

Urgent/ By Speed Post/ Email

फा. सं. 37001/2020/Div. III/NPPA (part)
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

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

Date: 16/07.2020

Subject: Availability of Drugs Methyl Prednisolone (IV), Enoxaparin and Dexamethasone– reg.

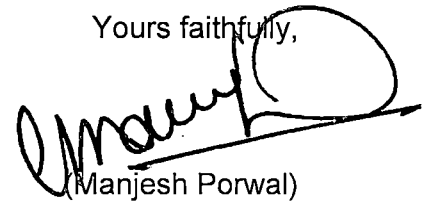
Sir,

Reference is invited to this office OM 37001/2020/Div. III/NPPA dated 03.07.2020 on above mentioned subject. In this regard, Ministry of Health & Family Welfare vides Office Memorandum 18-03/2020-DC/Covid-19 dated 9th July 2020 (Copy enclosed) has informed the revised projections of Drugs **Methyl Prednisolone (IV), Enoxaparin and Dexamethasone** as follows:

S.No	Drug Name	Quantity	Period (Up to)
1	IV Methyl Prednisolone	3.34 lakh(1000 mg Vials)	31.08.2020
2	Heparin (Enoxaparin)	1.15 crore vials (40mg), 14.07 Lakhs vials (60mg)	31.08.2020
3	Dexamethasone	1.11 crore tablet (~6mg)	31.08.2020

2. In view of above, the Manufacturers/Marketers/Importers of above mentioned drugs are directed to ensure the production of above mentioned drugs in adequate quantity (Quantity indicated above) and take proactive steps to maintain adequate stock and to ensure supply across the Country and also rush the stocks to ~~whole Country~~ and whenever and wherever short supply is reported.

Yours faithfully,


(Manjesh Porwal)

To,

The Managing Director/CEO,
All Manufacturers of Drugs Methyl Prednisolone (IV), Enoxaparin and
Dexamethasone as per indicative list enclosed (For immediate compliance).

Copy for necessary action to:

State Drugs Controllers (SDCs), with the request to issue necessary direction
to the Manufacturers/Marketers/Importers of above said drugs to ensure the
availability of these medicines across the country.

Copy for Information and necessary action to:

1. Sh. R.G. Singh, Under Secretary, MoHFW, Nirman Bhawan, New Delhi
2. DGHS, MoHFW, Nirman Bhawan, New Delhi.
3. DCGI, CDSCO, FDA Bhawan, New Delhi



(Manjesh Porwal)
Deputy Director (E)

(To be uploaded on NPPA website by Web Information Manager)

IMMEDIATE

No. 18-03/2020-DC/COVID-19,
Government of India
Ministry of Health & Family Welfare
(Drugs Regulation Section)

Nirman Bhawan, New Delhi
The 9th July 2020

OFFICE MEMORANDUM

Subject: Revised Clinical Management Protocol for COVID-19 and availability of important drugs for its management – regarding

The undersigned is directed to refer to this Department's OM of even number dated 6th July 2020 (copy enclosed) on the above subject and to say that in view of the advice received from Directorate General of Health Services, the technical wing of this Ministry, the projection of requirement has undergone some change in the case of IV Methylprednisolone (1000 mg) vials, Dexamethasone (6 mg) tablets, and Enoxaparin (40 mg) vials and the said revised projections are given in the table below:

Name of the drug	IV Methylprednisolone (1000 mg) vials	Dexamethasone (6 mg) tablets	Enoxaparin (40 mg) vials
Projection till 31.8.2020	3.34 lakh	1.11 crore	1.15 crore

2. The projection in the case of Hydroxychloroquine (200mg) tablets and Enoxaparin (60 mg) vials remains the same as conveyed vide above-referred OM dated 6th July 2020.
3. DoP / NPPA are requested to take the revised projections into consideration and ensure, as always, that there is sufficient availability of the drugs across the country.

Encl: as above

(R G Singh)
Under Secretary to the Government of India
Tel: 011-23063019

To
Secretary,
D/o Pharmaceuticals
Shastri Bhawan, New Delhi

Copy to:

1. The Chairman, NPPA
2. DGHS
3. DCGI, CDSCO

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Urgent/ By Speed Post/ Email

फा. सं. 37001/2020/Div. III/NPPA

Government of India/ भारत सरकार

Ministry of Chemicals & Fertilizers/ रसायन एवं उर्वरक मंत्रालय

Department of Pharmaceuticals/ औषध विभाग

National Pharmaceutical Pricing Authority/ राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण

3rd/5th Floor

YMCA Culture Centre Building

वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग

1, Jai Singh Road, N. Delhi-110001

1, जय सिंह रोड, नई दिल्ली-110001

Date/ दिनांक: 03.07.2020

Subject: Availability of Drug Methyl Prednisolone (IV), Enoxaparin and Dexamethasone-reg.

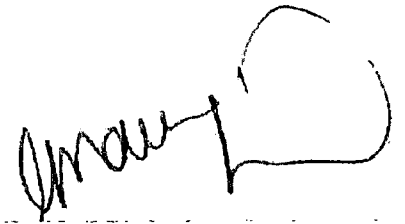
Sir,

The undersigned is directed to invite a reference to MoHFW letters no. 18-03/2020-DC/COVID-19 dated 29th June 2020, letter no-X.11035/206/2020-DR dated 24.06.2020 and letter No. X.11035/206/2020-DR dated 27.06.2020, regarding the requirement and availability of above mentioned drugs across the country since they are part of the clinical treatment protocol of COVID-19. DGHS has informed that the requirement is likely to be as follows:

S.No	Drug Name	Quantity	Period (Up to)
1	Methyl Prednisolone	138710 vials	31.07.2020
2	Heparin (Enoxaparin)	3015442 vials (40mg) 1407206 vials (60mg)	31.07.2020
3	Dexamethasone	33 lakh tablet (~6mg)	15.08.2020

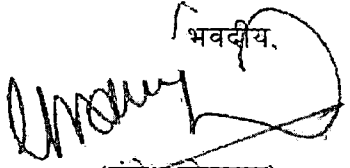
2. In view of above the Manufacturers of above mentioned drugs are directed to:

- Ensure the production of above mentioned drugs in adequate quantity (Quantity indicated above) and to take proactive steps to maintain adequate stock and ensure supply across the country.
- Make available adequate stocks across country and whenever and wherever short supply is reported.
- Immediately intimate details regarding:



(6)

- Production/Sale of above mentioned drugs during the last 2 years (FY. 2018-19, 2019-20)
- Stock lying with your Company as on date
- Production schedule for next six months
- Details of suppliers from whom you are sourcing API for above mentioned drugs and problems, if any, being faced in such sourcing
- Details of procurement orders placed by state governments
- Additional details may also be provided in the format enclosed

भवदीय.

(मंजेश पोरवाल)
उप-निदेशक (एम एंड ई)

To,

The Managing Director/CEO,

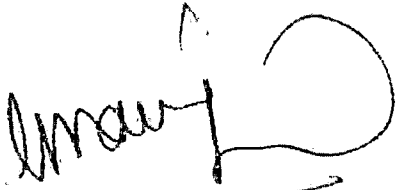
All Manufacturers of Drugs Methyl Prednisolone (IV), Enoxaparin and Dexamethsone as per list enclosed (For immediate compliance)

Copy for necessary action to:

All the State Drugs Controllers (SDCs) with the request to issue necessary direction to the manufacturers of above said medicine to ensure the availability of these medicines across the country.

Copy for Information and necessary action to:

1. Sh. R.G. Singh, Under Secretary, MoHFW, Nirman Bhawan, New Delhi
2. DGHS, MoHFW, Nirman Bhawan, New Delhi.
3. DCGL, CDSCO, FDA Bhawan, New Delhi





Major Manufacturer of Methyl Prednisolone

Sr. No.	COMPANY	Market Share %
1	PFIZER LTD	43.41%
2	SUN PHARMA LABORATORIES LTD.	28.92%
3	NEON LABORATORIES LTD	8.44%
4	INTAS PHARMACEUTICALS LTD	7.67%
5	ZYDUS CADILA	5.85%
6	Others	5.71%

Major Manufacturer of Enoxaparin Inj.

Sr. No.	COMPANY	Market Share %
1	BHARAT SERUMS & VACCINES LTD	18.89%
2	SANOFI INDIA LTD.	18.07%
3	EMCURE PHARMACEUTICALS LTD	13.41%
4	CIPLA LTD.	8.49%
5	ABBOTT HEALTHCARE PVT. LTD	6.75%
6	Others	34.40%

Major Manufacturer of Dexamethsone

Sr. No.	COMPANY	Market Share %
1	Wochardt LTD.	15.85%
2	CADILA PHARMACEUTICALS LTD	1.53%
3	ZYDUS CADILA	80.20%

