

SCHEDULES

SCHEDULE 34

Amendments to existing law

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

57. In regulation 47 (application of enforcement provisions of the Act)—

- (a) for “the Act” in the heading substitute “the 2012 Regulations”; and
- (b) for paragraph (1) substitute—

“(1) Regulations 2, 8(1), 322, 323(1), 324(1), 325 to 330, 332 to 339, 343 and Schedule 31 of the 2012 Regulations (“those provisions”) shall apply for the purposes of these Regulations as they apply for the purposes of the 2012 Regulations, but with the modifications specified in Schedule 9, and any reference in those provisions to the 2012 Regulations includes a reference to these Regulations.”; and

- (c) after paragraph (2) insert the following paragraph—

“(3) In those provisions as applying by virtue of paragraph (1), any reference to, or relating to, a requirement, a power, a function, a right, a duty, an entitlement, or a protection shall be read as a reference to, or relating to, that requirement, power, function, right, duty, entitlement, or protection as applied by this regulation.”.