STATUTORY INSTRUMENTS

2024 No. 832

The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024

Amendment to regulation 49

26. In regulation 49 (application for grant of UK marketing authorisation or parallel import licence)(**1**)—

(a) after paragraph (1), insert—

"(1ZA) If the licensing authority determines to grant a UKMA(UK) under paragraph (1), it must determine if one or more of the following criteria are met in relation to the medicinal product—

(a) it belongs to a category of medicinal product referred to in Article 3(1) of Regulation (EC) No 726/2004;

(b) it belongs to a category of medicinal product referred to in Article 3(2) of Regulation (EC) No 726/2004 and—

(i) the medicinal product contains an active substance which, on 20th May 2004, was not authorised in the European Union, or

(ii) the licensing authority considers that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that granting the marketing authorisation is in the interest of patients' health in the United Kingdom.

(1ZB) If the licensing authority determines that one or more of the criteria in paragraph (1ZA) are met, the marketing authorisation granted is a UKMA(UK)(Category 1).

(1ZC) If the licensing authority determines that none of the criteria in paragraph (1ZA) are met, the marketing authorisation granted is a UKMA(UK)(Category 2).

(1ZD) The licensing authority may grant a UKMA(NI) under Chapter 4 of Title III of the 2001 Directive where there is an application for a marketing authorisation for a medicinal product, unless there is a UKMA(UK), or an application yet to be determined for a UKMA(UK), for the same medicinal product.";

(b) in paragraph (1A)—

(i) in the opening words, for "UKMA(GB)" substitute "UKMA(UK)(Category 2)";

(ii) for sub-paragraph (a) substitute—

"(a) there is in place, or will be at the time the UKMA(UK)(Category 2) is granted, a UKMA(NI) in respect of the product authorising sale or supply in Northern Ireland,";

(c) in paragraph (3)—

(**1**) The heading to regulation 49 was amended and paragraph (1) substituted by S.I. 2014/1878; paragraph (3) was substituted by, and paragraphs (1A) and (9) inserted by, S.I. 2019/775 as amended by S.I. 2020/1488; paragraph (3)(a) was substituted by, and paragraph (3)(b) amended by, S.I. 2023/437.

(i) in sub-paragraph (a), for "a UKMA(UK) or UKMA(NI) must" substitute "a UK marketing authorisation must, subject to sub-paragraph (b),";

(ii) in sub-paragraph (b)—

(aa) for "UKMA(GB)" substitute "UKMA(UK)(Category 2)",

(bb) omit paragraph (ii);

(d) after paragraph (3), insert—

"(3ZA) Where a UKMA(UK)(Category 2) is granted under the unfettered access route, any UKMA(NI) granted in relation to the same medicinal product ceases to have effect.";

(e) in paragraph (9), omit sub-paragraph (b) (but not the "or" which follows it).