
STATUTORY INSTRUMENTS

2005 No. 2789

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

Additional standard provisions for manufacturers licences which relate to vaccines, toxins and sera

7.—(1) In addition to the standard provisions for manufacturer's licences set out in Schedules 1 and 2, there shall be the following additional standard provisions for manufacturer's licences, insofar as those licences relate to relevant medicinal products which are vaccines for human use—

- (a) for all vaccines, including smallpox and BCG vaccines, those provisions set out in Part 1 of Schedule 3;
- (b) for smallpox vaccine, those provisions set out in Part 2 of Schedule 3; and
- (c) for BCG vaccine, those provisions set out in Part 3 of Schedule 3.

(2) In addition to the standard provisions for manufacturer's licences set out in Schedules 1 and 2, there shall be the following additional standard provisions for manufacturers licences relating to relevant medicinal products which are toxins and sera for human use—

- (a) for toxins, those provisions set out in Part 4 of Schedule 3; and
- (b) for sera, those provisions set out in Part 5 of Schedule 3.

Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- [Regulations revoked by S.I. 2012/1916 Sch. 35](#)