PRS LEGISLATIVE RESEARCH

Standing Committee Report Summary

The Drugs and Cosmetics (Amendment) Bill, 2007

- The Standing Committee on Health and Family Welfare submitted its 30th Report on 'The Drugs and Cosmetics (Amendment) Bill, 2007' on October 21, 2008. The Chairperson was Shri Amar Singh.
- The Committee feels that the physiological and therapeutic impact of drugs and cosmetics on human bodies is completely different. Therefore, trials for drugs should be separate from that of cosmetics. The Committee thus recommends that there should be a separate set of provisions for clinical trials for regulating the dermatological safety of cosmetics. The Committee also suggests that a separate definition of clinical trial for medical devices may be included in the Bill. The Committee also feels that only new drugs should be subjected to clinical trials.
- The Committee strongly recommends that a dedicated division (as per Mashelkar Committee report) may be set up to deal with regulation, licensing, surveillance and monitoring of medical devices. The definition of medical devices should also be brought in line with the definition of Global Harmonisation Task Force.
- The Mashelkar Committee had recommended that the existing Central Drugs Standard and Control Organisation (CDSCO) be strengthened and equipped properly rather than creating a new authority. The Committee, thus, recommends that the CDSCO be strengthened and restructured as a Central Drug Administration, which shall be an independent body under the Ministry of Health and Family Welfare.
- The Mashelkar Committee had drawn a roadmap for centralisation of licensing in three phases. It had stated that the exercise should be complete within three years. However, the Ministry indicated that it might take five to 10 years to switch to the centralised licensing system. The Committee recommends that the roadmap drawn by the Mashelkar Committee be followed for a speedy switchover.
- The Committee suggests that the appellate authority for grievance redressal should be placed in the zonal and sub-zonal offices of the licensing authority so that small scale pharma units do not face any problems.
- The Committee is of the opinion that the central government would need to put substantive additional funds to strengthen the CDSCO.
- The Committee recommends that the Drugs Technical Advisory Board should be retained since it's a technical body with representation of experts from various fields whose main function is to advise the government.

Kaushiki Sanyal
kaushiki@prsindia.org

January 21, 2009