



# INDIAN DRUG MANUFACTURERS' ASSOCIATION

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## INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

30 December 2014

The Chairman,

National Pharmaceutical Pricing Authority,

Department of Pharmaceuticals,

Jai Singh Road,

New Delhi- 110001

दिनांक 31/12/2014  
प्राप्ति  
प्राप्ति और निर्गमन

**Subject: Request for extension of time limit for Online Registration on Integrated Pharmaceutical Database Management System (IPDMS)**

Dear sir,

This is with regards to the Online Registration (IPDMS) of our Members on the NPPA website. You have kindly extended the date of submission to 31 December 2014.

However, as informed earlier in our representation dated 10 October 2014 and in our subsequent meeting with you on 28 October 2014 and also our subsequent interactions, we understand from our Members that many of the concerns are yet to be addressed and resolved as below:

- There is no provision to distinguish between the primary composition and secondary / tertiary composition.
- In case of missed items / products, there is no provision to make changes to the submitted data and the company has to resubmit the entire data.
- The data, currently available with companies, is generally in either excel or text formats making collation and submission to IPDMS a cumbersome process.
- Sometimes a Company sources a particular product from multiple location/s. Which one should be entered? The sourcing can change and in such an event there is no provision to edit the data.
- We are unable to comprehend the relevance of seeking information such as Production Capacity, Capacity unit, Content Size and Content Unit as the same are not at all a part of any of the subsisting forms mandated under DPCO like Form II, Form V etc. In many cases the manufacturing capacity is not dedicated to a particular product and thus it is not possible to determine the production capacity.

Rec'd  
31/12

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- In case a contract manufacturer gets a particular product manufactured from a Loan Licensee, then whose address needs to be filled?
- Does the manufacturer need to give details of products which are manufactured by them or also details of products which are marketed by them but manufactured by third party vendors? Collecting this data from both manufactures and marketers will amount to duplication of data.

Since this Online Registration involves numerous as well as vast fields to be entered, to ensure accuracy as well as breadth of data to be keyed in, the Industry is of the view that there should be an option/provision for providing the worksheet in word or excel format online or offline to enable smoother and effective information.

With respect to incorporating any/every change online, the process currently envisaged is only by keying in every such change. This process is simply too cumbersome. Hence we request that a facility of attaching a word / excel file for every change in status may be allowed to easier facilitation of updating the information.

You had responded to some of our concerns in our meeting on 28<sup>th</sup> October 2014 and in our subsequent meetings as below:

1. **Production Capacity Details:** Would be made optional. Only the corporate Address will be sufficient and there will be no need for giving separate production details of various plants of the same company. It will be adequate to give the entire data under the corporate/single address of the company.
2. **Modifications:** Provision will be made for modifications and reasons for change will have to be given. Then the administrator will do the modification as requested.
3. **Change of Format to Excel**

Subsequently, IT experts from the industry had interacted with the IT team of NPPA on 11<sup>th</sup> December 2014 to sort out operational problems. At the said meeting it was decided that industry will upload dummy data and also provide NPPA IT team with steps to accept the data into their system within 10 days. The industry submitted the dummy data on 23<sup>rd</sup> December to NPPA. NPPA has not responded till date.

Additionally, we are also informed by some of our SME members, who do not have large range of products, that even though they have entered all data online on NPPA web site, the same is not getting saved on NPPA web site. NPPA needs to look into the said issues also.

We have also not received any minutes or notices from NPPA about the various revisions as above.

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Our Members have also informed us that their queries/ concerns raised directly with your office have also not been responded to till date. Hence they have had problems submitting the data online as required.

Looking at the concerns and difficulties as above that are yet unresolved, we request you to extend the time limit further by at least three months to 31<sup>st</sup> March 2015.

We look forward to your positive response.

Thanking you,

Yours sincerely,

A handwritten signature in black ink, appearing to read 'S. V. Veerramani', with a stylized flourish at the end.

S. V. Veerramani  
President