
STATUTORY INSTRUMENTS

1992 No. 755

The Medicines (Applications for Grant and Renewal of Licences) (Miscellaneous Amendments) Regulations 1992

Amendment of regulation 2(1) of the Principal Regulations

2. In regulation 2(1) of the Principal Regulations (interpretation)—
- (a) after the definition of “the Act” there shall be inserted the following:—

““allergen product” means any product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergising agent;”
 - (b) after the definition of “approved name” there shall be inserted the following:—

““blood product” means any industrially prepared medicinal product for human use derived from human blood or human plasma and includes albumin, coagulating factors and immunoglobulins of human origin, but does not include whole human blood, human plasma or blood cells of human origin;”;
 - (c) after the definition of “clinical trial certificate” and “animal test certificate” there shall be inserted—

““generator” means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and used in a radiopharmaceutical;”;
 - (d) at the end of the definition of “medicinal product” there shall be added the words “and any generator, kit or precursor as defined in regulation 1(2) of the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992”(1);
 - (e) after the definition of “proprietary medicinal product” and “ready-made veterinary drug”, there shall be inserted the following:—

““radiopharmaceutical” means any medicinal product for human use which, when ready for use, contains one or more radioactive isotopes which are included for a medicinal purpose;”;
 - (f) after the definition of “standard provisions for licences and certificates” there shall be inserted—

““vaccine”, “toxin” and “serum” means any such product for human use and include any agent which is used—

 - (a) to produce active immunity;
 - (b) to diagnose immunity; or
 - (c) to produce passive immunity.”.