

Indian Pharmaceutical Alliance

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10 July 2014

By Email/Fax/Courier

Ms Aradhana Johri
Secretary
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Shastri Bhawan, Room No. 218-A
New Delhi 110 001

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Dear Ms Johri,

Implementation of National Pharmaceutical Pricing Policy (NPPP) 2012

We refer to our letter of 29 January 2014 to the then Prime Minister inviting his kind attention to issues arising from the arbitrary implementation of the NPPP 2012 (Annex-1).

2. The resolution of issues raised in the said letter is still pending. In the meantime, the National Pharmaceutical Pricing Authority (NPPA) has unilaterally decided to extend price control to products outside the National List of Essential Medicines (NLEM 2011), i.e. non-schedule products.

3. This would not only enlarge the span of control hurting the industry, but the arbitrary method of price fixation of non-schedule products could also jeopardize their availability to the patients.

4. We, the IPA, which contributes 43% of total sales of NLEM products, are very disturbed by the unilateral action of the NPPA in disregard of the Drugs (Prices Control) Order, 2013 and the NPPP 2012.

5. We understand that the NPPA has invoked Para 19 of the Drugs (Prices Control) Order to fix prices of some non-scheduled formulations. The Para 19 reads as under:

“Fixation of ceiling price of a drug under certain circumstances – Notwithstanding anything contained in this order the Government may, *in case of extra-ordinary circumstances*, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.” (emphasis ended)

These powers, even if delegated to the NPPA, are to be exercised “*in case of extra-ordinary circumstances*”. We do not find that such extra-ordinary circumstances have risen since the promulgation of the DPCO 2013 to warrant their use. Moreover, these powers can be used only for price fixation within the framework, structure and methodology of price fixation laid down in the NPPP 2012 and the DPCO 2013. The pricing regulator has erred by framing a new method of price fixation.

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6. It is obvious that the DPCO 2013 flows from NPPP 2012. Hence Para 4(xii) of the NPPP 2012 overrides Para 19 of the DPCO 2013. Para 4(xii) states that:

“Non-price Control Drugs:.....In the proposed policy, all essential drugs are under price control. *It would follow that non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces.* However, in order to keep a check on overall drug prices, it is proposed that prices of such drugs be monitored on regular basis, and where such price increase at a rate of above 10% per annum is observed, the Government would be empowered to have the price of these drugs reduced to below this limit, for next 12 months” (emphasis added).

We therefore submit that the price fixation of non-scheduled formulations is without due authorization under the NPPP 2012 and the DPCO 2013 and should be stayed forthwith until this issue is thoroughly examined. The Government may also like to examine its impact on the investment and growth of pharmaceutical industry and availability of medicines.

7. At a time when the country is moving towards *universal healthcare* the industry would be required to increase production and improve availability of essential medicines. However, measures such as extension of price control beyond NPPP 2012 would, instead of promoting investment, could become a hindrance to new investment in the manufacturing and retard employment generation. We therefore seek your intervention for appropriate action to restore confidence of the industry in the faithful implementation of NPPP 2012.

Thanking you and with kind regards,

Yours sincerely,
For Indian Pharmaceutical Alliance


D G Shah
Secretary General

Encl: a/a

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29 January 2014

Dr Manmohan Singh
Hon'ble Prime Minister of India
South Block, Raisina Hill
New Delhi 110 011

Dear Sir,

Implementation of the National Pharmaceutical Pricing Policy (NPPP), 2012

We wish to bring to your kind attention that all sections of the pharmaceutical industry are deeply frustrated at the way the NPPP 2012 is being implemented. We were expecting that the Policy will usher in a new regime of mutual trust and progress. Instead, it has led to trust deficit between the industry and the Government.

2. The specific issues that hurt the industry most are listed below:


- (a) There was clear understanding that both high and low price brands with negligible volumes being an *Unrepresentative Benchmark* would be excluded from the Ceiling Price Calculation. However, inclusion of brands with negligible sales has led to deeper price cuts.
- (b) Likewise, inclusion of "generic versions" in Ceiling Price Calculation has resulted in expanding the Span of Control. Moreover, as "generics" are priced lower, the Simple Average Price is pulled down further making price cuts deeper.
- (c) The GoM had decided to restrict the price control to dosages and strengths as specified in NLEM 2011. However, inclusion of non-specified Novel Drug Delivery System (NDDS) products under price control has not only enlarged the span of control but is also a disincentive to innovation.
- (d) The boycott of NLEM products and selective boycott of companies by the Trade for inadequate margin is hurting the patients as the supply of essential medicines is affected. All efforts by the Government to discipline the trade have not succeeded as small chemists are unable to absorb the loss of margin. The stand-off between the Government and the Trade has left the industry in a limbo.

As the implementation is at variance with the Policy approved by the GoM and the Union Cabinet, we seek your intervention for appropriate corrections in the DPCO 2013 – the instrument for implementing the Policy.

Thanking you and with kind regards,

Yours sincerely,

For Indian Pharmaceutical Alliance


D G Shah

Secretary General