

*** IN THE HIGH COURT OF DELHI AT NEW DELHI**

Pronounced on: 10th July, 2015

+ W.P.(C) 7705/2013, CMs No.1744/2014 (*for directions*),
3126/2014 (*for addl. grounds*) & 10105/2014 (*u/O VI R-17 CPC*)

RECKITT BENCKISER (INDIA) LTD. Petitioner
Through: Mr. Kapil Sibal & Mr. Arvind
Nigam, Sr. Advs. with Mr. Jawahar Lal, Mr.
Amar Gupta and Mr. Raghav G., Advs.

Versus

UNION OF INDIA AND ANR Respondents
Through: Mr. Sanjay Jain, ASG with
Mr.Akshay Makhija, Mr. Kirtiman Singh,
Mr.Vidur Mohan, Mr.Gyanesh Bhardwaj,
Mr.Mansimran Singh, Ms. Noor Anand,
Mr.Waize Ali Noor, Ms. Mahima Bahl and
Mr.Rohitendra Deb, Advs. for UOI.

AND

+ W.P.(C) 2245/2014 & CM No.4708/2014 (*for stay*)

J.K. ANSELL LIMITED Petitioner
Through: Mr.Arvind P. Datar, Sr. Adv. with
Mr.Ramesh Singh and Mr. Debarshi Bhuyan,
Advs.

Versus

UNION OF INDIA AND ANR Respondents
Through: Mr. Sanjay Jain, ASG with
Mr.Akshay Makhija, Mr. Kirtiman Singh,
Mr.Vidur Mohan, Mr. Gyanesh Bhardwaj,
Mr.Mansimran Singh, Ms. Noor Anand,
Mr.Waize Ali Noor, Ms. Mahima Bahl and
Mr.Rohitendra Deb, Advs. for UOI.

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE MR. JUSTICE RAJIV SAHAI ENDLAW

J U D G M E N T

MS.G.ROHINI, CHIEF JUSTICE

1. Whether fixation of ceiling price under the provisions of the Drugs (Prices Control) Order, 2013 for male contraceptives (condoms) is in conformity with the powers vested under the Essential Commodities Act, 1955 read with the Drugs and Cosmetics Act, 1940 is the question that requires consideration in these two writ petitions.

2. The petitioners in both the writ petitions are the companies engaged in manufacturing/marketing of various health products including male contraceptives (Condoms). It is pleaded that the petitioner in W.P. No.7705/2013 manufactures and markets “condoms” under the brand name ‘Durex’ and ‘Kohinoor’, whereas the petitioner in W.P. No.2245/2014 manufactures and markets under the brand name ‘Kamasutra’.

3. Prior to coming into force of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) with effect from 15.05.2013, no ceiling price was fixed for sale of the condoms. However, by order dated 05.11.2013, the National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, in exercise of the powers conferred by Paragraph 4, 11 and 14 of the Drugs (Prices Control) Order, 2013, fixed the ceiling price of the condoms at Rs.6.56/- per unit (one condom).

4. The petitioners, who claim that the cost price of the branded condoms manufactured/marketed by them is much higher than the ceiling

price of Rs.6.56/- fixed by the National Pharmaceutical Pricing Authority (NPPA) are therefore aggrieved and accordingly these two writ petitions are filed with a prayer to declare the inclusion of male contraceptive (condoms) in Entry 18.3.3 of the First Schedule to DPCO, 2013 as ultra vires the provisions of the Essential Commodities Act, 1955 and/or contrary to the National Pharmaceutical Pricing Policy, 2012 apart from being violative of Articles 14 and 19(1)(g) of the Constitution of India. Consequently, the petitioners seek to set aside the order dated 05.11.2013 issued by the National Pharmaceutical Pricing Authority.

CM No.10105/2014 in W.P.(C)No.7705/2013

5. At the outset, it may be mentioned that this Court by order dated 13.12.2013 permitted the petitioner in W.P. (C) No. 7705/2013 to file a Review Application under Paragraph 31 of the DPCO, 2013 without prejudice to their rights and contentions. In terms thereof, the petitioner filed a Review Petition on 20.12.2013 seeking review of the impugned order dated 05.11.2013. Pursuant thereto, a fresh order dated 10.07.2014 came to be passed by the NPPA fixing the ceiling price of condoms at Rs.8.04 per unit. In the light of the said order, the petitioner in W.P. (C) No.7705/2013 filed CM No.10105/2014 under Order VI Rule 7 of CPC seeking amendment of the writ petition by adding a further prayer to quash the fresh order of NPPA dated 10.07.2014.

6. The said application was opposed by the respondents contending *inter alia* that the order dated 10.07.2014 by which the earlier order dated 05.11.2013 was superseded, has given rise to a fresh cause of action. It is also contended that against the order dated 10.07.2014, an alternative remedy of Review is available under Paragraph 31 of DPCO, 2013.

7. Both the objections raised by the respondents, according to us, are untenable since the order dated 10.07.2014 came to be passed during the pendency of the writ petition, particularly in terms of the liberty granted by this Court to the petitioner to file the Review under Paragraph 31 of the DPCO, 2013. That apart, the main contention in the writ petition is that the very inclusion of the 'condoms' within the purview of DPCO, 2013 is beyond the powers conferred under the Essential Commodities Act, 1955 apart from being contrary to the National Pharmaceutical Pricing Policy, 2012. Apparently, by virtue of the proposed amendment, the nature of the writ petition has not been altered in any manner whatsoever. Moreover, the proposed amendment is only on account of subsequent developments that took place during the pendency of the writ petition. Hence, we are of the view that the proposed amendment is essential for the purpose of determining the real questions in controversy between the parties and accordingly we allow the amendment as proposed in CM No.10105/2014.

8. It may also be added that the respondents have filed their reply to the amended writ petition and the same has been on record.

9. Before proceeding further, it is necessary for us to notice the legal position relating to the power of the Central Government to control the prices of certain essential commodities.

Essential Commodities Act, 1955

10. The Essential Commodities Act, 1955 (for short 'EC Act, 1955) has been enacted for the control of the production, supply and distribution of and trade and commerce in certain commodities. Section 3(1) of the said Act empowers the Central Government to provide by order for

regulating or prohibiting the production, supply and distribution of trade and commerce of any essential commodity, if it is of the opinion that it is necessary or expedient to do so for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices or for securing any essential commodity for the defence of India or the efficient conduct of military operations. Without prejudice to the generality of the powers conferred by sub-section (1), sub-section (2) of Section 3 further enables the Central Government to make orders providing for certain particular purposes including controlling the price at which the essential commodity may be bought or sold.

11. Section 3 of the EC Act, 1955 to the extent it is relevant for the purpose of the present case reads:

“3. Powers to control production, supply, distribution, etc., of essential commodities. – (1) If the Central Government is of opinion that it is necessary or expedient so to do for maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices [or for securing any essential commodity for the defence of India or the efficient conduct of military operations], it may, by order, provide for regulating or prohibiting the production, supply and distribution thereof and trade and commerce therein.

(2) Without prejudice to the generality of the powers conferred by sub-section (1), an order made thereunder may provide –

- (a) for regulating by licences, permits or otherwise the production or manufacture of any essential commodity;
- (b) for bringing under cultivation any waste or arable land, whether appurtenant to a building or not, for the growing thereon of food-crops generally or of specified food-crops and for otherwise maintaining or

- increasing the cultivation of food-crops generally, or of specified food-crops;
- (c) for controlling the price at which essential commodity may be bought or sold;
- (d) xxx xxx xxx
- (e) xxx xxx xxx.....”

12. The word ‘essential commodity’ was initially defined under Section 2(a) of the EC Act, 1955. However, by Amendment Act 54 of 2006, Clause (a) to Section 2 was omitted and Section 2A was inserted providing that the essential commodity means a commodity specified in the Schedule. By virtue of the said amendment, a Schedule was also added to the EC Act, 1955 enumerating the essential commodities. ‘Drugs’ is one of the commodities included in the Schedule to the EC Act, 1955 and it is explained that for the purposes of the said Schedule, ‘drugs’ has the meaning assigned to it in clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940.

Drugs and Cosmetics Act, 1940

13. The Drugs and Cosmetics Act, 1940 has been enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Under Section 3(b) of the Drugs and Cosmetics Act, 1940, the word ‘drug’ has been defined as under:

- “(b) ‘drug’ includes – (i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
- (ii) such substances (other than food) intended to affect the structure or any function of the human body

or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.”

14. It is relevant to note that the above-said definition was amended by Act, 68 of 1982 with effect from 01.02.1983. Before the said amendment, the definition of drug did not include the devices. It included only medicines for internal or external use of human beings or animals and all substances intended to be used for diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. However, by virtue of the Amendment Act 68 of 1982, clauses (iii) and (iv) have been inserted and devices as specified by notification have also been included in the definition of drug with effect from 01.02.1983.

15. In terms of clause (iv) of Section 3(b) of the Drugs and Cosmetics Act, 1940, the Central Government issued notifications dated 17.03.1989, 27.08.2002 and 06.10.2005 specifying altogether 14 devices intended for external or internal use in human beings as drugs. The devices so specified are (i) Disposable Hypodermic Syringes; (ii) Disposable Hypodermic Needles; (iii) Disposable Perfusion Sets; (iv) In Vitro Diagnostic Devices for HIV, HBsAg and HCV; (v) Cardiac Stents; (vi)

Drug Eluding Stents; (vii) Catheters; (viii) Intra Ocular Lenses; (ix) I.V. Cannulac; (x) Bone Cements; (xi) Heart Valves; (xii) Scalp Vein Set; (xiii) Orthopaedic Implants; & (xiv) Internal Prosthetic Replacements.

16. Section 12 of the Drugs and Cosmetics Act, 1940 empowers the Central Government to make Rules for the purpose of giving effect to the provisions of Chapter III of the said Act (providing for import of drugs) and such Rules inter alia may specify the drugs or classes of drugs for the import of which a license is required and prescribe the form and conditions of such licenses, the authority empowered to issue the same, the fees payable therefor and etc. Similarly, Section 33 of the Drugs and Cosmetics Act, 1940 empowers the Central Government to make Rules for the purposes of giving effect to the provisions of Chapter IV (which provides for manufactures, sale and distribution of drugs and cosmetics) and such Rules may inter alia prescribe the forms of licenses for the manufacture for sale or for distribution, for the sale and for the distribution of drugs or any specified drug or class of drugs, the form of application for such licenses, the conditions subject to which such licenses may be issued and the matters incidental thereto.

17. In exercise of the powers so conferred by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940, the Central Government made the Drugs and Cosmetics Rules, 1945. Part IV of the said Rules provides for licenses for import of drugs whereas Part VII provides for grant of or renewal of licenses for manufacture for sale of drugs other than homeopathic medicines. Schedule-A to the Rules prescribed the forms of applications for such grant or renewal of licenses. Part XII of the said Rules deals with the standards of drugs, substances, veterinary drug, patent of proprietary medicines, ophthalmic preparation and etc. Rule

125 contained in Part XII specifically prescribes the standards for substances intended to effect the structure or any function of human body-contraceptives. As per the said Rule, the standard for mechanical contraceptive shall be such as are laid down in Schedule-R to the Rules wherein various aspects including the description of the condoms, the material, the dimensions, the requirements for the average tensile strength elongation at break, procedure for testing, sampling of condoms, labelling and packing of the same have been dealt with in detail.

National List of Essential Medicines (NLEM)

18. For the first time in the year 1996, it was proposed by the Ministry of Health, Government of India to introduce the National Essential Drugs List for adoption in the country. A Committee of Experts constituted by the DGHS prepared the National Essential Drugs List taking note of the procurement of State Government, different Central Government Institutions and WHO Essential Drugs List. After subjecting the tentative list to scrutiny for therapeutic efficacy, availability and cost effectiveness and after consultation with experts in different disciplines of medicine, the draft list was finally adopted in the Meeting of Experts held on 04.04.1996. The said List is intended to be a dynamic document subject to change with addition and/or deletions, as medical knowledge advances and new drugs become available at remunerative pricing. Generic names have been used in the list for scientific clarity and the need of drugs included therein at various levels of medical care has been indicated by letters – P (Primary Health Care), S (Secondary Health Care), T (Tertiary Health Care) and U (Universal).

19. The purport and intentment of National Essential Drugs List was explained in the Preface to the National Essential Drugs List, 1996 as under:

“The National List is not intended as an imposition on the rights of State Governments, Government institutions, or private health care providers. It is meant to be used as a guideline to the concept of rational therapeutics and as an indicator of availability in the country. While the drugs selected are considered adequate to treat diseases common to most parts of the country, it is appreciated that specific regional requirements for drugs to treat diseases of local importance may not be available in the National List, and in such instances it will be appropriate for the State Health Administration (adopting the National List) to include drugs as may be considered adequate to treat these diseases.

The National Essential Drugs List implies that the drugs included in it are adequate to meet the common contemporary health needs of the general population of the country and general obligation of the health administrators to ensure abundant availability of such drugs in the country. The drugs included in this list are generally safe and effective, and are approved by the Drugs Controller General, India, and are currently available at affordable prices to the general public.”

20. The review of National Essential Drugs List 1996 was taken up in the year 2003. Since the word ‘drug’ is globally being considered to have a different (narcotic) connotation, the Expert Core Committee thought it fit to replace the word ‘drug’ with the word ‘medicine’, a term which is more widely used to describe therapeutic pharmaceutical substance. Accordingly, the said List was titled ‘National List of Essential Medicines, 2003’. The said List included the following three components, viz., definition, description of the selection criteria and description of the purpose for which the said List was developed.

Definition: Essential medicines are those that satisfy the priority health care needs of the population.

Selection criteria: Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

Purpose: Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality. Evidently, the word “Essential” does not purport to convey that number of other drugs available in the market are non-essential.

21. It is also pertinent to note that a new Section on medicines for HIV-AIDS was included in NLEM, 2003 and ‘contraceptives’ were included in Section 18 titled ‘Hormones, Other Endocrine Medicines and Contraceptives’. Condoms were mentioned in Entry 18.3.3 of NLEM-2003 under the caption “Barrier Methods” placing the same in the Category ‘U’ (Universal).

22. NLEM 2003 was revised again in the year 2010 and a fresh list being NLEM 2011 was issued based on the two important National Reference Documents, i.e., Indian Pharmacopeia 2010 and National Formulary of India, 4th Edition, 2010. Condoms have been included in NLEM 2011 also at Entry 18.3.3 under the caption “Barrier Methods” and describing the category at P, S, T. The salient features of NLEM 2011, states inter alia:-

“The medicines have been categorized according to therapeutic area. Therefore it is possible that a medicine with more than one indication appears in more than one category.

The issue of mentioning the strength of the medicine dose was deliberated. The committee took the considered view that the strength should be mentioned in the NLEM.

For essentiality of requirement the medicines have been categorized as follows:

- P, S and T denote essentiality at Primary, Secondary and Tertiary levels respectively while P, S, T (U in NLEM 2003) indicates essentiality at all the levels.

A total of 348 medicines (excluding repetitions) are present in NLEM 2011. In the NLEM 2011, 181 medicines fall under the category of P, S and T, 106 medicines fall under the category of S, T while 61 medicines are categorized as T only. In comparison to NLEM 2003, number of medicines deleted is 47 and 43 medicines have been added.”

National Pharmaceuticals Pricing Policy

23. Price control over drugs was first introduced in the country in the aftermath of the Chinese aggression with the promulgation of the Drugs (Display of Prices) Order, 1962 and the Drugs (Control of Prices) Order, 1963. These were promulgated under the Defence of India Act. With these orders, the prices of drugs were frozen with effect from 01.04.1963. Thereafter, a series of price control regimes were notified through various orders in the country from time to time based on different principles, in which the span of control of prices as well as the nature of control of prices varied from order to order as per the disposition of the respective Drug Policies. These were 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. Thereafter, 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. All these Policies were broadly based on the principle of effecting control over prices of essential drugs and later bulk drugs, as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth cost effective production, innovation and strengthening of capacity. The Drug Policy of 1994 was introduced in the context of the liberalization of economy and the abolishment of industrial licensing as well as allowing of foreign investment in the country, including in the drug industry. The principle adopted for price control in the Drug Policy, 1994 represented a radical departure from the earlier policies inasmuch as the said policy envisaged control over prices of drugs on the basis of economic criteria as represented in the market shares of different company in the context of total market sales turnover of various drugs. As per the criteria of 1994 Drug Policy, a list of 74 bulk drugs was identified and the said drugs as well as the formulations based on the said drugs were brought under the price control regime. The Drug Policy, 1994 was implemented through the Drugs (Prices Control) Order, 1995.

24. In the year 2002, a new Drug Policy was introduced increasing the turnover limit of the manufacturer for price control from Rs.4 crores to Rs.25 crores. The validity of Drug Policy, 2002 was challenged before the High Court of Karnataka and the operation of the same was stayed. The Union of India carried the matter to the Supreme Court and pending the proceedings before the Supreme Court the operation of the order of Karnataka High Court, to the extent it directed that the Drug Policy 2002 shall not be implemented, was suspended. There was also a direction to the Union of India to consider and formulate appropriate criteria for

ensuring essential and life saving drugs not to fall out of the price control. Subsequently, it was represented by the Union of India that it does not propose to implement the Drug Policy, 2002. Accordingly, the SLP was disposed of by the Supreme Court on 31.03.2011.

25. Thereafter, the Union of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals published a fresh policy called the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012) vide notification dated 07.12.2012 in continuation of the 1994 Policy.

26. The principles for pricing the essential drugs as laid down in the National List of Essential Medicines, 2011 have been promulgated in the NPPP, 2012. It is also specifically laid down in the NPPP, 2012 that the objective of the policy is to put in place a regulatory framework for pricing of drugs so as to ensure availability of the essential medicines at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry. One of the key principles for regulation of prices in NPPP, 2012 has been mentioned as ‘essentiality of drugs’, which is different from the academic criteria/market share principle adopted in the Drug Policy of 1994. The reasons for adoption of the principle of ‘essentiality’ as a key criteria have been mentioned in NPPP 2012 as under:

- “(i) The “Essentiality” criteria for drugs under the NPPP-2012 is to be met by considering the List of medicines specified in the National List of Essential Medicines as revised from time to time and most recently declared by the Ministry of Health and Family Welfare, Government of India.
- (ii) The NLEM has been prepared by an Expert Core Committee constituted by the Director General of Health Services (DGHS) out of the WHO model list of essential

medicines, Essential Drugs Lists of various States, medicines used in various National Health Programmes and Emergency Care Drugs.

- (iii) The NLEM contains such medicines that satisfy the priority health needs of the country's population.
- (iv) The NLEM medicines are required to be made available within the context of a functioning health system at all times in adequate quantities in the appropriate dosage forms to serve large public masses.
- (v) The Hon'ble Supreme Court in its Order dated 10.03.2003 in SLP No.3668/2003 (Union of India Vs. K.S. Gopinath and Others) has also emphasized the need to ".....consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control..."
- (vi) The current principle of economic/market share criteria needs to be changed now, given the fact that out of the 348 medicines listed in the NLEM-2011, only 34 drugs are included amongst the 74 drugs listed in the First Schedule of "The Drugs (Prices Control) Order, 1995 (DPCO 1995)."

27. It is also mentioned in NPPP 2012 that the regulation of prices of drugs would be on the basis of regulating the prices of formulations only, which is different from the earlier principle of regulating the prices of specified bulk drugs and their formulations adopted in the Drug Policy 1994.

28. For implementation of NPPP 2012, it was proposed to notify a new Drugs (Prices Control) Order as soon as possible and that the National Pharmaceuticals Pricing Authority (NPPA) will be the implementation authority.

The Drugs (Prices Control) Order, 2013

29. Section 3(1) of the EC Act, 1955 empowers the Central Government to control production, supply, distribution etc. of essential commodities by making orders for the said purpose and in particular Section 3(2)(c) enables making an order providing for controlling the price at which any essential commodity may be bought or sold. In exercise of the powers so conferred by Section 3 of the EC Act, 1955, the Central Government issued the Drugs Prices Control Orders from time to time regulating the prices of drugs following the Drug Policies declared by the Ministry of Chemical and Fertilizers, Department of Pharmaceuticals.

30. In tune with NPPP 2012 which seeks to promulgate the principles for pricing of essential drugs as laid down in the NLEM 2011, the Central Government in exercise of the powers conferred by Section 3 of the EC Act, and in supersession of the Drugs (Prices Control) Order, 1995 made the Drugs (Prices Control) Order 2013 vide S.O.1221(E) dated 15.05.2013 to regulate the prices of drugs and providing *inter alia* the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by the Government, penalties for contravention of provisions, etc. All essential medicines enumerated in NLEM, 2011 are included in the First Schedule to DPCO, 2013 and they are declared as “scheduled formulations” under Para 2(1)(zb) of DPCO, 2013.

31. ‘Condoms’ were included in the NELM, 2011 at Item-18.3.3 describing the same as medicines under the category of P, S, T, i.e., Primary, Secondary and Tertiary levels respectively and the same has

been incorporated in the First Schedule to DPCO, 2013 at Entry 18.3.3. It may be mentioned that Section 18 of the First Schedule deals with ‘Hormones, other endocrine medicines and contraceptives’ and ‘condoms’ have been included at Entry 18.3.3 under the caption ‘Barrier Methods’. Entry 18.3.3 of the First Schedule to DPCO 2013 may be reproduced hereunder for ready reference:

18.3.3: Barrier Methods			
Medicines	Category	Route of Administration/ Dosage Form	Strengths
Condoms	P,S,T		

32. The expressions ‘drug’ and ‘medicine’ have not been defined under DPCO, 2013. However, Para 2(2) of DPCO, 2013 provides that all other words and expressions used in DPCO, 2013 and not defined but defined in Essential Commodities Act, 1955 or the Drugs & Cosmetics Act, 1940 shall have the meanings respectively assigned to them in the said Acts. As mentioned in Para 13 (supra) the word ‘drug’ has been defined under Section 3(b) of the Drugs & Cosmetics Act, 1940. Therefore, in terms of Para 2(2) of DPCO, 2013, the word ‘drug’ shall have the meaning assigned to it in Section 3(b) of the Drugs & Cosmetics Act, 1940.

Impugned orders fixing the Ceiling Price for Condoms

33. ‘Condoms’ having been figured at Entry 18.3.3 of the First Schedule, have been expressly brought under the scheme of DPCO, 2013. Pursuant thereto, in exercise of the powers conferred by Paras 4, 11 and 14, the NPPA fixed the ceiling price of the ‘condoms’ initially at Rs.6.56

by Order dated 05.11.2013 and thereafter at Rs.8.04 by Order dated 10.07.2014.

34. As mentioned above, prior to DPCO, 2013 ‘condoms’ were not brought within the purview of any of the Drugs Price Control Orders made under Section 3 of the EC Act, 1955 and consequently, there was no fixation of the ceiling price. However, by virtue of the impugned orders issued under DPCO, 2013, the petitioners are compelled to market the branded condoms manufactured by them at the ceiling price fixed thereunder which is stated to be far less than the cost price. Hence these two writ petitions.

Case of the petitioners

35. The specific case of the petitioners is that condoms which act only as physical barriers and thus protect from Sexually Transmitted Infections and unwanted pregnancy are ‘devices’ and that by virtue of the notification dated 20.04.2010 issued in terms of Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940, by the Ministry of Health and Family Welfare, Government of India ‘condoms’ have been declared as “notified medical devices” and are brought within the definition of ‘drug’ under the D&C Act, 1940. In the light of the same, it is pleaded in the writ petitions that though there is no controversy with regard to the position that ‘condom’ is a drug within the meaning of Drugs and Cosmetics Act, 1940, the challenge in the writ petitions is to the inclusion of condoms within the purview of DPCO 2013 for the following among other grounds:

35.1 DPCO, 2013 to the extent of including ‘condoms’ in Entry 18.3.3 of First Schedule is *ultra vires* Section 3 of the EC Act,

1955 apart from being contrary to the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) enunciated by the Central Government.

- 35.2 Since NPPP 2012 intends to regulate the price of ‘formulations’ only and that as per para 2(1)(i) of DPCO 2013 ‘formulation’ has been defined as a medicine, it is clear DPCO 2013 is intended to regulate the price of medicines only and not medical devices like ‘condoms’. It is further contended that ‘condom’ which acts only as a physical barrier and does not have any ‘active pharmaceutical ingredient’ (API) as defined in Para 2(1)(b) of DPCO 2013 or any other medicinal substance is only a **medical device** but under no circumstances can be considered as a ‘medicine’. Therefore, ‘condoms’ are not ‘formulations’ and consequently their prices cannot be controlled by the DPCO 2013.
- 35.3 Without prejudice to the contention that Condom is not a **formulation** as defined in Para 2 (1) (i) of the DPCO, 2013, it is further contended that it is not a scheduled formulation but only a **non-scheduled formulation** as defined in Para 2 (1) (v) and therefore Para 4 providing for fixation of ceiling price is not applicable at all.
- 35.4 The price of condoms, which are non-scheduled formulations, can at the most be monitored under Paragraph 20 of DPCO, 2013 but no ceiling price can be fixed under Para 4 of DPCO, 2013 since Para 4 is expressly made applicable only to the scheduled formulations of specified strengths and dosages.

- 35.5 Since the Government itself distributes 55% of the condoms free or at highly subsidized prices in the interest of the general public, there is no need for issuing a Control Order for fixation of ceiling price of condoms and thus DPCO 2013, to the extent of inclusion of condoms in the First Schedule, is *ultra vires* the EC Act, 1955.
- 35.6 Even assuming that condoms can be brought within the purview of DPCO, 2013, the respondents failed to notice that the branded condoms manufactured/marketed by the petitioners form a distinct and different class from the basic/utility condoms and had erred in fixing a common ceiling price for all classes of condoms. The said action of the NPPA is violative of Article 14 of the Constitution of India.
- 35.7 The pricing mechanism adopted while determining the ceiling price under the impugned Orders dated 05.11.2013 and 10.07.2014 is arbitrary, irrational and does not sub-serve the intent and purpose of the DPCO, 2013 since NPPA failed to collect the market share and price in respect of all brands having a market share of 1% as required under Para 4 of the DPCO, 2013. The NPPA also failed to take into consideration 'Wholesale Price Index' (WPI) for the year 2014 though the same was issued on 10.07.2014.
- 35.8 The average sale price to retailers of the Durex brand condoms is Rs.41.67/- whereas its ceiling price was fixed at Rs.6.56/-. Thus, the petitioner incurs a huge loss. Since the pricing mechanism prescribed in DPCO 2013 does not take into consideration the variation in the raw material used, additional

ingredients, processes, additional features, applicable taxes, absence of generic version, etc., the ceiling price fixed for the brands of condoms marketed by the petitioners, which is illogical and irrational, has resulted in an absurd situation.

35.9 Premium condoms manufactured/marketed by the petitioners cannot be treated at par with basic condoms because of the method of manufacture, the technology involved, the ingredients used and research and development preceding the manufacture of such products. The NPPA failed to take into consideration that basic condoms are distributed free or at highly subsidised prices by the Governmental agencies whereas the condoms sold in market by the petitioners are of high end sophisticated version. Hence, the fixation of common ceiling price is violative of Article 14 of the Constitution of India. Though the petitioners in their Review Petition have pointed out the said distinction between the two categories, the NPPA failed to appreciate the same.

35.10 Since a large extent of condoms marketed by the petitioner which have a shelf life of three years have already been in the market with the previous MRP, it is practically impossible for the petitioner to withdraw the same from the market so as to implement the ceiling price fixed under the impugned orders within 45 days.

35.11 In the light of the ceiling price fixed under the impugned orders, the petitioners would have no option but to discontinue the sale of the branded condoms or sell them at huge loss. Therefore,

the action of the respondents is violative of Article 19 (1)(g) of the Constitution of India.

The case of the respondents

36. In the counter filed in response to the writ petitions, the respondent No.2 – NPPA contended that:

36.1 The DPCO, 1979 and DPCO, 1987 were issued following the declaration of Drug Policy, 1978 and Drug Policy, 1986 respectively which were broadly based on the principle of exercising control over prices of essential drugs and later bulk drugs as well as availability of drugs while at the same time attending to the requirements of the indigenous industry for growth, cost effective production, innovation and strengthening of capacity. Subsequently, the Drug Policy of 1994 was introduced in the context of the liberalization of economy and the abolition of industrial licensing as well as allowing of foreign investment in the country. The DPCO, 1995 was issued implementing the Drug Policy of 1994. In the Drug Policy of 1994, a list of 74 bulk drugs were identified and the said drugs as well as formulations based on the said drugs were brought under the price control regime. The paramount consideration was that the essential/life saving drugs that were included should be made available to the consumers at fair and reasonable prices. In the year 2000, further liberalization in the economy was effected in the light of which, Foreign Direct

Investment (FDI) in the pharmaceutical sector was brought in the automatic route and the limit of FDI was raised up to 100%. Following this, a new Drug Policy was introduced in the year 2002, however the same was not implemented. In the meanwhile, the Ministry of Health and Family Welfare, Government of India, in accordance with guidelines issued by the Supreme Court in *Union of India vs. K.S. Gopinath* (decided on 31.03.2011), revised the National List of Essential Medicines and accordingly, NLEM, 2011 which contains 348 formulations was published by Notification dated 08.06.2011.

- 36.2 Subsequently, the Central Government enunciated the National Pharmaceuticals Pricing Policy, 2012 (for short 'NPPP, 2012') which came into effect on 07.12.2012. The said policy is in continuation of the Drug Policy, 1994 and aimed at promulgating the principles for pricing of essential drugs as laid down in NLEM, 2011. One of the objectives of NPPP-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices.
- 36.3 Key principles for regulation of prices in NPPP, 2012 include 'essentiality of drugs', which criteria is to be met by considering the list of medicines specified in the NLEM, 2011.
- 36.4 Accordingly, the new Drug Prices Control Order i.e. DPCO, 2013 was notified on 15.05.2013 covering a large number of essential/life saving drugs in larger public interest. Thus, all formulations included in NLEM, 2011 have been included in

the First Schedule to DPCO, 2013 and they are declared as “scheduled formulations” under Para 2(1)(zb) of DPCO, 2013.

36.5 So far as the inclusion of condoms under DPCO, 2013 is concerned, it is explained that the condoms have been included in DPCO, 2013 for securing their equitable distribution and availability at fair prices.

36.6 Even assuming but not admitting that the assertion made by the petitioner that 55% of the condoms used in India are distributed free or at highly subsidized rate is correct, there is still a huge gap of 45% of the demand which has to be met at fair prices considering the fact that India is among the countries with highest number of HIV/AIDS affected population. This fact can be confirmed by the UNAIDS Report on the Global AIDS Epidemic, 2013. The importance of condoms has been highlighted in the “PATH, the World Health Organization, and the United Nations Population Fund, Essential Medicines for Reproductive Health; Guiding Principles for Their Inclusion on National Medicines Lists” as follows:

(a) Reproductive health is not simply the absence of disease. It covers a range of conditions that include healthy sexual development, reproductive and fertility regulation, prevention of STIs and HIV/AIDS, and safe motherhood. Reproductive health also means that people are able to have a satisfying and safe sex life and that they have the capability and freedom to make informed choices about reproduction. The International Conference on Population and Development, Programme of Action states that it is

the right of men and women to be “informed and to have access to safe, effective, affordable, and acceptable methods of family planning of their choice, as well as other methods of family planning of their choice, as well as other methods of their choice for regulation of fertility, which are not against the law.....”

- (b) Reproductive health problems, such as early and unwanted childbearing, HIV infection, STIs, and pregnancy-related illness and death, account for a significant part of the burden of disease amongst adolescents and adults in developing countries.
- (c) In many developing countries, the risk of death for children under age five is doubled or tripled after their mothers die. WHO estimates that up to 1,00,000 maternal deaths could be avoided each year if women who did not want children used effective contraception. Nevertheless, in many developing countries, the need for family planning and reproductive health medicines and services persists. At least 200 million women of reproductive age worldwide would like to prevent or space their births but are not using effective contraception. It also has been estimated that expanding contraceptive services to meet the needs of couples who wish to avoid pregnancy but currently are not using contraception could prevent as many as 850,000 deaths per year amongst children under age five.

- (d) Furthermore, every year there are an estimated 120 million unwanted pregnancies, resulting in 46 million abortions, 20 percent of which are unsafe and lead to severe morbidity and mortality for women. For example, unsafe abortion accounts for 13 percent of maternal deaths.
- (e) The spread of HIV has a tremendous impact on both national economies and household income. Households affected by HIV infection and AIDS are more likely to be poor than those not affected. The care and treatment of individuals with HIV, as well as the lost income when complications of AIDS make it impossible for the infected individual to work, can shrink household income by 66 to 80 percent.
- (f) If essential reproductive health medicines are available, affordable, of good quality, and properly used, they can significantly reduce reproductive health problems. One way to reverse this trend is to mandate that reproductive health medicines be included on EMLs and that EMLs be used to guide public expenditures and policies related to access.
- (g) There is compelling evidence that the male latex condom, when used consistently and correctly, protects against unwanted pregnancy and the transmission of HIV, the virus that causes AIDS. Condoms also protect against several other STIs, although the level of protection has not been quantified for each specific STI.

- 36.7 It is also contended that the price control on essential commodities being a policy decision of the Government warrants no interference in exercise of jurisdiction under Article 226.
- 36.8 It is also contended that in a number of countries, i.e. Bangladesh, Bhutan, Ghana, Nepal, Kenya, Myanmar, Pakistan, Sri Lanka, among others, condoms have been included in the Essential Medicines Lists. The WHO Model List of Essential Medicines, 18th Edition, 2013 also mentions condom as an 'essential medicine'.
- 36.9 Condoms have been included from the year 2003 onwards in the NLEMs notified from time to time and now the same have been incorporated in DPCO, 2013 as per NPPP 2012.
- 36.10 The allegation of the petitioners that the methodology adopted for arriving at the ceiling price of the condoms was erroneous has been denied and it is stated that if the generic versions of the drugs/medicine/formulation are not available, then the price of the branded drugs/medicine/formulations shall be taken into consideration. The non-availability of generic versions of a drugs/medicine/formulation will have no impact in determination of the ceiling price considering the particular case as stated above and will not lead to an unworkable situation.
- 36.11 The allegation that the price has been fixed by taking into consideration the retail prices of only three manufacturers whereas there are 11 manufacturers having market share of more than 1% has also been denied and it is stated that letters

were issued to seven companies and out of the same, only three companies furnished the data and on the basis of the said data the price was initially fixed at Rs.6.56 per piece.

Submissions of the learned counsel for the petitioners

37. We have heard Shri Kapil Sibal, Shri Arvind Nigam and Shri Arvind Datar, the learned Senior Counsels appearing for the petitioners at length, and their submissions are as follows.

37.1 ‘Condoms’ are not ‘drugs’ as defined under the Drugs and Cosmetics Act, 1940 and consequently the same cannot be considered as ‘Essential Commodity’ under Section 2A of EC Act read with the Schedule thereto. Therefore, inclusion of condoms in the First Schedule to DPCO, 2013 is *ultra vires* the EC Act.

(a) Elaborating the above contention, it is submitted by Shri Kapil Sibal, the learned Senior Counsel that the expression ‘drug’ as defined under Section 3 (b) of Drugs and Cosmetics Act, 1940 covers four categories namely (i) all medicines used for internal and external use of human beings and animals and all substances intended to be used for diagnosis, treatment, mitigation or prevention of any disease or disorder, (ii) such substances which are intended to effect the structure or function of the human body or intended to be used for destruction of vermin or insects as may be notified by the Central Government in the Official Gazette (iii) all substances which are intended to be used as components of a drug like gelatin

capsules, and (iv) such devices which are intended for internal or external use for diagnosis, treatment, mitigation or prevention of disease or disorder as may be notified by the Central Government in the Official Gazette and that condoms do not fall in any one of the said categories.

- (b) It is sought to be contended that 'condom' is not a medicine for internal or external use to treat or prevent disease in human beings, and that it does not have any active pharmaceutical ingredient as defined in Para-2(1)(b) of DPCO, 2013 or any other medicinal properties. On the other hand, 'condoms' act only as physical barrier and protect from Sexually Transmitted Infections (STI) and unwanted pregnancy. Pointing out that even in the First Schedule to DPCO, 2013 at Entry 18.3.3 'condoms' have been mentioned under the caption 'barrier method', it is submitted by the learned Senior Counsel that under no circumstances 'condom' can be treated as a 'medicine' so as to be brought under clause (i) of Section 3(b).
- (c) So far as the expression 'substance' used under Section 3(b)(i) is concerned, the learned Senior Counsel submitted that it only refers to a 'medical substance' which is used for diagnosis, treatment, mitigation or prevention of a disease. According to the learned Senior Counsel, 'substance' in the context of Para-3(b)(i) would only mean a component or active ingredient with medicinal or pharmacological properties and not the end product like 'condom'. Contending that 'condoms' sold in India do

not have any active pharmaceutical ingredient like ‘spermicide’, it is submitted by the learned Senior Counsel that ‘condoms’ are not even ‘substances’ within the meaning of Section 3(b)(i) of Drugs and Cosmetics Act, 1940.

- (d) With regard to the expression ‘substances’ used in Para-3(b)(ii) of the Drugs and Cosmetics Act, 1940, the learned Senior Counsel submitted that the same is not attracted at all not only because condoms do not fall within the meaning of the substances used in the context of the said clause but also because a notification is required to be issued by the Central Government in respect of the substances referred thereto.
- (e) According to the learned senior counsel, Section 3(b)(iii) is also not attracted since ‘condom’ is only an end product.
- (f) Coming to Section 3(b)(iv), the pleading in the writ petitions was that condom, which is a device, has been specified as a ‘drug’ by notification dated 20.04.2010 issued by the Ministry of Health & Family Welfare, Government of India. However, placing reliance upon a subsequent Office Order dated 09.07.2014, it is contended by the learned Senior Counsel that the earlier Notification dated 20.04.2010 stood modified and ‘condom’ can no longer be considered as a notified device. The learned Senior Counsel would also contend that by virtue of the order dated 09.07.2014, ‘condoms’ cannot even be

regulated under the Drugs and Cosmetics Act, 1940 with effect from 09.07.2014 and therefore renewal of licenses obtained under the Drugs and Cosmetics Act, 1940 is also not necessary.

- (g) For the aforesaid reasons, it is contended that condoms not being essential commodities, inclusion of condoms within DPCO, 2013 is *ultra vires* the EC Act, 1955.

37.2 Without prejudice to the above submission, it is contended that ‘condoms’ cannot be considered as ‘drugs’ even in terms of Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 since by the date of the amendment to the EC Act by Act 30 of 1974 inserting drugs within the definition of ‘essential commodity’ under Section 2(a)(iv a) read with the Explanation thereto, the definition of ‘drug’ under Section 3 (b) of the Drugs and Cosmetics Act, 1940 did not include ‘devices’.

- (a) It is sought to be explained by the learned Senior Counsels that by 29.08.1974 with effect from which ‘drugs’ were included within the definition of ‘essential commodities’ by amendment to the E.C. Act, 1955 by Act 30 of 1974 adopting the meaning assigned to “drugs” in Section 3 (b) of Drugs and Cosmetics Act, 1940, the definition of ‘drug’ under Section 3 of Drugs and Cosmetics Act, 1940 did not contain clause (iv) providing for ‘notified devices’ and that the same was incorporated only at a later date with effect from 1.2.1983 by Act 68 of 1982. Therefore, according to the learned Senior Counsel, ‘devices’,

including condoms, cannot be considered as ‘drugs’ within the meaning of the EC Act, 1955.

- (b) In support of the said submission, the learned Senior Counsel relied upon *Mahindra & Mahindra v. Union of India*, (1979) 2 SCC 529 wherein it was held that once the provision of a statute has been incorporated by reference, the provision becomes an integral part of the statute in which it is transposed and therefore there is no need to refer to the statute from which the incorporation is made and any subsequent amendment made in it has no effect in the incorporating statute.

37.3 Even assuming that ‘condom’ can be considered as a ‘drug’ as defined under the Drugs and Cosmetics Act, 1940, it is contended that issuance of the Control Order under Section 3 (1) of the EC Act is not warranted since a Control Order under Section 3 (1) can be issued only for the purpose of maintaining or increasing supply of any essential commodity or for securing their equitable distribution and availability at fair prices. According to the learned Senior Counsel, the said essential precondition has not been satisfied so far as ‘condoms’ is concerned and therefore no Control Order can be issued in exercise of the power conferred by Section 3 (1) of the EC Act, 1955.

- (a) It is contended by the learned Senior Counsel that the need to make the condoms available at reasonable prices has already been addressed since the Government itself distributes 55% of the condoms free or at highly

subsidised prices. It is also contended that 93.97% of condoms are available at below ceiling price even before the issuance of DPCO, 2013. Therefore, according to the petitioners, the essential pre-condition for issuing a Control Order providing for controlling the price of the condoms in exercise of the powers under Section 3 of the Essential Commodities Act, 1955 is not satisfied at all.

37.4 Since the scope of DPCO, 2013 is restricted to ‘formulations’ as defined in Para 2 (1) (i) which means a medicine processed out of or containing in one or more drugs, ‘condom’ which is only a barrier device but can under no circumstances be considered as a medicine does not fall within the definition of ‘formulation’ and consequently inclusion of the condoms in the First Schedule to DPCO, 2013 is contrary to NPPP-2012.

(a) It is contended that DPCO, 2013 does not include all ‘drugs’ as defined under Section 3 (b) of Drugs and Cosmetics Act, 1940, within the scope of price control/regulation but the scope is restricted only to ‘formulations’ as defined in Para-2 (1) (i) of DPCO, 2013. It is also submitted that since ‘condom’ is not a medicine, it is not a formulation. Referring to Para-3.2 (iv) of NPPP-2012, the learned Senior Counsel submitted that as per the policy decision, the proposed price control mechanism is only in respect of formulations to ensure more specific pricing control of the required medicine in the interest of the consumer from the point of view of the actual prescription by the Doctor. The learned Senior

Counsel would submit that ‘condom’ not being a prescriptive drug, inclusion of the same in the First Schedule to DPCO, 2013 is contrary to the public policy of the Union of India.

- (b) It is sought to be explained by the learned Senior Counsel that ‘condoms’ are included in NLEM-2011 only with an intention to address the priority health care needs of majority of population but not for the purpose of price control. It is also submitted that since NLEM has no legislative sanctity, it is not mandatory to incorporate in DPCO, 2013 all the medicines that are listed in NLEM-2011. In this regard, the learned Senior Counsel relied upon *Secretary, Ministry of Chemicals & Fertilizers, Government of India v. Cipla Limited And Ors.*, (2003) 7 SCC 1.

37.5 Since the dosage and strength of the condoms have not been specified in Entry 18.3.3 of the First Schedule to DPCO, 2013, ‘condom’ is a ‘non-scheduled formulation’ as defined under Para 2(1) (v) of DPCO, 2013 and therefore no ceiling price can be fixed for condoms under the provisions of DPCO, 2013.

- (a) Referring to the definitions of ‘formulation’, ‘scheduled formulation’ and ‘non-scheduled formulation’ under Para-2 (1) of DPCO, 2013, it is contended by the learned Senior Counsel that ‘condoms’ for which dosage and strengths have not been prescribed in the First Schedule to DPCO, 2013, fall within the definition of ‘non-scheduled formulation’ under Para-2 (1) (v). Consequently,

Paragraphs-4, 5, 6, 13 & 14 which exclusively deal with scheduled formulation, are not applicable at all to 'condoms' and therefore the question of fixation of ceiling price for condoms does not arise at all.

37.6 The methodology prescribed in Para-4 of DPCO, 2013 for calculation of ceiling price is unworkable in the case of condoms and does not apply at all for fixation of ceiling price for condoms since condoms do not have dosage and strength.

(a) Having regard to the admitted fact that the strength and dosages are not prescribed in respect of condoms in the First Schedule to DPCO, 2013, particularly in view of the fact that in case of condoms which are medical devices the raw material, process, features and etc., would differ, the learned Senior Counsel would contend that the methodology prescribed in Paragraph-4 is unworkable. It is also contended that while fixing the ceiling price by the impugned orders none of the mandatory provisions of DPCO, 2013 were followed. It is further contended that in respect of medical devices like condoms, no collated data was available with IMS Health while issuing the impugned price fixation orders.

37.7 Since the branded condoms manufactured and marketed by the petitioners are pleasure/poly isoprene condoms, i.e. an advanced version of pleasure condoms and thus form a distinct and separate class from the basic/utility condoms, fixation of a common ceiling for both the categories is violative of Article 14 of the Constitution of India.

- (a) The learned senior counsel further submitted that even assuming without conceding that the inclusion of the condoms within the purview of DPCO, 2013 is permissible under law, the action of the DPPA in fixing a common ceiling price for both the basic/utility condoms and the pleasure condoms manufactured/ marketed by the petitioners ignoring the fact that they belong to two distinct and separate classes is violative of Article 14 of the Constitution of India.
- (b) In this regard, the learned senior counsel has drawn the attention of this court to the specific pleading in the writ petition that basic/utility condoms are primarily used to act as a physical barrier against unintended pregnancy and sexually transmitted infections whereas pleasure condoms are targetted at increasing the pleasure element for the consumers during intercourse by providing features like ribbed, dotted, lubricated, scented, etc. and thus pleasure condoms constitute a distinct class as opposed to basic condoms from the point of view of not only the intended consumers but also the method of manufacture, the technology involved, the ingredients used and also the specific purpose of the use.

37.8 Placing reliance upon *Clariant International Vs. SEBI, (2004) 8 SCC 524* wherein it is held that when any criterion is fixed by a statute or by a policy, an attempt should be made by the authority making the delegated legislation to follow the policy formulation broadly and substantially and in conformity

therewith, the learned senior counsel further contended that DPCO, 2013 which is not in conformity with the parent statute cannot be sustained to the extent of inclusion of the condoms in the First Schedule treating the same as a 'scheduled formulation'. The learned counsel has also relied upon *Union of India v. Cynamide India Ltd.*, (1987) 2 SCC 720 to substantiate his contention that the price fixed by the Government can also be questioned on any ground on which a subordinate legislation may be questioned.

Submissions of the learned counsel for the respondents

38. On the other hand, Shri Sanjay Jain, the learned ASG appearing on behalf of the respondents contended that Condoms are 'drugs' within the meaning of Section 3(b) of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder and that all the drugs are essential commodities in terms of Section 2-A of EC Act, 1955 read with the Schedule thereto.

38.1 It is sought to be explained by the learned ASG that in exercise of the powers conferred by the Drugs and Cosmetics Act, 1940, Rules called Drugs and Cosmetics Rules are made laying down the conditions for obtaining the licenses and renewals for the manufacture of drugs and that Rule 125 (set out in Part XII) read with Schedule-R of the said Rules specifies the standards of drugs as well as the standards to be observed in the manufacture of contraceptive. It is submitted by the learned ASG that the petitioners being the licensees for manufacture/marketing of condoms granted under the Drugs and Cosmetics Act and the Rules made thereunder cannot now

contend that the very product in respect of which they have sought and obtained permission from time to time is not a drug.

- 38.2 Referring to *Chimmanlal Jagjivandas Seth vs. State of Mahara*, **AIR 1963 SC 665** wherein gauze was held to be a ‘drug’ and *Ponds Ind. Limited vs. CIT*, **(2008) 8 SCC 369** wherein Vaseline Petroleum Jelly was held to be a drug, the learned ASG contended that the definition of ‘drug’ under the Drugs and Cosmetics Act must be construed widely and extensively in view of the inclusive nature of the legislative mandate and keeping in mind the objective of the statute.
- 38.3 In view of Section 3(2)(c) of the Essential Commodities Act, which provides that without prejudice to the generality of the powers conferred by Section 3(1), an order made thereunder may provide for controlling the price at which essential commodity may be bought or sold, the learned ASG would submit that contraceptives which are identified as essential medicines in NLEM 2011 have been rightly included in Section 18 of the First Schedule to DPCO 2013.
- 38.4 It is also pointed out that the central objective of NPPP 2012 being promulgating the principles necessary for pricing of essential drugs as laid down in NLEM 2011, the ceiling price for condoms has been rightly fixed under DPCO 2013 which is based upon NPPP 2012.
- 38.5 First Schedule to DPCO 2013 specifically deals with contraceptives under Section 18 and ‘condoms’ are included at Entry 18.3.3 as medicines. Since the price fixation exercise can

be carried out for all the medicines listed in the First Schedule whether generic or branded, the price fixation of condoms is well within the powers conferred under DPCO.

- 38.6 While submitting that as per paragraph 2 (1) (zb) of DPCO 2013, 'scheduled formulation' means any formulation included in the First Schedule without having regard to specification of dosage and strengths, it is explained that the dosage has been specified in the Schedule only when that medicine is sold in that dosage for being considered as a scheduled formulation.
- 38.7 The learned ASG would further submit that the nature and scheme of the Essential Commodities Act and DPCO 2013 do not permit the creation of a sub-category of medicines on any ground whatsoever. Since the petitioners have not challenged any of the provisions of DPCO 2013, the learned ASG contends that it is not open to them to make any grievance about placing the pleasure condoms, stated to be manufactured/marketed by them, at par with basic/utility condoms. In fact, no details whatsoever were submitted by the petitioners while making the price fixation exercise culminating in the order dated 10.07.2014.
- 38.8 Placing reliance upon *K Janardhan Pillai vs. UOI*; (1981) 2 SCC 45, *Glaxo Pharmaceuticals Ltd. vs. UOI*; 2009 (107) DRJ 539, *UOI vs. Swiss Garnier*; (2013) 8 SCC 615, *Puma Ayurvedic Herbal (P) Ltd. vs. Commissioner, Central Excise, Nagpur*, (2006) 3 SCC 266, it is contended by the learned ASG that the scheme of EC Act and DPCO, 2013 prohibits any sub-

category in medicines on the basis of any consideration of 'luxury' or 'lifestyle'.

- 38.9 It is further contended that in examining any price fixation order, the primary consideration shall be that of the interests of the consumer and as such interference by this Court is warranted only where Control Order is vitiated by palpable unreasonableness or arbitrariness.
- 38.10 Rebutting the contention on behalf of the petitioners that issuance of Control Order is not warranted for price fixation of the condoms under Section 3 of the EC Act, it is contended that as per Section 3(1) of EC Act, the shortage of a product is not the *sine qua non* for exercise of the power to issue the control orders. Thus, it is submitted that the fact that 55% of the condoms used in India are either distributed free of cost or at highly subsidised rates cannot be a valid ground to contend that there cannot be price fixation for the products of the petitioners.
- 38.11 Finally, it is submitted by the learned ASG that no price control orders can be held to be vitiated merely on account of the alleged loss caused to an individual stakeholder. In support of his submission, the learned ASG cited *Union of India & Anr. vs. Cynamide India Ltd. & Anr.*, (1987) 2 SCC 720; *Glaxosmithkline Pharmaceuticals Ltd. vs. Union of India & Ors.*, (2014) 2 SCC 753; *Sree Meenakshi Mills Ltd. vs. Union of India*, (1974) 1 SCC 468 and *Prag Rice & Oil Mills vs. Union of India*, (1978) 3 SCC 459.

Points for consideration

39. In the light of the rival contentions noticed above, the following questions arise for consideration:

- (i) Whether ‘condoms’ can be considered as ‘drugs’ so as to be covered by Section 2-A read with Item-1 of the Schedule to the EC Act, 1955 and whether inclusion of condoms in the First Schedule to DPCO, 2013 is *ultra vires* the provisions of the Essential Commodities Act, 1955?
- (ii) Whether issuance of a Control Order for price fixation of condoms is permissible under law and whether the ceiling price fixed by NPPA by orders dated 5.11.2013 and 10.7.2014 in exercise of the powers conferred by Paragraphs-4, 11 & 14 of DPCO, 2013 is sustainable.

Point No.1

40. The contentions of the petitioners on this point are of two fold. Firstly, that condoms cannot be brought under any of the four categories i.e., medicines, substances, notified substances and specified devices so as to be treated as ‘drugs’ under Section 3 (b) of the Drugs and Cosmetics Act, 1940. Secondly, even assuming that condom is a notified device and thus is covered by Section 3(b)(iv), ‘condoms’ cannot be considered as ‘essential commodity’ within the meaning of the E.C. Act, 1955 since by the date of Amendment to EC Act, 1955 by Act 30 of 1974 inserting “drugs” in Section 2(a)(iva), the definition of ‘drug’ under Section 3(b) of the Drugs and Cosmetics Act, 1940 did not include devices. Consequently, issuance of DPCO-2013 in purported exercise of powers

conferred by Section 3(2) of Essential Commodities Act, 1955 is ultra vires the provisions of the said Act.

41. The contentions of the petitioners in this regard have already been elaborated in Paras 37.1 and 37.2 (supra). Per contra, it is contended by the respondents that 'condoms' fall under the category of 'medicines' and 'substances' under Section 3(b)(i) since various chemicals such as 'benzocaine' are used in the manufacture of condoms. Even assuming without conceding that no medicinal components are contained in condoms, according to the respondents the same is of no consequence to treat the condoms as a 'drug' having regard to the fact that even empty gelatin capsules are to be treated as drugs under Section 3(b)(iii) and various uses of condoms include mitigation and prevention of diseases or disorders in human beings. Pointing out that 'condoms' have been included in the National List of Essential Medicines (NLEM) from the year 2003 onwards treating the same as essential medicines the learned ASG would further contend that the contraceptives in the form of condoms play a crucial role both for increasing the reproductive health and decreasing and preventing innumerable life threatening diseases and therefore they are always considered to be 'medicines'. The learned ASG has also pointed out that the petitioners are holders of the licences for manufacturing/marketing and import of drugs under the Drugs and Cosmetics Act, 1940 read with the Rules made thereunder and that they have been manufacturing/marketing the condoms treating the same as 'drugs'.

42. Thus, it is vehemently contended by the learned ASG that the assertion on the part of the petitioners that condoms are neither medicines

nor medical substances but they are only non-medical devices is completely incorrect.

43. The said argument is sought to be rebutted by the learned counsel for the petitioners contending that the respondents have always maintained that “condom” is a device as specified under Section 3(b)(iv) of the Drugs & Cosmetics Act, 1940. It is submitted by the learned counsel for the petitioners that in view of the undisputed fact that condoms are to be regulated under the Drugs & Cosmetics Act, no doubt the licensing requirements and specifications of standards under Rule 125 are applicable for manufacture and sale of the condoms, however, the respondents have no power or authority to control the prices of the same. The learned counsel would also reiterate the new plea raised during the hearing that condoms cannot even be regulated now in view of the notification dated 09.07.2014 issued by the Ministry of Health and Family Welfare.

44. The contention of the learned ASG that condoms contain “spermicide” which is a medicine has been categorically denied by the learned senior counsel for the petitioners stating that condoms sold in India do not use “spermicide”. So far as the contention of the respondents that condoms are used for treatment since it contains medicinal properties i.e. benzocaine and thus it is a drug is concerned, it is contended that benzocaine is not a spermicide at all. It is also pleaded that benzocaine is coated on the inside of condom and in no way acts as a drug for treatment or mitigation of any disease or disorder.

45. We may, at the outset, mention that it is the case of the petitioners themselves that condoms have been brought within the definition of “drugs” under the Drugs and Cosmetics Act, 1940 by virtue of the order

dated 20.04.2010 issued in terms of Section 3(b)(iv) of the said Act. It was specifically pleaded in the writ petitions that by notification dated 20.04.2010 the Central Government has notified condoms as a “medical device” and on the basis of the same it was contended that there is no controversy with regard to the position that condom is a drug within the meaning of Drugs and Cosmetics Act, 1940, but the challenge in the writ petitions is with regard to the inclusion of condoms within the purview of DPCO, 2013. However, during the course of the hearing a new stand has been taken by the learned senior counsel for the petitioners on the basis of the Office Order dated 09.07.2014 issued by the Directorate General of Health Services, Ministry of Health and Family Welfare and it is sought to be contended that by virtue of the said Office Order “condom” has to be treated as a non-notified device w.e.f. 09.07.2014 and thus it can no longer be considered as a drug under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940 and it cannot even be regulated under the said Act.

46. Having carefully gone through the two orders dated 20.04.2010 and 09.07.2014 relied upon by the petitioners, we are unable to hold that the said orders are the notifications issued under Section 3(b)(iv) of the Drugs and Cosmetics Act. On a perusal of the same, it appears to us that the said orders were issued by the Central Drugs Standards Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare in a different context for the purpose of regulation of import and manufacture, sale or distribution of the drugs.

47. It may be added that the respondents never pleaded that condoms are notified devices under Section 3(b)(iv) and thus fall within the definition of “drugs” under the Drugs and Cosmetics Act, 1940. On the

other hand, it was specifically pleaded by them that the petitioners have always treated the condoms as drugs and that the petitioners who are holding licences for manufacturing/marketing of the condoms under the provisions of the Drugs and Cosmetics Act, 1940 read with Rule 69 of the Rules made thereunder are bound by the standards prescribed under Rule 125 read with Schedule R for contraceptives.

48. It is also specifically pleaded by the respondents that condom is a “medicine” and thus fall within the definition of “drug” under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940. The said plea is sought to be substantiated by referring to the fact that condoms have been included in the List of Essential Medicines from the year 2003 onwards treating the same as essential medicine.

49. The plea of the respondents that condoms are covered by Clause (i) of Section 3(b) of the Drugs and Cosmetics Act, 1940 has been opposed by the petitioners asserting that condoms do not contain any medicinal properties nor they are used for treatment or mitigation of any disease or disorder in the human beings. According to the petitioners condoms are mere physical barriers and even in the First Schedule to DPCO, 2013, condoms have been included in Entry 18.3.3 under the caption “Barrier Methods”.

50. We are unable to agree with the said contentions of the petitioners for the following reasons:-

- (a) The Ministry of Health and Family Welfare, Government of India while reviewing the National Essential Drugs List, 1996 and publishing the National List of Essential Medicines, 2003 declared that the “essential medicines” are those that satisfy the priority

health care needs of the population. The purpose of NLEM was mentioned as to make available the essential medicines within the context of functioning health systems at all times in adequate amounts. It is also pertinent to note that NLEM, 2003 contained a new Section i.e. Section 18 under the caption “Hormones, Other Endocrine Medicines & Contraceptives”. Under the said Section, “Adrenal Hormones and Synthetic Substitutes” are included at Entry 18.1 and “Androgens” are included at Entry 18.2 whereas “Contraceptives” are included at Entry 18.3. Entry 18.3 contains four categories of contraceptives enumerated from 18.3.1 to 18.3.4 as under:

18. Hormones, other Endocrine Medicines and Contraceptives				
	Medicine	Category	Route of Administration/ Dosage Form	Strengths
18.3	Contraceptives			
18.3.1	Hormonal Contraceptives			
	Ethinylestradiol + Levonorgesterol	U	Tablets	.03 mg + 0.15 mg
	Ethinylestradiol + Norethisterone	U	Tablets	0.035 mg + 1.0 mg
	Hormone Releasing IUD	T	Levonorgesterol Releasing IUD	
18.3.2	Intrauterine Devices IUD containing Copper	U		
18.3.3	Barrier Methods	U		
	Condoms			
18.3.4	Non Hormonal Contraceptive			
	Centchroman	U	Tablets	30 mg

- (b) Evidently, condom is one of the forms of contraceptives. Similarly “intra uterine device” included in Entry 18.3.2 is another form of contraceptive. “Hormonal contraceptives” and “non-hormonal contraceptives” which are in the form of tablets are included in Entries 18.3.1 & 18.3.4. Irrespective of the fact whether contraceptives are in the form of devices or in the form of tablets, all of them are treated as medicines since the purpose of all forms of contraceptives is reproductive and fertility regulation and safe motherhood. The importance of condoms as effective contraceptives has been highlighted by various International Health Organizations and adopting the guiding principles laid down by them, the expert body thought it fit to include contraceptives as essential medicines in the National List of Essential Medicines, 2003. It may also be added that so far as the condoms are concerned, indisputably the same are being used not only as contraceptives but they are also widely in use all over the world for protection against transmission of HIV – the virus that causes AIDS – as well as several other Sexually Transmitted Infections (STI). Therefore, condoms have been rightly considered as Essential Medicines and are included in the NLEM so as to ensure affordable health care to a majority of population and also to improve accessibility of drugs for anti-HIV etc. through special assistance scheme for subsidizing the prices especially for BPL & APL families.
- (c) It is not in dispute that the NPPP, 2012 has been promulgated on the basis of the principles for pricing the essential drugs as laid down in NLEM, 2011 with the objective of putting in place a

regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices. One of the key principles for regulation of prices in NPPP, 2012 is ‘essentiality of drugs’ and the said criteria has been met by considering the list of medicines specified in NLEM, 2011. Thus, it is clear that condoms have always been considered as medicines and from 2003 onwards they are treated as essential medicines.

- (d) In addition it appears to us that condoms are also ‘substances’ and therefore on that ground also clause (i) of Section 3(b) is attracted. It is relevant to note that Rule 125 of Drugs and Cosmetics Rule, 1945 describes contraceptives as substances intended to affect the structure or any function of human body and Schedule R thereof prescribes the standards for mechanical contraceptives.
- (e) Though it is contended by the petitioners that ‘mechanical contraceptives’ for which standards are prescribed in Schedule R of the Drugs and Cosmetics Rules, 1945 would only mean intra-uterine devices and condoms are only physical or barrier method contraceptives as has been classified in the First Schedule to DPCO-2013, we do not find any logic to draw any such distinction. The petitioners are not disputing the fact that condoms are being regulated under the Drugs and Cosmetics Act by way of licensing and prescribing the standards. Rule 125 in fact prescribes the standards for substances which are intended to affect the structure or any function of human body and included contraceptives in that category. As pleaded by the petitioners themselves, condoms act as a physical barrier and thus protect from STI, unwarranted pregnancy and etc. That itself shows that condom affects the

functions of human body. Therefore, it is difficult for us to agree with the contention of the petitioners that condoms are different from the mechanical contraceptives described under Rule 125 of the Drugs and Cosmetics Rules, 1945. In this regard, we may refer to the decision in *Chhimanlal Jagjivandas Sheth* (supra) wherein absorbent cotton wool, roller bandages and gauze were held to be “drugs” within the meaning of Section 3(b) of the Drugs and Cosmetics Act, 1940. While holding that the said articles are “substances” used for or in the treatment within the meaning of Section 3(b) and that the definition of “drug” is comprehensive enough to take in not only medicines but also substances intended to be used for or in the treatment of diseases of human beings or animals, the Supreme Court observed –

“This artificial definition introduces a distinction between medicines and substances which are not medicines strictly so-called. The expression “substances”, therefore, must be something other than medicines but which are used for treatment. The part of the definition which is material for the present case is “substances intended to be used for or in the treatment”. The appropriate meaning of the expression “substances” in the section is “things”. It cannot be disputed, and indeed it is not disputed, that absorbent cotton wool, roller bandages and gauze are “substances” within the meaning of the said expression. If so, the next question is whether they are used for or in “treatment”. The said articles are sterilized or otherwise treated to make them disinfectant and then used for surgical dressing; they are essential materials for treatment in surgical cases. Besides being aseptic these articles have to possess those qualities which are utilized in the treatment of diseases.”

In *State of Goa v. Leukoplast (India) Ltd.*; (1997) 4 SCC 82, the Court while considering the question whether plasters, dressings

and bandages produced by the assessee under licence from Drugs Controller whether liable to tax under the Central Sales Tax Act had also considered the question whether the same fell within the expression “drugs and medicines” and it was concluded that whether the products in question can be treated as drugs or medicines is basically a question of fact including the questions whether it is used to cure or alleviate or to prevent disease or to restore health or to preserve health.

Referring to the decision in *Leukoplast (India) Pvt. Ltd.* (supra), the Supreme Court in *Ponds India Ltd. v. Commissioner of Trade Tax Lucknow*; **(2008) 8 SCC 369**, made similar observations with regard to the definition of “drug” under Section 3(b) of the Drugs and Cosmetics Act, 1940. In the said case, the court was dealing with the question whether petroleum jelly is a “drug” or the “cosmetic” within the meaning of the provisions of the UP Trade Tax Act, 1948. While noticing the provisions of the Drugs and Cosmetics Act, 1940, particularly, the definition of the “drug”, it was observed –

“A drug as defined in Section 3(b) thereof would not only include a medicine which is used for external use of human beings, but if used for prevention of any disease or disorder in human being, shall also come within the purview thereof. The said definition is an extensive one. It even applies to preparations applied on human body for the purpose of killing insects like mosquitoes, which per se does not have any medicinal or any value for curing any disease or disorder in human beings.”

- (f) In the light of legal position noticed above, it can safely be concluded that condoms are medicines as well as substances for

use of human beings for mitigation or prevention of a disease or disorder in human beings as provided under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940.

51. In view of our conclusion that Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 is attracted and not Section 3(b)(iv) it is not necessary for us to go into the further contention of the petitioners that no device can be brought within the definition of ‘essential commodities’ under Section 2(a) (iva) of the EC Act, 1955 since Clause (iv) to Section 3(b) of the Drugs and Cosmetics Act, 1940 was not existing as on 29.08.1974, i.e., the date on which ‘drugs’ were included in the definition of ‘essential commodity’ under EC Act, 1955.

52. For the aforesaid reasons, we answer point No.1 holding that condoms are drugs within the definition of Section 3(b) of the Drugs and Cosmetics Act, 1940 as well as Item 1 of Schedule to EC Act, 1955 and thus the same are also the ‘essential commodities’ within the meaning of Section 2A of the EC Act, 1955. Hence, the inclusion of condom in DPCO-2013 cannot be held to be ultra vires the provisions of Essential Commodities Act, 1955.

Point No.2

53. Having held that “condom” falls within the definition of “drug” under Section 3(b) of the Drugs and Cosmetics Act, 1940 read with Item 1 of Schedule to the Essential Commodities Act, 1955, we shall now proceed to consider whether a control order can be issued under Section 3 of EC Act, 1955 for price fixation of condoms and whether the ceiling price fixed for condoms by NPPA by the impugned orders is in accordance with law.

54. DPCO, 2013 has been issued in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955, which enables the Central Government to issue Orders providing *inter alia* for controlling the prices at which the essential commodity may be bought or sold, if the Central Government is of the opinion that it is necessary or expedient so to do for the purpose of maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices.

55. In the light of the reasons stated supra, there can be no dispute that 'condom' is a 'drug' as specified in Item-1 of the Schedule to the Essential Commodities Act and thus it is an 'essential commodity' as declared under Section 2A of the Essential Commodities Act, 1955.

56. However, the contention of the petitioners is that the need to make the condoms available at reasonable prices has already been addressed since the Government itself distributes 55% of the condoms free or at highly subsidised prices. It is also contended that 93.97% of condoms are available at below ceiling price even before the issuance of DPCO, 2013. Therefore, according to the petitioners, the essential pre-condition for issuing a Control Order providing for controlling the price of the condoms in exercise of the powers under Section 3 of the Essential Commodities Act, 1955 is not satisfied at all. In other words, the contention is that an order under Section 3 of E.C. Act can be issued only where the Central Government is of the opinion that it is necessary or expedient so to do for maintaining or increasing the supplies of any essential commodity or for securing their equitable distribution and availability at fair prices. The contention of the petitioners is that none of

the circumstances specified in Section 3 is existing so far as condoms are concerned.

57. The said contention is sought to be rebutted by the learned ASG contending that even assuming that the plea of the petitioners that 55% of the condoms are distributed free in India or at highly subsidized rate is correct, there is still a huge gap of 45% of the demand and the same has to be met at fair prices considering the fact that India is among the countries with highest number of HIV/AIDS affected population. Placing reliance upon NPPP-2012, the learned ASG further contended that the policy decision of the Government to control the ceiling price of all the essential medicines included in NLEM-2011, including condoms, warrants no interference.

58. Admittedly DPCO, 2013 has been issued in tune with the policy decision of the Central Government vide NPPP-2012. The judicial review with such policy matters is unwarranted as held by the Apex Court in various decisions.

59. For the purpose of the present case, we may specifically refer to the following two decisions where the Supreme Court dealt with issues relating to price fixation.

60. In *Shri Sitaram Sugar Co. Ltd. v. Union of India*, (1990) 3 SCC 223, while holding that price fixation is not within the province of the Courts, it is observed :

“57. Judicial review is not concerned with matters of economic policy. The court does not substitute its judgment for that of the legislature or its agents as to matters within the province of either. The court does not supplant the “feel of the expert” by its own views. When the legislature acts within the sphere of its

authority and delegates power to an agent, it may empower the agent to make findings of fact which are conclusive provided such findings satisfy the test of reasonableness. In all such cases, judicial inquiry is confined to the question whether the findings of fact are reasonably based on evidence and whether such findings are consistent with the laws of the land. As stated by Jagannatha Shetty, J. in *Gupta Sugar Works*[1987 Supp SCC 476, 481] : (SCC p. 479, para 4)

“... the court does not act like a chartered accountant nor acts like an income tax officer. The court is not concerned with any individual case or any particular problem. The court only examines whether the price determined was with due regard to considerations provided by the statute. And whether extraneous matters have been excluded from determination.”

59. It is a matter of policy and planning for the Central Government to decide whether it would be, on adoption of a system of partial control, in the best economic interest of the sugar industry and the general public that the sugar factories are grouped together with reference to geographical-cum-agro-economic factors for the purpose of determining the price of levy sugar. Sufficient power has been delegated to the Central Government to formulate and implement its policy decision by means of statutory instruments and executive orders. Whether the policy should be altered to divide the sugar industry into groups of units with similar cost characteristics with particular reference to recovery, duration, size and age of the units and capital cost per tonne of output, without regard to their location, as recommended by the BICP, is again a matter for the Central Government to decide. What is best for the sugar industry and in what manner the policy should be formulated and implemented, bearing in mind the fundamental object of the statute, viz., supply and equitable distribution of essential commodity at fair prices in the best interest of the general public, is a matter for decision exclusively within the

province of the Central Government. Such matters do not ordinarily attract the power of judicial review.”

61. In *Dhampur Sugar (Kashipur) Ltd. v. State of Uttaranchal*, **(2007) 8 SCC 418** the scope of judicial review in policy matters has been reiterated observing:-

“63. In our judgment, it is well settled that public authorities must have liberty and freedom in framing policies. No doubt, the discretion is not absolute, unqualified, unfettered or uncanalised and judiciary has control over all executive actions. At the same time, however, it is well established that courts are ill-equipped to deal with these matters. In complex social, economic and commercial matters, decisions have to be taken by governmental authorities keeping in view several factors, and it is not possible for courts to consider competing claims and conflicting interests and to conclude which way the balance tilts. There are no objective, justiciable or manageable standards to judge the issues nor such questions can be decided on a priori considerations.”

62. In the light of the settled legal position, we are of the view that the policy decision of the Government to control the price of the condom which is admittedly an essential commodity having been taken keeping in view various social, economic and commercial factors is not amenable for judicial review by this Court. What is the best in the interest of the general public is a matter for decision exclusively within the province of the Central Government. It is no doubt true that before making a Control Order it is mandatory for the Central Government to form an opinion that it is necessary or expedient to make an order for the purpose of maintaining or increasing supplies of any essential commodity or for securing their equitable distribution and availability at fair prices, however, it cannot be concluded that the Government failed to form such

opinion merely on the ground that 55% of the condoms are available free or at subsidized prices by the Government.

63. Hence, we reject the contention that issuance of a Control Order for regulation of prices of condoms is not in conformity with the mandatory provisions of Section 3 of the EC Act, 1955.

64. For proper appreciation of the further contention of the petitioners that since the scope of DPCO-2013 is restricted only to formulations as defined in Para 2(1)(i), the inclusion of the condoms which do not fall within the said definition of ‘formulations’ is contrary to NPPP-2012, we may in the first instance refer to the definitions of the words ‘ceiling price’, ‘formulation’, ‘non-scheduled formulation’ and ‘scheduled formulation’ under Para 2(1) of DPCO-2013:

“2(1)(d) ‘**ceiling price**’ means a price fixed by the Government for Scheduled formulations in accordance with provisions of this Order.

2(1)(i) ‘**formulation**’ means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

- (i) any medicine included in any bona fide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;
- (ii) any medicine included in the Homeopathic system of medicine; and
- (iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply.

2(1)(v) ‘**non-scheduled formulation**’ means a formulation, the dosages and strengths of which are not specified in the First Schedule.

2(1)(zb) ‘**scheduled formulation**’ means any formulation, included in the First Schedule whether referred to by generic versions or brand name.”

65. Paragraph 4 of the DPCO 2013 which provides for calculation of ceiling price of a scheduled formulation and Paragraph 14 which provides for fixation of ceiling price of scheduled formulation may also be reproduced hereunder:

“4. Calculation of ceiling price of a scheduled formulation.-

(1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the First Schedule shall be calculated as under:

Step 1. First the Average Price to Retailer of the scheduled formulation *i.e.* P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one per cent of the total market turnover on the basis of moving annual turnover of that medicine)/(Total number of such brands and generic versions of the medicine having market share more than or equal to one per cent of total market turnover on the basis of moving annual turnover for that medicine.)

Step 2. Thereafter, the ceiling price of the scheduled formulation *i.e.* P(c) shall be calculated as below:

$P(c) = P(s) \cdot (1 + M/100)$, where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step 1 above.

M = % Margin to retailer and its value = 16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

14. Fixation of ceiling price of scheduled formulations.-

(1) The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.

(2) Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.”

66. As could be seen, the word ‘formulation’ has been defined as a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease. The contention of the petitioners that ‘condoms’ do not fall within the definition of ‘formulation’ is based upon the plea that ‘condom’ is not a medicine but only a barrier device.

67. The very same plea taken by the petitioners for the purpose of the contention that Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 is not attracted since ‘condom’ is neither a medicine nor a substance has already been considered in detail and rejected in para 50 (supra). We

have categorically held that ‘condoms’ are medicines and, therefore, the same fall within the definition of ‘drugs’ under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940. In the light of the view we have already expressed that ‘condom’ is a medicine, it has to follow that it is a ‘formulation’ within the definition of Para 2(1)(i).

68. Then the next question would be whether ceiling price can be fixed for condoms under Para 4 of DPCO-2013 since the dosage and strength of the condoms have not been specified in Entry 18.3.3.

69. It is submitted by the learned counsels appearing on behalf of the petitioners that since dosage and strength have not been prescribed in the First Schedule for condoms, they can be considered only as ‘non-scheduled formulations’ as defined in Para 2(1)(v) and therefore Para 4 of DPCO-2013 which provides for calculation of ceiling price of only ‘scheduled formulations’ is not applicable at all. Pointing out that Paragraphs 4, 5, 6, 13 and 14 of DPCO-2013 exclusively deal with ‘scheduled formulations’, the learned senior counsels appearing for the petitioners contended that DPCO-2013 does not contemplate price fixation of ‘condoms’ which are admittedly ‘non-scheduled formulations’. It is also contended that the condom is not a generic name for a medicine but it is the name of a device and therefore, on that ground also it is not a ‘scheduled formulation’, which is defined under Para 2(1)(zb) as any formulation included in the First Schedule whether referred to by the generic versions or brand name.

70. Per contra, it is contended by the learned ASG appearing for the respondents that under DPCO-2013 price fixation can be carried out for all the medicines listed in the First Schedule whether generic or branded. It is further submitted that dosage has been specified in the First Schedule

only when that medicine is sold in that particular dosage and that merely on the ground that dosage and strength have not been specified, no product would cease to be a medicine. Pointing out that for many of the medicines included in the First Schedule, dosage and strength have not been specified, the learned ASG further submits that a product in respect of which the dosage and strength has not been specified has to be sold after obtaining price approval in terms of Paragraph 2(1)(u) and Paragraph 15 unless it qualifies exemptions available under Paragraph 32 of DPCO-2013. Therefore, according to the learned ASG, once a product falls within the definition of ‘scheduled formulation’, Paragraph 4 is attracted irrespective of the fact whether its dosage and strength have been specified or not.

71. We find force in the submission of the learned ASG to the extent that a product would not cease to be a medicine merely on the ground that its dosage and strength have not been specified. However, we fail to understand as to how Paragraph 4 of DPCO-2013 can be made applicable to those formulations for which the dosage and strength have not been specified.

72. A perusal of Paragraph 4 of DPCO-2013 shows that the same provides for fixation of ceiling price of only a scheduled formulation of specified strength and dosage as specified under the First Schedule. Para 2(1)(d) defines ‘ceiling price’ as a price fixed by the Government for ‘scheduled formulations’ in accordance with the provisions of DPCO-2013.

73. It is evident from the First Schedule that it contains the formulations of which strength and dosage have been specified as well as the formulations of which strength and dosage have not been specified.

Para 2(1)(zb) defines scheduled formulations as formulation included in the First Schedule whether referred to by generic versions or brand name. Thus, it is clear that all formulations that are included in the First Schedule, irrespective of specification of strength and dosages, are ‘scheduled formulations’. In other words, scheduled formulations include non-scheduled formulations.

74. It may be added that though the definition of ‘ceiling price’ under Para 2(1)(d) does not draw any distinction between ‘scheduled formulations’ and ‘non-scheduled formulations’, Para 4 makes it clear that the ceiling price thereunder can be fixed only for ‘scheduled formulations’ of specified strength and dosages as specified under the First Schedule.

75. On a combined reading of Para 4, Para 2(1)(d) and Para 2(1)(zb), it appears to us that the specification of dosage and strength in the First Schedule has a specific bearing with regard to fixation of ceiling price under DPCO-2013. We are of the view that the words in the definition of ‘ceiling price’ under Para 2(1)(d) i.e. ‘in accordance with the provisions of this order’ make the intention of the Legislature abundantly clear and that the same shall be given due weight while implementing the provisions of DPCO-2013.

76. It may be added that Para 5 which provides for calculation of retail price of a new drug for existing manufacturers of ‘scheduled formulations’ and Para 6 which provides for ‘ceiling price of a scheduled formulations’ in case of no deduction in price due to absence of competition specifically referred to the calculation in sub-paragraph (1) of Paragraph of 4, the scope of which is expressly restricted to ‘scheduled formulations’ of specified strength and dosages’. Similarly, Para 14

which provides for fixation of ‘ceiling price of scheduled formulations’ states that the ceiling price shall be fixed and notified by the Government in accordance with the provisions of Para 4.

77. It is pertinent to note that DPCO-2013 contains a different method of regulation so far as ‘non-scheduled formulations’ are concerned. Para 20 of DPCO-2013 provides for monitoring the ‘maximum retail prices’ of the non-scheduled formulation and Para 25 mandates display of prices of non-scheduled formulation and price list thereof. The word ‘price list’ has been defined under Para 2(1)(10) as a price list referred to in Para 24 and Para 25. Para 25 provides for display of the price fixed for ‘scheduled formulations’ having ‘maximum retail price’ of that formulation based on the ceiling price whereas Para 25 provides for display of prices of ‘non-scheduled formulations’ and price list thereof. On a combined reading of above-noticed provisions, it appears to us that so far as calculation/fixation of ceiling price of ‘scheduled formulations’ is concerned, specific distinction has been drawn between those scheduled formulations for which strength and dosage are specified under the First Schedule and the ‘scheduled formulations’ for which strength and dosage are not specified under the First Schedule.

78. It is no doubt true that the objective of NPPP-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of ‘essential medicines’ at reasonable prices. It is also true that as per NPPP-2012, the regulation of prices of drugs would be on the basis of essentiality of drugs and the essentiality criteria is to be met by considering the list of medicines specified in the National List of Essential Medicines as revised from time to time. NPPP-2012 is sought to be implemented through DPCO-2013 and all the essential medicines

that were listed in the NLEM-2011 have been included in the First Schedule to DPCO-2013 so as to regulate the prices of the same. However, the question that arises for consideration is whether ceiling price can be fixed by the NPPA for all the formulations/medicines included in the First Schedule to DPCO-2013 ignoring the legislative intention that the said power be not extended to some of the formulations. Considering an identical issue, the Supreme Court in ***Secretary, Ministry of Chemicals and Fertilizers, Government of India Vs. CIPLA Ltd (supra)*** held that the contents of the policy documents cannot be read and interpreted as statutory provisions and that too much of legalism cannot be imported in understanding the scope and meaning of the clauses contained in policy formulations. It was also added that the Government exercising its delegated legislative power should make a real and earnest attempt to apply the criteria laid down by itself as a policy maker and that the delegated legislation that follows the policy formulation should be broadly and substantially in conformity with that policy, otherwise it would be vulnerable to attack on the ground of arbitrariness resulting in violation of Article 14. It was further held:

“4.3 True, the breach of policy decision by itself is not a ground to invalidate delegated legislation. But, in a case like this, the inevitable fallout of the breach of policy decision which the Government itself treated as a charter for the resultant legislation is to leave an imprint of arbitrariness on the legislation. When the selection or classification of certain drugs is involved for the purpose of price control, such selection or classification should be on a rational basis and cannot be strikingly arbitrary. No doubt, in such matters, wide latitude is conceded to the legislature or its delegate. Broadly, the subordinate law-making authority is guided by the policy and objectives of the primary legislation disclosed by the preamble and other provisions. The delegated legislation need not be

modelled on a set pattern or prefixed guidelines. However, where the delegate goes a step further, draws up and announces a rational policy in keeping with the purposes of the enabling legislation and even lays down specific criteria to promote the policy, the criteria so evolved become the guideposts for its legislative action. In that sense, its freedom of classification will be regulated by the self-evolved criteria and there should be demonstrable justification for deviating therefrom. Though exactitude and meticulous conformance is not what is required, it is not open to the Government to go haywire and flout or debilitate the set norms either by giving distorted meaning to them or by disregarding the very facts and factors which it professed to take into account in the interest of transparency and objectivity. Otherwise, the legislative act of the delegate in choosing some drugs for price control while leaving others will attract the wrath of Article 14. That is why the Union of India has taken the stand throughout that it stood by the policy while framing the legislation and that there was every endeavour to apply the criteria spelt out in the Drug Policy of 1994 before including the drugs in question in the First Schedule. The correctness of this contention should, of course, be examined.”

79. The principle laid down in the above case has been reiterated in *Clariant International Vs. SEBI*, (2004) 8 SCC 524 holding that when any criterion is fixed by a statute or by a policy, an attempt should be made by the authority making the delegated legislation to follow the policy formulation broadly and substantially and in conformity therewith.

80. In *S. Samuel Vs. Union of India*, (2004) 1 SCC 256, the State of Tamil Nadu, in exercise of the powers delegated by the Central Government by issuing a notification under Section 5 of the Essential Commodities Act, promulgated TN Scheduled Articles (Prescription of Standards) Order, 1997 for the purpose of maintaining and raising the

standards of quality of supply and sale of certain essential articles including Tea. The constitutional validity of the said order was challenged by the petitioners insofar as its applicability to Tea is concerned. Though the writ petition was dismissed by the High Court of Madras, the appeal was allowed by the Supreme Court holding

“As we have held that the State of Tamil Nadu could not have promulgated an order under Section 3 of the EC Act in the purported exercise of the power delegated by the Central Government to make an order applicable to tea, by wrongly assuming tea to be a foodstuff. The several provisions of the Tamil Nadu Scheduled Articles (Prescription of Standards) Order, 1977, must be held to be *ultra vires* the power of the State Government to the extent to which it makes provisions in relation to tea. The said Order cannot apply to tea.”

81. In the light of the legal position noticed above and for the reasons stated supra, we are of the view that the NPPA exceeded the powers conferred by Paras 4, 6 & 14 of DPCO-2013 while fixing the ceiling price for condoms. The language of Para 4 is unambiguous and makes clear the legislative intent that the ceiling price can be fixed only for scheduled formulations of specified strengths and dosages as specified under the First Schedule. Therefore, according to us, the provisions of Para 4 cannot be made applicable to ‘condoms’ the dosage and strength of which have admittedly not been specified under the First Schedule.

82. It may be added that since condoms are formulations included in the First Schedule to DPCO-2013, it may be open to the respondents to regulate the same by invoking the other provisions of the DPCO-2013 which deal with the non-scheduled formulations, i.e. the formulations, the dosage and strength of which are not specified in the First Schedule.

However, Paragraphs 4, 6 and 14 which exclusively deal with only those scheduled formulations of which strengths and dosages are specified in the First Schedule are not applicable. Consequently, the fixation of the ceiling price for condoms under Paragraphs 4, 6 and 14 of DPCO-2013 is impermissible under law.

83. In the light of the above conclusion, it is not necessary for us to consider the other contentions of the petitioners that the methodology prescribed in Para 4 of DPCO-2013 is unworkable in the case of condoms and that the advanced version of the pleasure condoms manufactured/ marketed by the petitioners form a distinct and separate class from the basic/utility condoms and, therefore, fixation of a common ceiling price for both the categories under the impugned orders is violative of Article 14 of the Constitution of India.

84. Since the impugned action of fixation of ceiling price is held to be bad on the ground that the NPPA exceeded the powers conferred by Para 4, 6 and 14 of DPCO-2013 and the policy decision under NPPP-2012 has not been interfered by us in any manner, it is also not necessary for us to refer to the various decisions cited by the learned counsel for both the parties with regard to the scope of judicial review vis-à-vis policy decision.

85. Accordingly, we declare that the Orders of NPPA dated 05.11.2013 and 10.07.2014 are illegal and unsustainable. In the result, both the said Orders are hereby set aside.

86. It appears that after we reserved the judgment, the Government of India, Ministry of Chemicals and Fertilizers, by Notification dated 09.03.2015 made an amendment to the DPCO-2013 by substituting the

definition of ‘non-scheduled formulation’ in Para 2(1)(v). The said fact was brought to our notice on 03.07.2015 by Shri Kirtiman Singh, the learned standing counsel for Union of India and a copy of the Notification dated 09.03.2015 has also been made available. As we could see, the Notification dated 09.03.2015 was published in the Gazette of India vide No. S.O.1221(E) dated 15.05.2015 and by virtue of the said amendment dated 09.03.2015, Para 2(1)(v) of DPCO-2013 reads as under:

“(v) ‘non-scheduled formulation’ means a formulation which is not included in Schedule-I.”

87. In view of the undisputed fact that the said amendment has come into operation from the date of publication, i.e. 15.05.2015, the same has no bearing for determining the validity of the Orders impugned in the writ petitions and, therefore, our conclusion in the writ petitions that the impugned Orders are liable to be set aside for the reasons stated supra needs no reconsideration.

88. The writ petitions are accordingly disposed of. There shall be no order as to costs.

CHIEF JUSTICE

RAJIV SAHAI ENDLAW, J.

JULY 10, 2015
anb