STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 2

Administration

Functions of the Commission

10.—(1) The Commission must give advice to either or both of the Ministers in relation to the matters listed in paragraph (2) if—

(a) the Minister, or Ministers, request it; or

(b) the Commission considers it appropriate to give it.

(2) The matters mentioned in paragraph (1) are matters—

(a) relating to the execution of any duty imposed by these Regulations or the Clinical Trials Regulations;

(b) relating to the exercise of any power conferred by these Regulations or the Clinical Trials Regulations; or

(c) otherwise relating to medicinal products.

(3) Without prejudice to paragraphs (1) and (2), or to any other functions conferred on the Commission by or under these Regulations, the Commission must—

(a) give advice with respect to the safety, quality and efficacy of medicinal products; and

(b) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given.

(4) The Commission must also advise the licensing authority if—

(a) the licensing authority is required under Schedule 11 (advice and representations) or the Clinical Trials Regulations to consult the Commission about any matter arising under those provisions; or

(b) the licensing authority consults the Commission about any matter arising under those provisions.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 10.