



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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A string of Bills related to pharma, health sectors await Parliament nod

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Ramesh Shankar, Mumbai

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<http://www.pharmabiz.com/article/detnews.asp?articleid=54197§ionid=>

At the Budget session of Parliament set to begin today, a string of Bills related to pharma and health sectors are waiting in the wings to be introduced in Parliament for its final nod. Two major Bills which are most likely to be introduced in this session are NBRA Bill and Clinical Establishments (Registration & Regulation) Bill. The session will conclude on May 7.

Though there are several Bills pending in these sectors, major Bills which are also likely to be included in the tentative list for transaction of business in the one-and-a-half month long session included HIV/AIDS Bill, Ethical Guidelines for Biomedical Research on Human Subjects Bill, Central Drug Authority (CDA) Bill and ART Bill.

In fact, National Biotechnology Regulatory Authority Bill (NBRA) Bill and the Clinical Establishment (Registration & Regulation) Bill along with the Transplantation of Human Organs (Amendment) Bill were listed among the 62 new bills to be introduced in the winter session of Parliament which concluded on December 21. While the Transplantation of Human Organs (Amendment) Bill was introduced in the winter session of Parliament, the other two Bills could not be introduced in Parliament due to several procedural delays.

While the NBRA Bill seeks to set up the NBRA as an independent, autonomous, statutory agency to safeguard the health and safety of the people and to regulate the safe development and deployment of biotechnology products and processes, the Clinical Establishments Bill, which was ratified by the union cabinet recently, aims to bring in uniformity in the healthcare delivery sector by making the registration of all clinical establishments mandatory and prescribing enhanced penalty for the defaulters. The Transplantation of Human Organs (Amendment) Bill aims to impose stringent penalties on those who engage in unlawful human organ trade activity.

The tabling of the CDA Bill in this session of Parliament looks difficult as the Union Health Ministry has once again sought the state governments' opinion on it. Though the Bill proposing to make amendments in the Drugs and Cosmetics Act, 1940, to facilitate the creation of CDA was to be introduced in Parliament during the last session of the last government in March this year, the government shelved the move at the eleventh hour, presumably under pressure from the small scale industry associations and other interest groups.

As for the Clinical Establishments Bill, the government has redrafted the bill in place of the already lapsed Clinical Establishments (registration and regulation) Bill 2007, to introduce mandatory registration of all healthcare establishments and is likely to be tabled in the winter session. The new Healthcare

Establishments (registration and regulation) Bill will have an expanded purview unlike in the previous bill which sought to cover only clinical establishments. The laboratories, diagnostic services, R&D facilities taking up clinical trials on patients and all systems of medicines will be included for compulsory registration in the new bill.

Yet another Bill, which has been waiting for Parliament nod is the HIV/AIDS Bill that aims to end discrimination to the HIV patients and ensuring access to treatment to them. The Bill is mired in controversy and is presently stuck in the Union Law Ministry. The prospect of its entry into Parliament in this session looks bleak as even if the law ministry clears it early, it has then to go to the union cabinet.

The tabling of Ethical Guidelines for Biomedical Research on Human Subjects Bill in this session is also difficult as the Indian Council of Medical Research (ICMR) is reviewing the Bill to make the punishment part of the Bill more severe as a deterrent.

As far as the Assisted Reproductive Technology (Regulation) Bill (ART Bill) is concerned, the Bill is also pending with the law ministry. Once the Bill is cleared by the law ministry, it will go to the union cabinet before its way to Parliament. The chances of the Bill, which aims to regulate thousands of infertility clinics that have mushroomed in the country over the past several years, tabling in this session also looks dim.