5. Comment on the Drugs and Cosmetic Rules 1992 as extracted from Amita Dhanda,Annual Survey on Central Subordinate Legislation, XXIX ASIL 413 (1993).

Draft Rules which stated the requirements to obtain a license for the collection, storage, processing, and distribution of whole human blood and human blood components were issued last year. In the survey year the rules on the subject have been issued by the central government after consultation with the Drugs Technical Advisory Board.

The body authorised to issue licenses has been changed in the final rules. In the draft rules after an inspection to sastisfy itself that the licensee fulfills the requirements of the rules, the licensing authority ahd been empowered to issue a license. In the final rules, however, possibly to promote uniformity of standards, licensing authority can only recommend its grant to the central licensing authority a centralised body empowered to issue licences. The licensing authrority, however, can refuse to grant the license if it is satisfied that the applicant will be unable to fulfil the minimum requirements. Appeals against orders of the licensing authority or the central licensing authority can be made to the state government or central government respectively.

The rules lay down in detail the requirements of space, equipment and supplies required for a blood bank. The minimum requirements for grant of licence to process blood components from whole human blood have also been laid down. Some of the changes introduced in teh final rules aim at further clarifying the substantive content of the requirements. Illustratively the draft rules required the label on the blood container to state that "(t)he contents should not be used if there are (sic) any visible evidence of deterioration." The final rules require container to specify under a caution heading that "(t)he contents should not be used if there is any visible evidence of deterioration like haemolyis, clotting or discolouration.

The rigorous standards introduced by the rules are an attempt to clean up the blood supply to prevent the spread of HIV (which can cause AIDS) and other disease causing viruses. These disease preventing measures needed to be non negotiable. Instead the rules confer discretion on the licensing authrotiy or central license approving authority having regard to the extent of the manufacturing operations, to relax or alter the requirements in the circumstances of a particular case.

Introduction of rigorous standards mandates immediate stoppage of operations following lower standards. The Rules require the holder of a blood bank licence under the earlier standards to apply for a licence under the new standards but allows him to continue his activities till the fresh application is decided by the authorities.

In a further effort to clean up the blood supply, the central government in pursuance of its power under Rule 68 A (i) of the Drugs and Cosmetics Rules 1945 directs that (i) whole human blood and blood products; (ii) large volume parentals (intravenous fluids) and (iii) sera and vaccines shall be manufactured, sold or distributed only after obtaining a licence from the central licence approving authority.