STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Validity of UK marketing authorisation

[F1Validity of parallel import licence

65A.—(1) Unless paragraph (2) applies, a parallel import licence remains in force for a period of 5 years from the date it is granted or renewed.

(2) A parallel import licence will cease to be valid if—

(a) the information supplied in the application for a licence no longer matches the information currently approved for the reference product by the licensing authority;

(b) details about the product imported under the licence are not consistent with the details supplied in the application; or

(c) the patient information leaflet supplied with the product is not consistent with latest version of the leaflet that is required to be issued with the product by the licensing authority, and

an application to vary the licence to update any details in relation to sub-paragraph (a) to (c) has not been granted by the licensing authority because the condition in regulation 68(11) has not been met.**]**

Textual Amendments

F1 Reg. 65A inserted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **9** and reg. 65A inserted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **9**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 65A.