F.No. 20 (08)/17/2020/Div.III/NPPA
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India
Ph: 23746642 Fax: 23746652

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

Dated: 26.08.2020

OFFICE MEMORANDUM

Subject: Development and Implementation of Eco System for timely disposal and monitoring of various applications filed with NPPA - reg.

NPPA envisages a fully automated Eco System for timely attending to, disposing of and monitoring of applications filed under various provisions of DPCO, 2013 to promote the Ease of Doing Business for 'Atmanirbhar Bharat'. While the same is under process, it has been decided to switch to an online time-bound system for addressing applications received under various provisions of DPCO, 2013 from Pharmaceutical Companies.

Accordingly, following procedure has been established and adopted:

2. **Submission of Form-I (Application for the pricing of New Drug):** The applicant companies can submit application with all requisite documents (checklist in **Annexure-I**) on email ID: pricing-nppa@gov.in. Further,

a) Confirmation of the receipt of application along with acknowledgement number would be provided via return e-mail.
b) Incomplete application without the requisite documents would be returned and the same shall be informed to the applicant via email.
c) Applicant can check the status of their pending applications on the NPPA website, which would be updated fortnightly.

3. **Submission of Form-II (Revised-Prices for Scheduled Formulations); Form-III (Quarterly Return in Respect of Production/Import and Sale of NLEM Drugs) and Form-V (Price List):** Presently, Form-II, Form-III and Form-V are submitted by pharmaceutical companies on Integrated Pharmaceutical Database Management System (IPDMS). The same procedure shall continue to be applicable and Pharmaceutical companies shall submit these Forms on IPDMS within the prescribed time lines.

4. **Submission of Form-IV (Discontinuation of Scheduled Formulation):** The applicant companies can submit Form-IV i.e. application for the discontinuation of the production of scheduled formulation with all requisite documents on email ID: monitoring-nppa@gov.in. Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return e-mail. Applicant can check the status of their pending applications on the NPPA website that would be updated on a monthly basis.

5. **Applications for Special price for packaging under paragraph 11(3) of DPCO, 2013:** Application can be submitted on email ID: pricing-nppa@gov.in. Further,

a) Confirmation of the receipt of the application with acknowledgement number would be provided via return e-mail.
b) Incomplete application without requisite documents would be returned and the same shall be informed to the applicant via email.
c) Applicant can check the status of their pending applications on the NPPA website fortnightly.

6. **Holding of Authority meeting:** The Authority meeting would be held preferably held every month. If due to certain circumstances the same could not be held in a particular month, the Authority meeting would be held in subsequent months as per requirement.

7. **Meeting of the Multidisciplinary Committee of Experts:** The meeting of the Multidisciplinary Committee of Experts, if required, would be held prior to the Authority meeting.

8. **Uniform Code of Pharmaceutical Marketing Practices (UCPMP):** UCPMP is a voluntary code of marketing practices for Indian Pharmaceutical Industry. It is to be effectively implemented by the Pharma associations and companies. Accordingly, all Indian Pharmaceutical Manufacturer Associations shall upload UCPMP on their website including the detailed procedure mentioned in the paragraph 10 of the UCPMP regarding lodging of complaints. All the associations shall provide on their website for uploading of complaint, the nature of complaint, details of the company against whom complaint is made, action taken by the committee under the association on such complaints including the current status of the complaint. All such details should be maintained for the period of three years on their website. A quarterly report mentioning details of the complaint received and decision taken thereon shall be submitted by the concerned association to NPPA within 30 days of the end of the quarter via email on email ID: monitoring-nppa@gov.in.

9. **Helpdesk:** A helpdesk for dealing with the problems of applicants while submitting their applications has been set up. Applicants facing any documentary or technical issue in submitting their applications can email or contact helpdesk between 10 AM to 6 PM (excluding holidays). Helpdesk numbers and email ID are given at **Annexure II**.

10. Prescribed timelines for submission of application and disposal of the applications is given at Annexure-II.

11. This is approved by the Competent Authority.

Encl: Annexure-I and Annexure-II

26/08/20

(S. S. Ojha)
Director (Pricing)

Annexure - I

Checklist for filing application for a New Drug pricing

1. Company has to submit the duly filled Form-I prescribed in Schedule-II of DPCO, 2013.
2. Approval for new drug formulation granted by the DCG (I).
3. Currently valid manufacturing permission by State Licensing Authority.
4. Agreement /contract between manufacturer and marketer OR Joint undertaking by manufacturing and marketing company with respect to the new drug.
5. Declaration that new drug formulation is not prohibited by DCGI/MoH&FW.
6. Declaration regarding non-discontinuation/non-reduction in production of scheduled formulation under NLEM, 2015, which has been combined with the new drug or if the strength is proposed to be changed.
7. CA/CMA certified quarterly production, sales for last six quarters in respect of the schedule component of the new drugs.
8. Drug category of the new drug (a, b, c, d, etc.) as per Kokate Committee report for FDC's.
9. Status of the new drug as per Drug Technical Advisory Board.

Note: Form-I and all enclosures should be duly stamped and signed by Authorized Signatory

Annexure – II

The Drugs (Price Control) Order, 2013 (prescribed timelines for disposal of applications received)

S. No.	Form No.	Purpose	Prescribed Timeline	Email ID for submission of application
1.	FORM – I	New Drug Prices	Within 60 Days by NPPA	pricing-nppa@gov.in
2.	FORM – II	Revised-Prices for Scheduled Formulations	Manufacturer shall file within 15 Days from the date of notification.	IPDMS
3.	FORM – III	Quarterly Return in Respect of Production/Import and Sale of NLEM Drugs	Manufacturer shall file within 15 Days from the date of the end of quarter.	IPDMS
4.	FORM – IV	Discontinuation of production of Scheduled Formulation.	Within 60 Days by NPPA	monitoring-nppa@gov.in
5.	FORM – V	Price list	Manufacturer shall file within 15 Days from the date of notification.	IPDMS

Other applications/reports

SI. No.	Purpose	Prescribed Timeline	Email ID for submission of application
1.	Application for Special price for packaging under Para 11(3)	Within 90 Days by NPPA	pricing-nppa@gov.in
2.	Quarterly report under UCPMP by the concerned association.	Within 30 days of the end of quarter.	monitoring-nppa@gov.in

Helpdesk

S.N.	Particulars	Email ID	Phone No.
1.	Form I	pricing-nppa@gov.in	011-23345175
2.	Form II, Form III, Form IV and Form V	monitoring-nppa@gov.in	011-23345177
3.	Technical IT/IPDMS related issues	nppa@nic.in	011-23360265