
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 16

Enforcement

Rights of entry

325.—(1) An inspector may at any reasonable time enter premises—

- (a) in order to determine whether there has been a contravention of a provision of these Regulations which the enforcement authority is required or empowered to enforce by virtue of regulations [323](#) and [324](#);
- (b) in order to verify whether the data submitted in respect of an active substance used as a starting material in order to obtain a conformity certificate issued by the European Directorate for the Quality of Medicines and Healthcare (“EDQM”) comply with the monographs of the European Pharmacopoeia, if the EDQM asks the enforcement authority to do so; and
- (c) for the purposes of any other function of the enforcement authority under these Regulations.

(2) A person may not exercise a right of entry under this regulation in relation to premises used only as a private dwelling unless 24 hours’ notice has been given to the occupier.

(3) A person exercising, or attempting to exercise, a right of entry under this regulation must produce identification on request.