File No. 20(5)/2022/IPDMS/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

3rd and 5th Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi - 110001

Dated: November 2022

OFFICE MEMORANDUM

Subject: Action taken and comments on the suggestions given by the stake holders on IPDMS Ver 2- Reg

A meeting with stakeholders was held on 13th October 2022 to discuss the implementation of IPDMS 2.0 and solicit further feedback on operational issues of the portal, if any.

2. The suggestions/feedback received from the stakeholders have been examined and action taken/ comments of NPPA on the suggestions received is attached as Annexure-1

Encl: As above.

14/11/22

(Rajesh Kumar T)
Deputy Director
011-23746794

Annexure - List of suggestions and comments of NPPA				
S. No.	IPDMS 2.0 Page	Issue	Comment/Suggestion	Comment(s) of NPPA
1	Company Registration	Requirement of CIN document	For companies having Certificate of Incorporation prior to 2006, CIN is not mentioned in the document. An alternative can be uploading screenshot of MCA website	The company can upload Certificate of Incorporation and extract from MCA website in single PDF
2	Login page	Login needs to be repeated multiple times	Single sign on login can be implemented to avoid such issues	Idle session time has been extended up to 1 Hour.
3	Company Registration	Alternate Contact cannot be CEO / CFO / Director	IPDMS and NPPA compliance are usually managed by either Market Access or Pricing or Finance or Corporate Affairs. Kindly allow managers to be alternate contact for company	The company may give primary contact details of any employee. However, secondary contact details are required from the senior management.
4	Company Registration	Alternate Contact PAN may not be available	Currently, while the text is DIN/PAN, Alphanumeric data is compulsory for input. Hence, the input should not be alphanumeric to allow for DIN.	Issue resolved.
5	Plant Source Details	Plant location is incorrect for migrated plant details	There are several issues in the address, name, state, pin code and district of plant source migrated from IPDMS 1.0. Kindly allow us to edit the same. Further, even after making appropriate changes, the state or district is still incorrectly displayed.	Facility has been provided to edit the Plant data.
6	Plant Source Details	Plant details cannot be edited	Companies should be allowed to change and edit plant source details	Facility has been provided to edit the Plant data.
7	Plant Source Details	Plant email id and office phone nos	This detail is not available, especially for imported products. These fields should not be kept as compulsory and should be made optional.	For Imported products - local importer details may be given
8	Plant Source Details	Plant verification takes too long and individual product verification is time	Plant verification has taken upto 3 weeks and this time must be reduced to allow smooth implementation	Plant verification approval will be removed. Under Process.

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9	Plant Source Details	Radio buttons are not consistent	For different selections, the radio buttons move from left to right and consistency is missing in the same. It is recommended that radio buttons are either placed one below the other or on the left	Issue resolved.
10	Product Details	Drug License to be uploaded for each formulation	Drug license is usually issued for the plant and has multiple formulations in serial number. We may upload plant manufacturing license in product source details but Drug license for each formulation is excessive due to quantum and uploading time	Issue resolved. Drug License upload is made optional.
11	Product Details	Production Capacity cannot be calculated for individual products	Most plants are multi-product manufacturing units wherein production capacity is not available for individual products. It is suggested in the meeting that an approximate value by indicated, thus, kindly remove the disclosure "*The information is true to the best of my knowledge" at the end of the product registration or keep production capacity as optional. Alternatively, production capacity may be shared in the product source details.	The label has been changed to "indicative Production Capacity"
12	Product Details	Pack Size is a drop down without "Others" as an option	For innovative medicines or differentiated dosages, the pack size not be available in the drop down list. Thus, an option of text input in "Others" should be made available.	The pack size column is a text input column. There is no drop down in it.
13	Product Details	Strength of API is a drop down and not text input	The strength of many non-scheduled formulations are not available in the drop down as provided. It is suggested that the input by made a text field instead of a drop down.	Impact analysis is under process. However, it is requested that possible strengths missing in the drop down given in IPDMS may be shared and the same shall be added in the drop down.

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14	Product Details	Product Name is not visible inspite of registration in IPDMS 1.0	For many formulations, Product Name is not available in the drop down list after migration, it is suggested that this field be made a text input instead of drop down. This will also be useful for new brands which may be launched in future course of business	User needs to select product from the drop down. If the product is not available in the drop down, then user can select other option and provide product name in the input field provided adjacent to the product drop down.
15	Product Details	Brand Name is not always available and is not needed under Schedule 2 of DPCO 2013	The field of brand name is repetitive after product name details have already been added. This field is not required under Schedule 2 of DPCO 2013 and should be either removed or made optional	User needs to select product from the drop down. If the product is available in the drop down, then user can select any of the product and brand name gets auto populated. If the product is not available in the drop down, then user can select other option and provide product name in the input field provided adjacent to the product drop down, in this case brand name is not required to be filled.
16	Product Details	Product launch date is not available for legacy products	Certain products of our members were launched prior to 1990 and details of formulations launch date are difficult. Companies may be able to provide details as before May 2013 or thereafter to aid NPPA in reviewing new product launches	If the product is launched before 2013, year to be captured. For products launched after 2013, entire date is to be captured. (Under process for updation)
17	Product Details	Product composition details are pre-filled for migrated products	For Certain migrated products, the product composition details are not prefilled and it takes as much if not more time for validating the same	Composition gets auto populated on selection of product name, as per the data available in the IPDMS version 1. If composition is not getting auto populated then user needs to select the composition from the drop down list.
18	Product Details	Product Type does not included option for "Patented" products	In addition to Scheduled, Non-Scheduled, New Drugs, Bulk drugs, and others, the erstwhile IPDMS had the option to register Patented formulations. This option needs to be added to Product Type to	Issue resolved

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			enable registration	
19	Product Details	Dosage types does not include injections alternatives	Injections are available as lipid, lyo, liquid, PFS (stacked and unstacked), cartridges, etc. Further, we cannot predict the various new age dosage types. Thus, dosage type should be a text input in addition to drop down.	Impact analysis is under process. However, it is requested that possible dosage types missing in the drop down given in IPDMS may be shared and the same shall be added in the drop down.
20	Product Details	Pack Size Unit is a drop down instead of a text input	Pack size unit may be varying and many inputs are not available in the drop down provided. Hence, NPPA must considering changing drop down to input text	Impact analysis is under process. However, it is requested that possible pack size units missing in the drop down given in IPDMS may be shared and the same shall be added in the drop down.
21	Product Details	Drug name is a drop down and not an exhaustive list.	Drug name in composition details are not exhaustive and many non-scheduled APIs are missing in the drop down. Further, text input will allow for new derivatives and analoges to be added.	Impact analysis is under process. However, it is requested that possible Bulk drugs/API names missing in the drop down given in IPDMS may be shared and the same shall be added in the drop down.
22	Product Details	Selection of drug strength is extremely time consuming and most options are not available	Drug strength was text input in IPDMS 1.0. The same practice must be continued.	Impact analysis is under process. However, it is requested that possible drug strengths missing in the drop down given in IPDMS may be shared and the same shall be added in the drop down.
23	Form I	Selection of one therapy may be misleading	Certain formulations have multiple indications and selection of one therapy may be misleading. A text input may be recommend for this data.	Issue resolved. Multiple selection of therapy is allowed

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24	Form I	Other documents have been marked as compulsory	Documents beyond the declarations and licenses as mentioned in Ecosystem for form 1 application cannot be compulsory. Kindly remove the red asterisks and make the field optional	Issue resolved. The fields are made optional.
25	Form II	Effective Batch number is not known in April and should be optional	Effective batch number is not a field mentioned in Form 2 as per schedule 2 of DPCO 2013 and further, companies do not know the effective batch number in the month of April when WPI impact is shared to NPPA. In case of imported formulations, the usual timeline for revision of MRP is between 4 to 8 months. Thus, effective Batch number should be an optional field.	Effective Batch no. and date are prerequisites of notified Form II and continue to be compulsory.
26	Form II/V	Purchased From' should be a drop down field	Many marketing companies frequently change the manufacturers and also have multiple manufacturers for the same formulation. Thus, the 'Purchased from' field should be a drop down or text input and not a pre-filled data.	Issue is under examination. However, the forms can be filled for multiple products in one go using excel feature.
27	Form III	Input requirements in Para 21 and Schedule 2 are quarterly whereas data is requested on monthly basis	IPDMS 1.0 was following the correct format of Form 3 data requirements, it is suggested that the format is commensurate with Schedule 2 of DPCO 2013	Under process and shall be implemented shortly.
28	Form IV	DG permission number may be multiple and may not be applicable in case of third party purchased formulations	When a marketing company files form 4 and intends to discontinue a formulation, the DG permission number may not be relevant as the manufacturer can continue producing the formulation for other marketing companies. Thus, this field should be either made optional or removed since it is not required as per Schedule 2 of DPCO 2013	The discontinuation Process under Form IV is to be followed even by the marketing companies. CDSCO/SDC permission details are required as per notified Form IV.

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29	Form IV	Requirement to upload newspaper advertisement	Uploading a newspaper advertisement for discontinuation of a formulation without approval from the Authority committee may increase the burden on companies to issue two notices since NPPA reserves the right to ask manufacturers to continue production beyond the intended date of discontinuation. This discrepancy between the Ecosystem of August 2020 and form 4 in IPDMS 2.0 must be resolved.	As per para 21 (2), public notice is to be given by the manufacturer for discontinuation and the same is to be intimated to the Govt. along-with Form-IV. Hence, Public notice continues to be a compulsory document.
30	Form V	Product type should be selected before the Form	In IPDMS 1.0, companies were able to select the product type namely Scheduled / Non-Scheduled / Patented / New Drugs / Para 19 prior to selection of form V. Kindly revise the format of Form V to reflect the same.	The user can submit the data of any category of product at once unlike in IPDMS Ver 1. The product type gets automatically fetched on selection of product name.
31	Form V	PTS is not defined in DPCO 2013 and varies from one supply chain to another	Price to Stockist is neither defined in DPCO 2013 nor is it consistent from one period or supply chain to another. Thus, PTS should be removed from form V submissions.	As per DPCO, 2013, PTS is required in Form V.
32	Form V	Manufacturer details may be indicative and not exhaustive	Marketing companies manufacture the same formulation in multiple product sources and thus, manufacturer names should be considered as indicative and not exhaustive. Companies further submit that MRP should be tracked against the product name and pack size rather than manufacturer in case of multiple product sources.	The manufacturer companies have been added as plants by marketing companies and such companies have chance to change the plant details further.
33	All forms	Copy - Paste	Copy Paste should be allowed in the application.	Due to security concerned copy paste option can not be given at present. However, it will be examined further.
34	All forms	IPDMS web forms	All the IPDMS web forms should be strictly as per DPCO.	All forms are designed based on the notified forms only

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35	All forms	Migrated data	It has been told that Migrated data is not clean.	The process of verification of existing data is prerequisite for using IPDMS 2.0 web forms. While verification of the same, the companies may update/correct the data
36	Old forms	Visibility of old forms	IPDMS version 1 - Previous forms should be made visible in the new version.	Under process and shall be implemented shortly.
37	Product details	Product verification	Multiple product verification facility is requested in one go.	Under examination
38	Pricing	Market data collection	Use of NPPA to collect market-based data using IPDMS for pricing decisions instead from third party data	Policy decision will be considered in due course.
39	Revision of Forms	All forms	Give facility to edit/ revise submitted forms	Under examination
40	All forms	Physical submission of forms	Whether the company is supposed to take the print out of the submitted form and submit the signed document through post/email?	Not required