

Process to grant licence to ASU manufacturers becomes swifter, paperless and more transparent

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The Ministry of Ayush has made the process to grant the license to manufacture Ayurveda, Siddha and Unani (ASU) drugs swift, paperless and more transparent by bringing the application system online.

The manufacturers can now save the trouble of making physical presence at the office of the licensing authority and can now apply for the license online at www.e-aushadhi.gov.in. The Ministry of Ayush issued a gazette order notifying the implementation of the Drugs (4th Amendment) Rules 2021, with effect from 1st October, 2021.

The license of the ASU drugs has been made perpetual i.e. with one-time registration fee the license of the product will be valid lifetime subject to online submission of self-compliance declaration every year or unless suspended or cancelled. While prior to the notification it had a validity period of 5 years.

The applicants will only have to get their Good Manufacturing Practices certification validated every five years to keep their license in force. The GMP certificate can also be retained with online submission of retention fee of Rs. 1000. The manufacturing unit of the ASU drugs will be subjected to inspection in a randomized manner every 5 years. Since the validity of the license has been increased, the license fee has also been revised from Rs 1,000 to Rs 2,000 for any number of generic ASU drugs and Rs. 3000 for upto 10 proprietary ASU drugs.

The Ministry has also reduced the maximum time in granting the license from three months to two months.

For six months from the date of gazette notification, both online and offline application process will co-exist before it turns completely online.

Making the application system online will bring uniformity in the whole process. The Ministry of Ayush will act as a facilitator in the licensing process.

These reforms/ measures will reduce the regulatory compliance burden on the ASU Drugs manufacturers with the intention to bring in ease of doing business while ensuring the quality, safety and efficacy of the ASU drugs.

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