STATUTORY INSTRUMENTS

2023 No. 1307

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

NATIONAL HEALTH SERVICE, SCOTLAND

HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Branded Health Service Medicines (Costs) (Amendment) (No. 2) Regulations 2023

Made - - - - at 10:20 a.m. on 4th December 2023

Laid before Parliament at 3:30 p.m. on 4th December 2023

Coming into force - - 1st January 2024

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 263(1)(c) and (5), 264(1)(b), 266(1) and (2) and 272(7)(a) and (b) and (8) of the National Health Service Act 2006(**a**).

The Secretary of State has consulted in accordance with sections 263(1) and (1A) and 264(1) of that Act.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) (No. 2) Regulations 2023 and come into force on 1st January 2024.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

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

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

(2) In regulation 3 (payment scheme)—

(a) in paragraph (1)—

(i) omit "(1B),", and

(**a**) 2006 c. 41. Section 263 was amended by the Health Service Medical Supplies (Costs) Act 2017 (c. 23) ("the 2017 Act"), sections 5 and 10(5). Section 264 was amended by the 2017 Act, section 10(6). Section 266 was amended by the 2017 Act, sections 6(5) to (9) and 7(6). See section 275(1) of the National Health Service Act 2006 for definition of "regulations" that is relevant to the powers being exercised.

(**b**) S.I. 2018/345. Relevant amending instruments are S.I. 2018/1255, 2020/258, 2022/593 and 2023/239.

(ii) for the table substitute—

"**Applicable period**	**Payment percentage**
1st January 2024 to the end of 2024	21.9%
1st January 2025 to the end of 2025	24.0%
1st January 2026 to the end of 2026 and any subsequent calendar year	26.8%",

(b) omit paragraphs (1B) and (1C),

(c) in paragraph (4), in sub-paragraph (d) for "presentation." substitute "presentation;" and after insert—

"(e) any item of new active substance presentation during the period beginning on the date on which the marketing authorisation is granted for the first therapeutic indication of the presentation and ending on the last day of the 36th month after that date;

(f) any item of presentation which is a line extension of a new active substance presentation to which sub-paragraph (e) applies which is supplied during the period referred to in sub-paragraph (e) for the new active substance presentation;

(g) any item of exceptional centrally procured presentation;

(h) any item of centrally procured vaccine presentation.", and

(d) after paragraph (5C) insert—

"(5D) For the purposes of paragraph (4)(e)—

(a) "new active substance presentation" means a presentation containing a new active substance with a marketing authorisation incorporating the first therapeutic indication for that active substance, but not other presentations marketed under a different brand name which nevertheless contain that new active substance (whether alone or in combination with other active substances); and

(b) a presentation is only to be considered to contain a new active substance where confirmation that the presentation contains a new active substance is provided by—

(i) a European Public Assessment Report published by the European Medicines Agency in relation to the presentation in accordance with Article 13.3 of the Regulation (EC) 726/2004 of the European Parliament and of the Council of 31st March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**a**), or

(ii) a assessment report published by the licensing authority in accordance with regulation 64(6) of the 2012 Regulations.

(5E) For the purposes of paragraph (4)(f), "line extension" means a new presentation with the same active substance as another presentation which is marketed under the same brand name and by the same manufacturer or supplier but is distinguishable by reference to its strength, an excipient, its pack size, its method of administration or its formulation.

(**a**) OJ No L 136, 30.04.2004, p 1. There are no relevant amendments.

(5F) For the purposes of paragraph (4)(g), "exceptional centrally procured presentation" means a presentation which—

(a) is part of stock procured by the Secretary of State;

(b) is procured for the purpose of emergency preparedness or stockpiling for national security or pandemic preparedness; and

(c) either—

(i) UKHSA manages the stockpiling and distribution of the relevant presentation, or

(ii) the Secretary of State gives a direction to the manufacturer or supplier to the effect that paragraph (i) need not be satisfied in relation to the relevant presentation.

(5G) For the purposes of paragraph (4)(h), "centrally procured vaccine presentation" means a presentation which—

(a) is part of stock procured by the Secretary of State;

(b) is a vaccine procured in accordance with a recommendation made or advice given by the Joint Committee on Vaccination and Immunisation(**a**)—

(i) for a national vaccination programme, or

(ii) for a branded medicine to be included in a national vaccination programme; and

(c) either—

(i) UKHSA manages the distribution of the vaccine as part of a national vaccination programme, or

(ii) the Secretary of State gives a direction to the manufacturer or supplier to the effect that paragraph (i) need not be satisfied in relation to the relevant presentation.

(5H) In this regulation—

"active substance" has the meaning given in regulation 8(1) of the 2012 Regulations;

"licensing authority" is to be construed in accordance with regulation 6 of the 2012 Regulations;

"UKHSA" means the executive agency of the Department of Health and Social Care known as the United Kingdom Health Security Agency; and

"vaccine" has the meaning given in regulation 8(1) of the 2012 Regulations.".

(3) In regulation 4 (direction to make payment), in paragraphs (2)(b) and (3)(c) omit ", (1B)".

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

Helen Whately
Minister of State
Department of Health and Social Care

At 10.20 a.m. on 4th December 2023

(**a**) The Joint Committee on Vaccination and Immunisation is a non-departmental public body first established in 1963 by the Secretary of State. It is a statutory expert Standing Advisory Committee constituted in England and Wales under the National Health Service Act 1977 (c. 49) (now consolidated in the National Health Service Act 2006 (c. 41) and the National Health Service (Standing Advisory Committees) Order 1981(S.I. 1981/597) as the Standing Advisory Committee on Vaccination and Immunisation.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Branded Health Service Medicines (Costs) Regulations 2018 (S.I. 2018/345) (the "Statutory Scheme Regulations"). The Statutory Scheme Regulations, amongst other matters, make a scheme for the purpose of requiring specific manufacturers and suppliers of branded medicines for health service use to pay certain amounts to the Secretary of State. These amounts are calculated by reference to the net sales income or estimated net sales income from supplies of such medicines.

Regulation 2(2)(a)(ii) makes provision to replace the payment percentages in the table in regulation 3(1) of the Statutory Scheme Regulations with new payment percentages of net sales income payable by manufacturers and suppliers subject to the Statutory Scheme Regulations from the 1st January 2024 for each applicable period. The payment percentage that will apply during 2024 is 21.9%; during 2025 is 24.0% and during 2026 and each subsequent year is 26.8%. The payment percentage figure is used to calculate the amount payable to the Secretary of State on net sales income for supplies of relevant medicines made during the applicable period to which the applicable payment percentage applies.

Regulation 2(2)(a)(i) and (b) and (3) makes amendments to the Statutory Scheme Regulations to remove transitory provisions that are no longer relevant as a consequence of the amendment made by regulation 2(2)(a)(ii).

Regulation 2(2)(c) and (d) makes provision to introduce exemptions from payments in respect of the net sales income on supplies of branded medicines that are new active substance presentations, line extensions of new active substance presentations, exceptional centrally procured presentations and centrally procured vaccine presentations in regulation 3(4) and new paragraphs (5D) to (5H) of the Statutory Scheme Regulations. The effect of these amendments is that manufacturers and suppliers who supply such branded medicines will not be liable to make the payments required by regulation 3(1) of the Statutory Scheme Regulations on the net sales income of such supplies from 1st January 2024.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU and is available on the www.legislation.gov.uk website.

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