STATUTORY INSTRUMENTS

# 2012 No. 1916

# The Human Medicines Regulations 2012

## PART 9

Borderline products

**Written representations procedure**

**161.**—(1) If a recipient makes written representations in accordance with regulation 160(2)(a) the licensing authority must appoint a panel of at least two persons ("the reviewers") to advise on the provisional determination.

(2) The licensing authority must provide the reviewers with—

(a) the recipient's written representations; and

(b) any written representations of the licensing authority.

(3) The reviewers must advise the licensing authority on the authority's provisional determination taking account of—

(a) the written representations; and

(b) any other evidence submitted to them.

(4) The licensing authority must take into account the reviewers' advice and make a final determination as to whether the product is a medicinal product.

(5) The licensing authority must—

(a) inform the recipient in writing of its final determination and of the reasons for it; and

(b) if the licensing authority disagrees with the reviewers' advice, inform the recipient in writing of the reasons for that disagreement.

**Changes to legislation:**
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 161.