



What's New

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NPPA issues internal guidelines on discontinuation of scheduled formulations under Para 21(2) of DPCO 2013

The National Pharmaceutical Pricing Authority (NPPA) has issued the internal guidelines regarding discontinuation of scheduled formulations under paragraph 21 (2) of the DPCO, 2013.

The Authority has approved the internal guidelines to dispose of Form IV applications of discontinuation of production/import of scheduled formulations under paragraph 21 (2) of the DPCO, 2013 for issuance of "no objection certificate" by the NPPA as per the following:

1. No objection will be granted by the NPPA without referring the cases to the Authority for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture/import and sell the drug for a period of minimum six months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is upto ten per cent. The company should not reduce level of production by more than 40 per cent (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).
2. In cases where Form-IV application is received for a formulation which is legally banned, "no objection" will be issued by the NPPA after being satisfied in this regard without referring the cases to the Authority.
3. No objection will be granted by the NPPA for gradual discontinuation and the applicant company will be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture/import and to sell the drug for a period of minimum nine months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is more than ten per cent but less than twenty five per cent subject to approval of the Authority. The company should not reduce level of production by more than 40 per cent (of last year production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

4. No objection will be granted by the NPPA for gradual discontinuation and the applicant company may be advised within a period of 60 days from the receipt of Form-IV to continue to manufacture/import and to sell the drug for a period of twelve months from the intended date of discontinuation, wherever MAT (in units) of the applicant company is more than twenty five per cent subject to approval of the Authority, if no other issues are involved.
5. In exceptional circumstances like where the manufacturer under consideration has more than 50 per cent of share and other, the cases will be examined on case-to-case basis and decided on merits, subject to approval of the Authority. NPPA will also explore the possibility of alternative arrangements to supplement the production gap likely to be caused by such withdrawal by referring the matter to DoP to request the government PSU's to produce such drug. NPPA may also consider an upwards price revision under Para 19 if the drug is being discontinued because of non-remunerative pricing. The company in any case, should not reduce level of production by more than 40 per cent (of last year's production in each quarter) after getting permission from NPPA. During this period the company shall follow the ceiling price fixed by the NPPA and notified from time to time. The company intending to discontinue the scheduled formulation from the market shall also issue a public notice in the attached format in atleast two national newspapers (one in English and one in Hindi newspaper).

Authority has observed that in some of the discontinuation cases, the manufacturers has not followed the ceiling price.it is decided that NPPA shall follow up all such cases on priority and recover the overcharged amount, if any, within a period of Three months.

[Guidelines regarding discontinuation of scheduled formulations under Para 21\(2\) of DPCO, 2013](#)