

### Re-Endorsement of Capacity of Drug Companies

1993. SHRI BHUBANESWAR KALITA. Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state;

*dnmtmrn*

(a) what was the licensed capacity of the items in respect of which re-endorsement of capacity was allowed to various companies under the 1982 and 1983 Policies, separately;

(b) what was the investment given in the applications based on which the capacities were licensed;

(c) when and what were the additions made in the investment by the companies concerned and whether such additional investments were approved by Government;

(d) what are the names of the companies where Government have found it expedient to inspect the premises in order to verify the details of plant and machinery installed; and

(e) what are the names of the companies inspected so far for the purpose and what are the findings of the

inspections and the items where unauthorised expansion/production were involved?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI VASANT SATHE); (a) The requisite details in respect of 29 cases finalised under April 1982 Policy have since been furnished while replying to Unstarred Question No. 2826 answered on 22nd August, 1983 Under April, 1983 Policy, 10 cases have so far been finalised. The details in respect of seven cases have already been supplied while replying to Unstarred Question No. 745 on 5th March 1984. Similar details in respect of 7 more cases subsequently finalised under April, 1982 Policy and 3 under April, 1983 Policy are given in the enclosed statement (*See below*).

(b) and (c) The details regarding investment were not required to be submitted while applying for re-endorsement of capacity.

(d) and (e) The requisite information has already been made available while replying Unstarred Question No. 1349 on 6th August, 1984.

### Statement

#### Applications Finalised under April 1982 Policy (7 Cases)

S. Name of the Company No.	Item	Existing Capacity	Unit	Re-endorsed Capacity
1	2	3	4	5
Formulations				
1. M/s Amrutnanjan Ltd.	1. Amrutnanjan Pain Balm 5.25 gm.	21.65	Lakh Nos.	Capacities have been re-endorsed as per Policy in terms of bulk drug requirements.
	2. Amrutnanjan Pain Balm 12 gms.	20.57	Million Nos.	
	3. Amrutnanjan Pain Balm 24 gms.	2.60	Lakh Nos.	
	4. Dermal Ointment	1.80	Lakh Nos.	

1	2	3	4	5	6
	<i>Bulk Drugs</i>				
2. M/s Chowgule & Co. .	1. Tetanus Toxoid;	50Lakh Doses.		17,529	Lts.
	2. Diphtheria Toxoid			1,833	Lts.
	3. Pertussis			165	Lts.
	<i>Formulations</i>				
	1. Vaccines			Capacities have been re-endorsed as per policy in terms of bulk drugs requirements.	
	2. Triple Vaccines				
	3. Dekasone Tabs.	9.21	Lakh Nos.		
	4. Dimiril Tabs.	4.50	Lakhs Nos.		
	5. Furoquinol Tabs	9.90	Lakh Nos.		
	6. Helkamon Tabs	15.00	Lakh Nos.		
	7. Neofluvenal Tabs	12.25	Lakh Nos.		
	8. Dimiril Expetorant	35600	Lts.		
	9. Mytrvite Syrup	2200	Lts		
	10. Tussigon Cough Syrup	3450	Lts.		
	11. Dermoscab Oint.	1300	Kgs.		
	12. Polyderm Cream	310	Kgs.		
	13. Orliiver Caps.	22.00	Lakh Nos.		
	14. Plynesuraon 12	2.654	Lakh Amp.		
	15. Nasodrin Nasal Drops	707	Lts.		
	<i>Bulk Drugs</i>				
3. M/s Cibatul Ltd.	1. Sulphathiazole/ Sodium	320	Tonnes	38.5	Tonnes
	2. Sulphasomidine/Sodium			243.0	Tonnes
	3. Sulphaphenazole; Sodium			113.5	Tonnes
	4. Sulphamethazine/ Sodium	320	Tonnes	12.5	Tonnes
	5. Sulphadiazine/ Sodium			44.5	Tonnes
	6. Acetyl Sulfanilyl; Chloride			1107.0	Tonnes
	7. 3-aminc-2-Phenyl Pyrazole	40	Tonnes	170	Tonnes
	<i>Bulk Drug</i>				
4. M/s Synbiotics Ltd.	Amphotericin	1	Tonnes	2.3	Tonnes

1	2	3	4	5	6
	<i>Bulk Drugs</i>				
5.	M/s Tamil Nadu Dadha Pharmaceutical Ltd.	Calcium Lactate	50 Tonnes	209 Tonnes	
	<i>Formulations</i>				
	1. Aminophylline IP 1	100 mg.	Within 89	Capacities have	
	2. APC IP		Million Nos.	been re-endor-	
	3. Chlorpheniramine Maleate IP 4 mg.		"	sed as per	
	4. Chlorpromazine IP 10mg/25 mg.		"	Policy in terms	
	5. Chlorpromazine Hcl 25/50/100 mg.		"	of bulk drugs	
	6. Chlororopramide IP; 250 mg.		"	requirements.	
	7. Compound Tabs of Vitamin BBC		"		
	8. Diazepam IP		"		
	9. Dexamethazone 0.5 mg.		"		
	10. Epedrine Hcl 30 mg.		"		
	11. Erythromycin Stearate IP 250 mg.				
	12. Ethenamide 25 mg/250 mg.		"		
	13. E.P.A.		"		
	14. Folic Acid 5 mg.		"		
	15. Frusemide 40 mg.		"		
	16. Hydrochlorthazide 250 mg/50 mg.		"		
	17. Imipramine Hcl 25 mg.		"		
	18. Metronidazole 200 mg.		"		
	19. Nitrofurantoin 50 mg.		"		
	20. Oxyphentutason BP 100 mg.		"		
	21. Phenformin Hcl.		"		
	22. Pheniramine Maleate 22.5/40mg.		"		
	23. Polyvitamine	Within 89	Million Nos.	Capacities have	
	24. Primidone 250 mg (including Demidone 20 mg.)		"	been re-endor-	
				sed as per	
				Policy in terms	
				of bulk drug	
				requirements.	

1	2	3	4	5	6
		25. Vitamin B Complex Vit. C & Folic Acid	Within 99 Million Nos.		Capacities have been re-en- dorsed as per policy in terms of bulk drugs require- ments.
		26. Pyridoxine Hcl 5/10 mg.		"	
		27. Sulphadimethoxine 500 mg.		"	
		28. Spironolactone 25 mg.		"	
		29. Pyrazinamide 500 mg.		"	
		30. Sulphasomidine 500 mg.		"	
		32. Thiamine Hcl 50mg/ 100 mg/5mg.		"	
		32. Vitamin C IP 100/500 mg.		"	
		33. Riboflavin 5 mg.		"	
		34. Calcium Lacate IP 300 mg.	109.33	Lakh Nos.	
		35. Diethyl Carbomazine Citrate 50 mg.	12	"	
		36. Di-iodohydroxy Quinoline 300 mg.	37.98	"	
		37. Phenylbutazone Amidopyrine (Dedhapyrine)	19.5	Kgs.	
		38. Phenylbutazone 100 mg.	32	Lakhs Nos.	
		39. Piperazine Citrate 500mg/344 mg.	11.92	"	
		40. Phenytoin Sodium	50	"	
		41. Phthalyl Sulpha- thiazole	11.06	"	
		42. Prednisolone 5mg.	19.47	"	
		43. Sulphaquanidine 500 mg.	10.89	"	
		44. Sulphamethizole N.F. 500 mg.	1.03	"	
		45. Chloroquin Phosphate IP 250 mg.	9.47	"	
		46. Phenobarbitone 30 mg.	25.06	"	
		47. Sufirin	12	"	

1	2	3	4	5	6
	48.	Liquid Paraffin IP	Within 4550	Lts.	Capacities have been re-endorsed as per Policy in terms of bulk drugs requirements.
	49.	Paracetamol		"	
	50.	Pholemin Brand Pheniramine Maleate		"	
	51.	Aromatic Spirit of Ammonia		"	
	52.	Benzyl Benzoate	6000	Lts.	
	53.	Diethyl Carbamazepine Citrate NPL	233	Lts.	
	54.	Piperazine Citrate USP	1595	Lts.	
	55.	Damycetin Sus.	3600	Lts.	
	56.	Ampicillin Dry Dry Syrup	6000	Lts.	
	57.	Camphorated Opium Tincture	490	Lts.	
	58.	Chloroform Spirit	384	Lts.	
	59.	Compound Cardamom Tincture	1810.5	Lts.	
	60.	Weak Ginger Tincture	1103	Lts.	
	61.	Ampicillin IP	Within 7.7 Million Nos.		
	62.	Chloromphenicol IP 250		"	
	63.	Indomethacin BP 250 mg./50 mg.		"	
	64.	Tetracycline IP 250 mg.		"	
	65.	Wilostrep		"	
	66.	Chlorpheniramine Maleate	39.30	Lts.	
	67.	Dadhalgin	Within 18355	"	
	68.	Morphine 10 mg/ml.	77.79	"	
	69.	Pethidine 50mg/ml.	within 18355	Ltd.	
	70.	Pholemin		"	
	71.	Vitamin B Complex		"	
	72.	Vitamin B12 ml.	148.20	"	
	73.	Vitamin B12 100 ml.	545.10	"	

1	2	3	4	5	6
		74. Thiamine Hot 100mg/ml.	Within 18355 Ltd.		Capacities have been re-endorsed as per Policy in terms of bulk drug require- ments.
		75. Cetrimide Cream	Within 7000 Kgs.		
		76. Hydrocortizone Acetate	"		
		77. Nitrofurayone	"		
		78. Salicylic Acid	910 Kgs.		
		79. Sulphur	466 Kgs.		
		80. Whifield	Within 7000 Kgs.		
		81. Zinc Oxide	285 Kgs.		
		82. Dextrose 5% Withn IP	6 Lakh bottles		
		83. Dextrose Inj. 10% W/V	"		
		84. Sodium Chloride 09%	"		
		85. Manitol Inj. 20% W/V	"		
		86. Sodium Chloride 09% WV & Dextrose W/V IP			
		87. Compound Sodium Lactate	" "		
		88. Cetrimide Tincture	12000 Ltd.		
		89. Chloramphenical Sodium Succinate	40000 Nos.		
		90. Vitamin B <sub>1</sub> , B <sub>6</sub> , B <sub>12</sub> (Larimin)	2,40,000 Nos.		
		91. Gentamycin Inj. (Tamicin)	25,000 Nos.		
		92. Trazepam	2,40,000 Nos.		
		93. Ampicillin Inj. (Tampicil)	30,000 Nos.		
		94. Tasimide Brand Frusemide Inj.	2,40,000 Nos.		
		<i>Bulk Drugs</i>			
6. M/s. Sandoz (India)		1. Calcium Lactobionate	Within 160 Tonnes	147 Tonnes	
		2. Calcibronate	Within 160 Tonnes	8.5 Tonnes	

1	2	3	4	5	6
		3. Ferrous Gluconate	Within 160 Tonnes		10 Tonnes
		4. Digoxin	Not specified.		4.7 Kgs.
		5. Magesium Gluconate	5.00 Tonnes		10.00 Tonnes
		<i>Formulations</i>			
		1. Digoxin Tab.	8.0 Million Nos.		Capacities have been re-endorsed as per Policy in terms of bulk drug requirements.
		2. Ferronnicum Syrup	18,000 Lts.		
		3. Calcium Sandoz Amps.	7,500,000 C.G.		
		4. Calocium Sandoz Vitamin C Amps.	20,000,000 C.G.		
		5. Ferronnicum Tabs.	7,500,000 Nos.		
7. M/s. Raptakos Bratt & Co.		<i>Bulk Drugs</i>			<i>Madras Thana Plant</i>
		1. Proteolysed River Extract	Not specified		103421 81640
		2. Pharma Peptone			68703 61321
		3. Iodised Peptone			5933 4140
		4. Haemolysed Blood			152487 183667
		5. Aluminium Hydroxide Gel.			2192 ..
		<i>Applications finalised under April 1983 Policy (3 Cases)</i>			
8. M/s. Organon (India) Ltd. (Now INVAR Ltd.)		<i>Bulk Drugs</i>			
		1. Nandrollone Decanoate Formulations Tabs	42.50 Kgs.		62.25 Kgs.
9. M/s. Bengal Chemicals & Pharmaceuticals		1. Ethambutol 400 mg.	10 Lakh Nos.		
		2. Ampicillin Tabs 125 mg.	73 -do-		
		3. Doxyeyoline Caps. BP. 1000 mg.	10 Lakh Nos.		Capacities have been re-endorsed as per Policy in terms of bulk drug requirements.
		4. Ampicillin Caps. I.P. 250 mg.	20 Lakh Nos.		
		5. Ampicillin Caps. 500 mg.			
		6. Tetracycline Caps. IB 250mg/125 mg.	20 "		
		7. Chloramphenicol BP Caps. 250 & 125 mg.	20 "		
10. M/s. Ranbaxy Ltd.		<i>Formulations</i>			
		1. Chloramsonone Drops	48 Lakh Vials		

Besides M/s. E. Merck have been issued supplementary endorsement in respect of two formulations viz. Evion Caps. (175 lakh L.G.) and Evion Tabs. (6.5 Lakh L.G.) in terms of bulk drug requirement under the Policy of REG 1982.