

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 1464
TO BE ANSWERED ON 28TH JULY, 2023**

“GUIDELINES FOR LICENSE TO NEW MEDICINES”

1464 SHRI VIJAY KUMAR DUBEY:

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

- (a) whether the Government has changed any guidelines with respect to the approval for license(s) to new medicines and if so, the details thereof;
- (b) whether the approval regarding the new medicines is pending with the Government;
- (c) if so, the details thereof along with the reasons for delay, medicine-wise and firm-wise;
- (d) whether any timeline has been set to grant the approval for license(s) to new medicines; and
- (e) if so, the details thereof?

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

(a) There is no provision for New Drug in Ayurveda, Siddha and Unani system of Medicine prescribed under Drugs and Cosmetics Act 1940 and Rules made there under. However the definition and application to manufacture 'New Homoeopathic medicines' is prescribed under Rule 30AA (inserted vide Subs. G.S.R. 680 (E), dt. 5-12-1980) and 85C of the Drugs Rules, 1945. There has been no change in the guidelines for approval of New Homoeopathic Medicines as of now in the said Rules.

During the outbreak of COVID-19, Ministry of Ayush has constituted an Interdisciplinary Technical Review Committee (ITRC) vide notification No. T-14020/5/2020-DCC dated 28.10.2020 for the examination of the applications/claims on Patent & Proprietary (P&P) 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, forwarded by State Licensing Authorities/ Individuals referred by Ministry of Ayush.

The ITRC has suggested/recommended following three Ayurveda medicines for the COVID-19:

S.no.	Name of the product	Company name	Observations of ITRC
1.	Coronil Tablet	M/s Patanjali Research Foundation Trust, Uttarakhand.	Coronil Tablet may be used as supporting measure in COVID-19.
2.	Clevira tablet	M/s Apex Laboratories Private Ltd., Chennai.	Recommended that Clevira tablet as a supporting measure for mild to moderate condition of Covid 19.
3.	NAOQ19 tablet	M/s Sri Sri Sriveda Sattva Pvt. Ltd., Bangalore.	Approved the formulation NAOQ19 as an add-on therapy for mild to moderate Covid-19.

(b) and (c) 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 licence of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

As mentioned in Rule 85-C of the Drugs and Cosmetics Rules, 1945, New Homoeopathy medicines shall be manufactured after being approved by the Licensing Authority mentioned in Rule 21 of the Drugs and Cosmetics Rules, 1945.

(d) and (e) There is no specific timeline prescribed for the grant of approval of New Homoeopathic medicines under the Drugs and Cosmetics Act 1940 and Rules made there under.
