (ISS)*; *Asociación Bengalensis et al. vs. Ministerio de Salud y Acción Social*;

⁴³ *Mr. Jorge Odir Miranda Cortez v. la Directora del instituto Salvadoreño del Seguro Social*, Constitutional Court of El Salvador, File n°348-99 (4 April 2001).

living with HIV/AIDS.⁴⁴ Similarly, In 1995, in *XXX v. Instituto de Seguros Sociales (ISS)*⁴⁵, the Columbian Constitutional Court, in 1997, in *William García Álvarez v. Caja Costarricense de Seguro Social*⁴⁶ and in 2000, the Argentinean Supreme Court in *Asociación Benghalensis et al. vs. Ministerio de Salud y Acción Social*⁴⁷, the respective Supreme Courts ruled that ARVs must be provided through the Government's social security scheme and public hospitals. The court based its decision on the importance of the rights to life and health. Moreover, a Colombian appellate court recently held that the Ministry of Health violated the right to health by not having Abbott comply with the reference price for Kaletra. Resultantly, the Ministry imposed this requirement and the price of Kaletra was reduced by 70 percent.⁴⁸ Therefore, this policy of the government is violating the right to health and right to life of people living with HIV/AIDS by not bringing affordable patented drugs within the Price Control Policy of the government, which is being implemented with the main aim of providing access to affordable lifesaving drugs.

Further in the on-going litigation in the Supreme Court, In *All India Drug Action Network (AIDAN) v. Union of India*⁴⁹, the Indian Supreme Court opined during the hearing in July 2012 that the government must make every effort to provide access to lifesaving drugs to the citizens. Hence, the patent exemption for 5 years must be reconsidered and the patented drugs must be brought within the price control policy of the government before the actual notification of the Price drug Order happens.

Conclusion

It is imperative for the government to reconsider the exemption clause for patented drugs under the NPP, 2012 and allow for exemption of price control of patented drugs only for a very short duration, if at all, and establish a robust mechanism by which prices can be fixed and these drugs can be made accessible to save lives of several people living with HIV/AIDSs. The TRIPS Agreement itself contains flexible mechanisms for balancing access to treatment with the

⁴⁴ *Mr. Jorge Odir Miranda Cortez v. la Directora del instituto Salvadoreño del Seguro Social*, Constitutional Court of El Salvador, File n°348-99 (4 April 2001).

⁴⁵ Sentencia T-271/95, Exp. 62714, of Seventh Court of Revision of the Constitutional Court (June 23, 1995).

⁴⁶ *Mr. William Garcia Alvarez v. Caja Costarricense de Seguro Social*, Constitutional court of Costa Rica, File 5778-V-97, 23 September 1997.

⁴⁷ *Asociación Benghalensis et al. v. Ministerio de Salud y Acción Social*, Supreme Court of Justice of Argentina, Fallos 323:1339, 1 June 2000.

⁴⁸ Public Citizen, Access Victories and Global Kaletra Campaign, available at <http://www.citizen.org/Page.aspx?pid=5798>

⁴⁹ Writ Petition (civil) no(s). 423 of 2003.

preservation of intellectual property rights, such as compulsory licensing, parallel importation and patent opposition procedures. However, these instruments will inherently be limited in enhancing access to treatment because the successful implementation of each depends on several legal, administrative and political factors. The litigation with Novartis⁵⁰ and the unsuccessful patent oppositions⁵¹ are some examples of such limitations that further delay or deny access to affordable lifesaving drugs. . The Indian Government must reconsider this and deliberate on whether the best interests of the country is allowing for an inclusive price control policy or struggle with other restrictive or limiting provisions available.

⁵⁰ Novartis AG v. Union of India (2007) 4 MLJ 1153.

⁵¹ *Supra* note 32.