F. No. 31015/90/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS
……..

A Wing, Shastri Bhawan,
New Delhi 110 001

Order

By this order the application dated 31.10.2017 filed under para 22 of DPCO, 1995 by M/s Lark Laboratories (India) Limited (hereinafter called the applicant) against notification S.O. No. 1355(E) dated 05/06/2008 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulation Livogard Syrup is being disposed of.

2. Initially, the applicant / company had not filed the review application. It moved to Hon'ble High Court of Rajasthan by way of writ petition. Hon'ble High Court of Judicature for Rajasthan Bench at Jaipur, vide its order dated 13/10/2017 disposed of the said petition (i.e. CWP no. 7198/2017) and relegated the petitioner (i.e. M/s Lark Laboratories (India) Limited) to file review petition under para 22 of Drugs (Prices Control) Order, 1995 (DPCO, 1995). Court also ordered that "if the petitioners approach by way of review within two weeks, no recovery shall be made by the respondents till 01/11/2017".

3. Submission of the applicant / company:

A. Notification S.O. No. 1355(E) dated 5th June, 2008

(i) Exemption to Small scale units and issues pertinent thereto as applicable to Livogard Syrup

The Company claims that they are an exempt SSI (Small Scale Industries) unit duly registered with Director of Industries of the state. DPCO, 1995, based on the Drug Policy, 1994 was notified on 6th Jan, 1995 and prior to that, Small scale sector units were totally exempt from price control under the previous price control orders issued from time to time up to specified turnover. The issue of Small Scale Sector units being an important aspect Govt. of India, Ministry of Chemicals and Fertilizers issued press release on 7th Jan, 1995, immediately on the heels of issuance of DPCO, 1995, clarifying the position with regard to SSI units as under vide paragraph 7 of the press release:-

"7.The new DPCO also provides for fixing of ceiling price for commonly used packs of formulations based on price controlled drugs and these prices would be applicable to all manufacturers and also to the single ingredient formulations sold under generic names. The small scale sector will not be required to come for price fixation of these packs and they will be required to only adhere to the discipline of observing the ceiling prices. In regard to other packs, they would continue to enjoy, as before, exemption from price control on formulations".

The said position is in the Policy itself which is sacrosanct and also defines where ceiling price can be fixed as such, price fixation cannot be for every product.

With regard to ceiling prices under paragraph 22.7.3, Drug Policy, 1994 has provided as under:-

“Ceiling price would be fixed for commonly marketed standard pack sizes of price controlled formulations and it would be obligatory for all, including small scale units, to follow the price so fixed.”

Therefore, the ceiling prices were required to be fixed only for commonly marketed packs having standard composition. Livogard Syrup of the company did not fall in that category. The above provisions also define the scope of intervention in the case of SSI units as the said provisions were applicable to all SSI units. NPPA has ignored all these provisions and need critical review.

(ii) Ministry of Chemicals and Fertilizers, vide S.O. No. 134(E) dated 2nd March, 1995, exempted all registered SSI units from the operation of paragraph 8 of DPCO, 1995 relating to fixation of retail price of Scheduled formulation if such scheduled formulation is not covered under paragraph 9 of DPCO, 1995 relating to fixation of ceiling price of Scheduled formulations provided the SSI unit was an independent unit, the formulation is marketed under its own brand name and a declaration complying with both these aspects is filed within sixty days from the date of notification in case of existing units and within sixty days of commencement of production in case of existing units. In note (ii) it was clarified that the product manufactured by one SSI unit in the factory of other SSI unit was also covered under the exemption.

(iii) The above notification made it clear that the normal mode of price fixation was fixation of retail price under Paragraph 8 of DPCO, 1995 and such price fixation was not required to be sought by SSI units. As an exception for standard packs and compositions ceiling price under Paragraph 9 was required to be notified based on the data submitted by the organized sector units and identifying major manufacturer among them. Since SSI units were not required to apply for price fixation, they were not required to submit any data under the Policy as well as said notification dated 2nd March, 1995. They were, however, required to follow the ceiling price wherever it was so notified under paragraph 9 for standard packs and compositions provided their product confirmed to such a product composition. Product composition and packs which were not covered under the ceiling price fell outside the scope of price fixation or extension of ceiling price in so far as SSI units are concerned. Livogard Syrup falls in that category.

(iv) The subject formulation was manufactured by company in their own factory upto April, 2009. Thereafter, they discontinued the production of the product in their factory and started procuring a totally non-scheduled product from other manufacturer as their product is not a Vitamin formulation but is meant for Hepatitis and other Liver ailments. They filed a declaration in terms of notification dated 2nd March, 1995 with the Ministry on 25th April, 1995. The contention of NPPA throughout had been that exemption is not automatic and approval of the same had to be necessarily accorded to by the Ministry which is not the correct position. No approval is required as per law and Ministry has not accorded any approval. Therefore, contention of NPPA is without any basis and contrary to law as laid down in the said notification. Company requested the Reviewing authority to look into the matter in true spirit of law once for all.

(v) The Company asked whether the notification is under paragraph 9 or under paragraph 11 or under both the paragraphs and under which authority or delegated power it has been issued. Whether it mitigates the sanctity of both the paragraphs, the

provisions of Policy and DPCO, 1995 be decided and reviewing authority should make its views known before granting a hearing.

(vi) Whether statue does not permit issuance of ceiling price notification under any provision of DPCO, 1995 other than Paragraph 9 as is clear from paragraph 2(c) and paragraph 9(1) of DPCO, 1995, then under what authority or delegated power mandatory provisions of DPCO, 1995 were violated. Such price fixation resulted in stoppage of production for most of the products as fake prices were fixed? Did NPPA have such powers?

(vii) What is the mandate and scope of paragraph 11 of DPCO, 1995 and in what manner it has been used. When orders under it were not required to be published in Gazette of India, why were they published to befool everybody. When it was not required to be used for fixing/ notifying ceiling prices, why this paragraph was used. When orders under this paragraph were to be confined for fixing individual prices of defaulters, how this paragraph was used in fixing fake ceiling prices and under what authority. Full disclosures may be made along with details of opinion of Ministry?

(viii) The crucial point is that any price which is not in accordance with the provisions of paragraph 9 of DPCO, 1995 cannot be called a ceiling price. The base for fixing ceiling price is the data received in Form III under Paragraph 8 from a major manufacturer. No other paragraph of DPCO, 1995 provides for submission of data in Form III. The issue that in which situation ceiling price is to be fixed is settled in Paragraph 22.7.3 of New Drug Policy, 1994. It lays down “ceiling prices would be fixed for commonly marketed standard pack sizes of price controlled formulations and it would be obligatory for all, including small scale units, to follow the price so fixed.” It is clear that such a price is required to be fixed for commonly marketed standard packs (compositions) in accordance with the provisions and procedure as laid down in Paragraph 9 of DPCO, 1995. Such a price has to be for standard packs and compositions of major manufacturers so that price notified for them becomes binding on the manufacturers having same composition and pack with paragraph 9(3) of DPCO, 1995 which provides for pro rata formula for changes in pack sizes. Such a price has necessarily to be notified in the Official Gazette so that it becomes binding on all manufacturers producing such packs.

Retail prices of formulations were required to be fixed/revised under Paragraph 8 of DPCO, 1995 for the organized sector units based on data to be submitted by them in Form III prescribed under the Second Schedule to DPCO, 1995. Details to be submitted include details of turnover, composition besides cost of production of a formulation. This form is common for paragraph 8,9 and 10 but only paragraph 8 prescribes for the submission of this form by the organized sector units as in paragraph 8(6) or for revision in retail price as in para 8(2) or for ceiling price as in paragraph 9(2) it is relevant. SSI units were exempted from submission of details for price fixation of formulations. Now whether an organized sector unit is major manufacturer or efficient or not is to be judged from Form III data only which was statutorily required to be submitted by the Organized Sector units based on which ceiling price can only be fixed provided pack has a standard composition. Therefore, normal mode of price fixation was fixation of retail price under Paragraph 8 of DPCO, 1995 and such price was required to be fixed for the organized sector units. As an exception, ceiling price could be fixed under paragraph 9 for single ingredient formulations and standard compositions and this was to be binding on all including SSI units. Reviewing authority must satisfy that after NPPA was created in 1997 and powers were delegated to it, it stuck to the said provisions in letter and spirit in general, and in their case in particular.

(ix) Paragraph 2(c) of DPCO, 1995 defines ceiling price as a price fixed by the Govt. for Scheduled formulations in accordance with the provisions of paragraph 9. Notification S.O. No. 134(E) dated 2nd March, 1995 also makes it clear that ceiling price fixed under Paragraph 9 is only binding on the SSI units. This clearly shows that any price fixation which is not in accordance with the provisions of Paragraph 9 or uses any other paragraph in support cannot be called a ceiling price. Nobody can violate this statutory provision and reviewer must ensure compliance in the instant case.

(x) Paragraph 9(1) relating to fixation of ceiling price provides that notwithstanding anything contained in this order, the Govt. may, from time to time, by notification in the Official Gazette, fix ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling price for all such packs including those sold under generic name and for every manufacturer of such formulations.

It is clear that major manufacturer of a formulation in the organized sector is required to be identified on the basis of his cost or efficiency and price is required to be notified based on the formula laid down in Paragraph 7. It is obligatory to notify such a price in the Official Gazette. Ceiling price is required to be notified for a specified formulation having standard pack and composition. No such price was fixed for Livogard Syrup with company's composition. Company's composition is different and after April, 2009, Company has been marketing a non scheduled formulation only.

Paragraph 9(3) provides for announcing a formula for fixing prices based on ceiling prices of packs different than packs for which ceiling prices were notified but having same composition. The said order was issued vide S.O. No. 83(E) dated 27th Jan, 1998. This notification was relevant for tablets and capsules. It is as such clear that paragraph 9 does not permit any compositional changes in the ceiling prices of commonly marketed standard packs and compositions notified under paragraph 9(1) of DPCO, 1995. This is so as any change if permitted would be against the formula laid down in Paragraph 7.

(xi) From the above facts it is clear that there was no provision which permitted NPPA to fix ceiling prices in a manner other than the one provided in Paragraph 9. In order to know as to when deviations from the laid down procedure were made by NPPA, they scanned the websites and found that up to the year 2000, NPPA followed the provisions of DPCO, 1995 in letter and spirit and fixed ceiling prices (under paragraph 9) as well as retail prices (under paragraph 8) in accordance with the provisions of DPCO, 1995. Some of the notifications pertaining to fixation of ceiling prices under paragraph 9 and letters/orders fixing retail prices for individual manufactures are available on the website and can be made available. From the year 2001, it appears that the process of fixing ceiling prices under paragraph 9 and 11 was started and gradually fixation of retail prices under paragraph 8 was significantly reduced or eliminated altogether. Details in Form III it seems were also dispensed with. This is a serious matter which needs to be looked into by the reviewing authority as fixation of fake prices was not only against the letter and spirit of DPCO, 1995, beyond the powers of delegate and was a deception of the highest order which reviewing authority must take cognizance of based on the details provided by us as well as based on its own motion. The notification which is being used against us firstly does not cover our product as it has different composition and secondly it fixes fake price which should be an independent matter for investigation.

(xii) The Company also sought disclosures which were never made. They once again sought the details in respect to the following which are pertinent to ceiling price notification:-

(a) who is the major manufacturer of the product covered under the notification in question,

b) Did he submit the details in Form III to DPCO, 1995 and if so when?

(c) Detailed break up of raw material cost raw material wise and source wise, conversion cost, packing material cost and packing charges. Quantity taken into consideration per unit for each raw material and rate taken into consideration. We are raising this issue as our raw material cost alone per unit is much more than the ex factory cost taken into consideration clearly establishing that fake price was fixed taking into consideration fake rates.

(d) Was he producing the product in question and if yes when did he cease to produce the product,

(e) Agenda and minutes of the meeting where the proposal for fixation of ceiling price was considered may be disclosed to us so that they can render their comments for consideration.

(xiii) Main points to be noted are that here powers were taken to fix the price for a manufacturer who does not furnish or submit the data/information within the stipulated period, mainly application for price fixation/revision of a formulation under paragraph 8(2) within thirty days consequent to fixation/revision in price of bulk drug then price was required to be fixed for such a manufacturer by a general order which was not required to be notified in the official Gazette. Such a price will be relevant to such a manufacturer and the order would be directed against him. Data could be called from such a manufacturer and Ministry seem to be following this practice which was abandoned by NPPA. Such a price cannot be a ceiling price as SSI units were not covered within the scope of Paragraph 8 of DPCO, 1995. Except paragraph 8(2), no other paragraph of DPCO, 1995 provided for submission of data in Form III within a stipulated period. Initially as shown above NPPA fixed the retail prices directed at the individual manufacturers as is clear from their website but later started misusing this paragraph to justify their wrong acts. One has to go through paragraph 8(6) to understand full implications. The said Paragraph provides that no manufacturer or importer shall market a new pack, if not covered under sub-paragraph 3 of paragraph 9, or a new formulation or a new dosage form of his existing scheduled formulation without obtaining the prior approval of its price from the Govt. What NPPA did was that it allowed big brands and companies to charge their own prices for years without issuing any notice for violation but to save them they wrongly fixed their prices to show to the courts that their action was in public interest and to justify their wrong acts. Since they were not required to give any data under paragraph 8 of DPCO, 1995, any price fixed under paragraph 11 was not applicable to them. Even on this ground no price could be deemed to be fixed under this paragraph for Livogard Syrup.

(b) Powers to fix prices in public interest is laid down in Paragraph 10 of DPCO, 1995 in the manner laid down therein and such power cannot be invoked to justify fixation of fake prices. Company requested the reviewing authority to look into these aspects and pass an appropriate order as extension of public interest beyond what is

laid down in paragraph 10 is not permissible. Public wrongs cannot be covered under the guise of public interest.

(c) It is for the reviewing authority to see that its delegate acted in a fair and just manner and its action was not ultravires the provisions of DPCO, 1995. After protracted and long drawn process, NPPA vide its letter 20th Nov, 2012 stated that it fixed the price in the said notification on a suomottu basis in public interest as no body submitted application to it. If that was so then the notification should have stated so and referred to the relevant provisions of DPCO, 1995 which have authorized the delegate to do so. It is admitted that price fixed by it is not under Paragraph 9. It could not have taken law into its hands. It went on fixing fake prices and issued notices in a subjective manner as is clear from the website and the minutes of its meetings. The rule of law was thrown to the winds including in their case as it is not a case of price fixation but butchering. In view of this admission by NPPA, it is incumbent upon the reviewing authority to go into the entire gamut of NPPA functioning and if this cannot be done at least in their case this needs to be done as a part of review which includes review of all aspects.

(xiv) (a) Perusal of the notification would show that it has been issued as ceiling price notification for multivitamin Syrup under paragraph 9 and 11 of DPCO, 1995 with specific composition which is different from the composition of their product. Tenacity and its sustainability under the provisions of DPCO, 1995 has to be decided by the reviewing authority after disclosing all the facts.

(b) Paragraph 2(c) of DPCO, 1995 clearly lays down that ceiling price in order to be binding on the followers(SSI units) having same composition as of the leader(major manufacturer) is required to be notified in the official gazette under paragraph 9 only and in accordance with the procedure laid down therein. It has to be notified based on the cost or efficiency or both of the major manufacturer and the cost has necessarily to be in Form III of the Second Schedule as is clearly laid down on its top. A ceiling price notification in order to be valid cannot use any other paragraph of DPCO, 1995 and it cannot be suomottu and contrary to the provisions of paragraph 9. Whether use of Paragraph 9 in the notification when none of its provisions have been followed is justified needs to be decided by the reviewing authority.

(c) Paragraph 11 of DPCO, 1995 cannot be used in a notification required to be notified in the official Gazette fixing ceiling price of a commonly marketed standard composition and packs of a formulation and the circumstances under which it can be used are specified therein. Paragraph 11 is not applicable to SSI units at all. This makes the notification dated 5th June, 2008 as illegal. It cannot be used against small scale units as the price notified under this paragraph cannot apply to them. NPPA must disclose as to who defaulted in giving data to them, when it was called and for what product as these are the vital factors for fixing retail price on suomottu basis even under paragraph 11. What is the justification of this para in the notification needs to be decided by the reviewing authority.

(d) Certain proposals for price fixation/revision were placed before the Body of Experts when composition was not tallying and fresh prices were fixed/ notified for organized sector units and violation of the type being treated here in their case was ignored and no notices for price violations which were actually there were issued and certain cases similarly placed were decided by the NPPA officers of their own without any decision of the Body of Experts or referring the matter to this body ignoring the position taken in those cases resorting to dual/multiple interpretation of law. It has to be noted that it is only body of experts which has been given powers to fix/revise prices. To

this extent the extension of non extendable price to Livogard Syrup and raising demand based on such a price are not tenable. These are the aspects on which Ministry should take a view on all the cases involved, some of which have been highlighted by them in their earlier submissions to which attention of the reviewing authority is invited for passing a speaking order. Why were the provisions of DPCO, 1995 and Drug Policy, 1994 not followed in fixing prices of formulations consistently and these provisions were consciously ignored in pursuit of self interests by NPPA officers is an issue which merit attention by the Ministry , Law did not permit selectivity but then why was it resorted to.

(e) NPPA have vide its notification S.O. No. 2769 (E) dated 27/11/2008 fixed a higher price for a formulation at entry S. no. 2, a formulation which was already covered and price for which was already fixed under S.O. No. 1665(E) dated 27/09/2007 at S. no. 2 of the said notification read along with its amendment and Note 1 thereto. This shows that NPPA is stating is not correct and exercise of discretion was extreme. Similarly, vide S.No.14 of Notification S.O. No. 2041(E) dated 30th Nov, 2007 specific price was fixed even when the product was covered under S.O. No. 1665(E) dated 27th Sept, 2007 at S.No. 1 thereof to save the company by such suomottu action under paragraph 9 and 11 instead of issuing them notice for marketing without price approval/overcharging the price as the unit was in the organized sector. Several other instances are given in their submissions and are not repeated for the sake of brevity but they are referred to as such.

(f). Even the Supreme Court in the Cyanamid case has held as under:-

“The Hon’ble Supreme Court in Cyanamid case reported in (1987)2 SCC 756 has held that the Court has a jurisdiction to enquire into the question, in appropriate proceedings, whether relevant considerations have been gone into and irrelevant considerations kept out of the determination of price. Further, if the Legislature has decreed the pricing policy and prescribed the factors which should guide the determination of price, if necessary, the Court will enquire into the question whether the policy and the factors are present to the mind of the authorities specifying the price”

As already outlined above neither the policy nor the relevant factors have been gone into and doer cannot be the reviewer. Even paragraph 7.11 of the Delhi High Court judgment in the case of Glaxo provides as under:-

“7.11 Before we go into the merits of the plea of the appellants, it is noteworthy that the appellant has not challenged the validity of Note III----“

The Company, however, challenge the validity of Notes to the extent they are contrary to the provisions of DPCO, 1995.

(g) The price notified as alleged ceiling price is so low with reference to actual cost factors that no body can afford to sell the product. Reviewing authority must get all the details and share with the company as they were never disclosed to us. When NPPA is now talking of suomottu action and public interest surely they have fixed faked price exceeding their rights under delegation. Reviewing authority need to deeply look into all these aspects.

(xv) (a) Product for which ceiling price is fixed and the product of the manufacturer in respect of which issuance of notice is to be examined has to be same i.e. identical to the leader (ceiling pack) and conforming. Clearly the product of the petitioner is not

conforming. As such the first part of this paragraph is not applicable. Here there is no legitimately fixed price.

(b) Price charged must be higher than the notified price and there must be a payable difference. There is no fixed or notified price for their Product and the extended price as communicated does not fall under the class of prices approved under the DPCO for their product. The price which is sought to be extended is also ultravires as it cannot be called a ceiling price under Paragraph 9.

(c) Responsibility to pay the difference is of the manufacturers or distributors and in fact both based on the scheme envisaged in the DPCO where trade commission is on the MRP and does not accrue to the manufacturer and is an outflow out of MRP. Trade has also charged higher trade commission based on the MRP rather than the ceiling price allegedly sought to be enforced and this aspect cannot be ignored. Reviewing authority must look into in view of the decided cases as without prejudice to the applicability of the alleged notification the computations are also wrong.

(d) Paragraph 13 does not confer any right to review over what NPPA has done. This is against the principles of natural justice. Since doer cannot be the reviewer, it is quite natural that such a right should not be exercised by the NPPA. If they have been doing so they are misusing their powers and it is high time that reviewing authority should interfere.

(e) In Company's case, the company repeatedly highlighted that after April, 2009, they have been procuring nonscheduled formulation which is not under price control and said notification is not applicable but still liability was worked out till Dec, 2012 without any justifiable reasons. Company invited attention to para(d) of their letter dated 26th Sept, 2012 which is a part of the hearing, their letter dated 17th Dec, 2012, para 8 of their letter dated 7th May, 2013, NPPA letter dated 11th July, 2013 asking company to furnish a certificate from practicing Cost/Chartered Accountant and their letter dated 31st August, 2013 furnishing the certificate as desired. There was no communication thereafter from NPPA. Company received notice of recovery from the Collector dated 7th March, 2017 where much exaggerated demand was communicated without disclosing any details. This clearly shows that submissions of the aggrieved were totally ignored at the hands of NPPA. Further vide notification S.O. No. 637(E) dated 4th Sept, 1997 powers under paragraph 24 of DPCO, 1995 which includes power to make reference to the collector have not been delegated to NPPA. The exercise carried out by NPPA was vindictive, lacked transparency and against the letter and spirit of law. Company also enclosed copy of control sample of one of the batches after April, 2009 procured from outside to show composition which would also highlight that NPPA action was without any basis and the basis of demand was wrong and without application of mind. Company requested the reviewing authority to go into the entire gamut with an independent mind.

(xvi) NPPA has been acting in the said manner can be seen from their submissions which were not responded at any stage. Company pleaded that motivated action should not be taken against the company which is SSI and is already struggling for its survival but nobody listened and it is clear that everything was put to the dustbin and high ended action continued forcing them to approach the Court as is clear from the facts.

It is clear that there was no right to equality before the law at the hands of delegate and it acted in most subjective, motivated and partisan manner in their case both with regard to applicability and making reference to Collector in a partisan manner

even ignoring facts on record. Several cases are referred and several are not referred and even not pursued. Show me the man and I would show you the rule is what is followed and reviewing authority is requested to go into the entire gamut and satisfy itself.

4. Response of NPPA:

The exemption to SSI units from price control is not automatic. As per S.O. No. 134(E) dated 02.03.1995, SSI units are required to apply to the Government within sixty days from the date of notification in case of existing units and sixty days from commencement of production in case of new units for benefit available to SSI units and exemption is granted by Department of Pharmaceuticals (DOP) with respect to paragraph 8 of DPCO, 1995 only subject to fulfillment of certain conditions mentioned in S.O. No. 134(E) dated 02.03.1995. It does not cover ceiling price notified under paragraph 9 of DPCO, 1995. Further, the company could not produce any specific order vide which exemption was granted to the company by DOP from price control. Moreover, the price notified vide S.O. No. 1355 (E) dated 05.06.2008 was a ceiling price under paragraph 9 of the DPCO, 1995 in respect of which no exemption is available to a SSI unit. The press release dated 07.01.1995 as referred to by the company is relevant to a SSI unit till the time no ceiling price is fixed. Once ceiling price has been notified under paragraph 9 of DPCO, 1995, all SSI units are covered under the said notification.

The price of the formulations mentioned in S.O. No. 1355 (E) dated 05.06.2008 was fixed by NPPA on suo-motto basis in the public interest under para 9 and 11 of DPCO, 1995 as no manufacturers submitted any application in Form-III & IV to NPPA for fixation of the price. Para 11 of the DPCO, 1995 clearly states that where any manufacturer, importer of a bulk drug or formulation fails to submit the application for price fixation or revision, as the case, may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be. The main object of notifying the price as ceiling price was to restrict the manufacturers to charge a price for their product not exceeding the notified price and this was done in public interest to make the medicines available in the market at reasonable price only. It was obligatory for the company to comply with the ceiling price so issued and the company was also required to seek prior approval from Govt. / NPPA in terms of note (e) and (g) of the notification, if the composition of the product was different and follow the existing notified price until a separate price was fixed by Govt. / NPPA for the product, if considered necessary, based on Form- III / IV submitted by the company. However, the company has failed to do so and continued to sell the product at a price which was 2.5 times higher than the ceiling price.

The company has contended that the product shown in notification is multivitamin syrup whereas the formulation manufactured by company is used for liver ailment, it is clarified that applicability of price notification is determined with reference to composition of formulation. Therapeutic purpose for which formulation is used is not relevant here. The basic composition of said formulation containing use of scheduled bulk drug was identical to the composition shown in the price notification. Except the quantity of Riboflavine Phosphate Sodium, the composition of the product 'LIVOGARD 60mg was same with the composition indicated in the notification. The quantity of Riboflavine Phosphate Sodium shown in the notified composition was 2.5 mg as against 0.64 mg contained in the said product. This means that Riboflavine Phosphate Sodium used in the product was substantially lower than the quantity considered in the

notification and if the same was considered, the ceiling price would have been even lower than the price notified in S.O. No. 1355 (E) dated 05.06.2008.

The notification S.O. 1355(E) dated 05.06.2008 has been issued under paragraph 9 & 11 of DPCO, 1995. The Government vide notification SO 637(E) dated 04.09.1997 directed NPPA to exercise the functions of the Central Government in respect of paragraphs 3,4,5,7,8,9,10,11,13,14,15,16,17,18,19,20 and 21 of DPCO, 1995. Hence, the price notified under paragraph 9 and 11 of DPCO, 1995 was very much valid and enforceable in law.

Paragraph 9 of DPCO, 1995 provides for fixation of ceiling price for the scheduled formulations. Further, as clarified above the Government has directed NPPA to exercise the functions under paragraph 9.

Paragraph 11 of the DPCO, 1995 provides that:-

"Where any manufacturer, importer of a bulk drug or formulation falls to submit the application for price fixation or revision, as the case may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be."

Hence, the prices under paragraph 9 of DPCO, 1995 are fixed on the basis of available information in case manufacturer, importer of a bulk drug of formulation fails to submit the application for price fixation or revision.

Paragraph 9 of DPCO, 1995 empowers the government for fixing of ceiling price of the scheduled formulation and the price so notified is to be complied with by all the manufacturers of scheduled formulations including SSI units. The price fixed shall not be increased except with the prior price approval. Para 9 of DPCO, 1995 provides that

(1) "Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette, fix the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations."

As Form-III was not submitted by the manufacturers, the price was notified suo-moto based on available information as per the standard practice followed in NPPA. The manufacturer was required to either file a review application to the Department of Pharmaceuticals if they were not satisfied with the notified price or they should have filed price application to NPPA for their product giving details of various ingredients used if the composition was different. Under any circumstances, the company cannot be allowed to charge 2.5 times higher price from public. NPPA, therefore, did not commit any wrong by notifying the ceiling price suo- moto based on available information. This was done in public interest to prevent the menace of charging higher price by the pharma companies. The contention of the Company that S.O. No. 1355 (E) dated 05.06.2008 was contrary to the provisions of DPCO, 1995 is wrong, hence not acceptable.

As already clarified the notification SO 1355(E) dated 05.06.2008 was issued under paragraph 9 & 11 of DPCO, 1995 complying all the requirements. Hence the said

notification is valid and applicable to the formulation manufactured by the company.

Ceiling price for the formulation specified in notification SO 1355(E) dated 05.06.2008 was issued in compliance of all the requirement of DPCO, 1995. The ceiling price so notified was published in the official Gazette. The notes given in the notification are an integral part of the notification. It is clearly mentioned in part (e) of the notes to the notification SO No. 1355(E) dated 05.06.2008 that for different packing material used or any special feature claimed, companies are required to approach NPPA for approval / fixation of specific prices. The part (g) of the said note states that the companies shall be required to take the requisite prior approval from the Competent Authority for any change in the composition with written prior intimation to the NPPA. The validity of the Notes to price notification order has been upheld by various High Courts and the Hon'ble Supreme Court of India. The manufacturers and marketing companies are, therefore, required to take requisite prior price approval for any change / difference in the composition of the scheduled formulation and for having non-conforming pack. The company cannot be left free to charge exorbitant price from public just because the composition of the scheduled formulation was not fully covered in the existing notifications or the medicines were sold in a non-conforming pack etc.

Paragraph 8 of DPCO, 1995 provides for fixing of retail price of the formulation. Paragraph 8 prescribes that

"(2) Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilises such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-Ill for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation."

On the other hand paragraph 9 of the DPCO'1995 provides for fixing of ceiling price of scheduled formulation. Paragraph 9 prescribes that

"(1) Notwithstanding anything contained in this Order, the Government may, from time to time, by notification in the Official Gazette, fix the ceiling price of a Scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for *all such packs including those sold under generic* name and for every manufacturer of *such* formulations."

Hence both the paragraph 8 and 9 of DPCO, 1995 are different in nature and have different application and applicability. Contention of the company regarding non-fixation of prices under paragraph 8 of DPCO, 1995, is irrelevant in nature and not tenable.

In the absence of Form-III/IV not submitted by the manufacturers, the price was notified suo-moto based on available information and a lump sum amount was considered for excipients as per the standard practice followed in NPPA.

Price of the formulation was fixed on the basis of a complaint received regarding formulation manufactured / marketed by M/s Zuventus Healthcare Limited for selling of scheduled formulation 'Lornit Syrup' without price approval. On the basis of complaint the price of the formulation was fixed vide SO 1355(E) dated 05.06.2008. The ceiling price so fixed is also applicable on the formulation manufactured by Petitioner Company having similar composition. Moreover, as already mentioned above, the company never

filed review of the notified price under paragraph 22 of DPCO, 1995. Details of cost for the said notification are as below:

Material Cost (A)	Rs. 12.32
Conversion Cost (B)	Rs. 0.36
Packing Material Cost (C)	Rs. 2.31
Packing Cost (D)	Rs. 0.95
Total (A+B+C+D=E)	Rs. 15.94
100% MAPE (F)	Rs. 15.94
Ceiling Price Fixed (E+F)	Rs. 31.88

As already clarified paragraph 9(1) of the DPCO, 1995 also provides that the Government may fix the ceiling price of scheduled formulation in accordance with the formula laid down in paragraph 7, keeping in view the cost or efficiency, or both, of major manufacturers of such formulations. As the requisite information regarding cost and efficiency was not submitted by manufacturers of the formulation, powers of paragraph 11 of DPCO, 1995 was used and the ceiling price of the formulation was fixed as per information available. Further, as clarified above, the manufacturer was required to either file a review application to the Department of Pharmaceuticals if they were not satisfied with the notified price or they should have filed price application to NPPA for their product giving details of various ingredients used if the composition was different.

The company's contention that the product shown in notification is multivitamin syrup whereas the formulation manufactured by company is used for liver ailment, has already been clarified above.

Also as clarified above, the notes given in the notification are integral part of the notification. It is clearly mentioned in part (e) of the notes to the notification SO No. 1355(E) dated 05.06.2008 that for different packing material used or any special feature claimed, companies are required to approach NPPA for approval / fixation of specific prices. The part (g) of the said note states that the companies shall be required to take the requisite prior approval from the Competent Authority for any change in the composition with written prior intimation to the NPPA. The validity of the Notes to price notification order has been upheld by various High Courts and the Hon Tile Supreme Court of India.

The company contention's regarding non-applicability of paragraph 11 of DPCO, 1995 on SSI units is wrong and misconceived. Paragraph 11 provides for fixation of price when the manufacturer, importer of bulk drug or formulation falls to provide the requisite information for fixation of ceiling price. Hence the same is very much applicable all entities including SSI units.

Regarding the company allegation that there are many formulations from organized sector which are being sold at prices much higher than the ceiling prices for which no notice has been issued, it is clarified that NPPA initiates action for overcharging as and when price violation case comes to its notice based on the complaints received from State Drug Controllers with detailed information about the product like its composition, MRP, name of the manufacturer / marketing company, batch no. and manufacturing date etc. or samples randomly purchased from market. The company has not furnished any sample or photocopy of the carton / strips in

support of allegation which can prima- facie establish that the formulation mentioned in letter were sold at a price higher than the ceiling price notified by the Government.

The contents specified in S. No. 2 of notification SO 1665(E) dated 27.09.2007 issued for multivitamin capsules is altogether different from the one notified vide SO 2769(E) dated 27.11.2008 S. No. 2, as the notification issued later is for a more specific composition of a multivitamin formulation. Moreover, the said notification also provides for many different multivitamin formulation containing different ingredients.

The Hon'ble Supreme Court in case of Union of India vs Cynaide India Ltd (1987)2 SCC 720 observed at page 736 that

"*Profiteering*, *by itself, is evil. Profiteering in the scare resources of the community, much needed life sustaining food stuff and life-saving drugs is diabolic. It is a menace which had to be fettered and curbed. One of the principle objectives of the Essential Commodities Act, 1955 is precisely that. It must be remembered that Art. 39(b) enjoins a duty on the state towards securing that the ownership and control of the material resources of the community are so distributed as best to sub serve the common good'. The Essential Commodities Act is legislation towards that end".*

As clarified earlier the company could have applied for review of price notification as per provisions of DPCO, 1995.

However, the company never applied for review of price notification and has willfully violated the provisions of the DPCO, 1995 by not following the ceiling price notified in S O. 1355(E) dated 05.06.2008 and sold the product at exorbitantly higher price to the consumers to gain unjust profit. The company has also neither filed any price application in Form III if the composition of the product was substantially different from the existing ceiling price notification nor applied for review of the ceiling price notified in S.O. 1355(E) dated 05.06.2008.

As already clarified above, the ceiling price is very much applicable to the formulation manufactured by the company. The validity of notes to the notification has been upheld by Hon'ble Supreme Court and High Court.

Paragraph 13 of DPCO, 1995 stipulates that the Government shall require the manufacturers, importers or distributors to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government. The company has overcharged consumers in sale of scheduled formulation to earn unjust enrichment, which it is liable to deposit to the government with applicable interest under section 7A of the Essential Commodities Act, 1955.

Paragraph 19 of DPCO, 1995 provides only 16% margins for retailers. Further, no separate margin for wholesalers and distributors are provided in the DPCO, 1995. Moreover, 100% Maximum allowable post manufacturing expenses was provided in para 7 of DPCO, 1995 which include such margin and marketing expenses etc. Accordingly, the company contention regarding non-accrual of the amount to the company is not tenable and the company is required to deposit the overcharged amount alongwith interest thereon.

Paragraph 22 of DPCO, 1995 provides power to review against any notification or order issued under paragraph 3,5,8,9 & 10 of the DPCO, 1995. Review of demand notice for overcharged amount issued under paragraph 22 of DPCO, 1995 is not

admissible.

The company has submitted that they are marketing non- scheduled formulation after April, 2009 and contended that the same submission raised earlier has not been addressed. The company vide letter dated 17.12.2012 has submitted that they have discontinued the production and had dropped scheduled bulk drug after issuance of notification. However, no documentary evidence regarding the same was submitted by the company. The company was also directed to submit copy of surrendered drug license vide NPPA's letter dated 11.07.2013. However, the company neither submitted the copy of surrendered license nor copy of fresh license obtained for the new formulation from drug controlling authorities. Hence, the company submission was denied and not accepted.

Due to non-submission of CA certified quantitative data by the company, reliance is placed on the data available with NPPA and overcharged amount was calculated on the ORG-IMS data available. The company submitted CMA certified data from July, 2008 to April, 2009. In the certificate submitted neither name of the company whose production / sales records were verified nor name of the formulation was mentioned. Moreover, it was mentioned that the composition mentioned in the notification 1355(E) dated 05.06.2008 was produced and sold by the company, which is contradictory to the claim of the company that their formulation is different from the one notified.

The company contention is wrong, misconceived and not tenable. The company never submitted any documentary evidence overcharging by other companies. In reply of the allegations raised, the company vide NPPA's letter dated 20.11.2012 was also requested to provide necessary documents / copy of carton / strips in support of their allegation. However, the company never submitted any documentary evidence. Hence the contention raised by mere allegation and company cannot be accepted.

5. Examination:

(i) The matter essentially relates to the demand notice issued by NPPA for recovery of overcharged amount, in excess of the notified ceiling price of a combination of 3 APIs in a multivitamin Syrup formulation. The applicant moved the Rajasthan High Court, Jaipur vide W.P. no. 7198/2017 against the NPPA's demand notice and the Hon'ble High Court, vide its order dated 13th October, 2017 relegated the petitioner to file review petition under para 22 of the DPCO, 1995 within a period of two weeks.

(ii) NPPA notified the prices of a multivitamin syrup (each ml contains L-Ornithine-L-Asparate-250 mg, Nicotinamide-20mg and Riboflavine-5-Phosphate Sodium-2.5 mg) vide their order dated 5th June 2008. These prices were notified in line with the powers conferred vide sub-paragraphs (1) and (2) of para (9) and para (11) of the DPCO, 1995. The prices were fixed considering these formulations having standard pack and composition. NPPA fixed the prices of subject formulation, suo-moto in public interest, as no major manufacturer came forward and requested price approval, in-spite of the formulation under reference contain Scheduled bulk drug; namely Riboflavine.

(iii) The major issues raised by M/s Lark Laboratories (India) Ltd. are as follows:-

(a) Being a SSI unit, they were not mandated to approach the Government for price approval as per DPCO 1995.

(b) The said S.O. 1355 (E) dated 05/06/2008 was issued as per para 9 & 11 of the DPCO, 1995. The Company raised the issue regarding non-fixation of the prices under para 8 of DPCO, 1995.

(c) The formulation Livogard Syrup marketed by the applicant is not a multivitamin Scheduled formulation and the notified prices are not applicable to their product.

5.2 With regard to para 5(iii)(a) above, as per S.O. no. 134 (E) dated 02/03/1995 exemption is granted by Department of Pharmaceuticals (DOP) with respect to paragraph 8 of DPCO, 1995 only subject to fulfillment of certain conditions mentioned in S.O. No. 134(E) dated 02.03.1995. It is pertinent to mention that the registration as SSI unit with Directorate of Industries is entirely different from seeking exemption under the provisions of DPCO, 1995 because for the purpose of DPCO, any SSI company had to file a declaration to DoP to seek exemption. Only finding on such declaration proper, in view of para 25 of DPCO, 1995, the DoP was recognizing these companies fit for exemption, which was not done by the company / applicant in the present case. Exemption does not cover ceiling price notified under paragraph 9 of DPCO, 1995 and since the S.O. 1355(E) dated 05/06/2008 was issued under para 9 and 11, an SSI exemption cannot be extended to the company.

5.3 With regard to para 5(iii)(b) above, the price of the formulations mentioned in S.O. No. 1355 (E) dated 05.06.2008 was fixed by NPPA on suo-motto basis in the public interest under para 9 and 11 of DPCO, 1995 as no manufacturers submitted any application in Form-III & IV to NPPA for fixation of the price. Para 11 of the DPCO, 1995 clearly states that where any manufacturer, importer of a bulk drug or formulation fails to submit the application for price fixation or revision, as the case may be, or to furnish information as required under this Order, within the time specified therein, the Government may, on the basis of such information as may be available with it, by order fix a price in respect of such bulk drug or formulation as the case may be. Further, para 8 of DPCO, 1995 provides for fixing of retail price of the scheduled formulations. On the other hand, para 9 of DPCO, 1995 provides for fixing of ceiling price of scheduled formulations. Hence both the paragraphs 8 and 9 of DPCO, 1995 are different in nature and have different application and applicability. Contention of the company regarding non-fixation of prices under para 8 of DPCO, 1995 is not tenable.

5.4 With regard to para 5(iii)(c) above, the applicant is attempting to establish that their formulation Livogard 60 ml is not a multivitamin formulation. This contention is hardly palatable as the composition of both the formulations is same with 3 APIs. Even the quantities of two of the ingredients is same in both of the formulations.

5.5 In view of the above, the applicant was mandated to follow the NPPA fixed ceiling prices and none of the manufacturers including the applicant, had approached the Government for review of the ceiling prices notified by the NPPA on 5th June 2008. As such the review application is devoid of any plausible substance and deserves to be rejected. The request of the company for stay on overcharging amount also does not have any merit and liable to be rejected.

6. Decision:

"The issues raised in the review application dated 31.10.2017 are devoid of merits and without any plausible substance and application stands dismissed. The

applicant is mandated to follow the ceiling price of formulation “Livogard Syrup” fixed by NPPA vide S.O. No. 1355(E) dated 05.06.2008.”

“Further, the request of the company for stay on overcharging amount does not have any merit and is rejected.”

Issued on this date of 4th day of September, 2018.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. M/s. Lark Laboratories (India) Limited, Lark House, A-105/2, Okhla Industrial Area, Phase - II, New Delhi-110020.
2. The Member Secretary, National Pharmaceutical Pricing Authority, 3rd & 5th floor, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi-110001.

3. PS to Hon’ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to Hon’ble MoS (C& F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department’s Website.