

✓ By Regd. A/D

WESTERN RAILWAY

Headquarter Office,  
Churchgate,  
Mumbai -400020.

Date: 06.4.2016  
13

No.MD/RTI/2005 Vol.X

To;  
Shri Prashant Reddy T.  
C/o. Lex one partners  
E-19, LGF  
Jungpura Extension,  
New Delhi-110014

Sir,

Sub: Supply of information under the provision  
of RTI Act, 2005.

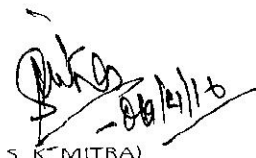
Ref: HQ RTI case no.G.542/1/2015-16/HQ/14718  
Your RTI application dt.03.2.2016 received on 09.3.2016

In reference to the above, four Postal Orders no.32F 174569, 32F 174570, 32F 174571 and 32F 174574 dt. 16.2.2016 of Rs.10/- each total amounting to Rs.40/- towards xerox charges for information is received. Following documents are enclosed herewith for information required by you pertaining to Medical Department (HQ) :

**Item No.1 & 2 :** Xerox copies enclosed herewith (who have supplied sub-standard drugs and action taken by Railway Board in the last 5 years) for your information please.  
(20 copies)

If you are not satisfied with the information from Medical Department-HQ, Appeal, can be preferred within 30 days from the date of the receipt of this letter to Appellant Authority i.e. The Chief Radiologist, Jagjivan Ram Hospital, Maratha Mandir Marg, Mumbai Central - 400 008.

Encl: as above ( 20 pages)

  
(Dr. S. K. MITRA)  
PIO (Medical) & ACMD(IH)

Copy to : CPIO-CCG

WESTERN RAILWAY

HEADQUARTER OFFICE  
CHURCHGATE  
MUMBAI - 20.

CONFIDENTIAL

No.E161/2012/03/151/P/V3/N  
144

Date : 30<sup>th</sup> Nov., 2012.

To,

CMD/CCG.

Sub :- Preventive check conducted in the Medical Store of  
Divisional Railway Hospital/RTM.

A preventive check was conducted on 31/10/2012 in the medical store of Divisional Railway Hospital/RTM for quality check of medicine. Some medicines were selected & sealed samples of those medicines were sent to Para Lab. Pvt. Ltd., Mumbai - 63 for quality testing / analysis.

Out of these medicines on medicine "Injection Sodium Chloride IP" (0.9 gm water) does not complies with prescribed standard as per IP. It is not of standard quality. Copy of Lab. report dt. 3/9/12 is enclosed herewith for your perusal, information & record.

Whenever drug sample on analysis are found to be not conforming to the standards, the suppliers are required to replace the whole quantity.

Analysis cost will be borne by the respective firm. Injection Sodium Chloride is manufactured by "Parantral Drugs (India) Ltd., Dudhiva, Indore 453 331 (M.P.)".

It is therefore requested to obtain replacement of entire batch & take suitable action against vendor. It may also be clarified as how much quantity has been supplied to different divisions & get that medicine replaced at the earliest. Copy of Joint Note dated 31/3/12 is enclosed herewith for your perusal, information & record.

Please take action at the earliest & under advice to this office.

Encl :- as above

*Handwritten signature/initials*

*Handwritten signature/initials*  
29/11/2012

(R. S. Gupta)  
For SDGM & CVO/CCG

Supine

23

**GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)**

New Delhi, Dated:- 26.06.2014.

No. 2014/H/4/1/Non Std.Tab.

M/s AFD Laboratories Pvt. Ltd.,  
Plot No. 4, Phase-II, Peenya Industrial Area,  
Peenya, Bangalore-560 058. (Through CMD/Western Railway)


**Sub:- Supply of sub standard drugs and medicines to Railway Hospital - Breach  
of terms of registration - Show -Cause Notice seeking explanation for  
failure.**

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Analytical test conducted on supply of drugs/medicines to Railway hospitals has revealed that M/s AFD Laboratories Pvt. Ltd. have supplied sub standard drugs to Railway hospitals which is a breach of trust. A copy of the report furnished by Western Railway vide their letter No. MD 75/5 (Sub Std.-Divisions) dated 24.02.2014 in this regard is enclosed.

The competent authority in the Ministry of Railways has decided to issue a Show-Cause Notice and call for explanation of M/s AFD Laboratories Pvt. Ltd. as to why the said firm should not be depanelled for supply of drugs/medicines to Railway Hospitals.

M/s AFD Laboratories Pvt. Ltd. is, therefore, called upon to furnish explanation giving causes of failure, remedial measure, if any, taken to avoid such lapses in future. If no explanation is received within the period of 15 days from the date of receipt of this Show-Cause Notice, it will be presumed that M/s AFD Laboratories Pvt. Ltd. have nothing to say and further decision in the matter will be taken.

  
(R.S. Shukla)  
Dy. Director /Health  
Railway Board.



Cmp

hup  
immediates

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11/7/14

GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

New Delhi, Dated:- 26.06.2014.

No. 2014/H/4/1/Non Std.Tab.

Chief Medical Director,  
Western Railway,  
Mumbai.

Sub:- Supply of sub standard drugs and medicines to Railway Hospital - Breach of terms of registration - Show -Cause Notice seeking explanation for failure.

Ref:- WR's letter No. MD 75/5 (Sub Std.-Division) dated 24.02.2014.

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A copy of Show-Cause Notice calling for explanation of M/s AFD Laboratories Pvt. Ltd. is enclosed herewith in original. It is requested that the Show-Cause Notice be got received by the said firm under proper acknowledgment. Further, reply on the Show-Cause Notice, if any, received from said firm may please be forwarded to this office urgently for submission before DG/RHS for his consideration & further decision in the matter.

(R.S. Shukla) 26  
Dy. Director /Health  
Railway Board.

P233c

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दि. ११/७/१४

AP. 11/7/14

Pl. put up on file with ATR

of my. 11/7/14

3/7/14



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24/10/2014

GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

New Delhi, Dated: 21.10.2014.

No. 2014/H/4/1 Non Std. Tab.

Chief Medical Director,  
All Indian Railways.  
Chief Medical Officers,  
All Production Units including RDSO.

Sub:- Supply of Sub Standard Drugs/ Pharmaceuticals Products - Consequential action thereon.

The under mentioned Drugs/Pharmaceuticals Products were found to be of Sub Standard Quality during random testing of the products supplied to the Indian Railways:-

S.No.	Railway	Name of Drugs	Manufacturers
1.	CR	Tab. Telmisartan I.P. 40mg plus Hydrochlorothiazide I.P. 12.5mg.	M/s Morepen Lab:
2.	WR	Tab. Cardem-30 (Diltiazem I.P.)	M/s AFD Laboratories Pvt. Ltd.
3.	ER	Tab. Nifedipine Retd. 20mg. (Brand-Nicardia Retard 20mg).	M/s J.B. Chemicals & Pharmaceuticals Ltd.

Accordingly, the manufacturing firms were issued Show-Cause Notice as to why their empanelment for supply of Drugs/Pharmaceuticals Products over Indian Railways should not be revoked. The representations of the above mentioned manufacturers have been considered. The following points have emerged:-

**M/s Morepen Laboratories Limited & AFD Laboratories Private Limited.**

The above manufacturers in support of their argument that their product is of standard quality, have enclosed reports of Private Laboratories in which it has been held that the products meet all the laid down standards.

In this context, it is noted that there are two contradictory reports of private testing labs viz. M/s Manish Analytical Laboratories Pvt. Ltd., Mumbai has declared the product of M/s Morepen Laboratories Limited as sub-standard and ITL Labs Pvt. Ltd. has held that the product is of standard quality. Both the testing labs are held by private ownership. Similarly, in case of M/s AFD Laboratories Private Limited their product has been found to be of sub-standard quality by M/s Manish Analytical Laboratories Pvt. Ltd. whereas the same product has been found to be of standard quality by M/s Bangalore Test House. These two labs are also held by private ownership.

Therefore, with a view to arrive at a definite conclusion on the quality of product, the manufacturer "M/s Morepen Laboratories Limited and M/s AFD Laboratories Private Limited" are directed to get their product of same batch tested in a Government Lab and submit the findings of the Lab. Till such time, the competent authority has decided that the empanelment of manufacturers "M/s Morepen Laboratories Limited and M/s AFD Laboratories Private Limited" be kept under suspension and neither any order be placed on them nor any supply of their products should not be accepted over Indian Railways.

**M/s J.B. Chemicals & Pharmaceuticals Limited**

The above firm in its reply has stated that the batch number of the product in question has not been provided to them. In this context it is noted that the Show-Cause Notice was served to M/s J.B. Chemicals & Pharmaceuticals along with which a copy of ER's letter No. MD.76/1/Sub-Std dated 06.03.2014 issued by CMD/ER. This letter very clearly mentions that product of the firm from batch No. AKG201 mfg date 12/2012, expiry date 11/2013 manufactured by M/s J.B. Chemicals & Pharmaceuticals Limited has been found to be of sub-standard quality. It has also been mentioned in the letter that product of batch No. KK1117 mfg date 10/2011, expiry date 09/2014 of the same manufacturer was previously declared to be sub-standard.

In view of the above, M/s J.B. Chemicals & Pharmaceuticals Limited be delisted from the list of empanelled manufacturers/suppliers over Railways and neither any order be placed on M/s J.B. Chemicals & Pharmaceuticals Limited nor any supply of their products should be accepted from them.

  
(R.S. Shukla) 2/11  
Dy. Director / Health  
Railway Board.



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**GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)**

New Delhi, Dated:- 29.10.2014.

No. 2014/H/4/1/Non Std.Tab.

M/s. Alembic Pharmaceuticals Ltd.,  
Prime Corporate Park, 2<sup>nd</sup> Floor,  
ITC Grand Maratha Sherelton Sahar Road,  
Andheri (East), Mumbai - 400 099.

&

M/s. Nitin Lifesciences Ltd.,  
Simour, (H.P.).

(Through CMD/Western Railway)


**Sub:- Supply of sub standard drugs and medicines to Railway Hospitals - Breach of terms of registration - Show -Cause Notice seeking explanation for failure.**

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Analytical test conducted on supply of drugs/medicines to Railway hospitals has revealed that M/s. Alembic Pharmaceuticals Ltd. have supplied Inj. Termeg 2ml. (Tramadol Hydrochloride Injection) having batch No. ANL 06203, DOM: 12/2012, DOE: 11/2014, Mfg by M/s. Nitin Lifesciences Ltd., to Railway hospitals which has been found to be of Sub-Standard quality, which is a breach of trust. A copy of the report furnished by Western Railway vide their letter No. MD75/5 (Sub-Std.-Divisions) dated 04.07.2014 in this regard is enclosed herewith.

The competent authority in the Ministry of Railways has decided to issue a Show-Cause Notice and call for explanation of M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. as to why the said firms should not be depanelled for supply of drugs/medicines to Railway Hospitals.

M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. are, therefore, called upon to furnish explanation-giving causes of failure, remedial measure, if any, taken to avoid such lapses in future. If no explanation is received within the period of 15 days from the date of receipt of this Show-Cause Notice, it will be presumed that M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. have nothing to say and further decision in the matter will be taken.

  
(R.S. Shukla)  
Dy. Director / Health  
Railway Board.

DA: WR's letter No. MD 75/5 (Sub-std.-Divisions) dated 04.07.2014.

CMD

282  
GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

Accounting  
out of 1  
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No. 2014/H/4/1/Non Std.Tab.

New Delhi, Dated:- 29.10.2014.

Chief Medical Director,  
Western Railway,  
Mumbai.

Sub:- Supply of sub standard drugs and medicines to Railway Hospital -  
Breach of terms of registration Show Cause Notice seeking  
explanation for failure.

Ref:- WR's letter No. MD75/5 (Sub-Std.-Divisions) dated 04.07.2014. P234

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A copy each of Show-Cause Notice calling for explanation of M/s Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. is enclosed herewith in original. It is requested that the Show-Cause Notice be got received by the said firms under proper acknowledgment.

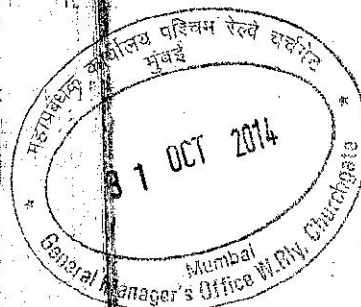
Further, reply on the Show-Cause Notice, if any, received from said firms may please be forwarded to this office urgently for submission before DG/RHS for his consideration & further decision in the matter.

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39/11  
(R.S. Shukla)  
Dy. Director /Health  
Railway Board.

DA: As above

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31/10/2014  
31/10



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GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

No. 2014/H/4/1/Non Std.Tab.

New Delhi, Dated:- 29.10.2014.

M/s. Alembic Pharmaceuticals Ltd.,  
Prime Corporate Park, 2nd Floor,  
ITC Grand Maratha Sheraton Sahar Road,  
Andheri (East), Mumbai - 400 099.

&

M/s. Nitin Lifesciences Ltd.,  
Simour, (H.P.).

(Through CMD/Western Railway)

Sub:- Supply of sub standard drugs and medicines to Railway Hospitals - Breach of terms of registration - Show-Cause Notice seeking explanation for failure.

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Analytical test conducted on supply of drugs/medicines to Railway hospitals has revealed that M/s. Alembic Pharmaceuticals Ltd. have supplied Inj. Termeg 2ml. (Tramadol Hydrochloride Injection) having batch No. A/L 06203, DOM: 12/2012, DOE: 11/2014, Mfg. by M/s. Nitin Lifesciences Ltd., to Railway hospitals which has been found to be of Sub-Standard quality, which is a breach of trust. A copy of the report furnished by Western Railway vide their letter No. MD75/5 (Sub-Std.-Divisions) dated 04.07.2014 in this regard is enclosed herewith.

The competent authority in the Ministry of Railways has decided to issue a Show-Cause Notice and call for explanation of M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. as to why the said firms should not be depanelled for supply of drugs/medicines to Railway Hospitals.

M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. are, therefore, called upon to furnish explanation giving causes of failure, remedial measure, if any, taken to avoid such lapses in future. If no explanation is received within the period of 15 days from the date of receipt of this Show-Cause Notice, it will be presumed that M/s. Alembic Pharmaceuticals Ltd. & M/s. Nitin Lifesciences Ltd. have nothing to say and further decision in the matter will be taken.

(R.S. Shukla) 28  
Dy. Director /Health  
Railway Board.

DA: WR's letter No. MD 75/5 (Sub-Std. Divisions) dated 04.07.2014.





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प्रधान कार्यालय  
चर्चगेट, मुंबई-400020  
दि. 6.11.2014

सं. एम.डी/75/5(IX)(डिविजन)  
कार्यकारी निदेशक (स्वास्थ्य)  
रेलवे बोर्ड, नई दिल्ली

विषय: Supply of sub standard drugs /Pharmaceuticals Products - Consequential action thereon -  
regarding Cardem 30 mg.

सन्दर्भ: (i) This office letter No. MD 75/5 (Sub Std Division) dated 24.2.2014 & 16.7.2014  
(ii) Railway Board's letter No.2014/H/4/1 Non Std. Tab. dt 26.6.2014 & 21.10.2014

A. In reference to the Tender enquiry no. MD 86/2/9/22/72092 due on 26.12.2012, the purchase order No. MD 86/2/9/22/72092 (583) dated 26.2.2013. (copy enclosed) for the supply of Tab Cardem 30 mg. was issued to M/s Anglo French Drugs & Industrials Ltd.

This product on testing, arranged by CMS Dahod, was found to be substandard. Since the strip of Tab. Cardem 30mg, revealed that it was manufactured in AFD laboratories Pvt. Ltd, Bangalore, the testing laboratory Food & Drug Laboratory, Vadodara has mentioned AFD Laboratories Pvt Ltd, Bangalore as a firm whereas it is only the manufacturing unit. Hence due to above reason, all subsequent correspondence were made addressing AFD Laboratories Ltd, Bangalore.

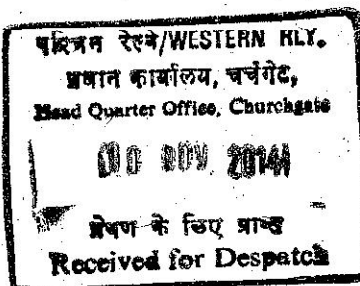
It is hereby clarified that the firm is registered on Western Railway as M/s Anglo French Drugs & Industrials Ltd. only and the Purchase order was issued for the same firm. However AFD Lab. Pvt Ltd is manufacturing unit which has been inspected by SWR and approved. This is for your information and necessary corrigendum may please be issued.

vide Railway Board's letter dt. 21.10.14 under reference (ii) above, the empanelment of the firm was suspended and the firm was intimated accordingly vide this office letter dt. 28.10.14. (Copy enclosed).

Now the firm has submitted the analysis report for tab. Cardem 30 mg Batch No. 023011P from AURIGA Research Limited (Govt approved), Bangalore (copy enclosed) wherein the sample is found to be of standard quality.

It is forwarded for perusal and guidelines in this regard.

Encl: AA



7/11/14  
(डॉ. अनिल कुमार)  
मुख्य चिकित्सा निदेशक

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**GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)**

No. 2014/H/4/1/Non Std.Tab.

New Delhi, Dated:- 20.11.2014.

**M/s Anglo French Drugs & Industrials Ltd.,  
Plot No. 4, Phase-II, Peenya Industrial Area,  
Bangalore-560 058.**

(Through CMD/Western Railway)

**Sub:- Supply of sub standard drugs and medicines to Railway Hospital - Breach of terms of registration - Show-Cause Notice seeking explanation for failure and as to why punitive action should not be taken.**

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Analytical test conducted on supply of drugs/medicines to Railway hospitals has revealed that M/s Anglo French Drugs & Industrials Ltd. have supplied sub standard drugs (DN 0230 I.P. manufactured by M/s AFD Laboratories Pvt. Ltd.) to Railway hospitals which is a breach of trust. A copy of the report furnished by Western Railway vide their letter No. MD 75/5 (Sub Std.-Divisions) dated 24.02.2014 in this regard is enclosed.

The competent authority in the Ministry of Railways has decided to issue a Show-Cause Notice and call for explanation M/s Anglo French Drugs & Industrials Ltd. as to why the said firm should not be depanelled for supply of drugs/medicines to Railway Hospitals.

M/s Anglo French Drugs & Industrials Ltd. is, therefore, called upon to furnish explanation giving cause(s) of failure, remedial measure(s), if any, taken to avoid such lapses in future. If no explanation is received within the period of 15 days from the date of receipt of this Show-Cause Notice, it will be presumed that M/s Anglo French Drugs & Industrials Pvt. Ltd. have nothing to say and further decision in the matter will be taken.

  
(R.S. Shukla)  
Dy. Director / Health  
Railway Board.

**DA: As above**

GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

No. 2014/H/4/1/Non Std.Tab.

New Delhi, Dated:- 20.11.2014.

Chief Medical Director,  
Western Railway,  
Mumbai.

Sub:- Supply of sub standard drugs and medicines to Railway Hospital - Breach  
of terms of registration - Show-Cause Notice seeking explanation for  
failure.

Ref:- WR's letter No. MD 75/5(IX) dated 07.11.2014.

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A copy of Show-Cause Notice calling for explanation of M/s Anglo French Drugs  
& Industrials Ltd. is enclosed herewith in original. It is requested that the Show-Cause  
Notice be got received by the said firm under proper acknowledgment. Further, reply  
on the Show-Cause Notice, if any, received from said firm may please be forwarded to  
this office urgently for submission before DG/RIS for his consideration & further  
decision in the matter.

(R.S. Shukla)  
Dy. Director /Health  
Railway Board.



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**GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)**

New Delhi, Dated: 05.01.2015.

No. 2014/H/4/1/Non Std.Tab.

Chief Medical Directors,  
All Indian Railways.

Chief Medical Officers,  
All Productions Units including RDSO.

Subj: Supply of Sub-standard drugs/pharmaceuticals products - Consequential action thereon.

- Ref:- 1. This office letter of even No. dated 21.10.2014.  
2. Show-Cause Notice issued vide letter of even number dated 29.10.2014.  
3. SR's letter No. MD/69/1/Quality Analysis dated 19.11.2014.

After consideration on the Railway's report, the following decisions have been taken:-

**M/s Anglo-French Drugs & Industries Limited**

After considering detailed representation of the firm, the competent authority in the Ministry of Railways has decided that the supply of drugs/pharmaceuticals products of the firm M/s Anglo-French Drugs & Industries Limited (including M/s APD Laboratories Private Limited) may be restored.

**M/s Morepen Laboratories Limited**

After considering detailed representation of the firm, the competent authority in the Ministry of Railways has decided that the supply of drugs/pharmaceuticals products of the firm M/s Morepen Laboratories Limited may be restored.

**M/s Alembic Pharmaceuticals Limited**

In reply to the Show-Cause Notice, M/s Alembic Pharmaceuticals Limited have disputed the report of the M/s Food and Drug Laboratory, Vadodara. In view of this, it has been desired that CMD, WR should get the same batch product of the company tested in the Government Lab and send the report of the Lab for decision in the matter. Pending report of the Government Laboratory, supply of drugs/pharmaceutical products from M/s Alembic Pharmaceuticals Limited would remain suspended.

**M/s RPG Life Sciences Limited**

Keeping in view the fact that Government Analyst of Drug Testing Laboratory has found the product (Arpitor-10) of the manufacturer as Sub-standard, supply of the drug/pharmaceutical products from M/s RPG Life Sciences Limited will remain suspended. The manufacturer M/s RPG Life Sciences Limited are directed to obtain clearance of Drug Controller of the State relating to marketing/supply/sale of the product (Arpitor-10) for final decision in the matter.

(Dr. Praval Pant)  
Director Industrial (Health)  
Railway Board.

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7/1/2015

CMD  
330  
GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

No. 2014/H/4/1/Non Std.Tab.

New Delhi, Dated:- 13.01.2015.

WR, Mumbai.  
Chief Medical Directors,  
All Indian Railways.

Chief Medical Officers,  
All Productions Units including RDSO.

Sub:- Supply of Sub-standard drugs/pharmaceuticals products - Consequential  
action thereon.

Ref:- NWR's letter No. MD/560/Drug Quality Control dated 30.12.2014.

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After consideration on the Railway's report, the following decision has been  
taken:-

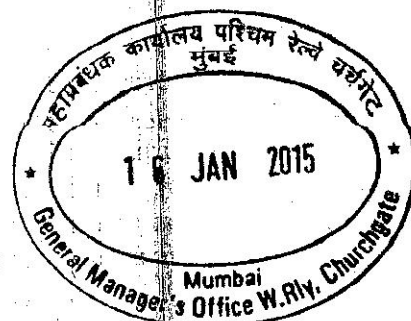
M/s Biocon Ltd.

Keeping in view the fact that Government approved Test Lab has found the  
product (Tab Bestor-10/Rosuvastatin 10mg, Batch No. BPSG 14105, D/M 08/2014 &  
D/E 07/16) of the manufacturer as Sub-standard, DG(RHS) has directed that  
CMD/NWR should refer the same batch product (Tab Bestor-10) to Government Lab for  
testing. Till the report of the Government Lab is received and examined in this Office,  
supply of the drugs/pharmaceutical products from M/s Biocon Ltd. and M/s Swiss  
Garnier Life Sciences will remain suspended.

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(R. S. Shukla) B  
Dy. Director (Health)  
Railway Board.

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See 1375

16/1/2015



CMD

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Amr/Ms  
S. S. Shukla

GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

No. 2014/H/4/1 Non Std. Tab.

New Delhi, Dated:- 03.02.2015.

Chief Medical Directors, WIR, Mumbai.  
All Indian Railways.  
Chief Medical Officers,  
All Production Units including RDSO.

Sub:- Supply of Sub Standard Drugs/ Pharmaceuticals Products - Consequential action thereon taken against M/s J. B. Chemicals & Pharmaceuticals Ltd. resumption of empanelment.

Ref:- RB's letter No. 2014/H/4/1 Non Std. Tab dated 21.10.2014.

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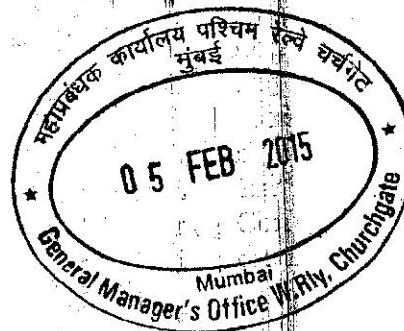
Vide this Office letter cited under reference M/s J. B. Chemicals & Pharmaceuticals Ltd. were delisted from the list of empanelled manufacturers/suppliers for supply of drugs/pharmaceuticals products over Indian Railways. Subsequent to the de-empanelment, M/s J. B. Chemicals & Pharmaceuticals Ltd. had approached the Drug Controller of the Gujarat State for inspection of their manufacturing premises for assessing suitability and adequacy of infrastructure etc for manufacturing of drugs/pharmaceuticals products. Drug Controller, Gujarat State vide letter dated 20.01.2015 has advised that they have inspected the manufacturing unit of M/s J. B. Chemicals & Pharmaceuticals Ltd. at Ankleshwar and have certified the adequacy of infrastructure for production of the drugs/pharmaceuticals products in the unit. Further, it has also been certified that the firm is following the laid down procedure for such manufacturing. The Drug Controller has arrived at a conclusion that the Sub-Standard product found during testing of their lab was due to reason beyond the premises of the manufacturer.

(57) In view of the above findings, the competent authority in the Ministry of Railways has reconsidered the decision and it has been decided to regularise empanelment of M/s J. B. Chemicals & Pharmaceuticals Ltd. for supply of drugs/pharmaceuticals products.

All the Zones, where M/s J. B. Chemicals & Pharmaceuticals Ltd are registered, are, therefore, advised to resume supply of drugs/ pharmaceuticals products of M/s J. B. Chemicals & Pharmaceuticals Ltd. as per terms and conditions for such supplies by empanelled firms.

1. M. R. ...

6/02/15



(R. S. Shukla)  
Dy. Director (Health)  
Railway Board. 03/

ACMS/MS 350  
94  
GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

New Delhi, Dated:- 10.04.2015.

WR  
No. 2014/N/4/1/Non Std.Tab.

Chief Medical Directors,  
All Indian Railways.  
Chief Medical Officers,  
All FUs including RDSO.

Sub:- Supply of Sub-standard drugs/pharmaceuticals products - Consequential action  
thereon-M/s Anglo-French Drugs & Industries Limited & M/s Zee Laboratories Limited.

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With reference to the reports of Government Analyst (Drug), the following decision has been taken:-

M/s. Anglo French Drugs & Industries Ltd.

South Central Railway had advised that as per the report of Govt. Analyst (Drug), report Tab Cardem-30MG (Tab Diltazem 30 mg IP, Batch No. 03402P, D/M 03/2014 D/E 08/2016) manufactured by AFD Laboratories Pvt. Ltd. & supplied by M/s Anglo French Drugs & Industries Limited, has been found to be of sub standard quality. This letter was received in this office in mid Feb 2015. However, keeping in view the process of revision of policy on the subject, action was not initiated on the report.

In the mean time, M/s AFD Laboratories Pvt. Ltd. has submitted the report of the State Drug Control Department wherein it has been found that the product is of standard quality.

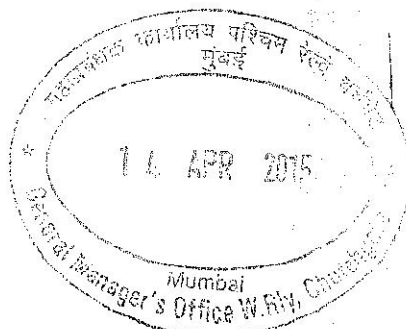
In view of the clearance given by the State Drug Control Department, it has been decided that no action is warranted to be taken on the report of the Govt. Analyst (Drug) in the matter. However, CMD/SC Railway to ensure that the drug of the Batch No. 03402P is replaced by the supplier.

M/s Zee Laboratories Limited

Arising out of the report of the Govt. Analyst (Drug) regarding supply of substandard medicine by the firm ("ZEPAFA-XT" Paracetamol Tablets, IP 650 Mg, Batch No. 414-1086, D/M 03/2014 D/E 06/16), it was decided to suspend supply of drugs/pharmaceutical products by M/s Zee Laboratories Limited vide this office letter of even number dated 09.02.2015. All the zones were accordingly advised not to accept any supply of drugs etc from the firm pending clearance by the State Drug Control Department. The firm has now submitted report of the State Drug Control Department vide certificate dated 24/03/2015 which has cleared the products of the firm.

In view of the clearance given by the State Drug Control Department, it has been decided that supply of the products of the firm (M/s Zee Laboratories Limited) be resumed. However, CMD/SCR would ensure that product of Batch No. 414-1086 supplied by the firm is replaced.

(R.S. Shukla)  
Dy. Director / Health  
Railway Board.





GOVERNMENT OF INDIA  
MINISTRY OF RAILWAYS  
(RAILWAY BOARD)

New Delhi, Dated: 05.01.2015.

No. 2014/H/4/1/Non Std.Tab.

Chief Medical Directors,  
All Indian Railways.

Chief Medical Officers,  
All Productions Units including RDSO.

Subj: Supply of Sub-standard drugs/pharmaceuticals products - Consequential action thereon.

- Ref: 1. This office letter of even No. dated 21.10.2014.  
2. Show-Cause Notice issued vide letter of even number dated 29.10.2014.  
3. SR's letter No. MD/69/1/Quality Analysis dated 19.11.2014.

After consideration on the Railway's report, the following decisions have been taken:

M/s Anglo-French Drugs & Industries Limited

After considering detailed representation of the firm, the competent authority in the Ministry of Railways has decided that the supply of drugs/pharmaceuticals products of the firm M/s Anglo-French Drugs & Industries Limited (including M/s. Anglo-French Laboratories Private Limited) may be restored.

M/s Morepen Laboratories Limited

After considering detailed representation of the firm, the competent authority in the Ministry of Railways has decided that the supply of drugs/pharmaceuticals products of the firm M/s Morepen Laboratories Limited may be restored.

M/s Alembic Pharmaceuticals Limited

In pursuance of the Show-Cause Notice, M/s Alembic Pharmaceuticals Limited have disputed the report of the M/s Food and Drug Laboratory, Madras. In view of this, it has been desired that CML will submit the same batch product of the company tested in the Government Lab and send the report of the Lab for decision in the matter. Pending report of the Government Laboratory, supply of drugs/pharmaceutical products from M/s Alembic Pharmaceuticals Limited would remain suspended.

M/s RPG Life Sciences Limited

In view of the fact that Government Laboratory of Drug Testing Laboratory has found the product (Arpor-10) of the manufacturer as Sub-standard, supply of the drug/pharmaceutical products from M/s RPG Life Sciences Limited will remain suspended. The manufacturer M/s RPG Life Sciences Limited are directed to obtain clearance of Drug Controller of the State relating to marketing/supply/sale of the product (Arpor-10) for final decision in the matter.

(Dr. Prayal Pant)  
Director Industrial (Health)  
Railway Board.

6/1/2015

Headquarter office,  
Churchgate, Mumbai-400 020.  
Phone: 22271 / 22377 (Railway)  
22097573 / (MTNL)  
Fax: 22017353  
e-mail: cmd@wr.railnet.gov.in  
Date: 10<sup>th</sup> July, 2015

No. MD 185/0 Drug Policy 20014.

M/s. Biocon Limited,  
20<sup>th</sup> KM Hosur Road, Electronics City,  
Bangalore-560 100.

M/s. Swiss Garnier Life Sciences,  
21-23, Industrial Area Mehalpur,  
Distt.: UNA(H.P): 174 315.

Dear Sirs,

Sub: Supply of Sub-standard drugs - Revocation of  
Suspension.

Ref: Railway Board's letter Nos.:  
(1) 2014/H/4/1 Non Std. Tab dated 13.11.2015  
(2) 2014/RSCW/779/13 dated 14.5.15.  
(3) 2006/H/4/1/Pt.A dated 6.7.15. &  
This office letter of even No. dated 19.5.15.

After consideration of revised policy guidelines of Railway Board, competent authority has decided that supply of drugs/pharmaceuticals products of the firm M/s. Biocon Limited & M/s. Swiss Garnier Life Sciences, H.P. may be restored except for Tab. Rosuvastatin.

The firm and manufacturing unit are advised to get clearance from State Drug Controller of respective state, followed by inspection by Railway Authority. Until such time the supply for Tab. Rosuvastatin will remain suspended. No offers for this product will be considered.

Yours faithfully,

(Dr. Ramesh J. Kumar)  
Addl. CMD (MS)  
for Chief Medical Director.

Copy to:  
The Dy. Director (Health),  
Railway Board, New Delhi for information

Copy to:  
MD - JRH/BCT  
CMS - BCT/BRC/RTM/RJT/BVP/DHD/ADI

WESTERN RAILWAY

6579641



Headquarter office,

Churchgate, Mumbai-400 020.

» 22271 / 22177 (Railway)

Phone: » 22097573 / (MTNL)

Fax : 22017333

e-mail : omd@wr.railnet.gov.in

Date : 10<sup>th</sup> July, 2015

No. MD/185/0 Drug Policy 20014.

M/s. RPG Life Science Ltd.,  
CEAT Mahal, 463, Dr. Annie Besant Road,  
Worli, Mumbai-400 030.

Dear Sirs,

Sub : Supply of Sub-standard drugs -- Revocation of  
Suspension.

Ref: Railway Board's letter Nos.  
(1) 2014/H/4/1 Non Std. Tab dated 5.1.2015  
(2) 2014/RSCW/779/13 dated 14.5.15.  
(3) 2006/H/4/1/Pt A dated 6.7.15 &  
This office letter of even No. dated 19.5.15.

After consideration of revised policy guidelines of Railway Board, competent authority has decided that supply of drugs/pharmaceuticals products of the firm M/s. RPG Life Science Ltd. may be restored except for Tab. Atorvastatin.

The firm and manufacturing unit are advised to get clearance from State Drug Controller of respective state, followed by inspection by Railway Authority. Until such time the supply for Tab. Atorvastatin will remain suspended. No offers for this product will be considered.

Yours faithfully,

(Dr. Ramesh J. Kumar)  
Addl. CMD (MS)  
for Chief Medical Director.

Copy to:

The Dy. Director (Health),  
Railway Board, New Delhi for information

Copy to:

MD - JRH-BCT  
CMS - BCT / BRC / RTM / RJT / BVP / DHD / ADI

WESTERN RAILWAY