INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

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Dr. V.K. Subburaj, IAS
Secretary to the Government of India,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizer,
Shastri Bhawan, New Delhi 110001.

Dear Sir,

SUB.: Settlement of old DPEA matters.

Background:

As you may be aware that based on the recommendations of the Hathi Committee, which envisaged selectivity in price control, the Central Government had announced the new Drug Policy on 29.03.1978 and based on which "Drugs (Prices Control) Order, 1979" (hereinafter referred to as DPCO 1979) was issued on 31.03.1979.

DPCO 1979 superseded DPCO 1970, which was then in operation and covered almost all drugs. DPCO 1979 itself was repealed and superseded by DPCO 1987, effective from 26.08.1987 based on Drug Policy 1986.

Under Drug Policy 1978, the formulations to be controlled were listed in Category I, II, III and those which were to be price decontrolled were listed in Category IV, under Annexure II.

Under DPCO 1979, there were 347 bulk drugs and its formulations were subjected to price control and were listed in FIRST or SECOND Schedule.

The concept of Drug Price Equalization Account (DPEA) was introduced under DPCO 1979 under paragraph 17. Basically the concept of DPEA was introduced to encourage production of bulk drugs indigenously and make the Industry self sufficient. At the time of promulgation of DPCO 1979 most of the bulk drugs were imported. Some of the bulk drugs were also being manufactured from intermediate stages/ basic stage besides being imported and for such cases price fixation of bulk drugs was dependent upon cost of production/ import of such bulk drugs. Therefore, the concept of pooled price/ retention price/ common selling price was introduced, in order to encourage domestic production in the country with ultimate objective to become self sufficient in drug production in the country.

Therefore, under Paragraph 6, for indigenously manufactured drugs the concept of common selling price and retention price was introduced and under paragraph 7(1) the concept of pooled price and retention price was introduced in cases of bulk drugs both indigenously manufactured as well as imported.

Whenever the manufacturer sold his bulk drug at pooled price or at common selling price, as the case maybe, and such pooled price/ common selling price being higher than his retention price, he was required to deposit the excess amount earned in DPEA under paragraph 17(1) (a) (ii). Incase his retention price was higher than the pooled price/ common selling price then the loss suffered by him was to be reimbursed through DPEA under Paragraph 17 (2) (a).

Also the concept of DPEA was developed to recover from the manufacturer the excess amount earned by him, whenever he procured such bulk drug at a lower price than the one allowed to him in his formulation, under paragraph 7(2).

The concept of DPEA was abolished under DPCO 1987, as per Drug Policy 1986, as it resulted into intractable administrative problems.

Sometime after repeal of DPCO 1979, the Government issued notices of recovery under paragraph 7(1) and 7(2) of DPCO 1979 read with paragraph 14 of DPCO 1987 to several manufacturers and most of which were challenged in the Court of Law and are still pending decisions.

Sir, the DPEA cases under DPCO 1979 are more than 27 years old, from the date of repeal of DPCO 1979 and 35 years from the date of promulgation of DPCO 1979.

The various issues, anomalies, mentioned below, resulted into so many litigations and consequential precious loss of time and money of both the Government and the industry, with no positive outcome so far.

The vexing issues, referred above, are as follows:

1. The "Allowed Price" of the bulk drug, as referred to under paragraph 7(2), were not informed to the concerned manufacturer.

2. While fixing price of the formulations, in quite a few cases, the price notified by the Government for the respective bulk drug was not taken into consideration. Such details are not shared with the industry.

3. For the purpose of determining the DPEA claim the entire period should be considered and not invoice wise. When any bulk drug was procured at a price lower than the allowed price DPEA liability is fixed but no consideration or adjustment have been given when the bulk drug is procured at a price higher than the price allowed. This has been one of the biggest anomaly in interpretation of DPEA provisions which is totally one sided.

4. Provisions of paragraph 10 and 11 of DPCO 1979, which are the backbone of price fixation, were also not followed by the Government in many cases.

   The practice of allowing only 60% markup under DPCO 1979 was introduced under paragraph 11 without any official announcement, in select cases of price fixation.

   Also it was observed that the mark up and incidental charges were adopted arbitrarily and selectively while fixing the price of the formulations.

5. The packaging material (PM) norms, which is one of the key ingredient in price fixation of formulations under paragraph 10 of DPCO 1979, were never notified during the operative period of DPCO 1979.

6. The conversion cost (CC) and packaging cost (PC) norms were to be revised from time to time under paragraph 10 of DPCO 1979. However, such CC/PC norms were not revised from time to time by the Government.

7. Details of price calculations fixing the price of the formulations were also not provided to the manufacturers despite the specific requests of the manufacturers.

8. No set-offs are allowed for supplies to Government, Hospitals and Institutions against Tenders, at price lower than the price fixed by the Government and thus passing on the benefit of lower price to the Government.

9. Whenever the manufacturer procured the scheduled bulk drugs at a price higher than the one fixed by the Government, the Government did not revise the price of the corresponding formulations despite of filing of price revision applications by the concerned manufacturers nor the excess price paid for the bulk drug was adjusted while calculating the DPEA liability.

10. When Government revised the price of bulk drugs, it took inordinate long time to revise the price of its formulations. Such resultant loss to the manufacturer was also not considered and adjusted while fixing the liability.

11. The voluntary price reductions by the manufacturers, below the price fixed by the Government, benefiting the consumers, were also not considered while fixing the DPEA liability.

12. There has been opaqueness in terms of overages/ excipients allowed in the formulations.

13. In most of the cases no action was initiated during the operative period of DPCO 1979 and the liability was fixed and demanded only after repeal of DPCO 1979.

The DPEA liability cases pertain to the period 1.4.1979 to 25.8.1987 and are thus, very old. It is understood that as per existing accounting procedures, the companies are required to maintain records for a period of 15 years only. It is, therefore, doubtful whether the companies would now be having records for this old period.

It is submitted that in most of the cases where liability has been determined by the Department and communicated to the companies under Paragraph 7(1) and 7(2), read with Paragraph 17 of DPCO 1979, are being disputed by industry and these are under litigation in various Courts in the country. The main reasons for such pendency and litigation are specified above.

Considering the prolonged litigations, and the Government's stake in DPEA under DPCO 1979 being very large, the Government in their Drug Policy drafted in 2006 proposed that it would be worthwhile to announce a onetime settlement scheme and efforts may be made by the Govt. to settle these complicated cases through a **One-Time Settlement scheme.**

In view of the position explained and detailed above, we in IDMA are of the considered view that there is an urgent need to review the matter and adopt a more practical and realistic approach for settlement, to end the protracted and costly litigations, in a reasonable and fair manner. It would, only be fair and desirable to announce a **onetime settlement scheme for all DPEA cases under DPCO 1979.**

We, request you sir, to look into the matter of DPEA liability afresh and announce a onetime settlement scheme (with grant of suitable installments) to settle these complicated cases once and for all.

Sir, in case if any further clarification is required we shall be pleased to provide the same.

Thanking you,

Yours sincerely,

S.V. Veerramani
President