

STATUTORY INSTRUMENTS

2018 No. 1255

**The Branded Health Service Medicines
(Costs) (Amendment) Regulations 2018**

Amendment of the Branded Health Service Medicines (Costs) Regulations 2018

2.—(1) The Branded Health Service Medicines (Costs) Regulations 2018(1) are amended as follows.

(2) In regulation 1 (citation, commencement and interpretation)—

(a) after the definition of “audited sales report” insert the following definition—

““biological medicinal product” has the meaning given to it by regulation 8(1) of the 2012 Regulations;” and

(b) in the definition of “relevant medicine” at paragraph (a), after “branded medicine” insert “or a biological medicinal product (whether or not it is a branded medicine)”.

(3) In regulation 3 (payment scheme)—

(a) in paragraph (1)—

(i) for “paragraph (4),” substitute “paragraphs (4) and (5A),” and

(ii) for “7.80%” substitute “for the applicable period specified in the first column of the table below, the payment percentage specified in the corresponding entry in the second column of that table”; and

(b) at the end of paragraph (1) insert the following table—

“Table

<i>Applicable Period</i>	<i>Payment Percentage</i>
2019	9.9%
2020	14.7%
2021 and any subsequent calendar year	20.5%”

(c) after paragraph (1), insert the following paragraph—

“(1A) Where, in respect of an applicable period, as a consequence of an amendment to these Regulations, there is an amendment (in any manner) of a payment percentage specified in the second column of the table, the applicable payment percentage for payments payable under paragraph (1) in respect of supplies of an item of presentation under any contract entered into on or after 1st January 2019, including—

(a) a contract with a contracting authority based on a framework agreement where that framework agreement was entered into following a tender which closed on or after 1st January 2019; or

- (b) a public contract entered into following a tender which closed on or after 1st January 2019,
is, for that applicable period, the amended percentage.”.
- (d) after paragraph (5), insert the following paragraphs—
- “(5A) Where paragraph (5B) applies, the payment percentage referred to in paragraph (1) for the applicable period is 7.80% and not the percentage specified in the corresponding entry for that applicable period in the second column of the table.
- (5B) Subject to paragraph (5C), this paragraph applies in respect of payments payable under paragraph (1) in respect of supplies of an item of presentation under—
- (a) a contract with a contracting authority based on a framework agreement where that framework agreement was entered into on or after 1st April 2018 but before 1st January 2019, or was entered into following a tender which closed on or after 1st April 2018 but before 1st January 2019;
- (b) a public contract entered into on or after 1st April 2018 but before 1st January 2019 or was entered into following a tender which closed on or after 1st April 2018 but on or before 1st January 2019.
- (5C) Paragraph (5B) does not apply to payments payable in respect of supplies of any item of presentation added to a framework agreement or public contract that falls within paragraph (5B)(a) or (b) where that item is added on or after 1st January 2019.”.
- (4) In regulation 4 (direction to make payment)—
- (a) in paragraph (2)(b), for “7.80%” substitute “the relevant payment percentage referred to in regulation 3(1) or (5A)”; and
- (b) in paragraph (3)(c), for “7.80%” substitute “the relevant payment percentage referred to in regulation 3(1) or (5A)”.
- (5) In regulation 21 (sales report), in paragraph (1)—
- (a) after sub-paragraph (f) insert—
- “(fa) with respect to the net sales income received in respect of the supply of an item of presentation under a contract with a contracting authority based on a framework agreement for which a payment percentage is determined in accordance with regulation 3(5A), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;
- (fb) with respect to the net sales income received in respect of the supply of an item of presentation under a public contract for which a payment percentage is determined in accordance with regulation 3(5A), details of the public contract and item of presentation so supplied;
- (fc) the total of the net sales income received in respect of the total supply of all of the items of presentations referred to in sub-paragraphs (fa) and (fb);”;
- (b) in paragraph (n), before the first “the” insert “to the extent not already required by paragraph (b),”.
- (6) In regulation 22 (presentation report) after paragraph (f) insert—
- “(fa) with respect to the net sales income received in respect of the supply of an item of presentation under a contract with a contracting authority based on a framework agreement for which a payment percentage is determined in accordance with regulation 3(5A), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;

- (fb) with respect to the net sales income received in respect of the supply of an item of presentation under a public contract for which a payment percentage is determined in accordance with regulation 3(5A), details of the public contract and the item of presentation so supplied;
- (fc) the quantity supplied and the total gross sales income and total net sales income received in respect of the supply of—
 - (i) each presentation which was supplied under a contract with a contracting authority based on a framework agreement, where the framework agreement was entered into on or after 1st April 2018 but before 1st January 2019 or was entered into following a tender which closed on or after 1st April 2018 but before 1st January 2019, and
 - (ii) each presentation which was supplied under a public contract entered into on or after 1st April 2018 but before 1st January 2019, or was entered into following a tender which closed on or after 1st April 2018 but before 1st January 2019;”.