SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 4

Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

50. In regulation 67 (insertion of new regulations 60A (condition as to the submitting of samples and other information to the appropriate authority))—

(a) in the heading to the regulation, at the end insert " and 60B (submitting of samples and other information: EU marketing authorisations) "

(b) in the inserted regulation 60A—

(i) in paragraph (1), for the definition of "the batch testing exemption" substitute—

""the batch testing exemption" means that—

(a) in the case of a medicinal product for sale or supply in Northern Ireland only—

(i) a certificate has been issued by a laboratory in an EEA State, and

(ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or

(b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and

(iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority's own examination of a sample from the batch, the appropriate documentation or both.";

(ii) in paragraph (2)(b), omit "medicinal";

(iii) in paragraph (5) after "paragraph (6)" insert " and regulation 60B(5) ";

(iv) in paragraphs (9)(a) and (b), after "batch testing exemption" insert " under this regulation or regulation 60B ";

(v) after paragraph (13) insert—

"(14) The appropriate authority may, in any particular case, apply this regulation to a medicinal product imported into the United Kingdom pursuant to a parallel import licence and accordingly any reference in this regulation to—

(a) a UK marketing authorisation should be read as a reference to a parallel import licence for a medicinal product,

(b) the holder of a UK marketing authorisation should be read as a reference to the holder of a parallel import licence, and

(c) the approved specifications in a UK marketing authorisation should be read as a reference to the approved specifications in the UK reference product specified for the purposes of the parallel import licence in accordance with paragraph 4 of Schedule 8A.

(15) Where, pursuant to paragraph (14), this regulation is applied to a medicinal product imported into the United Kingdom pursuant to a parallel import licence, sub-paragraph (a) of the definition of "the batch testing exemption" does not apply.

(16) In the application of this regulation to a medicinal product for sale or supply in Northern Ireland only to which Article 114 of the 2001 Directive applies, a reference in this regulation to a laboratory is to an Official Medicines Control Laboratory or a laboratory referred to in that Article.";

(c) after the inserted regulation 60A insert—

"**Submitting of samples and other information: EU marketing authorisations**

60B.—(1) In this regulation—

"the appropriate authority" is to be construed in accordance with section 57(7) of the Health and Social Care Act 2012 [M1];

"appropriate documentation", in relation to a sample of a batch submitted to the appropriate authority in accordance with the batch testing requirement or pursuant to a notification under paragraph (8), means such documentation as the appropriate authority notifies the holder of the EU marketing authorisation to which the sample relates that it requires;

"approved country list for batch testing and certification of biological medicinal products" means the list described in regulation 60A(5), and "approved country for batch testing and certification of biological medicinal products" means a country included in that list;

"the batch testing exemption" means that—

(a) (i) a certificate has been issued by a laboratory in an EEA State, and

(ii) in relation to a product of a kind listed in Article 114(1) of the 2001 Directive, the certificate was issued in the same EEA State as that in which the batch was manufactured, or

(b) (i) a certificate has been issued by a laboratory in a country other than the United Kingdom,

(ii) an agreement has been made between that country and the United Kingdom (whether or not the agreement is solely with that country, a group of countries or an organisation of which that country is a part), and

(iii) that agreement is to the effect that the appropriate authority will recognise that certificate in respect of the batch of the medicinal product, in place of the appropriate authority's own examination of a sample from the batch, the appropriate documentation or both;

"the batch testing requirement", in respect of an EU marketing authorisation, is a requirement that, unless the batch testing exemption applies, the holder of the EU marketing authorisation—

(a) must submit a sample from each batch of the medicinal product that is the subject of that authorisation to the appropriate authority, together with appropriate documentation; and

(b) must not sell or supply, or offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the batch is in conformity with the approved specifications in the EU marketing authorisation.

(2) The licensing authority may impose the batch testing requirement on the holder of an EU marketing authorisation for a medicinal product—

(a) that is—

(i) a live vaccine;

(ii) an immunological product used in the primary immunisation of infants or other groups at risk;

(iii) an immunological product used in public health immunisation programmes;

(iv) subject to paragraph (3), a new immunological product manufactured using new or altered kinds of technology or new for a particular manufacturer; or

(v) derived from human blood or human plasma, and

(b) which is intended for sale or supply in Northern Ireland.

(3) If the licensing authority imposes the batch testing requirement in respect of an EU marketing authorisation for a medicinal product of a kind mentioned in paragraph (2)(a)(iv), it must, in imposing that requirement, specify a period of time for the duration of the requirement.

(4) The appropriate authority must complete its examination of the sample for testing, the appropriate documentation or both (as the case may be) within the period of 60 days, beginning with the date on which the appropriate authority is in receipt of both the sample for testing, and the appropriate documentation.

(5) Where a holder of an EU marketing authorisation, in order to comply with the batch testing requirement, submits appropriate documentation that includes a certificate issued by a laboratory in an approved country for batch testing and certification of biological medicinal products in respect of the batch, the appropriate authority must, in addition to any other factors it considers relevant, take that into account in determining whether the appropriate authority needs to undertake any further testing of the medicinal product submitted to it.

(6) Where a holder of an EU marketing authorisation relies on the batch testing exemption in relation to a batch of a medicinal product, that holder must submit the certificate in respect of that batch to the licensing authority and the appropriate authority, and such other documentation as those authorities may notify that holder they require, before it sells or supplies, or offers to sell or supply, a medicinal product that forms part of that batch in Northern Ireland.

(7) Paragraph (8) applies where the appropriate authority considers that there are public health concerns in respect of a batch of a medicinal product ("the relevant batch") in relation to which the batch testing exemption would otherwise apply.

(8) Where this paragraph applies, the appropriate authority must, subject to paragraph (9), notify the holder of the EU marketing authorisation in respect of the relevant batch that it nevertheless requires that holder—

(a) to submit a sample from the relevant batch to the appropriate authority, together with appropriate documentation; and

(b) not to sell or supply, or to offer to sell or supply, a medicinal product that forms part of that batch in Northern Ireland until the appropriate authority has examined—

(i) the sample from that batch,

(ii) the appropriate documentation, or

(iii) both that sample and that documentation,

and confirmed that it is satisfied that the relevant batch is in conformity with the approved specifications in the EU marketing authorisation.

(9) The appropriate authority may only exercise its powers under paragraph (8) if the agreement made between the country in which the certificate was issued, and the United Kingdom (whether the agreement is solely with that country, a group of countries or an organisation of which that country is a part) provides for the relevant batch to be re-examined by the appropriate authority in the circumstances described in paragraph (7).

(10) A reference in this regulation to a laboratory (other than in paragraph (b) of the definition of "the batch testing exemption" in paragraph (1)) is to an Official Medicines Control Laboratory or a laboratory referred to in Article 114 of the 2001 Directive.".

Commencement Information

I1 Sch. 2 para. 50 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Marginal Citations

M1 2012 c.7.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 50.