

Annex 12

REQUIREMENTS FOR DRIED BCG VACCINE

**(Requirements for Biological Substances No. 11)
(Revised 1985)**

Amendment 1987

In view of the progress that has been made in maintaining the stability of lyophilized BCG vaccines, Part A, section 10.2, of the Requirements for Dried BCG Vaccine (Revised 1985) (WHO Technical Report Series, No. 745, 1987, Annex 2, p. 81) should be replaced by the following.

“10.2 Expiry date

The date after which dried BCG vaccine should not be used shall be determined in relation to the experimental evidence referred to in Part A, section 5.6, and with the approval of the national control authority. Unless there is evidence of a greater stability, the expiry date shall be not more than 24 months after the date of distribution by the manufacturer, provided that this is not more than 36 months from the date of the last satisfactory test for viability referred to in Part A, section 5.5, and provided that the vaccine has been stored continuously at the specified storage temperature and protected from daylight. In any event, the expiry date shall be not more than 4 years after the date of harvest. Each manufacturer shall test the stability of the vaccine to ensure that it satisfies these conditions.”