

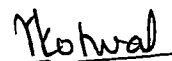
F No. 31(170)/2020/Div. III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th / 3rd Floor
YMCA Cultural Centre Building
1, Jai Singh Road, Delhi – 110001
Dated the 14th August, 2020

OFFICE MEMORANDUM

Subject: Revised guidelines regarding discontinuation of scheduled formulation under Para 21 (2) of DPCO, 2013.

The Authority in its 209th (overall) and 77th meeting held on 06.08.2020 has approved the guidelines for dealing with cases of discontinuation of scheduled formulations under Para 21(2) of DPCO, 2013. These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases.



(Vinod Kotwal)

Member Secretary, NPPA

Enclosed: Revised Guidelines

National Pharmaceutical Pricing Authority

Dated the 14th August, 2020

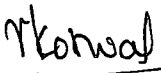
Subject: Revised Guidelines for dealing intimations of discontinuation of Scheduled formulations under Para 21 (2) of DPCO, 2013.

1. Paragraph 21(2) of the DPCO,2013 provides that any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in **Form-IV** of this order at least six months prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with the required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation. A copy of the draft public notice is attached.

2. Taking the above into consideration, the Authority in its **209th** (overall) and **77th** meeting held on **06.08.2020** approved the following guidelines to deal with intimations received in Form-IV (Schedule-II of DPCO, 2013) for discontinuation of production/import of scheduled formulations under Paragraph 21(2) of the DPCO, 2013:

- i) Companies may submit duly filled Form-IV (as per Schedule-II of DPCO,13) for intimation, duly signed and stamped by Authorised Signatory, for the discontinuation of the production of scheduled formulation with all the requisite documents on email ID: monitoring-nppa@gov.in, at least six months prior to the intended date of discontinuation.
- ii) Confirmation of the receipt of Form-IV along with acknowledgement number would be provided via return e-mail. Incomplete intimation without the requisite documents would be returned for re-submission and the same shall be informed to the applicant via email within 10 working days.
- iii) Wherever Moving Annual Turnover (MAT) of the company is 1% or less than 1% of total MAT value, company has to inform at least six months prior to the proposed / intended date of discontinuation and to issue public notice in at least one newspaper. Such cases will be noted without issuing any direction to the company and case will be **deemed approved** except where intimation has not been submitted six months prior to the proposed/ intended date of discontinuation or the market share of the company is more than 1%; such cases will be dealt appropriately as per Para-2(iv) of the guidelines.

- iv) Wherever Moving Annual Turnover (MAT) of the company is more than 1% of the total MAT Value, company will be directed, with the approval of Chairman, NPPA, within a period of sixty days from the receipt of Form-IV that intimation request has been noted and further directed to issue public notice in the prescribed attached formats in at least two national newspapers one in English and one in Hindi. The company will also be directed to continue production / import and sale of the formulation for a period of up to twelve months from the date of issue of public notice and to ensure that there is no shortage of the formulation during this period.
- v) Notwithstanding provisions of Paras 2(iii) & 2(iv) above, whenever concerns regarding shortage is apprehended or a formulation is found to be critical for public health; based on circumstances and also in cases where it is established that the company is intending to discontinue production/import and sale of a scheduled formulation and has already launched or intends to launch 'a new drug' to evade price control; cases requiring continuance of production/import and sale beyond twelve months or any other case; with the approval of Chairman, NPPA will be referred to a Standing Committee. The Standing committee will comprise of Advisor (Cost), NPPA and representatives from CDSCO and DGHS as Members of the Committee. The recommendation of the Committee will be put up to the Authority.
- vi) MAT shall be calculated in 'value terms' as defined in Para 2 (s) of DPCO, 2013, except in cases where market share cannot be calculated by MAT in value, the same will be calculated by MAT in units. Market share is determined from Market Database referred by this office.
- vii) The company shall not reduce level of production by more than 25% (of last year production in each quarter) after getting direction from NPPA.
3. The provisions of these guidelines are also applicable to scheduled Medical Devices which have been notified as Drugs by Government of India from time to time.
4. NPPA will upload list of discontinuation of scheduled formulations filed by pharmaceutical companies and approved by competent authority, on the website of NPPA on monthly basis.
5. These guidelines will be effective with immediate effect and be applicable to all cases under consideration and future cases.


(Vinod Kotwal)
Member Secretary, NPPA

सार्वजनिक सूचना

(मूल्य नियंत्रण आदेश, 2013 के पैराग्राफ 21(2) के अंतर्गत)

कंपनी का नाम	:-
कंपनी के पंजीकृत कार्यालय का पता	
अपने दूरभाष विवरण सहित	:-
सीआईएन सं.	:-
वेबसाइट	:-
ई-मेल	:-
फोन नं.	:-

सामान्य जन का ध्यान इस तथ्य की ओर आकर्षित किया जाता है कि उपरोक्त पते पर पंजीकृत कार्यालय वाली कंपनी (कंपनी का नाम) जोकि अनुसूचित विनिर्मितियां नामतः (ब्रांड नाम) (संघटन और प्रबलता/खुराक) (जिसें यहां बाद में दवा के रूप में संदर्भित किया गया है) का विनिर्माण/विपणन करती है। (कंपनी का नाम) उपर्युक्त उत्पाद (दवा) के निर्माण/विपणन को इस नोटिस की तारीख से 6/12 माह की अवधि के उपरांत बंद करना चाहती है।

उपरोक्त दवा को बंद करने के बाद यह बाजार में उपलब्ध नहीं हो पाएगी। इसलिए ऐसी दवा का उपयोग करने वाले मरीज अपने डॉक्टर से मिलकर वैकल्पिक दवा निर्धारित करवा सकते हैं। सभी डॉक्टर/चिकित्सा से जुड़े व्यक्ति भी इस पर ध्यान दें।

<कंपनी के सचिव का नाम/प्राधिकृत व्यक्ति>

पदनाम

कंपनी का नाम

दिनांक:

स्थान:

Public Notice

(Under paragraph 21(2) of the Drugs Price Control Order, 2013)

Name of the company
Registered office Address of the company
with their contact details

CIN no.

Website:

E-mail:

Phone no:

Attention of general public is drawn to the fact that (name of company) having registered office at aforesaid address is manufacturing / marketing scheduled formulations namely (brand name) with (composition and strength / dosage) (hereinafter referred to as medicine). (Name of company) wants to discontinue and stop the manufacture / marketing of the above said product after a period of six / twelve months from the date of this notice.

After discontinuation of the above medicine, the same may not be available in the market. Therefore, patients using such medicine may consult their doctor for prescribing alternate medicine. All the doctors / Medical Personals may also make note of this.

<Name of the company Secretary/Authorised person>

Designation

Name of the company

Date:

Place: