STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 48 (application of Part 5)

47.—(1) Regulation 48(**1**) is amended as follows.

(2) In paragraph (2)—

(a) at the appropriate place insert—

""EU reference medicinal product" means a medicinal product which falls within paragraph (b) of the definition of "reference medicinal product";";

(b) for the definition of "generic medicinal product", substitute—

""generic medicinal product", in relation to a reference medicinal product, means a medicinal product—

(a) that has the same qualitative and quantitative composition in active substances as the reference medicinal product;

(b) that has the same pharmaceutical form as the reference medicinal product; and

(c) whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies;";

(c) for the definition of "parallel import licence" substitute—

""parallel import licence" means a licence that is granted by the licensing authority under this Part authorising the holder to place on the market a medicinal product imported in to the United Kingdom from an EEA State where that product—

(a) has been granted an EU marketing authorisation or a marketing authorisation in an EEA State under the 2001 Directive; and

(b) is essentially similar to a product that has been granted a UK marketing authorisation;"; and

(d) for the definition of "reference medicinal product", substitute—

""reference medicinal product" means a medicinal product—

(a) authorised under regulation 49(1)(a), in accordance with the provisions of regulation 50; or

(b) in relation to which an EU marketing authorisation was in force on exit day, but in relation to which no UK marketing authorisation is in force because the holder of the EU marketing authorisation notified the licensing authority in

(**1**) Regulation 48 was amended by S.I. 2014/1878.

accordance with paragraph 6(3) of Schedule 33A that it did not wish to be the holder of a converted EU marketing authorisation.".

(3) After paragraph (2) insert—

"(3) In this Part, references to a medicinal product to be imported that is "essentially similar to a product that has been granted a UK marketing authorisation" are to be read as references to a medicinal product to be imported that—

(a) has been manufactured to the same formulation as a product that has been granted a UK marketing authorisation ("the UK product");

(b) contains the same active ingredients as the UK product;

(c) has the same therapeutic effect as the UK product,

and for the purposes of sub-paragraph (a), any differences in a product's formulation are to be ignored in so far as they are considered to be immaterial by the licensing authority.

(4) For the purposes of the definition of generic medicinal product—

(a) the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy; and

(b) the various immediate-release oral pharmaceutical forms are considered to be the same pharmaceutical form.

(5) When a medicinal product has been granted a UK marketing authorisation under regulation 49(1)(a) in accordance with the provisions of regulation 50 ("initial marketing authorisation"), any additional strengths, pharmaceutical forms, administration routes, presentations, variations and extensions in relation to which a UK marketing authorisation is granted under regulation 49(1)(a), or which are included in the initial UK marketing authorisation, belong to the same "global marketing authorisation".

(6) Paragraph (7) applies if a medicinal product—

(a) belongs to a global marketing authorisation but is not the initial marketing authorisation; and

(b) is used as a reference medicinal product in accordance with regulations 51 to 53.

(7) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) as if it had been authorised on the date of authorisation of the medicinal product to which the initial marketing authorisation relates.

(8) Paragraph (9) applies in relation to a medicinal product if—

(a) it is an EU reference medicinal product;

(b) it is used as a reference medicinal product in accordance with regulations 51 to 53; and

(c) it belongs to a global marketing authorisation, as described in the second paragraph of Article 6(1) of the 2001 Directive; but

(d) it is not the initial marketing authorisation for the purposes of that global marketing authorisation.

(9) Where this paragraph applies, the medicinal product is treated for the purposes of the application of regulation 51(1) and (8) as if it had been authorised on the date of authorisation of the initial marketing authorisation for the purposes of the global marketing authorisation to which the product belongs.".