

संख्या / F. No. 19(78)/2014/Div. II/NPPA

भारत सरकार

Government of India

रसायन और उर्वरक मंत्रालय

Ministry of Chemicals & Fertilizers

औषध विभाग

Department of Pharmaceuticals

राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण

National Pharmaceutical Pricing Authority

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1, Jai Singh Road, N. Delhi – 110001.

दिनांक : 16.01.2018

**OFFICE MEMORANDUM**

**Subject : Status of Form-IV applications for discontinuation of scheduled medicines – reg.**

The undersigned is directed to refer to Form-IV applications for discontinuation of scheduled medicines received in this office till 30.12.2017 from companies mentioned below and convey response to the same as detailed below :

- A. In the following cases, discontinuation requests of Companies was approved and they were asked to issue public notice, which they have issued and submitted a copy of the same to this Office. Accordingly, their discontinuation requests of scheduled formulations indicated against their name have been approved subject to conditions mentioned in column (D). Manufactures are required to follow the conditions :

Sl. No.	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
1	Astrazeneca Pharma India Ltd.	Novaclex TM	Company may continue to manufacture/ import and sell the formulation till June 2018. Till then, Company may follow the ceiling price fixed by NPPA and notified from time to time and not reduce level of production by more than 25% (of previous year's production in each quarter).
2	Sanofi India Limited	Claforan Oral Suspension -30ml	Company may continue to manufacture/ import and sell the formulations for a period of six months (as already intimated to them) from the intended date of discontinuation or date of public notice, whichever is later. During this period of six months, Company may follow the ceiling price fixed by NPPA and notified from time to time and not reduce level of production by more than 25% (of previous year's production in each quarter).
3	Sanofi India Limited	Claforan O Tablets 200 mg	
4	Sanofi India Limited	Clavohext Suspension 228.5 mg	
5	Sanofi India Limited	Clavohext Tablet 625 mg	
6	Abbott Healthcare Pvt. Ltd.	Pedialyle200 ML	
7	Indoco Remedies	Favorit 200 DT	
8	Indoco Remedies	Clopirad 75 tablet	
9	Indoco Remedies	Vcef-o 200 DT	

Sl. No.	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
10	Baxter (India) Pvt. Ltd	Dextrose 5% (500 ml)	Company may continue to manufacture/ import and sell the formulations for a period of twelve months (as already intimated to them) from the intended date of discontinuation or date of public notice, whichever is later. During this period of twelve months, Company may follow the ceiling price fixed by NPPA and notified from time to time and not reduce level of production by more than 25% (of previous year's production in each quarter).
11	Baxter (India) Pvt. Ltd	Dextrose with Normal Saline 500ml	
12	Baxter (India) Pvt. Ltd	Inj. Ringer Lactate (500 ml)	
13	Baxter (India) Pvt. Ltd	Inj. 0.45% Sodium Chloride	

- B. In the following cases, requests of Companies for discontinuation of scheduled formulations indicated against their name, have been approved subject to conditions mentioned in column (D) and they are requested to issue public notice as per details in column (D) and provide a copy of the same to this Office immediately :

Sl. No.	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
1	M/s Magnet Labs Private Ltd. (Mankind)	1 Napilex CR 200 tablet	<p>(i) Company will issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office immediately.</p> <p>(ii) Company will continue to manufacture/ import and sell the formulation for a period of 9 months from the date of public notice.</p> <p>(iii) During this period of 9 months, it will follow the ceiling price fixed by NPPA and notified from time to time and will not reduce level of production by more than 25% (of previous year's production in each quarter).</p>

- B. In the following cases, requests of Companies for discontinuation of scheduled formulations indicated against their name, have been approved subject to conditions mentioned in column (D) and they are requested to issue public notice as per details in column (D) and provide a copy of the same to this Office immediately :

Sl. No.	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
1	M/s Magnet Labs Private Ltd. (Mankind)	1 Napilex CR 200 tablet	(i) Company will issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office immediately. (ii) Company will continue to manufacture/ import and sell the formulation for a period of 9 months from the date of public notice. (iii) During this period of 9 months, it will follow the ceiling price fixed by NPPA and notified from time to time and will not reduce level of production by more than 25% (of previous year's production in each quarter).
2	M/s Magnet Labs Pvt. Ltd.	2 Cope MD tablets	(i) Company will issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office immediately.
3	M/s Magnet Labs Pvt. Ltd.	3 Napilex CR 500 tablet	
4	M/s Magnet Labs Pvt. Ltd.	4 Tryal tablet	
5	M/s Magnet Labs Pvt. Ltd.	5 Eptokind 100 tablet	
6	Raptakos, Brett & Co. Ltd.	Igol(90 gm)	(ii) Company will continue to manufacture/ import and sell the formulations for a period of 6 months from the date of public notice. (iii) During this period of 6 months, it will follow the ceiling price fixed by NPPA and notified from time to time and will not reduce level of production by more than 25% (of previous year's production in each quarter).
7	Raptakos, Brett & Co. Ltd.	Igol(250 gm)	
8	Baxter (India) Pvt. Ltd.	Inj Normal Saline 0.9% 1000 ml	
9	Baxter (India) Pvt. Ltd.	Inj. Ringer Lactate (1000ml)	
10	Baxter (India) Pvt. Ltd.	Inj. Mannitol 20% (100 ml)	
11	Fulford (I)Ltd.	Virferon Peg 120 mcg	
12	Strassenburg Pharmaceuticals Ltd.	Parasafe Suspension	
13	LG Life Science India Pvt. Ltd.	(Venofer) 5ml ampoule;	
14	Sanofi India Limited	Arava 10mg	
15	Sanofi India Limited	Arava 20mg	
16	A. Menarini India Pvt. Ltd.	Azcre 500 tablets	
17	A. Menarini India Pvt. Ltd.	Cropara 650 tablets	
18	A. Menarini India Pvt. Ltd.	Cropara 250 Suspension 60ml	
19	A. Menarini India Pvt. Ltd.	Reggi Syrup 30ml	
20	A. Menarini India Pvt. Ltd.	Reggi Syrup 450ml	
21	A. Menarini India Pvt. Ltd.	Reggi Tablets 500	
22	A. Menarini India Pvt. Ltd.	Reggi Tablets 25*10	
23	A. Menarini India Pvt. Ltd.	Cropara Suspension 60ml	
24	Seagull Pharmaceutical Pvt. Ltd.	Captol 650 mg Tablet	

- C. In the following cases, requests of Companies in respect of scheduled formulations indicated against their name, were approved subject to conditions mentioned in column (D). These companies were also directed to issue public notice and submit a copy of the same to this Office which they have not submitted so far. These Companies are again directed to issue

Sl. No.	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
2	M/s Magnet Labs Pvt. Ltd.	2 Cope MD tablets	<p>(i) Company will issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office immediately.</p> <p>(ii) Company will continue to manufacture/ import and sell the formulations for a period of 6 months from the date of public notice.</p> <p>(iii) During this period of 6 months, it will follow the ceiling price fixed by NPPA and notified from time to time and will not reduce level of production by more than 25% (of previous year's production in each quarter).</p>
3	M/s Magnet Labs Pvt. Ltd.	3 Napilex CR 500 tablet	
4	M/s Magnet Labs Pvt. Ltd.	4 Tryal tablet	
5	M/s Magnet Labs Pvt. Ltd.	5 Eptokind 100 tablet	
6	Raptakos, Brett & Co. Ltd.	Igol(90 gm)	
7	Raptakos, Brett & Co. Ltd.	Igol(250 gm)	
8	Baxter (India) Pvt. Ltd.	Inj Normal Saline 0.9% 1000 ml	
9	Baxter (India) Pvt. Ltd.	Inj. Ringer Lactate (1000ml)	
10	Baxter (India) Pvt. Ltd.	Inj. Mannitol 20% (100 ml)	
11	Fulford (I)Ltd.	Virferon Peg 120 mcg	
12	Strassenburg Pharmaceuticals Ltd.	Parasafe Suspension	
13	LG Life Science India Pvt. Ltd.	(Venofer) 5ml ampoule;	
14	Sanofi India Limited	Arava 10mg	
15	Sanofi India Limited	Arava 20mg	
16	A. Menarini India Pvt. Ltd.	Azcre 500 tablets	
17	A. Menarini India Pvt. Ltd.	Cropara 650 tablets	
18	A. Menarini India Pvt. Ltd.	Cropara 250 Suspension 60ml	
19	A. Menarini India Pvt. Ltd.	Reggi Syrup 30ml	
20	A. Menarini India Pvt. Ltd.	Reggi Syrup 450ml	
21	A. Menarini India Pvt. Ltd.	Reggi Tablets 500	
22	A. Menarini India Pvt. Ltd.	Reggi Tablets 25*10	
23	A. Menarini India Pvt. Ltd.	Cropara Suspension 60ml	
24	Seagull Pharmaceutical Pvt. Ltd.	Captol 650 mg Tablet	

- C. In the following cases, requests of Companies in respect of scheduled formulations indicated against their name, were approved subject to conditions mentioned in column (D). These companies were also directed to issue public notice and submit a copy of the same to this Office which they have not submitted so far. These Companies are again directed to issue public notice as per details in column (D) and provide a copy of the same to this Office immediately :

Sl. No	Company Name	Brand Name of Formulation	Approval is subject to following Conditions
(A)	(B)	(C)	(D)
1	Mankind Pvt. Ltd.	Clindatime 150 capsule	(i) Company will Issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office. (ii) Continue to manufacture/ import and sell the formulation for a period of six months from the date of public notice. However, from the seventh month production/import may be reduced @ 15% every month for another five months and at the end of the twelfth month, it may be withdrawn completely. (iii) During above mentioned period of twelve months, follow the ceiling price fixed by NPPA and notified from time to time and maintain the level of production as stated at (ii) above.
2	Astrazeneca Pharma India Ltd	Iressa TM	(i) Companies will issue a public notice in prescribed format (copy enclosed), in at least two national newspapers (one in English and one in Hindi newspaper) and provide a copy of the same to this Office immediately.
3	Unichem Laboratories Ltd.	XT PARA Drops	(ii) Companies will continue to manufacture/ import and sell the formulations for a period of six months from the date of public notice. (iii) During this period of six months, it will follow the ceiling price fixed by NPPA and notified from time to time and time and not reduce level of production by more than 25% (of previous year's production in each quarter).
4	Panacea Biotec Ltd.	Lower A- 10	

- D. In the following cases, Companies, in respect of their request for discontinuation of scheduled formulations indicated against their name have been asked certain information/explanation as indicated in column (D) to enable this office to process their requests. These companies are advised to forward the requisite information/explanation to NPPA immediately.

Sl. No.	Company Name	Brand Name of Formulation	Approval held up due following information/explanation awaited from Company
(A)	(B)	(C)	(D)
1	Mylan Pharmaceuticals Pvt. Ltd.	Viread	Explanation from company for discontinuing the formulation without consent of NPPA awaited.

Sl. No.	Company Name	Brand Name of Formulation	Approval held up due following information/explanation awaited from Company
(A)	(B)	(C)	(D)
2	Medopharm Pvt. Ltd.	Alworm tablet	Explanation for discontinuing the formulations without consent of NPPA and information regarding year-wise production/sale awaited from company.
3	Medopharm Pvt. Ltd.	Alworm suspension	
4	Medopharm Pvt. Ltd.	Combet 1000	
5	Medopharm Pvt. Ltd.	Fungiban 150	
6	Medopharm Pvt. Ltd.	Jalan-20	
7	Medopharm Pvt. Ltd.	Jalan-D	
8	Medopharm Pvt. Ltd.	Medomol-125	
9	Medopharm Pvt. Ltd.	Cledomox 1.2gm Inj.	
10	Medopharm Pvt. Ltd.	Medomol Suspension	
11	Medopharm Pvt. Ltd.	Medofer-xt Syrup	
12	Medopharm Pvt. Ltd.	Medofer-xt Tablet	
13	Medopharm Pvt. Ltd.	Medocid 1gm Inj.	

(Rajesh Agrawal)  
Joint Director (Monitoring)

To : All Apex Pharma Organizations/Associations i.e., OPPI, IDMA, AISSPMA, PICCI, CII, IPA, FOPE (through website) and concerned companies (through email) for immediate necessary action.