SOP FOR QUOTA ALLOCATION OF CONTROLLED SUBSTANCES FOR LOCAL CONSUMPTION

1. (a) Applications for quota allocation of controlled substance(s), shall be submitted by the firm(s)/applicants(s) latest by 7th January for each year, with consumption data (manufacturing & sale) till 31st December of previous year (this condition shall be applicable on the first meeting of the Committee for Allocation of Quota of Controlled Substances i.e. CAQCS, of that year only).

(b) The first four meetings of the Committee shall be convened on monthly basis and then after every 45 days. Excluding any exigency, last date for submission of application of imported controlled substances shall be **15th September** of each year except those locally produced/purchased controlled substance(s). The applications received till 7th date of each month for first four monthly meetings of the year shall be considered in the respective forthcoming monthly meeting of the Committee.

(c) The filled in checklist **(Annexure-I)** submitted with application shall be duly signed by MD / CEO of the firm/company. However due to unavoidable circumstances, the next senior most management person can be authorized by the MD/CEO to sign the said checklist, with undertaking on stamp paper giving the reason(s) for such authorization. Specimen signature of authorized person shall be attested in triplicate by MD/CEO and notarized which will be applicable /valid for one year, provided that in case of any change in management, such fresh authorization shall be furnished to this effect.

(d) Application(s) complete in all respects, having 65% consumption in manufacturing and 55% consumption in sales of the last allocation of the controlled substance, will be considered by the Committee in its meetings for quota allocation subject to the condition that the firm shall submit 100% manufacturing and 100% sales consumption other than last allocation (Carried Forward/quantities), except for locally produced substances for which condition of 75% (manufacturing) and 65% consumption (sale) shall remain intact.

(e) Each application will be evaluated initially by the concerned Assistant Director/Desk Officer, Division of Controlled Drugs, DRAP. The shortcomings so observed in the application(s) shall be communicated to the applicant after preliminary evaluation by the Division of Controlled Drugs, DRAP with the approval of Additional/ Deputy Director of Division of Controlled Drugs, DRAP within ten working days of receipt of application giving seven days' time to the applicant for submission of reply for further evaluation of the case by the Division of Controlled Drugs, DRAP again. The application so evaluated by the Division shall

be scrutinized subsequently by the Scrutiny Committee comprising of officers of Ministry of Narcotics Control, Anti Narcotic Force (ANF) and DRAP.

(f) Only those applications shall be included in agenda of meeting of CAQCS for its consideration and decision which have been evaluated by Scrutiny Committee and found complete. However incomplete applications/cases as determined by the Scrutiny Committee along with recommendations shall also be included in the agenda for consideration/endorsement of the CAQCS.

(g) The agenda of meeting(s) for quota allocation of controlled substances shall include the minutes of respective meeting(s) of Scrutiny Committee and the miscellaneous cases.

(h) Chronological/FIFO principle (First In First Out) will be ensured for smooth functioning of the CAQCS for quota allocation of controlled substances.

(i) In case of any reservation on the deferment of the application/case, the applicant(s) may apply / request to the Chairman CAQCS for personal hearing regarding redressal of the grievances.

2. Only those firms will be granted quota of Controlled Substances, which have fulfilled the conditions / procedures, as laid down in the quota allocation letter and import permit/authorization (as per **Annexure-K & L**).

3. The firms having sales reported in the IMS should submit the relevant IMS data along with their application dossier. The IMS data will be considered for framing of ALR.

4. All firms shall submit notarized copies of following documents along with their application(s):-

i. For imported controlled substances, the record of last three-year allocation letters (Routine + Enhancement, if any), Import Authorizations, along with notarized copy of import invoices cleared by respective Assistant Director, DRAP.

ii. Copies of invoices of locally purchased/procured controlled substances.

iii. Consumption certificate (for controlled substances mentioned in para-8/N).

5. Allocation of the controlled substances to the applicant firms will be made on the basis of below mentioned formula as approved by CAQCS.

i. Allocations will be done on the basis of average of 03 years consumption of the respective controlled substance or last year's allocation or fixed quantity for new registration (first time allocation) of Controlled Substances as per Annex-C of the SOP for allocation of quota of controlled substances approved in 78th meeting of CAQCS, whichever figure is higher subject to demand of the firm. If the firm did not avail/import last year's allocated quota due to any reason, then the average consumption will be considered on the basis of

previous two years consumption. However, this condition will not be applicable on the applicant who at its own did not apply for quota allocation in the last year.

ii. 5% increase on routine allocations will be given to those firms which have mentioned the demanded quantity in their application. However, this 5% increase will not be applicable on Ephedrine and Pseudoephedrine or any other Controlled substance which the Committee deems/considers appropriate at the time of meeting.

iii. If any firm applies for enhancement of quota the Committee may allocate up to 10% of routine allocation of the said controlled substance except Ephedrine to the firm taking into consideration the facts/reasons on ground/record on following criteria:

a. Availability of Annual Legitimate Requirement (ALR) of the controlled substance on the day of meeting of CAQCS.

b. Number of applicants for quota allocation (routine /enhancement)

c. Allocation of enhancement shall be made uniform for all applicant firms in case the available ALR of that particular substance is not sufficient for total enhancement allocation.

iv. In case, a firm does not apply for allocation of quota for consecutive 03 years than allocation shall be made according to first time allocation as per annexure-C of the SOP.

6. (a) The firms shall provide documentary evidence to justify their existing quota by submitting the following:

i. Manufacturing record of last three years on **Annexure-A** (Both hard and soft copies in Excel format on Protected CD/USB)

ii. Sales record of last three years on **Annexure-B** (Both hard and soft copies in Excel format on Protected CD/USB)

iii. Secondary sales data/record as per **Annexure-D** shall be submitted by firms in following conditions.

1. If all the stock had been sold to a single distributor.
2. In case of single distributor with multiple depots, the manufacturer will provide stock position of the regional branches (Main warehouse to 2nd Tier) of the distributor.

(b) All the firms will provide list of their authorized distributors.

(c) Annexures submitted with the applications shall be signed only by specified persons as mentioned in the respective annexure format. However, in unavoidable circumstances, the senior most management person can be authorized by the MD / CEO to sign the annexures, with undertaking giving the reasons for such authorization thereof. The specimen signature of authorized person shall be attested in triplicate by MD/CEO and notarized which is applicable/valid for one year, provided that in case of any change in management, such fresh authorization shall be furnished to this effect.

7. The quota for the firm(s) who have applied for the new registration (first time allocation of controlled substance) will be allocated as per quantity fixed for the said purpose as per **Annexure-C.** However, in case of special circumstances/emergencies the CAQCS can allocate other than the fixed quantity and the reasons for such allocations shall be recorded in that particular minutes of the meeting of the Committee.

8. Consumption certificate issued by the authorized officer of DRAP, based on physical inspection / verification, would be mandatory for controlled substances namely;
Alprazolam, Buprenorphine, Codeine, **Clonazepam**, Diazepam, Fentanyl, Morphine, Pethidine, Pentazocine and Phenobarbitone.

9. The firms shall have to submit following notarized undertakings with their quota allocation application (s):-

i. Undertaking for fulfilment of the conditions of previous allocation(s) of controlled substance on **Annexure-F-I.**
ii. Undertaking for utilization of controlled substance in Licit manufacturing of the registered product(s) on **Annexure-F-II.**

10. All documents (photo copies) attached with the application shall be marked as “Certified True Copy" of the original and the same shall be notarized from Notary Public.

11. a) **The application(s) of the firm(s) for enhancement of quota of imported controlled substance(s) will be entertained by the Committee from 01st July onward till 15th September & till 15th November of each year for locally purchased Controlled substances.** Provided that the enhancement will be granted once in a year with the condition of consumption of 75% manufacturing & 65% sales of last allocation.

b) Audit/verification of the consumption record may be done at any stage by the Division

of Controlled Drugs, DRAP and/or by the panel approved by the CAQCS.

12. Enhancement and allocation applications will be considered at any time in case of natural calamities and any other emergencies declared by the Government(s) and deemed appropriate by the CAQCS.

13. While providing information regarding source for import of Controlled Substance(s), name(s) and address(es) of Manufacturer and Exporter shall be provided along with notarized copy of valid GMP certificate of manufacturer abroad.

14. Following documents shall be submitted by the firm(s)/applicant(s) as pre-requisites with application for allocation of quota of controlled substances for import of Reference Standard(s) for testing/ analysis purpose.

i. Application on letter head of the firm mentioning the quantity of controlled substance (Reference Standards) to be imported with justification and mentioning name and complete address of the exporter/manufacturer abroad.
ii. Notarized copies of valid Drug Manufacturing License (DML) **along with Psychotropic Section Approval Letter issued by the Licensing Division of DRAP** and Product Registration Letter **with renewal record/renewal**.
iii. Reference of Monograph of the Controlled Substance (Reference Standard).
iv. SOP of the applicant firm describing the utilization of reference standard as per cGMP.
v. Notarized copy of proforma invoice for import.
vi. Approved processing fee as per SRO.

15. Following documents shall be submitted by the firm(s)/applicant(s) as pre-requisites with application for allocation of quota of controlled substances for import/local purchase of controlled substances (APIs) for conducting the stability studies/new source qualification,

i. Application on company's letter head mentioning the quantity of controlled substance (API) to be imported with justification and mentioning name and complete address of the exporter/manufacturer abroad.
ii. Notarized copies of valid Drug Manufacturing License (DML) and Product Registration Letter.
iii. Reference of Monograph of the relevant Controlled Substance.

iv. SOP of the firm for carrying out stability studies, new source qualification/vendor approval etc.

v. The firm will submit data/record of manufacturing and QC analysis of stability/trial batches.

vi. The trial batches manufactured for stability studies after their expiry, will be destroyed with the approval of the Committee as per approved SOP.

vii. If the product is not yet registered with DRAP, the case will be considered in the meeting of CAQCS after recommendation of the Drug Registration Board, DRAP for conducting such studies.

viii. Notarized copy of proforma invoice for import.

ix. **Approved processing fee as per SRO**.

16. Pre-requisites/documents for change of name/address of source/origin to import any controlled substance (API/Finished Product) by the applicant firms for the issuance of fresh import Authorization/permit after approval of Chairman of the CAQCS to import the allocated Quantity of the Controlled Substances from new identified source:

i. Application on the letter head of the Company regarding the change of supplier/source with reason(s) thereof.
ii. SOP of the firm for vendor/source qualification or the change of supplier/source of the API/Controlled Substance(s).
iii. No import certificate duly issued by concerned area Assistant Director, DRAP, in respect of earlier/previous issued Import Authorization/Permit by DRAP.
iv. Notarized under-taking on stamp paper duly signed by the MD/CEO of the firm regarding no import of the allocated quantity of controlled substance against the already issued import authorization/permit.
v. Notarized copy of valid cGMP certificate of the newly identified manufacturer/source abroad issued by the regulatory authorities of the respective country.
vi. Import authorization/permit (both original as well as exporter's copy) previously issued by the Division of Controlled Drugs, DRAP, Islamabad in light of the firm's earlier request.
vii. Proforma invoice by the vender/supplier regarding the import of controlled substance from the newly identified source/origin.

viii. Approved processing fee as per SRO.

17. Pre- requisites for extension of validity of import/ export permit (s)

i. Application on the letter head of the firm stating the reason(s) of extension of validity of import/export permit.
ii. Processing fee i.e. Rs.5000/ as per S.R.O 765(I)/2018 dated 19th June 2018.
iii. No import/export Certificate issued by concerned Assistant Director, DRAP.
iv. Under-taking on stamp paper by the CEO/MD of the applicant firm stating that quantity of controlled substances issued vide earlier import Authorization No. date is not imported.

****

Annexure -I

CHECK LIST FOR ALLOCATION OF QUOTA OF CONTROLLED SUBSTANCE(S)

Name of Applicant firm with complete Address_____ Name of Controlled Substance: _____ Year: _____
Quantity Demanded _____

Sr. #		Name of Document			Yes/ No	Page#	Quantity (where applicable)	Remarks
1	1.1	Application is for	**I**. Routine allocation ☐	**II.** First Time ☐				
			III. Enhancement ☐					
2	2.1	Notarize Undertaking on stamp paper for fulfillment of conditions of previous allocation letter as per **Annexure-F1**						
3	3.1	Sales reported in the IMS along with IMS data, if applicable.						
4	4.1	Quota allocation letter and Import Authorization for the year , 2017						
	4.2	Quota allocation letter and Import Authorization for the year, 2016						
	4.3	Quota allocation letter and Import Authorization for the year, 2015						
5	5.1	Notarized Copies of Purchase invoices cleared/attested by Assistant Director, DRAP (for Imported Controlled Substances) and Notarized Copies of Purchase Invoices (for Locally Purchased Controlled Substances).						
6	6.1	Manufacturing record for the year, 2017 as per **Annex-A**.						
	6.2	Manufacturing record for the year , 2018 as per **Annex-A**						
	6.3	Manufacturing record for the year , 2019 as per **Annex-A**						
7	7.1	Consumption for the year 2017 supported by documents of sales record as per **Annex-B**.						
	7.2	Consumption for the year 2016 supported by documents of sales record as per **Annex-B.**						
	7.3	Consumption for the year 2015 supported by documents of sales record as per **Annex-B.**						
	7.4	Consumption for the each year supported by documents of sales record as per **Annex-D** (If Applicable).						
	7.5	Average consumption for the three years						
	7.6	Percentage (%) of Consumption of last allocation (Manufacturing and Sales)						
8	8.1	Consumption certificate from concerned Area Assistant Director, DRAP for the Alprazolam, Buprenorphine, Codeine, **Clonazepam,** Diazepam, Fentanyl, Morphine, Pethidine, Pentazocine and Phenobarbitone.						
9	9.1	Undertaking on stamp paper for licit manufacturing as per **Annex-F2**						
10	10.1	Copy of the valid Registration letter of the drug (with status of renewal)						**As per Annex-E**
11	11.1	Copy of valid Drug Manufacturing License (with status of renewal)						
	11.2	**Psychotropic/Narcotic Section Approval by the Central Licensing Board, DRAP.**						
	11.3	**NOC from Ministry of Narcotics Control after combined ground check by DRAP & ANF (when applicable).**						
	11.4	**Soft data of Annexure-A & B on excel format along with PDF Scan (Not more than 5MB) of complete application on USB**						

Name, Seal & Signature of MD/CEO/Authorized Person

Annexure -A

MANUFACTURING RECORD FOR THE YEAR_____(w.e.f. 1ST JANUARY TO 31ST DECEMBER)
TO BE SUBMITTED ALONG WITH THE APPLICATION OF QUOTA ALLOCATION FOR THE YEAR_____

1. NAME OF THE CONTROLLED SUBSTANCE …… ……2. QUANTITY ALLOCATED (Year)…… (Gram/Kg)
3. BALANCE QUANTITY (Carry Forward) FROM PERVIOUS YEAR …….. …….4. TOTAL QUANTITY ……(Gram/Kg)

Sr. #	Name (Brand) of the Drug	Registration #	Batch #	Pack size	Date of Manufacture	Quantity of Packs Manufactured	Composition for the controlled substance	Quantity of R.M consumed	Remarks

1	Pack size with strength of the Finished Drug of Commercial Packs and Physician sample *	Strength								
		Pack Size								
2	No of Units Manufactured									
3	Quantity of Controlled Substance Consumed (Gram/Kg)									
4	Yield Loss during Manufacturing percentage and quantity (% & Gram/Kg)									
5	Total Quantity of Controlled Substance Consumed in QC/QA Sample (Gram/Kg)									
6	Total Quantity of Controlled Substance Consumed(Gram/Kg)									
7	Quantity of raw material in balance (Gram/Kg)									

Name, Seal & Signature
PRODUCTION MANAGER

Name, Seal & Signature
QUALITY CONTROL MANAGER

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

*Add row(s) where required.

Annexure -B

SALE RECORD FOR THE YEAR_____ (w.e.f. 1ST JANUARY TO 31ST DECEMBER)
TO BE SUBMITTED ALONG WITH THE APPLICATION OF QUOTA ALLOCATION FOR THE YEAR_____

NAME OF THE CONTROLLED SUBSTANCE ……CARRY OVER FINISHED STOCKS FROM PERVIOUS YEAR ……Kg/Gram

Sr. #	Name (Brand) of the Drug	Registration #	Pack Size	Batch Number	Date of Manufacture	Quantity of Packs Manufactured	Name of the Distributor (s) with Address, City and Province	Quantity Sold	Warranty Number/ Sale Invoice with date	Remarks

1	Pack size with strength of Finished Drug of Commercial Packs and Physician sample *	Strength							
		Pack size							
2	Total Unit Packs sold								
3	Quantity of raw material consumed (Gram/Kg)								
4	Total Unit Packs unsold (lying in warehouse)								
5	Quantity of raw material for Unit Packs unsold (Gram/Kg)								
6	Total Quantity of raw material consumed (Gram/Kg)								

Name, Seal & Signature
DIRECTOR/ MANAGER SALES

Name, Seal & Signature
AUTHORIZED WARRANTOR

Name, Seal & Signature
MANAGING DIRECTOR/
CHIEF EXECUTIVE OFFICER

*Add row(s) where required.

Annex-C

Approved fixed quantity for New Registration (first time allocation)		
S.No.	**Controlled Substance**	**Fixed Quantity for New Registration (First Time Allocation of Controlled Substance)***
1	Alprazolam	01Kg
2	Bromazepam	4.5 Kg
3	Buprenorphine	18.10 Gram
4	Chlordiazepoxide	10Kg
5	Clobazam	3.75Kg
6	Clonazepam	02 Kg
7	Codeine	50 Kg
8	Diazepam	25Kg
9	Diphenoxylate	05 Kg
10	Ephedrine	10 Kg
11	Ergotamine	2Kg
12	Ergometrine	--
13	Estazolam	1Kg
14	Fentanyl	15 Grams
15	Fludiazepam	--
16	Lorazepam	02 Kg
17	Lormetazepam	1Kg
18	Methylphenidate	3.83 Kg
19	Meprobamate	--
20	Medazepam	
21	Midazolam	3.74Kg
22	Morphine	01 Kg
23	Nimetazepam	--
24	Nitrazepam	2.10Kg
25	Oxazepam	--
26	Pinazepam	--
27	Pentazocine	3Kg
28	Pethidine	2.5Kg
29	Phenobarbitone	15Kg
30	Pholcodine	5Kg
31	Prazepam	--
32	Pseudoephedrine	**50 Kg
33	Temazepam	6 Kg
34	Triazolam	--
35	Zolpidem	1Kg

******* ***The above mentioned quantities are fixed for the new registration (first time allocation of controlled substance), however in case of special circumstances the CAQCS can allocate other quantity and the reasons for such allocations shall be recorded in that particular minutes of the meeting of the Committee.***

******** ***The Committee also decided that the firms holding three (3) or more formulations containing Pseudoephedrine due to line extension/strengths, different combinations formulations and different dosage forms shall be allowed additional quota of 50% of standard batch size of brand leader (50Kg).***

Annexure -D

SECONDARY SALE RECORD/DATA FOR THE YEAR_____ (w.e.f. 1ST JANUARY TO 31ST DECEMBER)

TO BE SUBMITTED ALONG WITH THE APPLICATION of QUOTA ALLOCATION FOR THE YEAR_____

NAME OF THE CONTROLLED SUBSTANCE …….CARRY OVER FINISHED STOCKS FROM PERVIOUS YEAR …… (Kg/Gram)

Sr. #	Brand Name of the Drug	Registration #	Pack Size	Batch Number	Date of Receiving	Quantity of Packs Received	Name of the Distributor (s)/Chemist/Pharmacy with Complete Address to whom the stock(s) sold	Quantity Sold	Warranty Number/ Sale Invoice with date	Remarks

1	Pack size with strength of the Finished Drug of Commercial packs *	Strength							
		Pack size							
2	Total Unit Packs sold								
3	Quantity of raw material consumed (Gram/Kg)								
4	Total Unit Packs unsold (lying in warehouse)								
5	Quantity of raw material for Unit Packs unsold (Gram/Kg)								
6	Total Quantity of raw material consumed (Gram/Kg)								

Name, Seal & Signature
Managing Director/
Chief Executive Officer/Proprietor Of The Distributor

Name, Seal & Signature
Managing Director/
Chief Executive Officer Of The Manufacturer

*Add row(s) where required.

Annexure-E

MANUFACTURER / IMPORTER DETAIL

Sr. #	Name of Manufacturer with Address	Type Of license	License No.	Date of Issue	Last Renewal	Remarks
1						

BRAND(s) DETAIL

Sr. #	Brand (S)	Registration No	Approved Pack Size	Approved Composition	Date of Registration	Date of Transfer of Registration (If Any)	Last Renewal of Reg.	Remarks
1*								
2								

*Add rows as per brands and pack size if required.

Annexure -F1

UNDERTAKING FOR FULFILLMENT OF CONDITIONS OF PREVIOUS ALLOCATION OF CONTROLLED SUBSTANCE

I……..……. CNIC # …… resident of…… hereby undertake, on behalf of M/s…….. Drug Manufacturing License No..... situated at ……., that the firm has fulfilled all the conditions of the previous allocation as per DRAP's letter # ……dated……. regarding the controlled substance i.e. ……. quantity Allocated…….. in the year……

Name……

Signatures…….

Seal/Stamp……..

Designation: MD/CEO/Authorized Person

Annexure -F2

UNDERTAKING FOR LICIT MANUFACTURING OF CONTROLLED SUBSTANCE

I……..……. CNIC # …… resident of…….. hereby undertake, on behalf of M/s…….. DML#..... situated at ……., that

- The quota of controlled substance i.e. ……. granted in the last allocation i.e. year……. as per DRAP's letter # …….dated……. has been utilized in the licit manufacturing of registered product(s) (Product Name, Registration #, Valid till [date]) and new quota will also be used for licit manufacturing of the said registered product(s) and maximum precautions will be taken to avoid any possible diversion.
- All documents attached with the application are true copies of the original and the same have been notarized from notary public and marked as "Certified True Copy".
- All other submitted information is true and correct.

The under signed and the firm M/s…….. shall be held responsible and shall be liable for legal proceeding/action under the law in case any submitted information is found incorrect/misleading at any stage.

Name……
Signatures…….
Seal/Stamp……
Designation: MD/CEO/ Authorized Person

Annexure-K

Conditions of Allocation Letter

1. This permission is valid up to **31-12-20……..**
2. Maintain proper record of purchase of raw material, utilization/manufacture & sale of finished drugs containing the above mentioned controlled substance as required by National as well as International Agencies.
3. Furnish the following data / information to this Division, and the Federal Inspector of Drugs, Assistant Director (I&E) and Provincial Health Department concerned within two days of the purchase/release of consignment from the customs:
   a. Name and quantity of the raw material purchased/imported alongwith a notarized copy of invoice cleared / endorsed by the concerned Assistant Director (I&E)
   b. Date on which the raw material was purchased/ consignment was released from the customs.
   c. Address of premises/godown, where the material/ consignment is stored.
   d. As and when the above raw material is to be consumed (this information can be given before or on the same date on which the raw material is to be used).
   e. Batch size and theoretical yield.
4. Furnish the following data/information regarding consumption of the raw material and drugs manufactured from it to F.I.D, Assistant Director and Provincial Health Department concerned.
   a). Name and quantity of the drug(s) manufactured.
   b). Batch No(s).
   c). Date of Manufacture.
   d). Mode of transaction/sale of the drug(s) along with name(s) and address(es) of firm / distributor(s) to whom the drug was sold.
5. Further allocation will be considered after receipt of utilization of raw material purchased/ imported earlier which shall be supplied forthwith immediately after its consumption.
6. You will be responsible to ensure that drug(s) manufactured from above raw material are supplied to only those firms /distributors who are maintaining their record of sale and utilization at distribution/wholesale level. The distributor(s)/wholesaler(s) must be instructed to get compliance from retailers regarding prescription requirement & proper record keeping / maintenance as per requirement of the respective Drugs Sales Rules.
7. The drug(s) shall be promoted to the Registered Medical Practitioners only and the literature shall be amended accordingly.
8. Necessary formalities as required under the Drugs (Import & Export) Rules, 1976 may be completed through concerned Assistant Director (I&E).
9. *Compliance must be made to above mentioned conditions. Noncompliance could hold you responsible for an action under the Drugs Act, 1976 or/and Control of Narcotic Substances Act, 1997 or any other law which is for the time being in force.*
10. Notarized copy of valid Good Manufacturing Practices (GMP) Certificate clearly indicating name of the controlled substance of the manufacturer abroad is required along with the request for issuance of Import Authorization.
11. **Any other condition deemed appropriate by the Committee in its purview…..**

Annexure-L

Conditions of Import Permit/Authorization

1. This permission is valid for **180 days** from the date of issue or till **31-12-20…..,** whichever is earlier.
2. Part shipment is not allowed.
3. Utilization report of Import Authorization along with copy of invoice must be submitted to this Authority immediately on receipt of the consignment
4. Separate record of import, stock consumption and sale of drug manufactured should be maintained
5. Furnish the following data / information to this Division and the Federal Inspector of Drugs, Assistant Director (I&E) and Provincial Health Department concerned within two days of the release of consignment from the customs:
   a. Name and quantity of the raw material imported.
   b. Date on which the consignment was released from the customs.
   c. Address of premises/godown, where the consignment is stored.
   d. As and when the above raw material is to be consumed (this information can be given before or on the same date on which the raw material is to be used).
   e. Batch size and theoretical yield.
6. Furnish the following data/information regarding consumption of the raw material and drugs manufactured from it to F.I.D, A.D. and Provincial Health Department concerned.
   a). Name and quantity of the drug manufactures.
   b). Batch No.
   c). Date of Manufacture.
   d). Mode of transaction/sale of the Drugs along with name(s) and address(s) of firm to whom the drug w sold.
7. Further allocation will be considered after receipt of utilization of raw material imported earlier which shall be supplied forthwith immediately after its consumption.
8. You will be responsible to ensure that drugs manufactured from above raw material are supplied to only those who are maintaining their record of sale and utilization at distribution/wholesale level. The distributor/wholesalers must be instructed to get compliance from retailers regarding prescription requirement & proper record maintenance.
9. The drug shall be promoted to the Registered Medical Practitioners and the literature shall be amended accordingly.
10. Necessary formalities as required under Drugs (Import & Export) Rules, 1976 may please be completed through concerned field officer.
11. ***Compliance must be made to above mentioned conditions otherwise necessary action will be initiated against the firm under the Drugs Act, 1976 or Control of Narcotic Substances Act, 1997 or any other law which is for the time being in force.***
12. Please make sure the correct source of procurement since no amendment letter for change of Source and Exporter's address will be issued. However fresh Import Permit will be issued after approval by the Competent Authority.
13. **Any other condition deemed appropriate by the Committee in its purview…..**

End of Document

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