I have cited. But those cases which are linked with so many complicated things like human trafficking, which the hon. Member mentioned about, for that the Home Ministry has constituted various Committees and there is a legislative provision also which is passed by this hon. House, and there are various steps being taken. If the hon. Member wants to know the percentage of those cases referred to the specialized units, then I will get back to the hon. Member in due course of time.

Recalling of batches of drug exports

*108. SHRI DEREK O'BRIEN: Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) the number of batches of Indian drug exports that were recalled or withdrawn due to quality lapses;

(b) the number and details of manufacturers involved in these cases;

(c) whether individual cartons of drugs exported from India are mandated to carry barcodes or tracking chips;

(d) if so, how many exporters have not yet met the mandated requirements and the steps taken by Government to implement these requirements; and

(e) the measures taken by Government to improve the quality of all drug exports to meet international standards?

THE MINISTER OF STATE OF THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI NIRMALA SITHARAMAN): (a) to (e) A Statement is laid on the Table of the House.

Statement

(a) and (b) No such information is maintained by India's drug regulatory agency, Central Drugs Standard Control Organisation (CDSCO) regarding batches of Indian drug exports that were recalled or withdrawn due to quality lapses. For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country. Regulatory agencies of major importing countries like USA (USFSDA), EU (EDQM), UK (UK MHRA) etc. publish such information periodically on their websites. As per the information available on these websites, there are some recalls of Indian products. Details of companies involved and number of recalls/withdrawn during 2015 is enclosed as a Statement-I (*See* below).

(c) Yes, the manufacturer or exporter of drug formulations will print the bar code as per GSI Global Standard at different packaging levels to facilitate tracking and tracing of their products as per the procedure prescribed *vide* DGFT Public Notice

No.52/2015-2020 dated 5th January 2016 (copy enclosed as Statement-II (*See* below). This is to ensure that Indiandrugs are not counterfeited or spurious drugs are sold under "Made in India" label in foreign countries. This is to enhance brand image of the Indian Pharma products and consequent value realisation.

(d) and (e) Some manufacturers and exporters especially the small scale units have been representing to Department of Commerce that they would require extended time period for implementation of the track and trace system in view of the hardware and software change that are required to be undertaken, to be compliant of the prescribed procedure. After careful consideration of the representations and in consultation with various stakeholders, *vide* DGFT Public Notice No 52/2015-2020 dated 5.1.2016, Government has exempted all SSI drug manufacturers from the requirement of maintaining Parent Child relationship in packaging levels for a period up to 31.03.2017.

This initiative by Government would help in countering the adverse campaign against quality of Indian drugs in the international markets by big pharma companies. Besides, Government in various bilateral and international forums and through regular interactions with major regulatory bodies have also been highlighting the initiatives taken to improve the quality of Indian drugs. Most of Indian drugs are compliant of WHO GMP standards and have been approved by many regulatory agencies like USFDA (USA), PMDA (Japan), EDQM (EU), UKMHRA (UK) etc. The State Licensing Authorities (SLAs) also ensure that manufacturers comply to the requirements of the importing country including the standards of quality and Good Manufacturing Practices (GMP).

Statement-I

Details of companies involved and number of recalls/withdrawn during 2015

Year of recall	No of companies making recall	Total no of products recalls
2015	15	102

Details of the year 2015

Sl. No	Manufacturer	Total number of Product Recalls
1.	Actavis Pharma Manufacturing Pvt. Ltd	3
2.	Apotex Research Private Limited	6
3.	Aurobindo Pharma Limited	1
4.	Cipla Ltd.	1
5.	Dr. Reddy's Laboratories Limited	14

Sl. No	Manufacturer	Total number of Product Recalls
6.	Emcure Pharmaceuticals Ltd.	2
7.	Micro Labs Limited	3
8.	Mylan Institutional LLC	7
9.	Onco Therapies Limited.	1
10.	Par Pharmaceutical Companies	1
11.	Reckitt Benckiser Parsippany	7
12.	Sandoz Private Limited	1
13.	Sun Pharmaceutical Ind. Ltd.	3
14.	Unichem Laboratories Ltd.	1
15.	Wockhardt Limited	51
	TOTAL	102

Statement-II

Copy of procedure presccribed vide DGFT Public Notice

To be published in the Gazette of India Extraordinary Part-I, Section-l
Government of India
Ministry of Commerce and Industry
Department of Commerce
Directorate General of Foreign Trade

Public Notice No. 52/2015-2020
New Delhi, Dated the 5 January, 2016

Subject: Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments.

In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.89A of Handbook of Procedure, 2015-20, as notified *vide* Public Notice No. 4/2015-20 dated I .04.2015 (as amended), as under, for laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations:

2. **"2.89 A**

Procedure for Implementation of the Track and Trace system for export of drug formulations

(i) The manufacturer or the exporter of drug formulations will print the barcode as per **GSI Global Standard** at different packaging levels to facilitate tracking and tracing of their products. The details are as follows:

(a) Primary Level:

Incorporation of two dimensional (2D) barcode encoding unique and **universal global product identification** code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the primary pack. The bar code labeling at primary level is exempted till further notification; however, the above mentioned details are required to be printed in human readable form on **optional basis** till further notification.

(b) Secondary level:

Incorporation of one or two dimensional (1D or 2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTN) along with batch number, expiry date and a unique serial number of the secondary pack. However, incase of monocartons manufacturer or exporter shall affix bar code **on mono carton containing one primary pack on optional basis till further notification.**

(c) Tertiary Level:

Incorporation of one dimensional (1D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the tertiary pack *i.e.* Serial Shipping Container Code (SSCC).

(ii) **Parent-Child Relationship/Effective dates for SSI and Non-SSI Manufacturers:**

The manufacturer or exporter shall maintain the data in the parent-child relationship for three levels of packaging *i.e.* Primary, Secondary and Tertiary packaging and their movement in its supply chain.

(a) All Manufacturers (SSI and Non-SSI Manufacturers):

As one time exemption all manufacturers are exempted from maintenance of parent-child relationship in packaging and its uploading on Central Portal (*http://dava.gov.in*) till 31.03.2016. However, the requirements of printing of barcoding on the different levels or packaging will be applicable as prescribed.

(b) Extended Date of Exemption to SSI Manufacturers:

All SSI drug manufacturers are exempted from requirement of maintaining Parent-Child relationship in packaging levels for a further period up to 31.03.2017. However, they are required to upload Tertiary level data on the central portal mandatorily as prescribed in public notice no. 13/2015-2020 dated 22.05.2015.

(iii) The data mentioned in (ii) above shall be uploaded on the Central Portal of the Government of India by the manufacturer or exporter or its designated agency before release of the drug formulations for sale or distribution.

(iv) The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer or exporter.

(v) The above rules (i) to (iv) will not be applicable to those drug formulations manufactured for export purposes, where the government of the importing country has mandated or formally notified its intention to mandate a specific requirement and the exporter intends to avail the option of printing the barcodes in their format after duly obtaining the permission of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per (i)(c) above in addition to importing country's requirement, if any.

(vi) Export of drugs manufactured by non-SSI units and having manufacturing date prior to 31.03.2016 and export of the drugs manufactured by SSI units and having manufacturing date prior to 31.03.2017 are exempted from requirement of data uploading on Central Portal.

(vii) All drugs manufactured by non SSI units with manufacturing date on or after 01.04.2016 and all drug manufactured by SSI units with manufacturing date on or after 01 .04.2017 can be exported only if both tertiary and secondary packaging carry barcoding as applicable and the relevant data as prescribed by DGFT is uploaded on the Central Portal.

Explanation:

(a) For the purpose of this rule,

(i) Drug formulation means a formulation manufactured with a license from Drug Control Authority under the provisions of Drugs and Cosmetics Act and Rules made there under and registered as "Drug" with the FDA of importing country.

(ii) Primary packaging means the package which is in direct physical contact with the active ingredient.

Secondary packaging means a carton containing one or more primary packs and includes a mono carton containing one primary pack.

The tertiary packaging means a shipper containing one or more secondary packs.

(b) All relevant guidelines regarding grant of specific exemption (s) if any, procedure of data requirement/maintenance/upload on Central Portal and clarifications issued under this notification etc. will be available on the Central Portal *i.e. http://dava.gov.in*

(c) It will be the responsibility of the drug manufactures/exporters as the case may be, to satisfy the customs authorities that the export consignment satisfies the conditions of the notification".

3. **Effect of this Public Notice:**

In suppression of the earlier Public Notice no. l3/2015-2020 dated 22.05.2015, the dates for implementation of Track and Trace System for export of drug formulations alongwith maintaining the Parent-Child relationship in packaging have been extended to 01.04.2016 for non SSI manufactured drugs and to 01.04.2017 for SSI manufactured drugs.

Sd/-

(Anup Wadhawan)
Director General of Foreign Trade
E-mail: dgft@nic.in

(lssued from F.No. 01/91/180/648/AM 09/Export Cell)

SHRI DEREK O'BRIEN: Sir, the hon. Minister in the reply of five pages gives a good certificate to the Indian Pharmaceutical companies in a very positive way. In the light of that, I am putting my supplementary. Sir, there is 74 per cent FDI in pharma sector. This 74 per cent FDI in pharma sector can also go up to 100 per cent, by just having a cursory review by the FIPB. Sir, if you look at the Standing Committee recommendations of 2013, it was very clearly mentioned there that this increase in FDI would take the medicine prices go up for the common man. There is, for example, in Bengal, 48 to 77 per cent discount on medicines. Sir, my supplementary is: What steps is the Government taking to make medicines affordable and ensure that the domestic market is not affected by FDI and the campaign, which they call 'Make in India', actually becomes a campaign * ? ...(*Interruptions*)...

*Withdrawn by hon. Member.

MR. CHAIRMAN: That is not a question.

SHRI DEREK O'BRIEN: Sir, that is a comment to a question.

MR. CHAIRMAN: So, just ask the question.

SHRI DEREK O'BRIEN: If you want me to withdraw this slogan, then I will withdraw.

MR. CHAIRMAN: Please do. No slogans in question time.

SHRIMATI NIRMALA SITHARAMAN: Thank you for explaining the question that was put with a lot of narrative. Controlling spurious drugs is a very important thing because Indian pharmaceutical companies have achieved a certain stage internationally for producing quality goods. As we have said in the written answer, we don't maintain statistics about how many withdrawals have been made by our companies, whereas from the websites of those regulatory bodies in countries abroad, where the imports happened, we have extracted some information which has been provided in the answer. The steps that we take, and because this industry has already achieved a certain level of international acceptance and quality, we have found that on occassions majority of the spurious drugs which are going around are, unfortunately, being manufactured elsewhere with countries using 'Made in India' brand and the brand names which are used by the Indian pharmaceuticals. Spurious drugs are being sent both within India and also exported to countries where we have an export. So, the steps that we are taking are to ensure that quality medicine is available for Indians as much as when we export quality medicines abroad because the brand image that Indian pharmaceuticals have created for themselves cannot be upset either for the Indian consumers or the patients or for people who want Indian goods.

SHRI DEREK O'BRIEN: Sir, I accept the answer from the Minister on the quality of drugs. I appreciate that. My second supplementary is regarding Cancer and Thalassemia drugs. These are critical drugs. Now, the 5 per cent exemptions, which were granted by the CBEC, have been removed. Since then, it has gone from 0.5 to 10 per cent. So, there has been an increase, and these drugs are for Cancer, Thalassemia and many other critical diseases. Withdrawal of this exemption has created an impact. So, what is the current status of these exemptions? Has the Government taken any specific steps to ensure that the prices of these drugs do not go up because exemptions on these 15 drugs were, in fact, withdrawn? Sir, I have no questions on the quality. I accept that answer, but then, what steps will the Government take to ensure that the critical drugs, as outlined by the WHO and the National List of Essential Medicines, for example, for Cancer and Thalassemia, are kept at affordable limits so that everyone can afford?

SHRIMATI NIRMALA SITHARAMAN: Sir, regular and periodic consultations do take place on this particular concern regarding life-saving drugs. The NPPA and the Ministry of Health regularly review and essentially try to hold the prices of these life-saving drugs well under control, so that it is made available and remain affordable for all. These periodic reviews are done in all seriousness and I have participated in many of them. We can only say that these reviews, being done by the Ministry of Health and the NPPA, aim at ensuring that such drugs are available and also at affordable rates.

SHRI SHANTARAM NAIK: Sir, as far as sale of drugs is concerned, there is an important issue. Sale of drugs has been going on through courier services for some time now and objections have been raised by various companies. Established pharmacists have also protested because these courier companies don't have to pay tax, they do not have any liability and the business of established pharmacists is also being affected. Secondly, we don't know as to what types of drugs are being sold by these courier companies. We do not know whether these are medicinal drugs or other types of drugs which are being sold through courier services. Therefore, I would like to know whether the Government is thinking of any legislation to prevent or regulate selling of drugs through courier service.

SHRIMATI NIRMALA SITHARAMAN: Sir, the hon. Member's concern is well taken, but at the moment, there is no consideration.

SHRIMATI VIJILA SATHYANANTH: Sir, hon. Chief Minister of Tamil Nadu has raised a strong voice against opening up of FDI in the retail sector, especially in the pharmaceutical sector. I would like to know whether the Government is visibly aware of the hazardous effects of sale of medicines through Internet. I suppose the Government is going ahead with the amendments in the Drugs and Cosmetics Act, and I want the Government to focus thoroughly on the hazardous effects of sale of medicines through Internet. It should be completely discouraged and the on-line marketing of drugs should be banned.

SHRIMATI NIRMALA SITHARAMAN: Sir, the previous question raised by hon. Member, Shri Shantaram Naik, also, in a way, referred to this aspect only, and I have certainly tried to address it. The Ministry of Health and the Indian Regulator have both taken note of the Web pharmacy issue and it is they who are working towards seeing as to how this sector can be regulated. So, I can only go that far in answering this question, that the Regulator and also the Ministry of Health are the concerned authorities looking into this matter.

SHRI SANJIV KUMAR: Sir, there are certain medicines which are listed as Schedule-H drugs, but, at the same time, these are listed as Narcotic Drugs. So,

I want to know from the hon. Minister whether these drugs, which are listed as Schedule-H drugs, namely, Diazepam, Lorazepam, Alprax, Hydrotalcite, are being exported. If yes, how are these drugs being exported? Is there any special licence required or any conditions laid down?

SHRIMATI NIRMALA SITHARAMAN: Sir, there are licences which will have to be obtained and those are periodically notified under the Narcotics Act. The Narcotics Drugs are anyway regulated through the Ministry of Finance which has a wing, which takes care of the narcotics and psychotropic drugs, and, therefore, that is regulated by the notifications which are periodically issued by the Ministry of Finance, which manages the Narcotic Drugs Act.

Ceasefire with insurgent groups of Assam

*109. SHRI RIPUN BORA: Will the Minister of HOME AFFAIRS be pleased to state:

(a) the details of insurgent groups of Assam with which ceasefire agreement has been made so far;

(b) the organisation, name, location and number-wise details of designated camps that have been opened in Assam to keep the insurgent groups under ceasefire;

(c) whether any allowance, financial support is being provided to surrendered extremists staying in designated camps;

(d) if so, the amount given to them per month, per head;

(e) whether Government is taking up any rehabilitation scheme for them; and

(f) if so, the details of schemes and present status of implementation and progress of the rehabilitation schemes?

THE MINISTER OF STATE IN THE MINISTRY OF HOME AFFAIRS (SHRI KIREN RIJIJU): (a) to (f) A Statement is laid on the Table of the House.

Statement

(a) and (b) Government of India and Government of Assam have entered into suspension of operation agreements with insurgent groups of Assam which includes ULFA (Pro-Talk), NDFB (Progressive), NDFB (RD) and KLNLF. In addition, Government of Assam has entered into suspension of operation agreements with ACMA, BCF, KRA, UKDA, AANLA, STF, APA, KLO/KLA and HPC(D). There are certain designated camps for these insurgent groups in Assam where cadres of insurgent groups under suspension of operation live. Details of these designated