STATUTORY INSTRUMENTS

2018 No. 1255

NATIONAL HEALTH SERVICE, ENGLAND AND WALES
NATIONAL HEALTH SERVICE, SCOTLAND
HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

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

Made - - - -	*28th November 2018*
Laid before Parliament	*3rd December 2018*
Coming into force - -	*1st January 2019*

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 263(1), (2), (4), (5A) and (6), 264A(2), (5), and (7), 265(1), (3), (4), (5) and (5A), 266(1) and (2) and 272(7) and (8) of the National Health Service Act 2006(**1**) and in accordance with section 266(3), (4) and (4A) of that Act.

The Secretary of State has consulted in accordance with sections 263(1) and (1A), 264C(1) and 265(9) of that Act(**2**).

Citation and Commencement

1. These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 and come into force on 1st January 2019.

(**1**) 2006 c. 41; section 263 was amended by the Health Service Medical Supplies (Costs) Act 2017 (c.23) ("the 2017 Act"), section 5 and 10(5). Section 264A was inserted by the 2017 Act, section 8. Section 265 was amended by the 2017 Act, section 6(2) to (4), 7(5) and 10(7) to (14). Section 266 was amended by the 2017 Act, section 6(5) to (9) and 7(6). *See* section 275(1) of the National Health Service Act 2006 for the definitions of "prescribed" and "regulations" that are relevant to the powers being exercised.

(**2**) Section 264C was inserted by the 2017 Act, section 8.

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

2.—(1) The Branded Health Service Medicines (Costs) Regulations 2018(**3**) 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**

Applicable Period	*Payment Percentage*
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 1stJanuary 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

(**3**) S.I. 2018/345.

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);"; and

(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;".

Signed by the authority of the Secretary of State for Health and Social Care.

O'Shaughnessy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

28th November 2018

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the United Kingdom, amend the Branded Health Service Medicines (Costs) Regulations 2018 ("the Statutory Scheme Regulations").

Regulation 2(2) inserts a definition of biological medicinal product and amends the definition of "relevant medicine" so that the payment mechanism, price control, information requirement and enforcement provisions all apply to all biological medicinal products, whether or not the biological medicinal product is a branded medicine.

Regulation 2(3)(b) and (c) insert a table in regulation 3(1) of the Statutory Scheme Regulations. The table sets out the percentage of its nets sales income that the manufacturer or supplier must pay to the Secretary of State for the applicable periods. Regulation 2(4) amends the payment percentage in regulation 4 of the Statutory Scheme Regulations, which applies to deemed net sales income, in a similar way.

Regulation 2(3)(a) and (d) makes clear that where there is an amendment to the payment percentages specified in the table, the amended payment percentage will apply to the sales of presentations supplied under a contract entered into on or after 1st January 2019, including where the manufacturer or supplier enters into a contract with a contracting authority based on a framework agreement on or after 1st January 2019 or enters into a public contract on or after 1st January 2019. However, a manufacturer or supplier that entered into a contract with a contracting authority based on a framework agreement or entered into a public contract on or after 1 April 2018 but before these Regulations came into force will be required to pay 7.80% on the net sales income from products supplied under those contracts throughout the length of those contracts. Before these Regulations came into force, this was the applicable percentage for all net sales income and deemed net sales income.

Regulation 2(5) and (6) update the corresponding information requirements in the Statutory Scheme Regulations, and requires manufacturers and suppliers to provide details of the framework agreements and public contracts, and details of the sales.