

## SCHEDULE 6

Regulation 15

### TRANSITIONAL PROVISIONS

#### **Wholesale dealer's licences granted before 30th October 2005 relating to the import of medicinal products from third countries**

- 1.—(1) This sub-paragraph applies—
  - (a) where a wholesale dealer's licence has been granted by the licensing authority pursuant to section 20 of the Act before 30th October 2005 and remains in force as at that date; and
  - (b) insofar as such licence relates to the import from a third country of medicinal products.
- (2) Where sub-paragraph (1) applies—
  - (a) the licence shall have effect as though it were a manufacturer's licence granted by the licensing authority in respect of the import from a third country of those medicinal products;
  - (b) insofar as the licence relates to relevant medicinal products, the provisions of paragraph 3 of this Schedule shall accordingly apply to the licence as though it were a manufacturer's licence; and
  - (c) insofar as the licence relates to medicinal products which are not relevant medicinal products—
    - (i) the standard provisions as respects manufacturer's licences set out in Schedule 2 to the Standard Provisions Regulations shall, notwithstanding the provisions of section 47(4) of the Act, be deemed to be incorporated into those licences with effect from 30th October 2005; and
    - (ii) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
      - (aa) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
      - (bb) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (cc) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
      - (cc) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into the licence with such exceptions or modifications as may be specified in the application; and
      - (dd) references to applications to the licensing authority to so direct, and shall be construed in accordance with paragraphs (bb) and (cc),  
and subsection 47(7) shall be construed accordingly,
    - (iii) subsection 47(8) of the Act shall not apply as respect those standard provisions; and

- (iv) any standard provisions set out in Schedule 3 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.

### **Applications for wholesale dealer's licences made before 30<sup>th</sup> October 2005**

2.—(1) This paragraph applies where—

- (a) an application has been made to the licensing authority before 30<sup>th</sup> October 2005 for the grant or variation of a wholesale dealer's licence;
- (b) as at 30<sup>th</sup> October 2005 the licensing authority has not granted or refused the application; and
- (c) that application relates to the import from a third country of medicinal products.

(2) The application, insofar as it relates to import from a third country, shall be treated by the licensing authority as though it were an application for grant or variation of a manufacturer's licence in respect of the import from a third country of medicinal products.

### **Manufacturer's and wholesale dealer's licences granted before 30<sup>th</sup> October 2005**

3.—(1) This sub-paragraph applies where a manufacturer's or wholesale dealer's licence has been granted by the licensing authority pursuant to section 20 of the Act before 30<sup>th</sup> October 2005 and remains in force as at that date.

(2) Where sub-paragraph (1) applies and insofar as that licence relates to relevant medicinal products—

- (a) the standard provisions as respects such licences set out in Schedules 1, 2 3 and 4 to these Regulations insofar as they are applicable in each case to the licence shall, notwithstanding the provisions of section 47(4) of the Act, be incorporated into those licences with effect from 30<sup>th</sup> October 2005; and
- (b) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
  - (i) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
  - (ii) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (iii) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
  - (iii) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into the licence with such exceptions or modifications as may be specified in the application; and
  - (iv) references to applications to the licensing authority to direct shall be construed in accordance with paragraphs (ii) and (iii),

and subsection 47(7) shall be construed accordingly;

- (c) subsection 47(8) of the Act shall not apply as respect those standard provisions, and
- (d) any standard provisions set out in Schedule 2, 3 or 4 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.

(3) Where sub-paragraph (1) applies and insofar as that licence relates to medicinal products which are not relevant medicinal products—

- (a) the standard provisions as respects such licences set out in Schedules 2, 3 and 4 of the Standard Provisions Regulations as amended by Part 2 of Schedule 5 to these Regulations shall, notwithstanding the provisions of section 47(4) of the Act, apply to such licences with effect from 30th October 2005.
- (b) subsection 47(6) of the Act shall apply as respects those standard provisions with the modifications that—
  - (i) the reference to any time after the Regulations are made and before the end of the period of three months from the date on which they come into operation, shall be read as though it were a reference to any time after these Regulations are made and before 1<sup>st</sup> February 2006;
  - (ii) the references to the licensing authority directing that the operative standard provisions shall not be deemed to be incorporated into the licence shall be read as though they were references to the licensing authority directing that the standard provisions referred to in paragraph (iii) shall be deemed, from the date upon which the application is determined by the licensing authority, to no longer be incorporated in that licence;
  - (iii) the reference to the licensing authority directing that the operative standard provisions shall be deemed to be incorporated into the licence subject to such exceptions and modifications as may be specified in the application, shall be read as though it were a reference to the licensing authority directing that the standard provisions shall be deemed, from the date upon which the application is determined by the licensing authority, to be incorporated into the licence with such exceptions or modifications as may be specified in the application; and
  - (iv) references to applications to the licensing authority to direct shall be construed in accordance with paragraphs (ii) and (iii),

and subsection 47(7) shall be construed accordingly; and

- (c) subsection 47(8) of the Act shall not apply as respect those standard provisions; and
- (d) any standard provisions set out in Schedule 2, 3 or 4 to the Standard Provisions Regulations which were incorporated in that licence before 30<sup>th</sup> October 2005 shall no longer be provisions of that licence.