STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Obligations of holder of marketing authorisation

Obligation to take account of scientific and technical progress

- **74.**—(1) The holder of a UK marketing authorisation must keep under review the methods of manufacture and control of the product to which the authorisation relates, taking account of scientific and technical progress.
- (2) As soon as is reasonably practicable after becoming aware of the need to do so, the holder must apply to vary the marketing authorisation to make any changes to those methods that are required to ensure they are generally accepted scientific methods.