STATUTORY INSTRUMENTS

2023 No. 1307

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

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 3 (payment scheme)—

(a) in paragraph (1)—

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

(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

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

(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(**2**), 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.

(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(**3**)—

(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.

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

(**3**) 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.

(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)".