

## SCHEDULES

### SCHEDULE 34

#### Amendments to existing law

### PART 4

#### The Medicines for Human Use (Clinical Trials) Regulations 2004

**63.** In paragraph 5(2) of Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

“(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and”;

(b) in sub-paragraph (b) after “Crown” insert “, the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister”.

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 63.