

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO. 4250
TO BE ANSWERED ON 13TH DECEMBER, 2019**

PATENT RIGHTS OF AYUSH PRODUCTS

4250. SHRI SISIR KUMAR ADHIKARI:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) whether the Government has any mechanism in place for regular monitoring on safety, rights and well being of the products of AYUSH;
- (b) if so, the details thereof and whether the international standards and the patent formulas are maintained by the domestic units; and
- (c) the details of products with patent rights and the manufacturing units, State/ UT-wise?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

(a) to (c): Ayurvedic, Siddha and Unani (ASU) drugs are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. License for manufacturing for sale of these drugs is granted and renewed by the respective Licensing Authorities appointed by the State Governments. State Licensing Authorities oversee the enforcement of the legal provisions for ASU drugs and are empowered to take action in case of any violation or contravention of the provisions for licensed manufacturing and quality of drugs. Rule 158-B of the Drugs and Cosmetics Rules, 1945 provides the requirement of proof of safety and effectiveness including data of clinical studies for grant of license for manufacturing of various types of ASU products. Voluntary certification scheme in accordance with international standards for ASU products is administered by Drugs Controller General on the basis of WHO-GMP Guidelines and to grant AYUSH Premium mark by Quality Council of India. Drugs & Cosmetics Act, 1940 has provisions for Patent or Proprietary ASU medicines and the licenses for such products have been granted to the drug manufacturers in the country. However, Ayurvedic medicines and other traditional medicines are not patentable in accordance with the provisions of Section 3 (p) of the Indian Patents Act, which provides that, an invention, which in effect is based on traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components, is not an invention for the purpose of the Patents Act. However, patents can be granted for an invention relating to new formulations based on herbal and plant-related products or processes, which fulfill the criteria of patentability under the Patents Act.

Department for Promotion of Industry and Internal Trade under Ministry of Commerce and Industry has informed that 201 patents have been granted by Controller General of Patents, Designs & Trade (CGPDTM), Govt. of India for inventions related to herbal medicinal products/processes/formulations during the period from 01.01.2005 to 31.01.2019. Central Council for Research in Ayurvedic Sciences (CCRAS) has obtained patents on 17 Ayurvedic drugs and filed patent applications for 19 new Ayurvedic drugs. Similarly, Central Council for Research in Unani Medicine (CCRUM) has obtained patents for 17 Unani drugs and Central Council for Research in Siddha (CCRS) has filled patent applications for 05 Siddha drugs. State/UT wise number of licensed AYUSH drug manufacturing units is given in the **annexure**.

State wise number of Licensed Pharmacies under AYUSH as on 1-4-2018

S.No.	State / UT	Ayurveda	Unani	Siddha	Homoeopathy	Total
1	2	3	4	5	6	7
1	Andhra Pradesh	298	16	0	12	326
2	Arunachal Pradesh	1	0	0	0	1
3	Assam	43	0	0	0	43
4	Bihar	216	22	0	48	286
5	Chhattisgarh	31	0	0	0	31
6	Delhi	83	25	0	0	108
7	Goa	6	0	0	0	6
8	Gujarat	563	0	0	8	571
9	Haryana	458	0	0	0	458
10	Himachal Pradesh	159	0	0	8	167
11	Jammu & Kashmir	20	3	0	3	26
12	Jharkhand	30	0	0	7	37
13	Karnataka	248	0	0	11	259
14	Kerala	766	4	3	0	773
15	Madhya Pradesh	684	5	0	18	707
16	Maharashtra	782	13	0	39	834
17	Manipur	0	0	0	0	0
18	Meghalaya	0	0	0	0	0
19	Mizoram	0	0	0	0	0
20	Nagaland	0	0	0	0	0
21	Odisha	84	0	0	5	89
22	Punjab	277	0	0	0	277
23	Rajasthan	337	0	0	0	377
24	Sikkim	2	0	0	0	2
25	Tamil Nadu	152	60	205	9	426
26	Telangana	425	178	0	34	637
27	Tripura	0	0	0	0	0
28	Uttar Pradesh	1576	292	0	30	1898
29	Uttarakhand	281	2	0	0	283
30	West Bengal	151	5	0	160	316
31	A&N Island	0	0	0	0	0
32	Chandigarh	1	0	0	0	1
33	D&N Haveli	7	0	0	0	7
34	Daman&Diu	9	0	0	0	9
35	Lakshdweep	0	0	0	0	0
36	Puduchery	28	0	6	5	39
	Total	7718	625	214	397	8954