GOVERNMENT OF INDIA MINISTRY OF AYUSH

LOK SABHA UNSTARRED QUESTION NO.1012 TO BE ANSWERED ON 22ND JULY, 2022

"AYUSH MEDICINES"

1012. SHRI ANURAG SHARMA: DR. T. SUMATHY (A) THAMIZHACHI THANGAPANDIAN:

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

- a) whether the approval of several indigenous medicines from the ministry of Ayush have been pending since last three-four years;
- b) if so, the details thereof and their current status;
- c) whether the applications for approval of medicines from the AYUSH Ministry have been deliberately kept pending for long periods alongwith only few approvals; and
- d) if so, the detailed list of Ayush medicines registered for approval, finally approved, rejected and pending during the last five years including the state of Uttar Pradesh?

ANSWER THE MINISTER OF AYUSH (SHRI SARBANANDA SONOWAL)

(a) & (b) No Sir, 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, and Unani 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 and Unani medicines in accordance with the proof of safety and effectiveness.

As per allocation of Government Business Rules 1961 and Drugs and Cosmetics Act, 1940 and Rules 1945, approval of any product is not granted by the Ministry of Ayush in Central Government. It is granted by the concerned State/UT Government.

(c) & (d) As per the information received from State/ UT Governments, list of Ayush medicines registered for approval/finally approved/rejected and pending during the last five years is at **Annexure I.**

S.no.	Name of the	Information received from State/ UTs regarding Ayush						
	State/UT	medicines registered for approval/got approved/rejected						
1.	Arunachal Pradesh	approval and pending approval in the last five years						
2.	Madhya Pradesh	No application pending 3000 approval given						
3.	Goa	No application pending						
4.	Uttar Pradesh	Ayush medicines registered for approval – 315						
٦.	Ottal Tradesii	Ayush medicines approved – 300						
		Applications pending for approval due to incomplete documents– 15						
5.	Himachal Pradesh	No application pending						
6.	Uttarakhand	Year	Permission granted	Rejec		ected	Pending	
		2019-20	approximate 2700	ely 0			0	
		2020-21	approximate 3000	•			0	
		2021-22	approximate 2500				0	
		2022-23	approximate	ely 354 0			0	
7.	Tamil Nadu	Year	No. of	No.		No. of	No. of	
			ASU	ASU		ASU	ASU	
			application	application		pending	1 -	
		2010	received	approved		application		
		2018	40	33		-	7	
		2019	24	22		2	3	
		2020	45 37	40		6		
		2021 2022 (up to	29	31 13		16	-	
		30.06.2022)	29	13		10		
8.	Karnataka	30.00.2022)						
		Year	Ayush medicines registered for	Approved		Rejected	Pending approval	
			approval					
		April 2019 to July 2022	4768	460	8	63	97	
9.	Puducherry	NIL						
10.	Jharkhand	Total 4280 products. No application pending.						
11.	Rajasthan	No application pending						