
STATUTORY INSTRUMENTS

2010 No. 1882

MEDICINES

The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010

Made - - - - - *21st July 2010*
Laid before Parliament *26th July 2010*
Coming into force *19th August 2010*

**THE MEDICINES FOR HUMAN USE (ADVANCED
THERAPY MEDICINAL PRODUCTS AND
MISCELLANEOUS AMENDMENTS) REGULATIONS 2010**

1. Citation, commencement and interpretation
2. Disapplication of section 7 of the Medicines Act 1968 to exempt advanced therapy medicinal products
3. Licence conditions for exempt advanced therapy medicinal products
4. Traceability
5. Traceability in the event of bankruptcy or liquidation of holder of manufacturer's licence for exempt ATMP
6. Amendment of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971
7. Amendment of the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971
8. Amendment of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994
9. Amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004
10. Amendment of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005
Signature

SCHEDULE 1 — Requirement that holders of manufacturer's licences comply with certain obligations in relation to the manufacture and assembly of exempt advanced therapy medicinal products

Status: This is the original version (as it was originally made).

SCHEDULE 2 — Standard provisions for manufacturer's licences insofar as those licences relate to exempt advanced therapy medicinal products

1. The holder of a manufacturer's licence must—
2. The manufacturer's licence holder may use a contract laboratory pursuant...

SCHEDULE 3 — Requirement that holders of wholesale dealer's licences comply with certain obligations in relation to exempt advanced therapy medicinal products

SCHEDULE 4 — Standard provisions for wholesale dealer's licences insofar as those licences relate to exempt advanced therapy medicinal products

SCHEDULE 5 — Amendments to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

1. Amendment of regulation 1
2. Amendment of Schedule 1
3. Amendment of Schedule 3
4. Amendment of Schedule 6

Explanatory Note