**Article Content**

**Title**： Regulations Governing the Allocation and Purchase Limitation of Schedule 1 and 2 Controlled Drugs CH

**Amended Date**： 2022-09-20

**Category**： Ministry of Health and Welfare（衛生福利部）

**Attachment**： Attached table Quota of yearly purchases of schedule 1 and 2 controlled drugs table.pdf
Attached table Quota of yearly purchases of schedule 1 and 2 controlled drugs table.doc

Article 1 The regulations are issued in accordance with Article 22 of the Controlled Drugs Act (hereinafter "this Act").

Article 2 For medical institutions, drug stores, veterinarian institutions and pasturage veterinarian institutions, the yearly (from January 1 to December 31 of the same year) purchases of schedule 1 and 2 controlled drugs quantities shall not exceed the requirement of the attached table. If the drug inventory exceeds half the annual quota, the purchase quantity shall be restricted.
The institutions in the preceding Paragraph, if the actual requirement exceeds the quota listed in the attached table, may submit controlled drugs quota increase application form and relevant data and apply to the Food and Drug Administration, Ministry of Health and Welfare (hereinafter "FDA"). After approval, the annual quota will follow the new approved quota.Attached table Quota of yearly purchases of schedule 1 and 2 controlled drugs table.pdf
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Article 3 For research laboratories, the purchases of schedule 1 and 2 controlled drugs shall follow Article 6 of this Act approved medicine education and research experiment program required quantity restriction.

Article 4 For human medicine manufacturers and veterinary medicine manufacturers, the purchase of schedule 1 and 2 controlled drugs in the form of raw material drug to produce drugs containing controlled drug component, they shall fill out application form. The purchased quantities are limited by the production plan

required raw material drug quantities. If the raw material drugs inventory exceeds 50% of the previous purchased quantity, the FDA may limit its purchase quantity.
If the above-mentioned applications for drugs in the form of raw material drugs are to produce schedule 3 and 4 controlled drugs, it shall follow Article 20 of this Act to apply for controlled drug production agreement form. If they are used to produce non-controlled drug, it shall be reported monthly, in accordance to the final retail sales objects' data of that drug, to the FDA and local health administration at each sales locality.

Article 5 The total quantities of schedule 1 and 2 controlled drugs for basic military medical units, shall be estimated annually (from January 1 to December 31 of the same year) by the military medical control organization. After the application to the FDA is approved, the purchases shall be in batches and made to the controlled drugs pharmaceutical plant of the FDA.

Article 6 The regulations shall come into force from the date of their promulgation.

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