

SCHEDULE 7

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 3

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

6. Where the holder of the authorisation has been informed by the licensing authority that any batch of any investigational medicinal product to which his authorisation relates has been found not to conform as regards strength, quality or purity with—

- (a) the specification of the relevant product; or
- (b) the provisions of these Regulations, [^{F1}the 2012 Regulations] or any regulations under the Act that are applicable to the investigational medicinal product,

he shall, if so directed, withhold such batch from distribution for use in clinical trials, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

Textual Amendments

- F1** Words in Sch. 7 Pt. 3 para. 6 substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), [Sch. 34 para. 62\(b\)\(i\)](#) (with Sch. 32)

Status:

Point in time view as at 14/08/2012.

Changes to legislation:

There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Paragraph 6.