Annex 2

Requirements for meningococcal polysaccharide vaccine (Amendment 1999)
(Requirements for Biological Substances No. 23)

Introduction

The WHO Expert Committee on Biological Standardization, at its twenty-seventh meeting, adopted Requirements for Meningococcal Polysaccharide Vaccine, which were published in its report (1). These were subsequently amended in the Committee’s twenty-ninth report (2). Since that time, an evaluation of the use in WHO Recommendations/Requirements of the abnormal toxicity test to control vaccines has shown considerable variation in specifications for the test. A specific example is in the 1975 Requirements for Meningococcal Polysaccharide Vaccine (1), as amended in 1977 (2), where there is a specification for five guinea-pigs instead of the normal two. At its fiftieth meeting, the WHO Expert Committee on Biological Standardization considered this to be an anomaly. It is therefore appropriate to amend, as follows, the Requirements for Meningococcal Polysaccharide Vaccine (WHO Technical Report Series, No. 594, 1976, Annex 2). No attempt has been made to review the entire Requirements.

Replace section 5.5.2.1, Guinea-pig toxicity, by the following:

5.5.2.1 Guinea-pig toxicity. Two guinea-pigs weighing approximately 350g each shall be injected intraperitoneally with 500µg of the polysaccharide(s). The animals shall be observed for 7 days and the injection shall cause neither significant symptoms nor death during this period.

References