STANDARD OPERATING PROCEDURE (SOP) FOR QUOTA ALLOCATION OF PHARMACEUTICAL PRODUCTS CONTAINING CONTROLLED SUBSTANCES TO TERTIARY CARE HOSPITALS LOCATED IN ICT, ISLAMABAD

1. **Requirements/Pre-requisites:**

   a) Application to be made on letter head of the hospital/institution duly signed by Head (CEO/MD/MS/ED) of the hospital/institution and Head of Pharmacy department of the hospital clearly indicating the quantity of registered pharmaceutical products containing Narcotic substances to be purchased/ procured.

   b) Checklist duly filled and signed by Head of the hospital/institution and Head of Pharmacy Department along with its related information/documents as mentioned in checklist **(Annexure-III).**

   c) All applicant hospitals shall prepare and implement their internal SOP as per Control of Narcotics Substances Rules, 2001 and relevant Drugs Sale Rules for storage, distribution/dispensing and prescription of pharmaceutical products containing controlled substances along with the record keeping.

2. **Procedure:**

a) The application(s) will be preliminary evaluated by concerned Assistant Director/Desk Officer, Division of Controlled Drugs, DRAP. In case of shortcoming(s) in application the same will be communicated to applicant after the approval of the Additional/Deputy Director, CD, DRAP.

b) ***The Controlled Drugs Division, DRAP shall cause inspection of the Hospital by its Officer (s) as early as possible on fulfilment of requirement as per SOP.*** The panel shall inspect the hospital/institution to verify the consumption of previously allocated quantity of controlled medicine through the following: -

   i. Record and documented evidence for utilization of controlled drugs/medicines,
   ii. Empty ampules/containers/packs available at the site/premises etc.

iii. Patient File/record for cross checking of utilization of the drug/stock, kept as evidence.

c) The panel will also check/observe the storage condition of the drugs/medicines as per their standard/prescribed requirement and also recommend the quantity of drug(s) to be purchased/procured for a certain period keeping in view the monthly consumption as per record /data reviewed.

d) In case of first-time application, the above panel shall determine the justified quantity in the light of demanded quantity and also check the arrangement for storage of these drug(s) and verify the specialties in the hospital/institution to utilize the required Narcotics/Controlled drugs along with recommendation.

e) Panel after inspection shall submit report thereof to Division of Controlled Drugs, DRAP, for further processing / necessary action.

f) ***The Controlled Drugs, Division, DRAP will send recommendations to Ministry of Narcotics Control for issuance of No Objection Certificate (NOC) to the concerned hospital of the ICT, Islamabad for procurement of the narcotic drugs.***

g) In case of non-recommendations, the hospital/institution will be informed by the Division of Controlled Drugs, DRAP. If the observations/shortcomings pointed out by the panel are addressed by the hospital management, re-inspection on the written request of the applicant may be carried out by the panel for verification and report thereof.

h) ***Controlled Drugs Division, DRAP may conduct a detailed panel inspection of the Hospital (s) on yearly basis and may co-opt any member for the said function.***

3. <u>Conditions:</u>

a) Hospitals applying for the first time for permission for purchase/procurement of Narcotic medicine or enhancement in the previous allocated quota shall provide justification of demanded quantity duly recommended by the head of specialty to the panel of inspectors. This may include specialty details in which narcotic medicine are to be used, Number of beds with patient influx, estimated consumptions specialty wise details.

b) Application for subsequent allocation of quota of Narcotic medicine shall be made after documented evidence of consumption of **50%** of quota of previous allocation. Hospitals shall furnish consumption details of previous allocation on **Annexure- H**.

c) All the hospitals located in Provinces shall apply to the Ministry of Narcotics Control, Islamabad for issuance of NOC for procurement of drugs containing controlled substances through the Director General Health Service of the respective province with the recommendations.

4. Following pre-requisites/documents are required from applicant hospital for change of supplier/vendor for procurement/purchase of products containing controlled substances for the hospital located in ICT, Islamabad

I. Application by the head of Pharmacy/ Chief Pharmacist /Medical Superintendent/ or any authorized person for the said purpose on letter head of the hospital stating the reason of change of supplier / vendor.

II. Under-taking on stamp paper by the head of Pharmacy/ Chief Pharmacist /Medical Superintendent/ or any authorized person for the said purpose of the Institution stating that products containing controlled substances as per NOC # dated issued by the MNC was not purchased or quantity remaining to be purchased from the new supplier/vendor/source. (In case of public sector hospitals such information may be given on the official letter head of the institute)

III. Notarized copies of Inventory register/ Stock register of the said products containing controlled substances stating the current stock status of the drug.

IV. Consent in written for availability of the drug products containing controlled substances along with proforma invoice from the vendor/supplier from which hospital has applied to purchase the products containing controlled substances.

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Annexure -III

Check List for Allocation of Quota of Registered Pharmaceutical Products Containing Narcotic/ Controlled Substances to the Tertiary Care Hospitals Located in Islamabad Capital Territory (ICT), Islamabad.

Sr. #		Name of Document	Yes/No	Page#	Remarks
1		Application is for first time/routine allocation or for Supplementary Quota.			First time/ Routine/Supplementary
2		Documented evidence for previous allocation			
	(a)	Copy of Recommendation letter by DRAP			
	(b)	Copy of approval/NOC letter issued by Ministry of Narcotics Control, Islamabad			
	(c)	Copy of Purchased invoices with signature date and stamp of In charge Head of Pharmacy Department of Hospital and countered signed by Head (MS/CEO/ED) of the hospital.			
	(d)	Extension letter for purchase of controlled drugs (if applicable)			
	(e)	Copy of previous consumption verification report by panel			
5		Consumption detail of last allocation as per **Annex-H for** year ……			……Ampoules/Oral unit dose
6		Average consumption of last allocation per month			……Ampoules/Oral unit dose
7		Percentage consumption of previous allocation **(Not less than 50%)**			
8		• The Hospitals/Institutions shall submit the Undertaking on stamp paper stating that the quota granted previously has been consumed in the licit use for patient care management and new quota will also be consumed for licit use and maximum precaution will be taken to avoid any possible diversion/pilferage. • All other documents/information submitted information are true and correct.			

Name, Seal & Signature
CEO/MD of Hospital/Institute

Name, Seal & Signature
CEO/MD/Head of Pharmacy Department of Hospital/Institute

Annexure -H

CONSUMPTION RECORD FOR THE ALLOCATION OF THE DRUG(S) CONTAINING CONTROLLED SUBSTANCES TO BE SUBMITTED ALONGWITH THE QUOTA APPLICATION BY THE HOSPITAL LOCATED IN ICT, ISLAMABAD.

1. Name of the Registered Product ……. ……. 2. Name of Controlled Substance(s)……
3. Quantity Allocated (Year)……
4. Balance Quantity from Pervious Allocation …….. …… 5. Total Quantity …….Ampoules/oral unit dose
6. Name of the Manufacturer/Supplier…….. …7. Invoice #.....dated……..

Sr.#	Name of Registered product containing Controlled substances	Patient Name	Patient ID/ Registration No.	Department	Diagnosis	Prescribed by	Date of Dispensing	Quantity dispensed	Dispensed by (name with designation)	Administered by (name with designation)
	*									

1	Strength & Pack size of the Finished Product*		
2	Batch No		
3	Expiry date		
4	Total units consumed		
5	Total Quantity of medicine expired/rejected/damaged/Broken (If Any)		
6	Total Quantity of medicine in balance		
7	Summary of specialty wise issuance of narcotic medicine(s)	Department Name	Quantity Issued

Name, Seal & Signature
CEO/MD/MS of Hospital/Institute

Name, Seal & Signature
Head of Pharmacy Department

*Add row(s) if required.

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