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- A- List of forms used for making applications for issuing licences, granting license, sending memorandums.
- **B-** Fees for test or analysis by the Central drug laboratory or Government analyst.
- C- Biological and special product.
- C(1) Other special products (the import, manufacture and sale of Schedule C & C(1) drugs Governed by special provisions)
- D- List of drugs exempted from the provisions of import of drugs.
- E- (1) List of poisonous substances under the ayurvedic (including siddha) and unani systems of medicine.
- F- & F₁- Provision applicable to the production, testing, storage, packaging and labeling of Biological & special product.
- F2- Standards for surgical dressings.
- **F3-** Standards for sterilized umbilical tapes.
- FF- Standards of ophthalmic preparations.

PHARMACEUTICAL JURISPRUDENCE

Drugs & Cosmetic Act: The Drugs & Cosmetic Act was passed in 1940 (10th April), with the main object to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

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- R- Standards for mechanical contraceptives.
- S- Standards for cosmetics.
- T- Requirements of factory premises and hygienic conditions for ayurvedic (including siddha) and unani drugs.
- U- Particulars to be shown in manufacturing, raw material and analytical records of drugs.
- U1- Particulars to be shown in manufacturing, raw material and analytical records of cosmetics.

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- V- Standards for patent or proprietary medicines.

X- List of habit forming, psychotropic and other such drugs.

Y Requirements and guidelines on clinical trial for import and manufacture of new drugs.

FORMS FOR MANUFACTURE, SALE, REPACKAGEING AND IMPORT OF DRUGS

Sr. No.	Purpose	Drugs	Application made in Form No.	Licence granted in Form No.
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32

- W- List of drugs which shall be marketed under generic name only.
- X- List of habit forming, psychotropic and other such drugs.
- Y Requirements and guidelines on clinical trial for import and manufacture of new drugs.

FORMS FOR MANUFACTURE, SALE, REPACKAGEING AND IMPORT OF DRUGS

Sr. No.	Purpose	Drugs	Application made in Form No.	Licence granted in Form No.
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32
		ii. Loan manufacture of Cosmetics	31A	32A
		3. i. Ayurvedic and Unani drugs.	24D	25D
		ii. Loan manufacturing of A and U drugs	24E	25E
		4. i Drugs specified in Schedule C, C1 and X	27B	28B
	PS	ii. Drugs specified in Schedule C and C1, excluding those specified in Schedule X	27	28
	WU	iii. Drugs other than those specified in	24	25

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Sr. No.	Purpose	Drugs	Application made in Form No.	Licence granted in Form No.
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32
		ii. Loan manufacture of Cosmetics	31A	32A
		3. i. Ayurvedic and Unani drugs.	24D	25D
		ii. Loan manufacturing of A and U drugs	24E	25E
		4. i Drugs specified in Schedule C, C1 and X	27B	28B
	100	ii. Drugs specified in Schedule C and C1, excluding those specified in Schedule X	27	28
	90	iii. Drugs other than those specified in Schedule C, C1 and X	24	25
		iv. Drugs specified in Schedule X	24F	25F

No.	r ar pose		made in Form No.	granted Form N
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32
		ii. Loan manufacture of Cosmetics	31A	32A
		3. i. Ayurvedic and Unani drugs.	24D	25D
		ii. Loan manufacturing of A and U drugs	24E	25E
		4. i Drugs specified in Schedule C, C1 and X	27B	28B
	100	ii. Drugs specified in Schedule C and C1, excluding those specified in Schedule X	27	28
6	90	iii. Drugs other than those specified in Schedule C, C1 and X	24	25
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
II	Sale of drugs	i. Homeopathic drugs		20D
	A. Wholesale	ii. Drugs other than those specified in		20B

No.	r ar pose	Di ugo	made in Form No.	granted Form N
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32
		ii. Loan manufacture of Cosmetics	31A	32A
		3. i. Ayurvedic and Unani drugs.	24D	25D
		ii. Loan manufacturing of A and U drugs	24E	25E
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	90	iii. Drugs other than those specified in Schedule C, C1 and X	24	25
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
II	Sale of drugs	i. Homeopathic drugs		20D
	A. Wholesale	ii. Drugs other than those specified in		20B

No.	1 ai posc	Z.ug ³	made in Form No.	granted Form N
I	Manufacture	1. Homeopathic drugs	24C	25C
		2. i. Cosmetics	31	32
		ii. Loan manufacture of Cosmetics	31A	32A
		3. i. Ayurvedic and Unani drugs.	24D	25D
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	4	iii. Drugs other than those specified in Schedule C, C1 and X	24	25
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
П	Sale of drugs	i. Homeopathic drugs	-	20D
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4	yu	iii. Drugs other than those specified in Schedule C, C1 and X	24	25
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
II	Sale of drugs	i. Homeopathic drugs	The state of the s	20D
	A. Wholesale	ii. Drugs other than those specified in		20B

		2. i. Cosmetics	1.0 2.0 3.0	
		Z. 1. Cosmetics	31	32
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	0.	ii. Drugs specified in Schedule C and C1, excluding those specified in Schedule X	27	28
	UR	iii. Drugs other than those specified in	24	25
	0	Schedule C, C1 and X		
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
П	Sale of drugs	i. Homeopathic drugs	7	20D
	A. Wholesale	ii. Drugs other than those specified in Schedule C, C1 and X		20B
		iii. Drugs other than those specified in Schedule C. Cl and X from a motor vehicle		20BB

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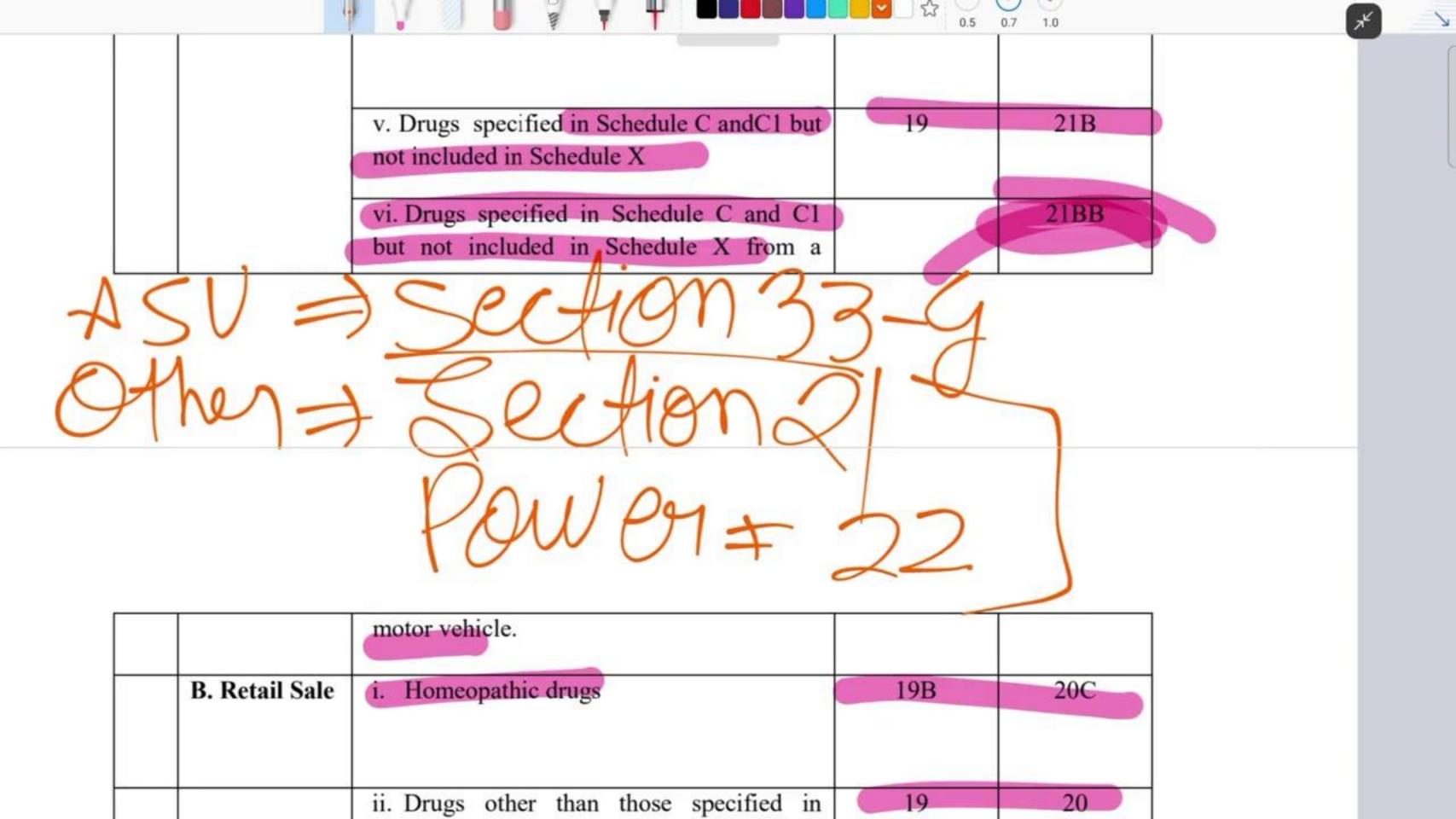
		iv. Drugs specified in Schedule X	24F	25F
		5. Manufacture for examination test or analysis.		29
П	Sale of drugs	i. Homeopathic drugs		20D
	A. Wholesale	ii. Drugs other than those specified in		20B
		Schedule C, C1 and X		
				2000
		iii. Drugs other than those specified in		20BB
		Schedule C, C1 and X from a motor vehicle.	<u> </u>	
		iv. Drugs specified in Schedule X	19B	20G
		IV. Drugs specified in Schedule A	190	200
		v. Drugs specified in Schedule C andC1 but	19	21B
		not included in Schedule X		
		vi. Drugs specified in Schedule C and C1		21BB
		but not included in Schedule X from a		

	(-)		1.0 2.0	3.0	
		motor vehicle.			
	B. Retail Sale	i. Homeopathic drugs	19B	20C	
	b. Retail Sale	1. Homeopathic drugs	191	200	
		ii. Drugs other than those specified in	19	20	
		Schedule C, C1 and X			
		D		21	
		iii. Drugs specified in Schedule C and C1		21	
		excluding Schedule X			
		iv. Drugs specified in Schedule X		20F	
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	(C)	i. Drugs other than those specified in		20A	
	Restricted	Schedule	_		
		C, C1 and X	< _		
		ii. Drugs specified in Schedule C, C1 but		21A)
		not in Schedule X			
		The state of the s	7		
III	Repackaging	Drugs specified in Schedule C and C1	24B	25B	
	XO.		- 0		
IV	Import	i. Drugs specified in Schedule C and C1	8/	10	
	200	rung I II	wu	iuu	
		ii. Drugs specified in Schedule X	8a	10a	

ı	(*)	Schedule C, CI and X	1.0 2.0	3.0
,		iii. Drugs specified in Schedule C and C1 excluding Schedule X		21
		iv. Drugs specified in Schedule X		20F
	(C) Restricted	i. Drugs other than those specified in Schedule C, C1 and X		20A
		ii. Drugs specified in Schedule C, C1 but not in Schedule X		21A
Ш	Repackaging	Drugs specified in Schedule C and C1	24B	25B
IV	Import	i. Drugs specified in Schedule C and C1	8	10
	0	ii. Drugs specified in Schedule X	8a	10a
		iii. Import of drugs for testing		11
		iv. Small quantity of drugs for personal use	12	12B

		0.5 0.7 1.0
	v. Drugs specified in Schedule C andC1 but not included in Schedule X	19 21B
	vi. Drugs specified in Schedule C and CI but not included in Schedule X from a	21BB
ASU =	=> Section 33	

		motor vehicle.		
	B. Retail Sale	i. Homeopathic drugs	19B	20C
		ii. Drugs other than those specified in	19	20



iii. Import of drugs for testing	A	11
iv. Small quantity of drugs for personal use	12	12B

PHARMACY ACT:

The Pharmacy Council of India is made up of the following members:

A. Elected members:

- i. Six members, among whom at least one is a teacher of Pharmaceutical Chemistry, Pharmacy, Pharmacology and Pharmacognosy of an Indian University, or a college affiliated thereto, which grants a degree or diploma in Pharmacy, elected by the University Grants Commission.
- ii. One member elected from amongst themselves by the Members of the Medical Council of India.
- iii. One member to represent each State, nominated by State Government, who shall be a Registered Pharmacist.

B. Nominated members:



iii. Import of drugs for testing		11
iv. Small quantity of drugs for personal use	12	12B

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- iii. One member to represent each State, nominated by State Government, who shall be a Registered Pharmacist.

B. Nominated members:

- i. Six members, four of whom are persons possessing a degree or diploma in, and practicing, pharmacy or pharmaceutical chemistry, nominated by the Central Government.
- ii. A representative of the University Grants Commission and a representative of the All India Council for Technical Education.
- iii. One member to represent each State elected [from amongst themselves] by the members of each State Council, who shall be a Registered Pharmacist.
- C. Ex-officio members
- Director General of Health Services, or a person authorized by him.
- ii. Drugs Controller of India or a person authorized by him.
- iii. Director of Central Drugs Laboratory.

The President and the Vice-president of PCI are elected by the Members of Council from

- i. Six members, four of whom are persons possessing a degree or diploma in, and practicing, pharmacy or pharmaceutical chemistry, nominated by the Central Government.
- ii. A representative of the University Grants Commission and a representative of the All India Council for Technical Education.
- iii. One member to represent each State elected [from amongst themselves] by the members of each State Council, who shall be a Registered Pharmacist.
- C. Ex-officio members
- i. Director General of Health Services, or a person authorized by him.
- ii. Drugs Controller of India or a person authorized by him.
- iii. Director of Central Drugs Laboratory.

The President and the Vice-president of PCI are elected by the Members of Council from

attend the meetings. A casual vacancy in the PCI shall be filled by fresh nomination or election, and the person so nominated or elected shall hold the office only for the remaining term.

The council shall appoint (1) A Registrar, who shall act as its Secretary and, if necessary, its Treasurer, as well; and (2) Other Officers and Servants carrying out its statutory functions. The executive committee of the PCI consists of the President (Chairman of the Committee) and the Vice-president and five other members elected by the Central Council from amongst its members.

STATE PHARMACY COUNCIL

State Pharmacy Council and Joint State Pharmacy Council are also constituted by State Governments. Two or more states may also agree that the State Council of one state shall serve the, needs of the other participating States. Two or more States may also enter into agreement (inter-state agreement) for definite specified period, to form Joint State Council. Any pharmacist willing to practice in the state, has to get himself/herself registered in the State through the State Pharmacy Council and Joint State Pharmacy Council, as follows-

Pharmaceutical Chemistry, or be Registered

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State Council	Joint Council		
1. Six Registered Pharmacists elected from amongst themselves.	1. 3-5 Registered Pharmacists of each of participating State, elected from amongst themselves. However, if agreed, the number of members elected by each of the participating state may not be the same, but shall vary from 3-5.		
2. One member elected from amongst themselves by the Members of the Medical	 One member elected by Medical Council of each State from amongst its members. 		
Council of the State. Nominated Members	A P R		
 Five members, of whom at least three shall possess a degree or diploma in Pharmacy or Pharmaceutical Chemistry, or be Registered Pharmacists, nominated by the State 	1. 2-4 members nominated by each participating State of whom more than half shall possess a degree or diploma in Pharmacy or Pharmaceutical Chemistry or be Registered		

Government.

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Pharmacists. However, if agreed, the number of members nominated by each of the participating State may not be the same, but shall be 2-4 only.

Ex-officio Members:

- 1. Chief of Administrative Medical Officer of the state.
- 2. Officer—in-charge of Drugs and Cosmetics Act, 1940.
- 3. Government Analyst under the Drugs and Cosmetics Act, or where there is more than one, such as the State Government may appoint in this behalf.
- 1. Chief of Administrative Medical Officer of each of the participating states.
- 2. Officer—in-charge of the Drugs Control Organisation of each participating state.
- 3. Government Analyst of each participating state under the Drugs and Cosmetics Act, or where there is more than one in each state, such one as the State Government may appoint in his behalf.

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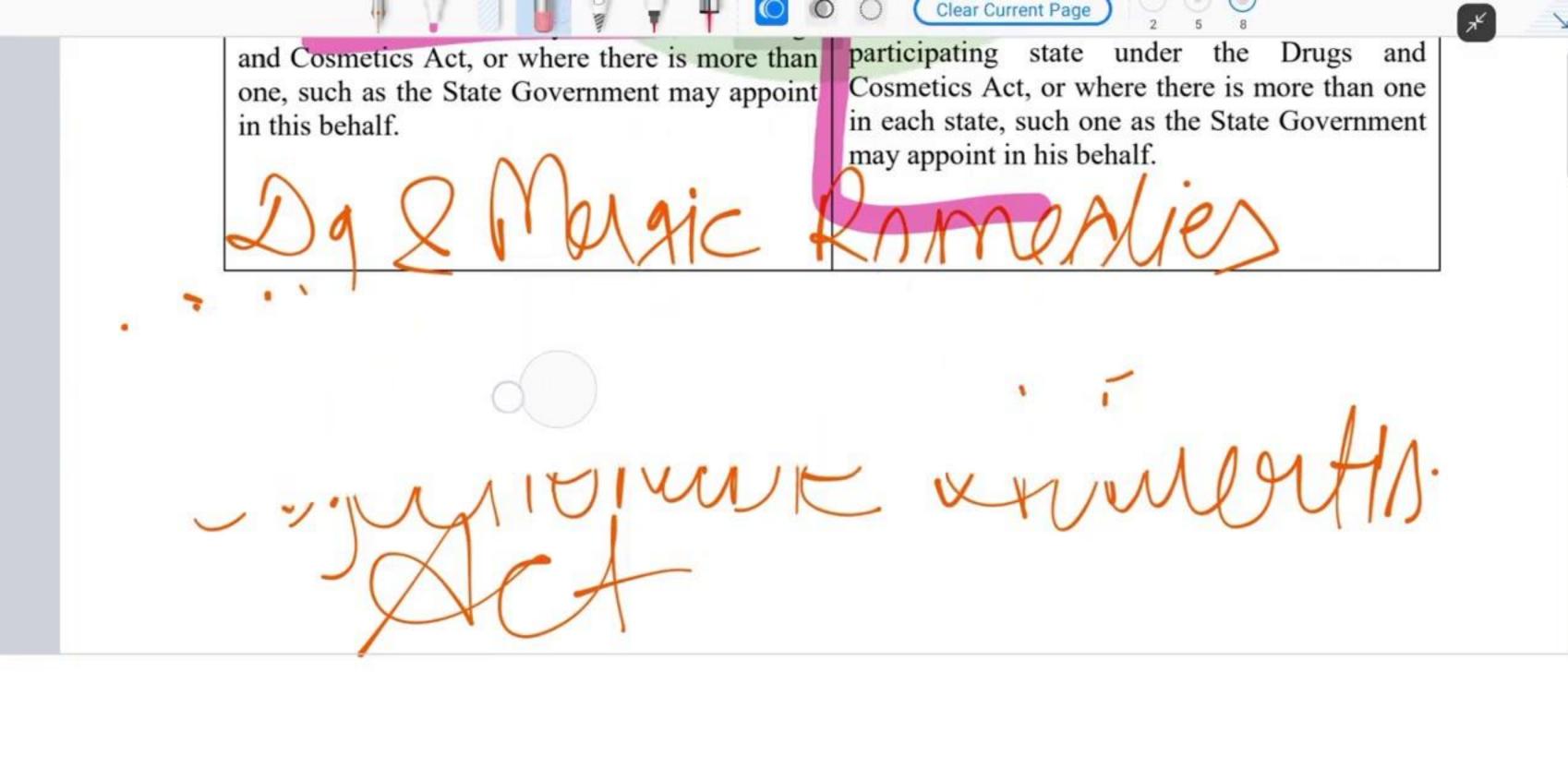
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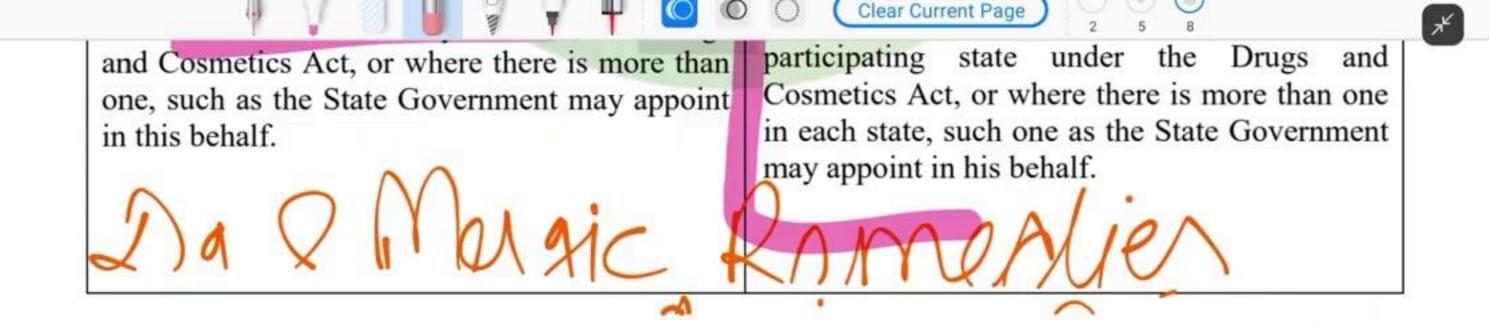
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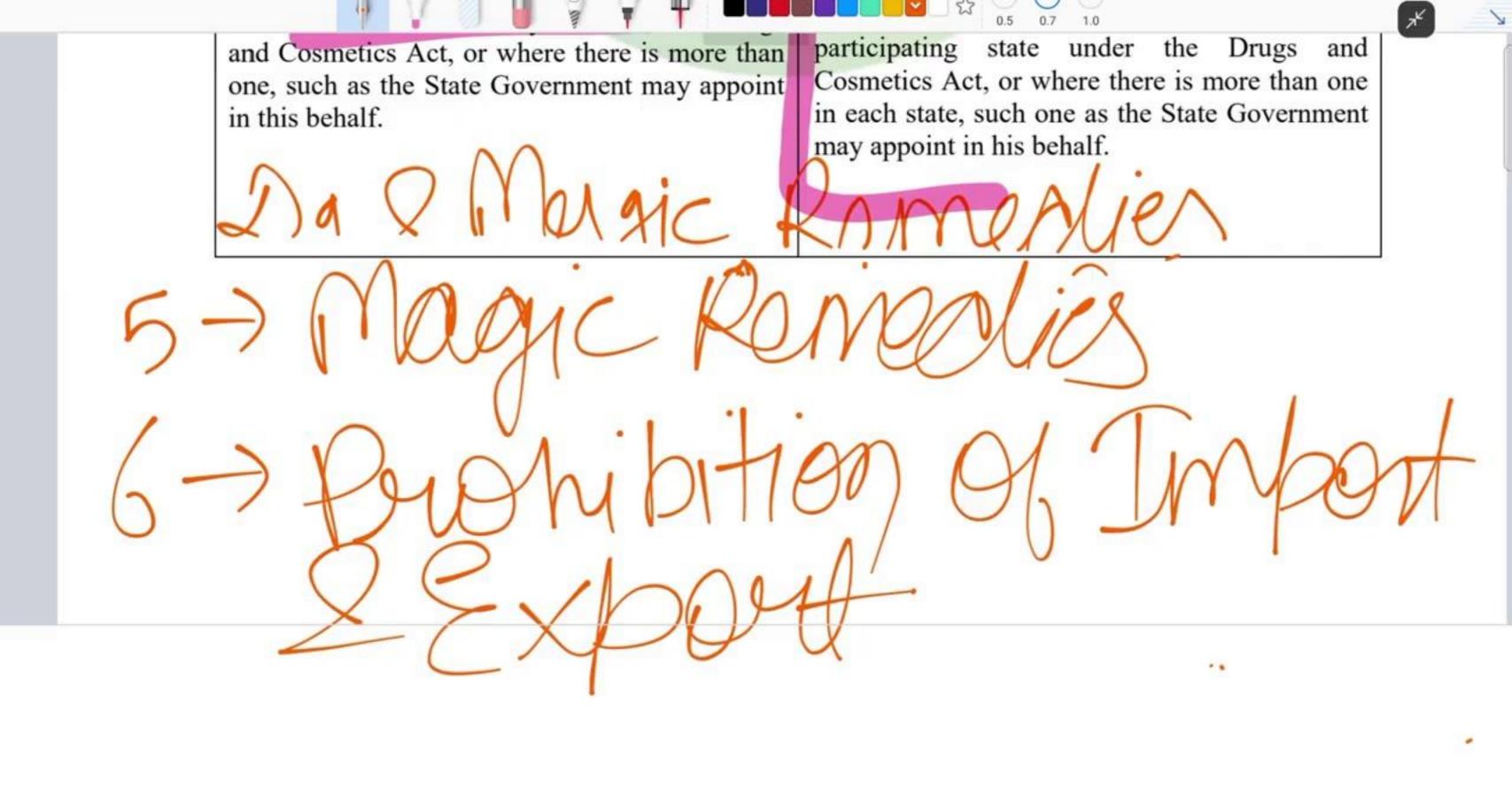
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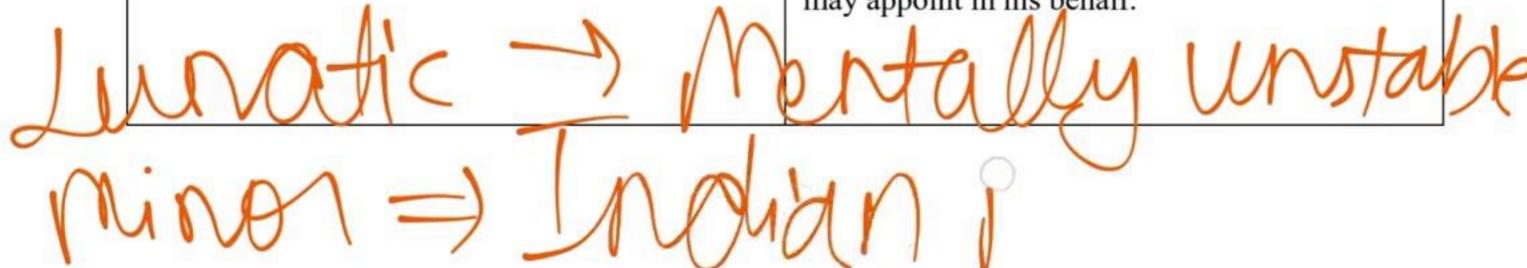
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