GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAVAN,
TILAK MARG, JAIPUR

No. DC/D-1/Export of Medicine/2014/ Dated:-

All Asstt. Drugs Controller's, Rajasthan State.
All Drugs Control Officer's, Rajasthan State.

Sub:- Clandestine Export of Medicines through Clandestinely operated websites.

Reference to subject cited above, Photocopies of letter & its enclosures received from Jt. Commissioner (HQ), Food & Drug Administration (M.S.) 341, Bandra Kurla Complex, Bandra (East), Mumbai-400051 is hereby enclosed for necessary action at your end. You are requested to keep watch on such type of activities.

Encl.:- As above.

Sd/

(Ashok Bhandari)
Drugs Controller
Rajasthan, Jaipur

No. DC/D-1/Export of Medicine/2014/ 331 Dated:- 20/06/2014

Copy to:-

1. Sh. O.S. Sadhwani, Jt. Commissioner (HQ), Food & Drug Administration (M.S.) 341, Bandra Kurla Complex, Bandra (East), Mumbai-400051 in ref. of D.O. letter No. WHO-GMP/1243-2014/11 dt. 02.05.2014
2. Drugs Controller-II, Rajasthan, Jaipur.
3. Incharge, Server Room Hqrs; with request to please upload this letter with its enclosures on Departmental website & E-mail to All Asstt. Drugs Controller, Rajasthan State. Encl. As above

Sd/

(Ashok Bhandari)
Drugs Controller
Rajasthan, Jaipur

5/N

No. WHO-GMP/1243-2014/11

COMMISSIONER,
FOOD & DRUG ADMINISTRATION (M.S.)
341, Bandra Kurla Complex,
Bandra (East), Mumbai 400 051.
Tel. : 26590548, Fax : 26591959
Email : comm.fda-mah@nic.in

Date 03/06/2014

06 JUN 2014
5915
क्रमांक

To,

All State Drug Controllers

Sub: **Clandestine Export of medicines through Clandestinely operated websites**

Reference: **D.O. letter from Food and Drug Administration, Maharashtra State, D.O. letter No. WHO-GMP/1243-2014/11 dated: 2/5/2014**

This is to bring to your kind notice that the matter of clandestine operations of export of medicines from the country directly to the customers violating the various legal provisions of the Drugs and Cosmetics Act and the regulatory requirements of importing country, that in the process affect, the mainstream export of medicines. So, the subject matter was also taken up with the Department of Commerce, Ministry of Commerce and industry, Government of India.

The Department of Commerce has suggested "rather than seeing it as a case in isolated manner; DCGI may share it with other state regulatory also and evolve an action plan to counter such sales including suspension of manufacturing licenses, wherever required. DCGI may share its perspective on the issue so that DOC is also able to response on this issue."

A copy of letter received from the Department of Commerce, Ministry of Commerce and industry, Government of India is forwarded herewith for your perusal and necessary action.

Yours

Joint Commissioner (HQ)
and Controlling Authority
Food and Drug Administration
Maharashtra State

Most Immediate

F.No.15/08/2014-EP (Pharma)
Government of India
Ministry of Commerce & Industry
Department of Commerce
EP (Pharma) Section
*****

Udyog Bhawan,
New Delhi
Dated: 19th May, 2014

To

Shri G.N. Singh,
DCGI,
FDA Bhavan, ITO, KOtla Road,
New Delhi.

Sub.: Export of medicines through clandestinely operated websites.

Sir,

I am directed to forward herewith a copy of letter dated 29.04.2014 (along with its enclosure) received from Commissioner, Food & Drug Administration Maharashtra on the above mentioned subject, including the directions of the Court on the case under reference.

2. In the note attached as Annexure 'A' on online pharmaceuticals sales, the FDA Maharashtra have indicated the impact on the revenue of the Government through such sales and also likely imports by Indian Customers on similar lines. More importantly, as you are aware such exports of drugs has huge potential to damage the credibility by Indian pharma exports, for which Department of Commerce has been harping about strong measures to be taken by the regulatory regime of the country.

3. It is suggested rather than seeing it as a case in isolated manner; DCGI may share it with other state regulator also and evolve an action plan to counter such sales including suspension of manufacturing licenses, wherever required. DCGI may share its perspective on the issue so that DOC is also able to evolve response on this issue.

4. Action taken in the matter may be intimated to the Department within a fortnight.

(N. Ramakrishnan)
Deputy Secretary to the Govt. of India
Tel. : 011-23062525
e-mail: ramakrishnan.n@nic.in

Encl: as above.

Copy to :

1. Dr. P.V. Appaji, Director General, Pharmexcil, Hyderabad.
2. Shri Mahesh Zagade, Commissioner, FDA, Mumbai, Maharashtra.
3. Dr. Arun Kumar Panda, Joint Secretary, Department of Health & Family Welfare.

O.S. Sadhwani
Jt. Commissioner (HQ)
and Controlling Authority

कार्यालय
औषधि नियंत्रक (राज.) जयपुर
06 MAY 2014
क्रमांक .....

D. O. No. WHO-Gmp/1243-2014/11

COMMISSIONER,
FOOD & DRUG ADMINISTRATION (M.S.)
341, Bandra-Kurla Complex
Bandra (East), Mumbai 400 051.
Tel. : 2659 0548, Fax : 2659 1959
Email : comm.fda-mah@nic.in

Date : 2/5/2014

Dear Sir,

I am enclosing herewith a detailed note regarding clandestine export of medicine on the basis of demands generated through clandestinely operated websites. These medicines include drugs like sexual potency enhancing sildenafil, tadalafil, addictives like tramadol, some higher antibiotics which can develop resistance because of improper use and some habit forming antidepressant drugs. The details of this clandestine export are annexed herewith as annexure "A".

As this activity is a clandestine operation, it generates huge profits and it is also said that this could be used as a ploy for money laundering. When this was brought to my notice a few months back, a concerted action has been initiated to curb this clandestine export.

The same illegal and clandestine operations may also be carried out not only in Maharashtra but many other cities of the country. In view of the action taken by FDA, Maharashtra and the orders passed by the Hon'ble High Court (copy enclosed), you are requested to take appropriate measures for unified action by all the authorities under different Acts in India to control this illegal export of drugs, which violates Drugs and Cosmetics Act and other Acts.

It is also observed that these licensees are now transferring their business from Maharashtra to other states where they can carry out this illegal business without regulatory hurdles.

Therefore you are requested to take necessary action with respect to D.O. letter addressed to Drug Controller General (India), New Delhi dated: 03/04/2014 which is attached herewith for your perusal.

Thanking you

With regards

Yours Sincerely

O.S.Sadhwani

To,

Shri.Ashok Bhandari
Drugs Controller
Swasthya Bhawan, Tilak Marg,
Jaipur-302015, Rajasthan.

Annuxure "A"

NOTE ON INTERNET OR ONLINE PHARMACEUTICAL MARKETING

Regular export to various countries is a routine process, where the stock exported by India lands in to particular countries and is distributed through regulated distribution mechanism of the said importing country.

However, it is observed that, direct internet orders are placed with some overseas dealer/website by the patients / persons and these websites or agents forward these orders to the dealers situated in India. In this process, stock of the goods is supplied to the consumer/s however the sale invoices are sent to the broker or agent which clearly reveals that supply chain is manipulated which clearly violates the provisions of Drugs & Cosmetics Act. This process leads to self medication / abuse/misuse of the drugs without knowledge of the regulator of the importing country.

The Food & Drugs Administration, Maharashtra State received the information that the high risk drugs like Sildenafil Tablets, Antibiotics, Antihypertensive and Antidepressants etc are being exported and delivered directly to the patients by the wholesalers/retailers, licensed by Maharashtra and other State regulators without following the provisions of Section 18 (c) read with Rule 65 conditions of license issued to these dealers.

THE MODUS OPERANDI

1. Orders through internet or some specific websites like India mart, e-commerce, health cart plus etc. via e-mails sent by the agents or brokers or sometimes by the customers himself are received by some specific wholesale medicine dealers situated in Mumbai, Pune or Nagpur. The agents or brokers who sent these e-mails are seem to be corporate entities which are carrying out this entire business of supply of medicine through e-mails and internet only.
2. As soon as the orders received through an email, wholesalers in India will start searching the cheapest available brands for the ordered drugs which are then purchased through local distributors.
3. These purchased drugs then packed in the envelopes of suitable sizes, labeled it with the patients name and address, Name & address of the sender, EMS number attached with a custom declaration form.
4. These envelopes are then transferred to the authorized agent of Indian post, where EMS tracking no is generated and franking of the envelopes done. This envelope is stamped for no objection certificate by the Assistant Drugs Controller Custom. However these

envelopes are sent without a valid sales invoice and packing list which manipulates the supply chain.

5. A custom declaration form is filled by the wholesalers and all the envelopes along with the reports sent to Assistant Drugs Controller, Custom, where either a representative packets or the doubtful parcels are checked.
6. After the checks through Assistant Drugs Controller (Customs) these envelopes are sent to the respective consumers through International air post and EMS tracking number is sent to the broker or agent.
7. As soon as the confirmation of delivery received by the concerned broker the payment for these drugs are released by the broker or agents.

PLACEMENT OF ORDER

1. The major drawback of this system is , the orders placed are either with a system generated anonymous prescription or without any valid prescription which is a clear violation of Rule 65 (9)(a) which says that " substances specified in Schedule H or Schedule X shall not be sold by retail except on and in accordance with the Registered Medical Practitioner . And as the dealers having wholesale license are supplying these medicine by way of retail to direct to customers are violating the condition no 3(ii) of wholesale license which says" No sale of any drugs shall be made to a person not holding the requisite license to sale, stock or exhibit for sale or distribute the drugs." And Section 18 (c) which reads as " No person shall himself or by any other person on his behalf manufacture for sale or for distribution or sale or stock or exhibit or offer for sale or distribute any drugs or cosmetics except under and in accordance with the conditions of, a license issued for such purpose under this Chapter.
2. The drugs which are exported by this way are prescription drugs in the importing countries, which require a valid prescription from the medical practitioner of the importing countries and this prescription along with the doses regime shall be issued to the concern patients. However most of the consignments are sent without any valid prescription and the quantities of these drugs are more than the doses regime of these drugs which is extremely dangerous with the patient's health and safety.
3. In this process, the transaction of money is takes place either in advance payment or payment after the delivery of the goods. However in most of the cases the mode of western union money transfer is adopted for the payment after a delivery of the goods.
4. These emails are generated through the websites located in the countries like USA, UK, Australia, Dubai etc. however medicines envelopes are sent to many individual consumers or customers who are located in the countries other than these countries

SUPPLY

1. These drugs are mainly acquired through the local distributors situated in the Mumbai, which are licensed by the Food & Drugs Administration, Maharashtra State. However in some instances drugs are also purchased directly from the manufacturers.
2. The drugs purchased from the local distributors like R. Mahendra Kumar & Company, Mumbai-2, Jeet Pharma ,Ghatkopar, Evershine Marketing etc. maintain the purchase records of the drugs supplied to distributors for export as well as local market , however thorough and detailed investigation of these distributors is required to verify the economic irregularities.
3. The suppliers of these medicines purchase these drugs from the distributors or manufacturers without valid export order or documents.
4. The drugs which are meant for the local sale are also export by the online pharmacy. However in some countries registration of the importing drugs are mandatory to regulate the quality of the imported drugs which grossly remain ineffective in the process of trading of medicine through internet.
5. The sale of any medicine to the patient by way of retail shall be done in accordance with the provisions of Rule 65 (3)(1) , 65 (4)(3) by issuing a valid sale bill containing the details like details of the supplier , date of sale, name of patient, name of prescriber, name of drugs, batch number, expiry date and manufacturers details, however these important provisions of Drugs & Cosmetics Act is not complied in this process.
6. Whenever the drug has to be imported for personal use in India , as per Rule 36 of the Drugs & Cosmetics Act
    i. The licensing authority, on an application made to it in Form 12-A is satisfied that the drug is for bonfide personal use
    ii. The quantity to be imported is reasonable in the opinion of the licensing authority and is covered by prescription from a registered medical practitioner. And
    iii. The licensing authority grants a permit in respect of the said drug in Form 12-B.
7. Similar provisions may be applicable to other importing countries which are not complied in the process of supply of medicine through online orders.

INTERFACE TO GOVERNMENT

1. **Food & Drugs Administration –**
    I. As per the Drugs & Cosmetics Act, regular inspections of the licensee where drugs are been sold, distributed or stocked has to be conducted to

verify the condition of licenses. In these conditions the channel of distribution till the customer is tracked as well as the storage conditions of the drugs during storage and transportation is verified, however this is not possible in the online trade.

II. Any drugs by way of wholesale have to be sold only to license retailers but in online distribution drugs are distributed to the consumers on the orders of agent or brokers. This contravene the provision of section 18 (c)

III. The drugs distributed to the consumers are either with a system generated prescription or without prescription of Registered Medical Practitioner which is a contravention of the provision of Rule 65 (9).

IV. The supply of drugs specified in Schedule X of the Drugs & Cosmetics Act has to be acknowledged on the prescription and should not be dispensed more than once, however this is not possible in the online distribution which contravene the provision of Rule 65(11)(b).

2. Assistant Drugs Controller CDSCO

i. The quality of the drugs moving in the international market has to be monitored and for this the manufacture who complies with the provisions of good manufacturing practices for the quality standards are only permitted to export their medicines in the international market. However in the online marketing, the source of the drugs may or may not comply with the international quality standards which may adversely affect the reputation of the country in the international market.

ii. The supply of these drugs is not always through the authorized agent of the post. Sometimes the envelope can be dropped in post box or sent through courier.

iii. Drugs which are sent through authorized agent are required no objection certificate from ADC custom, However drugs which sent by other ways are not scanned by ADC custom.

iv. For the reputation of the country, every drugs exported in international market has to be tested for its strength, purity and safety. However this is not possible with the every consignment sent through online marketing.

3. The Customs Act 1962

a. "Smuggling" in relation to any goods means any act of omission which will render such goods liable to confiscation under section 111 of section 113 of the Customs Act 1962.

b. The distribution of drugs through internet orders, supplied through air post contravenes many provisions of the regulations of exporting as well as importing country, hence this distribution is smuggling as per the definition. Smuggling activities are having an increasingly deleterious effect on the national economy and thereby a serious adverse effect on the security of the state.

c. As this entire process is violating many provisions of Drugs & Cosmetics Act 1940 & Rules there under, it comes under the purview of section 113 (Confiscation of goods attempted to be improperly exported, etc.) of the Customs Act 1962.

INTERNATIONAL ACTIONS

1. US FDA has taken a serious view on the purchase of drugs over internet and they started cracking down on these quack websites for the safety of the health of US citizens. The FDA news release of Feb. 16, 2007, **"FDA alerts consumer to unsafe, mispresented drugs purchased over the internet".** In the similar news release of dated 27 June 2013, **"FDA takes action to protect consumers from dangerous medicines sold by illegal online pharmacies",** - The US Food & Drugs Administration, in partnership with international regulatory and law enforcement agencies, took action this week against more than 9,600 websites that illegally sell potentially dangerous ,unapproved prescription medicines to consumers.
2. The news further states - Many of these websites appeared to be operating as a part of an organized criminal network that falsely purported its website to be "Canadian Pharmacies ". These websites displayed fake licenses and certifications to convince US consumers to purchase drugs they advertised as "Brand name "and "FDA approved". The drugs received as part of Operation Pangea were not from Canada, and were neither brand nor FDA approved.
3. Operation Pangea is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. Coordinated by INTERPOL, the annual operation brings together customs, health regulators, national police and the private sector from countries around the world. Activities target the three principal components used by illegal websites to conduct their trade – the Internet Service Provider (ISP), payment systems and the delivery service.
4. United Kingdom has also stopped the illegal sale of medicines over the internet, news published in the Blood index times – **"The MHRA has**

conducted a coordinated operation against the sale and supply of illegal and unlicensed medicines over the internet. There is an increased risk to the public from obtaining medicines through unregulated websites".

CONTRAVENTIONS

Indian suppliers –

a. Medicines are sold by way of retail without a valid prescription of registered medical practitioner contravene the provision of Rule 65(9)(a)
b. Medicines are sold by way of wholesale to the person who does not hold any license or registration, contravene the section 18(a)(vi),18(c),/Rule 65(9)(b).
c. The drugs belongs to Schedule H or X, at the time of dispensing prescription is not acknowledged by the retailer, contravene the provision of Rule 65(11)(c).
d. The sale bills are not issued to the customer with a valid details as per the Rule contravene the provision of Rule 65(3)& 65(4)
e. Many times it is observed that there are change in the brands of the medicine, contravene Rule 65(11)(a). (Sustitute are given)
f. The supplies having licenses for retail sale however as per Rule 65(15)(b) the words " Chemist & Druggist " is not displayed on the premises.
g. Some suppliers dispensing medicines directly to the patients or consumers without having retail license and services of registered pharmacist contravene the provisions of section 18(c), and Rule (2) & (3).

Note –

1. Prescription – For the purpose of clause 9 , a prescription shall
    a. Be in writing and be signed by the person giving it with his usual signature and be dated by him.
    b. Specify the name and address of the person, for whose treatment it is given....
    c. Indicate the total amount of medicine to be supplied and the dose to be taken.
2. Registered Medical Practitioner – As defined Rule 2(ee) of the Drugs & Cosmetics Act , Registered Medical Practitioner means
    a. Holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act 1916 or specified in schedules to the Indian Medical Council act 1956.

Post offices –

1. Superintendent, Department of post, Mumbai 99, India vide their letter no SUPDT/SPCC/OSA/ADC-NOC/Oct-2012 dated 31/10/2012 , issued a instructions " No any EMS articles containing medicines should be accepted by SPCC without any ADC NOC stamp affix on it. ADC clearance is must before booking of international articles at SPCC. However this procedure is not adopted for the supply of medicine by routes other than EMS.

Assistant Drugs Controller, Custom –

1. Considering the reputation of the country in the international trade, the drugs having appropriate quality standard shall be exported, however no system of checking of the quality parameters is adopted at this stage. Analyzing this loop hole, there is a reasonable doubt that, the antisocial elements may push their substandard, counterfeit, rejected or reprocessed material by this system.
2. The envelopes of the medicines are packed and sealed at the suppliers' license premises or sometimes by their agents at unlicensed premises. These envelopes are only stamped; the contents are not personally verified or checked by the ADC.

EFFECT ON ECONOMY OF THE COUNTRY AND INTERNATIONAL REPUTATION

Smuggling severely harms the economy of a country in multidimensional ways. It undermines the local industry, discourages legal imports and reduces the volume of revenues collected from duties and levies by the state. Unfortunately a parallel underground economy has taken roots by this process. A major proportion of the revenue to be collected by the Government is being lost, over and above the adverse impact that the smuggled items cause to our industry. If it is unchecked for a longer period of time a similar kind of process may be initiated in this country as well, the price conscious Indian customer will attract to the substandard, counterfeit and unsafe medicines manufactured in China or other similar countries will be purchased by the Indian customers which will inflicted the economy of this country which we will not be able to control by any means.

(R.B. Banarse)
Jt. Commissioner Gr. Mumbai
Food and Drug Administration M.S.
Mumbai 51

VAI

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY ORIGINAL CIVIL JURISDICTION

WRIT PETITION (L) No.496 OF 2014

Kayem Pharmaceuticals P. Ltd. ...Petitioner
Vs.
The State of Maharashtra,
Through Secretary Department
Food and Drug Department and Ors. ...Respondents

WITH
WRIT PETITION (L) No. 508 OF 2014

Fedelty Healthcare Pvt. Ltd. ...Petitioners
Vs.
The State of Maharashtra and Ors. ...Respondents

****

Mr.J.Reis, Senior Counsel with Mr. Yadhunath Chaudhary i/b. Reena Salunkhe for Petitioner
Mr.D.J. Khambhata, Advocate General with Ms. Geeta Shastri-AGP for Respondent Nos.1 and 2
Mr.Parag Vyas with Mr.A.R. Verma for Respondent No.3
MR. Daya Shukl, Asstt. Supdt. (Legal) for Respondent No.3

****

CORAM : V. M. KANADE &
A.K. MENON, JJ.

DATE : MARCH 10, 2014

P.C.

1. After the matter was heard at length, Shri Shukl, the Asstt. Superindent (Legal) on behalf of the Foreign Post Office-Respondent No.3 herein, submits that no parcel is detained by the Foreign Post Department.

2. The grievance of the Petitioners in this petition is that Respondent No.2 took inspection of the licensed premises of the Petitioners on 5.2.2014 and, thereafter, directed the Petitioners not to dispose of the stock for 20 days from 14.2.2014 and also directed Respondent No.3 - Foreign Postal Department, Dak Bhavan, Bellard Estate, Mumbai -1 not to export the goods.

3. The contention of the Petitioners is that they are the manufacturers of the pharmaceutical and they dispose of the pharmaceutical products manufactured by them on principal to principal basis after obtaining requisite permissions from the authorities under the Act. It is the contention of the Petitioners that the Petitioners export its products to various foreign countries mainly by sending the products by postal delivery. It is the contention of the Petitioners that they hold all the necessary permissions, authorizations and licenses that are required to be obtained for carrying out these activities.

4. It is submitted that on 5.2.2014, Respondent No.2 inspected

the licensed premises of the Petitioners and prepared an inspection report in Form 35 and, thereafter, passed the impugned order. The Petitioners, therefore, are constrained to file this petition under Article 226 of the Constitution of India seeking an appropriate writ, order and direction for setting aside the impugned order passed by Respondent No.2.

5. After the petition was filed, a show cause notice has been issued to the Petitioners dated 24.2.2014 in which, it is alleged that the Petitioners have violated the provisions of Section 18(C), 18(A) (vi) r/w. Rules 65(9) (a) and 65(5) of the Drugs and Cosmetics Act, 1940. It is submitted that Respondent No.2 does not have jurisdiction or authority to issue the said show cause notice or give a direction to the Postal Authorities not to export the said goods. He submitted that the Petitioners have valid Import Export Code(IEC) License issued under section 7 of the Foreign Trade (Development and Regulation) Act, 1992. It is submitted that, therefore, the said impugned order is liable to be quashed and set aside.

6. The learned Senior Counsel appearing on behalf of the Petitioners has invited our attention to the Foreign Trade Policy Manual and the procedures prescribed thereunder and also the relevant provisions of the Acts and Rules framed thereunder. It is submitted that several letters have been written by the Central Government, informing Respondent No.2 and other Authorities under the Food and Drug Act that they had no authority to impose

the said restrictions. It is submitted that, therefore, the impugned order is liable to be set aside and the Petitioners may be permitted to carry out the exports.

7. On the other hand, the learned Advocate General appearing on behalf of the State has invited our attention to the license issued by the Assistant Commissioner, Food and Drug Administration (Maharashtra State). He submitted that in the said license, it is clearly mentioned that the Petitioners are permitted to sell and distribute their products on wholesale basis and strictly prohibited in selling the products on retail basis. It is submitted that the Petitioners are sending their goods directly to the individual customers and, therefore, the FDA Authorities are justified in issuing the show cause notice to the Petitioners. He submitted that if the reply is filed within one week by the Petitioners, the FDA Authorities shall hold an inquiry and decide the same within three weeks thereafter.

8. It is not disputed that after the petition was filed, a show cause notice has been issued by the Respondents. No reply has been filed by the Petitioners to the said show cause notice. The learned Advocate General has submitted that if reply is filed by the Petitioners, the inquiry would be completed within three weeks. Therefore, at this stage, we are not inclined to grant stay to the impugned order passed by Respondent No.2. We, therefore, direct the Petitioners to give the reply to the show cause notice within one

week and Respondent No.2 shall complete the inquiry within three weeks thereafter. With these directions, both the writ petitions are disposed of. Liberty is granted to the Petitioners to challenge if any adverse order is passed by Respondent No.2. All contentions raised by the Petitioners and Respondents in these petitions are kept open. Respondent No.2 shall not be influenced by dismissal of these petitions since we have not expressed our opinion on merits of the case.

Sd/-
[A.K. MENON, J.]

Sd/-
[V. M. KANADE, J.]

Mahesh Zagade
Commissioner

D. O. No. WHO-GMP/985-2014/11.

COMMISSIONER,
FOOD & DRUG ADMINISTRATION (M.S.)
341, Bandra Kurla-Complex
Bandra (East), Mumbai 400 051.
Tel. : 2659 0548, Fax : 2659 1959
Email : comm.fda-mah@nic.in

Date : 3/4/2014

Dear Dr. Singhsaheb,

The matter of clandestine operations of export of medicines from the country directly to the customers violating the various legal provisions of the Drugs & Cosmetics Act and the regulatory requirements of importing country, that in the process affect, the mainstream export of medicines, was investigated by the officers of this administration and the huge stock of medicines was prohibited vide form 15 at the foreign post office and the premises of various such licensees who are involved in such clandestine operations.

This matter had been referred to you vide D.O. letter No. WHO-GMP/570-14/11 dated: 20/02/2014 and E-mail dated: 24/02/2014 (Copies attached), and the same communication had been marked to:

1) Shri. Nazib Shah, Director General, Directorate General of Revenue Intelligence.
2) Smt. J. M. Shanti Sundaram, Chair Person of Central board of Excise and Customs.
3) Shri.Pradeep Kumar, Commissioner, Central Vigilance Commissioner.
4) Dr.Anup K.Pujari, Director General of Foreign Trade.
5) Dr.Kavita Gupta, Additional Director General of Foreign Trade.
6) Smt.Shobha Madhale, Director Mails and Business Development, The office of Chief Postmaster General, Maharashtra.

1. In view of the above, two of the licensee M/s. Kayem Pharmaceuticals Pvt. Ltd. and M/s. Fedelty Healthcare Pvt. Ltd. filed a writ petition No. 496 of 2014 and 508 of 2014 respectively to the Hon'ble High Court, Mumbai. In this writ petition, both the petitioner claimed that, the prohibitory orders issued by the Drugs Inspectors do not give any hint as to which are the provisions of section 18 that have been violated, and the prohibitory order is illegal, have been made in most arbitrary and high handed manner, which suspended the business of the petitioner.

2. In the above cases, Drugs Inspectors of this administration also issued a letter to foreign post office with the directions that the packets of pharmaceuticals lodged with them should not be dispatched until further orders.

3. In reply to the above writ petitions, the affidavit was filed by this administration with the following major points.
   i) This entire operation is not a wholesale transaction but a retail transaction where specific quantity/number of strips of drugs to be delivered to various individual person, directly without the services of the registered pharmacist. However petitioner does not have requisite license in form 20 & 21 as per section 18(c) and thus contravened the Rule 61(1), 61(2) and 67(c) of the Drugs & Cosmetics Act, 1940..
   ii) The drugs/ medicines were sold without prescription from a doctor, in absence of the registered pharmacist, as the nature of transaction reflected was of a retail nature and thus amounted to violation of section 18(a)(vi) read with Rule 65(2), 65(3)and 65(a) of the said rule. The said transaction further revealed that the delivery was made to the person but the bill was issued in the name of the party who had placed the order through internet.
   iii) The order in form 15 is an interim and temporary order just prevent further commitment of an offence under section 18(c), 18(a)(vi) of the said act r/w Rules 65 of the said Rules.

iv) The Drugs Inspector also issued an intimation dated 5th Feb 2014 to the Assistant Director of Postal Authorities to stop the export of the drugs/medicine of the petitioner and other parties, as the said stock of drug was being sold and distributed without requisite retail sales license, without prescription and proper sales bill in the name of recipient. Hence it was in contravention of the provision of the said Act and therefore the order was issued under section 22 of the said Act.

4. The above matter was presented before the Hon'ble High Court by the Advocate General and Additional Govt. Pleader of High Court. The argument was continued for more than three hours and after the argument Hon'ble High Court has disposed of both the writ petitions of the petitioners and directed them to reply to the show cause notice issued by the Licensing Authority and Licensing Authority to take the appropriate decision in three weeks.(Copy of the judgment dated 18/3/2014 attached herewith for your perusal)

5. All the drugs exported through this clandestine operations fall in the category of prescription drugs and have very high potential to developing adverse drug reactions if taken without prescription. To avoid indiscriminate consumption of drug like the exported through this operation the United State of America has passed statute called by Ryan Haight online pharmacy consumer protection Act of 2008. The Act was passed when a 19 year boy called Ryan Haight died after consumption of similar drug sourced from the internet pharmacy. Therefore such export of drugs to individual customer in U.S. is not legal and could be termed as clandestine.

The Indian regulators therefore cannot allow such clandestine export to the other countries, especially on the background that similar or such drugs are easily available through mainstream export.

6. The clandestine export of the drugs from India in the manner carried out by these licensee has very serious consequences as there is no guarantee that, the drug declared to be exported are the same drug or is substandard drug or an imitation or counterfeit or even narcotic preparation as the envelope is not opened by the authorities and the chemical contents are not verified or sample is not retained or any other robust method is not available to verify any one of the above This has a very serious consequences for one legitimate export trade. India's image abroad can get tarnished by such clandestine exports and our long term trade relations based on trustworthiness can get distorted.

7. The same illegal and clandestine operations may also be carried out not only in Maharashtra but many other cities of the country. In view of the action taken by FDA, Maharashtra and the orders passed by the Hon'ble High Court, you are requested to take appropriate measures for unified action by all the authorities under different Acts in India to control this illegal export of drugs, which violates Drugs and Cosmetics Act and other Acts.

It is also observed that these licensees are now transferring their business from Maharashtra to other states where they can carry out this illegal business without regulatory hurdles.

8. The normal official export, the importing country approves the drug like USA/UK approve the manufacturing plants after stringent inspections or other countries import drugs on WHO-GMP certification by the Government of India and States. The official channel trade constitutes more than Rs.70,000 crores and is one of the main foreign exchange earners of the country and it has been developed on the basis of the trust of the importing countries in the Indian regulatory system. Unlike the official export, the export of individual consumers lack any such inspection and therefore may have impact on the official trade channel in the long run as the trust of importing countries in Indian systems may not be as robust.

As per the Office memorandum No. DCGI/MISC/2014 (31) dated: 05/03/2014 issued by Drugs Controller General of India, serious concerns are raised regarding the quality of medicines exported from India and expected to be investigated on top priority. In internet based exports no quality checks are exercised and therefore substandard drugs could get exported as mentioned in the memorandum dated: 05/03/2014

9. The local official of the DCGI giving NOC to individual packet do not and cannot check to ensure about the quality and or authenticity of the drug is spurious, NSQ etc drugs may be getting exported, still worse even here is possibility of narcotic drugs getting exported in guise of medicines. These possibilities will have serious impact on image of the country internationally and it has potential of affecting huge export on long term basis.
10. Since, this individual consumer based export apparently generates huge clandestine money because the kind of threats, pressure & machination, I have been encountering intense pressure and all kinds of troubles ever since actions have been initiated in Maharashtra.

In view of the above, I suggest the following:

1) The DCGI may give instructions to all his regional Offices to stop this clandestine activity.
2) The Authorities concerned with this clandestine Export like Customs, Post, DGFT and DRI may be sensitized accordingly and especially the legal frame work as appreciated by Hon. High Court in its Order dated: 18/03/2014.
3) All the drugs controllers in the country may be give appropriate directions to control this menace and protect official export.
4) The unsubstantiated information suggest that it is also one of the routes for money laundering and therefore this fact may also be brought to the notice of concerned authorities like DRI etc.
5) The representatives of US FDA and some investigating agencies visited my office recently and informed me that this is the serious matter, and

state should try to curb it. It was also briefed to me that, they are working with Interpol to control this clandestine activity.

You may therefore requested to take up this matter at National level.

6) My field staff suggests that huge transaction of illicit money takes place on the basis of per packet illegal gratification which could be in corers. In view of this, it is strong case to handover this case to CBI, as it involves private operators and Government agencies and its spread across entire country.

With warm regards,

Yours sincerely,

(Mahesh Zagadé)I.AS
Commissioner
Food & Drug Administration, M.S.

To,
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