

F.No.X.11035/159/2015-DFQC(pt.)  
Government of India  
Ministry of Health & Family Welfare  
Department of Health & Family Welfare  
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Nirman Bhavan, New Delhi  
Dated the 16<sup>th</sup> Sep., 2015

To,  
Shri Prashant Reddy T, Advocate,  
C/o Lex One Partners,  
E-19, LGF,  
Jungpura Extension,  
New Delhi-110014.

Subject: RTI application of Shri Prashant Reddy T., Advocate-Regarding.

Sir,

Reference is invited to your RTI application dated 14.08.2015 forwarded by RTI Cell of this Ministry vide letter No.A.60011/FTS-198688/2015-RTI Cell dated 19.08.2015 wherein you have sought information in respect of two points. Information is as follows:-

- a. As desired by you, the letter written by Shri Deepak Mittal to this Ministry is enclosed.
  - b. As desired by you, copy of file noting prepared by this Ministry in respect of the letter of Shri Mittal alongwith the correspondence that followed is enclosed.
2. If you want to see any further document regarding this matter, <sup>you</sup> can visit this office on any working day (Monday to Friday) and inspect the relevant file. Photocopies of the documents can be taken after payment of fee @ Rs.2/- per page through the prescribed mode. Please make the visit within 15 days of receipt of this letter. Kindly let us know (on telephone) the date and time when you intend to come so that the availability of the concerned officials is ensured.
3. In case you are not satisfied with the reply, you may file an appeal to the Appellate Authority enclosing photocopy of your RTI application and reply received from this office within a period of thirty days. The particulars of the Appellate Authority are- Dr. Shailendra Kumar, Director, M/o Health and F.W., R.No.301-D Nirman Bhawan, Maulana Azad Road, New Delhi.

Yours faithfully,



(R.G. Singh)

Under Secretary (Drugs Quality Control) & CPIO  
Telefax: 23063019

Copy to:

Ms. Sindhu Patil, Section Officer, RTI Cell, MoH&FW.

F.No.X-11035/43/2013-DFQC  
Government of India  
Ministry of Health & Family Welfare  
(DFQC Section)

Sub:Black Listing of Indian Pharma companies - reg.

A copy of the email received from Consulate General of India, Vietnam on the subject mentioned above was forwarded to DCG(I) for necessary action vide this Ministry's letter dated 02.01.2014.

2. FR is a letter dated 06.02.2014 of DCG(I) addressed to all Zonal and Sub Zonal offices, CDSCO and copy endorsed to this Ministry, wherein all Zonal and Sub Zonal offices, CDSCO have been requested to investigate the matter <sup>in respect of</sup> the exporters and manufacturers located in their respective zone immediately and take necessary action under intimation to DCG(I).

Submitted pl.

P  
13/2

*[Signature]*  
13/2

S.O.(D)

US(D)

*[Signature]*  
18/2

17/2/14 *[Signature]*

We may now request the DCG (I) to send the progress made so far because we have not shown concrete results.  
May kindly consider.

*[Signature]*  
19/2

JS(AK)

Arbunde  
20/2

Dir(D)

*[Signature]*  
20/2

*[Signature]*  
21/2

*[Signature]*  
21/2

Pl. issue the signed letter placed below  
S.O. R/14  
21/2

Pl. issue i.e.  
S.O. R/14  
21/2

*[Signature]*  
6/3

*[Signature]*  
6/3

*[Signature]*  
2 Feb

DFAC Section

Reference on pre-page/N

2. This is regarding an OM dated 24.02.2014 of Department of Commerce regarding violation of Quality Control Regulation and Drug Registration in Vietnam by certain Indian Pharma Companies

The same was referred to DCU(D) for comments vide ~~to~~ letter from Dir (D) but the requisite comments have not been received so far.

In this connection we may remind DCU(D) as per DFA pls.

so (DFAC) ol  
02/04/14

us (D)

for  
24.14

21. 2. 2014

Plc issue

sh R/sh. 4

12:38 AM (0 minutes ago)

Dr. G.N. Singh via nic.in

to me

----- Forwarded message -----

From: "Dr. G.N. Singh" <dci@nic.in>  
To: dfqcsection <dfqcsection@gmail.com>  
Cc:  
Date: Wed, 16 Sep 2015 12:35:33 +0530  
Subject: Fwd: Blacklisting of Indian pharma companies

----- Forwarded message -----

From: Consul General <cg.hcm@mea.gov.in>  
To: secyhfw@gmail.com, js1tpd-doc@nic.in, dci@nb.nic.in, DCM <dcm.hanoi@mea.gov.in>, jssouth <jssouth@mea.gov.in>, ED <ed@pharmexcil.com>  
Cc:  
Date: Tue, 24 Dec 2013 19:36:41 +0700  
Subject: Blacklisting of Indian pharma companies

**DEEPAK MITTAL**  
Consul General  
Tel: (84-8) 3823 7050  
Fax: (84-8) 3823 7047

**CONSULATE GENERAL OF INDIA**  
55 Nguyen Dinh Chieu Street, District 3  
Ho Chi Minh City (Vietnam)  
E-mail: [cg.hcm@mea.gov.in](mailto:cg.hcm@mea.gov.in)

**Fax/E-mail Message**

No. HCM/202/4/2013

December 24, 2013

To : Ministry of Health and Family Welfare, New Delhi  
Rptd : 1. Shri Sanjay Bhattacharyya, JS(South), MEA  
2. Shri Sudhanshu Pandey, JS, Department of Commerce  
3. Shri Srinivas Gotru, Cd'A a.i. Embassy of India, Hanoi  
4. Dr. G.N. Singh, Drug Controller General of India  
5. Dr. P.V. Appaji, Director General, Pharmexcil

**Secretary(Health & Family Welfare) from Consul General**

This is further to the message sent by Cd'A a.i. Embassy of India, Hanoi on 23 December 2013 regarding blacklisting of Indian pharmaceutical companies in Vietnam.

2. **Enclosed** herewith is a list of 66 foreign companies, whose products have been blacklisted for quality violations by the Drug Administration of Vietnam (DAV), during the period between January 1, 2011 to 25 October 2013. The list, which has been put out on DAV website, includes 46 Indian companies.

3. In view of the fact that a large number of Indian companies have been listed as defaulters by the Vietnamese authorities, it is requested that necessary background checks on these companies may kindly be undertaken in India to see if there are complaints against them from other countries and steps be initiated to penalise them for bringing bad name to the Indian pharma industries abroad.

4. We would request that Mission/Post may kindly be kept apprised of the action taken so as to reassure the local authorities of our commitment to continue to be a reliable supplier to quality drugs/medicines.

Kind regards,

Deepak Mittal

*Foreign*  
*List of Companies having drugs violated quality from 1/1/2011-25/10/2013*  
**Danh sách các công ty nước ngoài có thuốc vi phạm chất lượng**

Từ ngày 01/01/2011 đến ngày 25/10/2013

(Cập nhật theo quy định tại Công văn 13719/QLD-CL ngày 23/8/2013

của Cục Quản lý dược) Updated as per official document No. 13719/

STT	Nước sản xuất	Công ty sản xuất
1	Bangladesh	Công ty General Pharmaceuticals Ltd, Bangladesh
		Công ty Globe Pharmaceuticals Ltd - Bangladesh
2	Canada	Công ty Apotex Inc - Canada
3	Cyprus	Công ty Holden Medical Ltd, Cyprus Europe
4	France	Công ty Pfizer PGM, France
		Công ty Famar Lyon, France
5	Germany	Công ty Denk Pharma GmbH & Co. KG, Germany
6	Indonesia	Công ty PT Kalbe Farma Tbk, Indonesia
7	India	Công ty Flamingo Pharmaceuticals Ltd., India
		Công ty Umedica Laboratories Pvt. Ltd., India
		Công ty AMN Life Science Pvt Ltd., India
		Công ty M/s Minimed Laboratories Pvt. Ltd, India
		Công ty Minimed Laboratories Pvt Ltd. - India
		Công ty Axon Drugs Pvt.Ltd.,-India
		Công ty XL Laboratoires Pvt., Ltd, India
		Công ty Maiden Pharmaceuticals Limited - India
		Công ty Marksans Pharma Ltd, India
		Công ty Mediwin Pharmaceuticals
		Công ty Medley Pharmaceuticals Ltd, India
		Công ty Amtec Health Care Pvt. Ltd. - India
		Công ty Strides Arcolab Limited India
		Công ty Swyzer Laboratories Ltd.-India
		Công ty Clesstra Healthcare Pvt Ltd - India
		Công ty Santa Pharma Generix Pvt, Ltd., India
		Công ty Cooper Pharma - India
		Công ty Fine Pharmachem, India
		Công ty ACI Pharma Pvt., Ltd., India
		Công ty ATOZ Pharmaceuticals Pvt. Ltd., India
		Công ty Miracle Labs (P) Ltd., India
		Công ty Chethana Drugs & Chemicals (P) Ltd., India
		Công ty Overseas Laboratoires Pvt., Ltd _India
		Công ty Marek Biosciences Ltd India
		Công ty Windlas Biotech Limited India
		Công ty Yeva Therapeutics Pvt., Ltd-India
		Công ty Euro Healthcare - India
		Công ty Eurolife Healthcare Pvt. Ltd., India
		Công ty Zee Laboratories, India
		Công ty Unique Pharmaceutical Labs. - India sản xuất
		Công ty Global Pharm Healthcare Pvt., Ltd., India
Công ty Medico Remedies Pvt. Ltd., India		
Công ty Celogen Pharma Pvt., Ltd, India		

QLD-CL  
 dated 23/8/2013  
 of The Drug  
 Administration  
 of Vietnam

STT	Nước sản xuất	Công ty sản xuất
7	India	Công ty Lekar Pharma Ltd, India
		Công ty Raptakos, Brett&Co.Ltd, India
		Công ty Hyrio Laboratories Pvt., Ltd., India
		Công ty Gracure PharmaceuticalsLtd., India
		Công ty Syncom Formulations (India) Ltd.
		Công ty Cure Medicines (India) Pvt. Ltd. India
		Công ty M/s MedEx Laboratories, India
		Công ty Chemfar Organics (P) Ltd., India
		Công ty Kausikh Therapeutics (p) Ltd. India
		Công ty Penta Labs Pvt Ltd. India
		Công ty Systs Labs - India
		Công ty Nestor Pharmaceuticals Limited India
		8
Công ty Dae Han New Pharm Co, Ltd, Korea		
Công ty Deawoo Pharm Co., Ltd - Korea		
Công ty Dachwa Pharmaceuticals, Korea		
Công ty Union Korea Pharm Co.Ltd		
Công ty Hankook Korus Pharm Co,Ltd, korea		
Công ty Young Il Pharm. Co. Ltd		
Công ty Dongsung pharm. Co. Ltd., Korea		
Công ty Hanall Pharmaceutical Co., Ltd, Korea		
9	Pakistan	Công ty Navegal Laboratories Pakistan
10	Philippines	Công ty Amherst Laboratories, Inc, Philippines
11	Russia	Công ty Sintez Joint Stock Company, Russia
12	USA	Công ty Robinson Pharma Inc.,USA

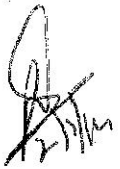
(Danh sách có 66 Công ty của 12 Quốc gia)

**MOST IMMEDIATE**

No. X. 11035/43/2013-DFQC  
Government of India  
Ministry of Health & Family Welfare  
DFQC Section  
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Nirman Bhawan, New Delhi  
Dated the 2<sup>nd</sup> January, 2014

To



The Drugs Controller General (India),  
FDA Bhawan, Kotla Road,  
Near Bal Bhawan,  
New Delhi

Subject: Blacklisting of Indian pharma companies -regarding.

Sir,

I am directed to forward herewith a copy of letter/e-mail dated 30.12.2013 received from:  
Shri Deepak Mittal, Consul General of India on the subject mentioned above for necessary action.

**Encl: A/a**



Yours faithfully



(Om Prakash)  
Section Officer  
Telefax: 23062419