STATUTORY INSTRUMENTS

2019 No. 62

The Human Medicines (Amendment) Regulations 2019

Amendment of regulation 36 (conditions for manufacturer's licence)

4. In regulation 36(**1**), after paragraph (3) insert—

"(4) The requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were provisions of a manufacturer's licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

(a) Article 4 (composition of the unique identifier);

(b) Article 5 (carrier of the unique identifier);

(c) Article 6 (quality of the printing of the two-dimensional barcode);

(d) Article 7 (human-readable format);

(e) Article 10 (verification of the safety features) insofar as it relates to manufacturers;

(f) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to manufacturers;

(g) Article 12 (unique identifiers which have been decommissioned);

(h) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to manufacturers;

(i) Article 14 (verification of the two-dimensional barcode);

(j) Article 15 (record keeping);

(k) Article 16 (verifications to be performed before removing or replacing the safety features);

(l) Article 17 (equivalent unique identifier); and

(m) Article 18 (actions to be taken in case of tampering or suspected falsification).

(6) In distributing a medicinal product by way of wholesale dealing, the requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (7) shall apply to the holder of a manufacturer's licence and have effect as if they were provisions of the licence.

(7) The provisions mentioned in paragraph (6) are—

(a) Article 20 (verification of the authenticity of the unique identifier by wholesalers), subject to the exemption contained in Article 21 (derogations from Article 20(b));

(b) Article 22 (decommissioning of unique identifiers by wholesalers); and

(c) Article 24 (actions to be taken by wholesalers in case of tampering or suspected falsification).".

(**1**) Regulation 36 was amended by S.I. 2013/1855.