SCHEDULES

SCHEDULE 4

Standard provisions of licences under Part 3

PART 3

Manufacturer's licence relating to exempt advanced therapy medicinal products

24. The provisions of paragraphs 25 to 27 are incorporated as additional standard provisions of a manufacturer's licence relating to the manufacture and assembly of exempt advanced therapy medicinal products.

25. The licence holder must ensure that the immediate packaging of an exempt advanced therapy medicinal product is labelled to show the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the expiry date in clear terms including the year and month and, if applicable, the day;

(c) a description of the active substance, expressed qualitatively and quantitatively;

(d) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and of their specific origin;

(e) the pharmaceutical form and the contents by weight, volume or number of doses of the product;

(f) a list of excipients, including preservative systems;

(g) the method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated;

(h) any special storage precautions;

(i) specific precautions relating to the disposal of the unused product or waste derived from the product and, where appropriate, reference to any appropriate collection system;

(j) the name and address of the holder of the manufacturer's licence;

(k) the manufacturer's licence number;

(l) the manufacturer's batch number;

(m) the unique donation code referred to in Article 8(2) of Directive 2004/23/EC; and

(n) where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words "for autologous use only".

26. The licence holder must ensure that the package leaflet of the exempt advanced therapy medicinal product shall include the following particulars—

(a) the name of the exempt advanced therapy medicinal product;

(b) the intended effect of the medicinal product if correctly used, applied, administered or implanted;

(c) where the product contains cells or tissues of human or animal origin—

(i) a statement that the product contains such cells or tissues, and

(ii) a short description of the cells or tissues and, where such cells or tissues are of animal origin, their specific origin;

(d) where the product contains a medical device or an active implantable medical device, a description of that device and, where that device contains cells or tissues of animal origin, their specific origin;

(e) any necessary instructions for use, including—

(i) the posology,

(ii) the method of use, application, administration or implantation and, if appropriate, the route of administration,

(iii) a description of symptoms of overdose,

(iv) action to be taken in the event of overdose, including any emergency procedures,

(v) action to be taken if one or more doses have been missed, and

(vi) a recommendation to consult the doctor or pharmacist for any clarification on the use of the product;

(f) where adverse reactions are known, a description of those which may occur under recommended conditions of use of the product and, if appropriate, an indication of action to be taken in such a case;

(g) an instruction that the patient report any adverse reaction not specified in the package leaflet to the doctor or pharmacist;

(h) the expiry date in clear terms and a warning against using the product after that date;

(i) any special storage precautions;

(j) a description of any visible signs of deterioration;

(k) a complete qualitative and quantitative composition;

(l) the name and address of the holder of the manufacturer's licence; and

(m) the date on which the package leaflet was last revised.

27. The licence holder must keep the data referred to in paragraph 8 of Schedule 6 for such period, being a period of longer than 30 years, as may be specified by the licensing authority.