

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 4126
TO BE ANSWERED ON 24TH MARCH, 2023**

INDIGENOUS MEDICINES

**4126. SHRI OMPRAKASH BHUPALSINH
ALIAS PAWAN RAJENIMBALKAR:
DR. SANGHMITRA MAURYA:
SHRI SANJAY JADHAV:**

Will the Minister of **AYUSH** be pleased to state:

- (a) the details of indigenous medicines whose approval is pending with the Government during the last three years and the current year;
- (b) whether applications for approval for many medicines are pending with the Government since a long time and a very few medicines have been approved; and
- (c) if so, the details thereof along with the list of AYUSH medicines approved, rejected and pending for approval during the last three years?

**ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)**

(a) to (c) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T &

Schedule M-I of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush has set up a Interdisciplinary Technical Review Committee (ITRC) for the examination of the applications/ claims on patent & proprietary (Ayurveda, Siddha, Unani & Homoeopathy) ASU&H medicines/classical ASU&H medicines with new indication or Re-purposing of licensed P&P, ASU&H medicines for Covid-19 and label claim for Covid-19. The details of total number of applications/claims received, Applications / claims were not put before the ITRC as no detailed documents were provided by the applicant, applications/claims discussed in ITRC, not recommended, pending and recommended are as follows:

Total no. of applications/claims received	101
No. of applications / claims were not put before the ITRC as no detailed documents were provided by the applicant.	50
No. of applications / claims discussed in ITRC	51
No. of applications/Claims not recommended	47
No. of applications pending at the end of applicant.	01
No. of applications/Claims recommended.	03

As per the information received from State/UT government, the detailed list of AYUSH medicines approved, rejected and pending for approval during the last three years are as follows -

S.no.	Name of the State/UT	Detailed list of AYUSH medicines approved, rejected and pending for approval during the last three years					
1.	Andhra Pradesh	Eye drops and P, K, L, F of Sri. B. Anandaih of Mutthukura Mandal of Nellore Dist. which were claimed to have high success rate in Covid-19 were rejected for not complying with the Pharmacopoeial standards prescribed by PCIM&H and Pharmaceutical standards prescribed by Ayurvedic texts and also the statutory standards prescribed by D&C Act, 1940 and Rules thereunder.					
2.	Tamil Nadu	Year	No. of ASU applications received	No. of ASU applications approved	No. of ASU pending applications	No. of ASU rejected applications	
		2020	45	40	2	3	
		2021	37	32	5	-	
		2022	64	60	4	-	

		2023 (up to 28.02.2023)	7	3	4	-																															
3.	Karnataka	Approval of 95 Ayush medicines is pending and 51 Ayush medicines have been rejected. From January 2020 to March, 2023, 3930 Ayush products have been approved.																																			
4.	Odisha	Year	No. of applications for Ayurvedic medicines approved	No. of applications for Ayush medicines rejected	No. of applications for Ayush medicines pending for approval																																
		2020	13	1	NIL																																
		2021	16	1	NIL																																
		2022	15	1	NIL																																
5.	Uttarakhand	<ul style="list-style-type: none">• In year 2020-21, approximately 3000 Ayurvedic Patent & Proprietary Products approved, no application is pending and rejected.• In year 2021-22, approximately 2500 Ayurvedic Patent & Proprietary Products approved, no application is pending and rejected.• In current year 2022-23 approximately 2600 Ayurvedic Patent & Proprietary Products approved, no application is pending and rejected.																																			
6.	Uttar Pradesh	37 applications from last three years and 118 applications in current year are pending for approval. 220 Ayush medicines applications registered for approval 183 got approved and 37 applications are pending for approval.																																			
7.	Kerala	<div>Details of applications pending for approval is as follows-</div> <table><tr><th>Year</th><th>Pending approval</th></tr><tr><td>2020</td><td>9</td></tr><tr><td>2021</td><td>12</td></tr><tr><td>2022</td><td>16</td></tr><tr><td>2023</td><td>12</td></tr></table> <div>Details of no. Ayush medicines pending, approved and rejected are as follows -</div> <table><tr><th>Year</th><th>Pending</th><th>Approved</th><th>Rejected</th></tr><tr><td>2020</td><td>45</td><td>900</td><td>0</td></tr><tr><td>2021</td><td>60</td><td>1415</td><td>0</td></tr><tr><td>2022</td><td>75</td><td>1546</td><td>0</td></tr><tr><td>Total</td><td>180</td><td>3861</td><td>0</td></tr></table>						Year	Pending approval	2020	9	2021	12	2022	16	2023	12	Year	Pending	Approved	Rejected	2020	45	900	0	2021	60	1415	0	2022	75	1546	0	Total	180	3861	0
Year	Pending approval																																				
2020	9																																				
2021	12																																				
2022	16																																				
2023	12																																				
Year	Pending	Approved	Rejected																																		
2020	45	900	0																																		
2021	60	1415	0																																		
2022	75	1546	0																																		
Total	180	3861	0																																		
8.	Maharashtra	<div>No applications for approval of indigenous medicines are pending during the last 03 years. The details of indigenous medicines approved, rejected and pending for approval is as follows -</div> <table><tr><th>Period</th><th>1 Jan 2020 to 31 Dec 2020</th><th>1 Jan 2021 to 31 Dec 2021</th><th>1 Jan 2022 to 31 Dec 2022</th><th>1 Jan 2023 to 31 Dec 2023</th></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table>						Period	1 Jan 2020 to 31 Dec 2020	1 Jan 2021 to 31 Dec 2021	1 Jan 2022 to 31 Dec 2022	1 Jan 2023 to 31 Dec 2023																									
Period	1 Jan 2020 to 31 Dec 2020	1 Jan 2021 to 31 Dec 2021	1 Jan 2022 to 31 Dec 2022	1 Jan 2023 to 31 Dec 2023																																	

		Granted	9521	6967	6465	6979
		Rejected	636	506	435	354
		Ongoing	0	0	1763	2295
9.	Goa	No applications are pending				
10.	Manipur	NIL				
11.	Ladakh	NIL				
12.	Jammu & Kashmir	NIL				
13.	Arunachal Pradesh	NIL				
14.	Puducherry	NIL				
15.	Bihar	NIL				
16.	Chandigarh	NIL				
17.	Tripura	NIL				
18.	Lakshadweep	UT of Lakshadweep does not have any manufacturing unit for Ayush medicines.				
19.	Chhattisgarh	NIL				
20.	Delhi	NIL				
21.	Mizoram	NIL				
22.	West Bengal	NIL				
23.	Himachal Pradesh	NIL				
24.	Jharkhand	NIL				
25.	Haryana	NIL				
26.	Gujarat	NIL				
