STATUTORY INSTRUMENTS

2024 No. 1277

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 2024

Made - - - -	*3rd December 2024*
Laid before Parliament	*4th December 2024*
Coming into force - -	*1st January 2025*

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 263(1)(b) and (c), (2), (4), (5) and (5A), 264(1), 264A(2), (4), (5) and (7), 265(1), 266(1) and 272(7)(a) and (b) and (8) of the National Health Service Act 2006(**a**) having had regard to the matters specified in section 266(3), (4) and (4A) of that Act.

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) Regulations 2024 and come into force on 1st January 2025.

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

Amendments to the Branded Health Service Medicines (Costs) Regulations 2018

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

(**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). Sections 264A and 264C were added by the 2017 Act, section 8. 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, 2023/239 and 2023/1307.

Amendments to regulation 1

3. In regulation 1 (citation, commencement and interpretation), in paragraph (2), insert the following definitions at the appropriate places—

""calendar quarter" means a period of three months beginning on—

(a) 1st January;

(b) 1st April;

(c) 1st July; or

(d) 1st October;";

""calendar year" means a period of 12 months beginning on 1st January;";

""combination medicine" is to be construed in accordance with regulation 3B(8);"

""licensing authority" has the meaning given to it in regulation 3(5H);";

""medicines information standard" means the inter-operability standard for the transfer of medicines information that is published by NHS BSA in the document known as the dictionary of medicines and devices(**a**);";

""newer presentation" is to be construed in accordance with regulation 3B;";

""older presentation" is to be construed in accordance with regulation 3B(4) and (5);";

""originator" means, in relation to an active ingredient, or in the case of a combination medicine the combination of active ingredients, of a relevant medicine for a presentation—

(a) the person who—

(i) received the first marketing authorisation for the virtual therapeutic moiety of that active ingredient or combination of active ingredients, or

(ii) is not the same as the person specified in paragraph (i) but who holds a valid supplementary protection certificate for the active ingredient or combination of active ingredients; or

(b) a person who acquires the ownership of the presentation from a person specified in sub-paragraph (a);";

""originator licensee" means a person, other than an originator, who is marketing a presentation and, during the period the presentation was a newer presentation, was—

(a) doing so under a licence from the originator permitting marketing of the relevant medicine; or

(b) in the same group as the originator for the relevant medicine;";

""vaccine originator" means, in relation to an active ingredient or a combination of active ingredients of a relevant medicine for a presentation that is a vaccine—

(a) the person who—

(i) received the first marketing authorisation of any presentation for the applicable virtual therapeutic moiety,

(**a**) The dictionary of medicines and devices may be accessed at www.nhsbsa.nhs.uk. NHS BSA does not produce a paper version of the dictionary of medicines and devices.

(ii) is not the same person specified in paragraph (i) but who holds a valid supplementary protection certificate for the active ingredient or combination of active ingredients, or

(iii) if different from the persons specified in paragraph (i) or (ii), was the first person to place the relevant medicine on the market for health service use and, at the time, the licensing authority designated the presentation to include a new active substance; or

(b) a person who acquires the ownership of the presentation from a person specified in sub-paragraph (a);";

""vaccine originator licensee" means a person, other than a vaccine originator, who is marketing a vaccine and was, during the period the presentation is a newer presentation—

(a) doing so under a licence from the vaccine originator permitting the marketing of the relevant medicine; or

(b) in the same group as the vaccine originator for the relevant medicine;";

""virtual therapeutic moiety" means the abstract representation of an active ingredient or active ingredients of a relevant medicine formulated in the medicines information standard as—

(a) a medicinal product; or

(b) in the case of a vaccine, an indication or indications;".

Amendments to regulation 3

4.—(1) Regulation 3 (payment scheme)(**a**) is amended as follows.

(2) For paragraph (1), substitute—

"(1) Subject to paragraphs (1AA), (4) and (5A), the manufacturer or supplier that is responsible for the first relevant supply of an item of presentation must pay for the applicable period specified in the first column of the table below the payment percentage specified in the—

(a) second column for each newer presentation; or

(b) third column for each older presentation,

of that table of the net sales income received in respect of that supply to the Secretary of State in accordance with Schedule 1.

Table

Applicable period	**Newer presentation payment percentage**	**Older presentation payment percentage**
1st January 2025 to the end of 2025	15.5%	10.6%
1st January 2026 to the end of 2026	17.9%	11%
1st January 2027 to the end of 2027 and any subsequent calendar year	20.1%	10.9%.".

(3) After paragraph (1A), insert—

(**a**) Regulation 3 was amended by S.I. 2018/1255, 2020/258, 2022/593 and 2023/1307.

"(1AA) Subject to paragraph (4A), in addition to any sum that may be required to be paid under paragraph (1)(b), the manufacturer or supplier that is responsible for the first relevant supply of an item of presentation that is an older presentation must pay the payment percentage calculated in accordance with regulation 3A of the net sales income received in respect of that supply to the Secretary of State in accordance with Schedule 1.".

(4) In paragraph (4), for "paragraph (1) does" substitute "paragraphs (1) and (1AA) do".

(5) After paragraph (4), insert—

"(4A) Paragraph (1AA) does not apply to the net sales income received by a manufacturer or supplier in respect of the supply of—

(a) any item of presentation that is a plasma derived medicinal product; or

(b) any item of presentation that is an older presentation where the cumulative net sales income from all older presentations with a common relevant virtual therapeutic moiety that the manufacturer or supplier supplies for health service use does not exceed £1,500,000 during a relevant calendar year.".

(6) In paragraph (5H), after the definition "licensing authority", insert—

""plasma derived medicinal product" means a presentation that includes an active ingredient from any of the following virtual therapeutic moieties—

(a) albumin human;

(b) anti-D immunoglobulin;

(c) C1- esterase inhibitor;

(d) factor VIII plus von Willebrand factor;

(e) factor X;

(f) factor XIII;

(g) fibrinogen;

(h) high purity factor IX;

(i) human alpha$_1$ -proteinase inhibitor;

(j) human prothrombin complex concentrate;

(k) normal immunoglobulin human;

(l) protein C human; or

(m) von Willebrand factor;".

Insertion of new regulation 3A

5. After regulation 3 (payment scheme), insert—

"Older presentation additional payments

3A.—(1) Subject to paragraphs (2) to (4), the manufacturer or supplier responsible for the first relevant supply of an item of presentation that is an older presentation must pay in relation to the observed price decline specified in the first column of the table below, the payment percentage specified in the corresponding entry in the second column of that table of the net sales income for that item of presentation during the relevant period.

Table 1

Observed price decline	Payment percentage
10% or less	25%
11%	24%
12%	23%
13%	22%
14%	21%
15%	20%
16%	19%
17%	18%
18%	17%
19%	16%
20%	15%
21%	14%
22%	13%
23%	12%
24%	11%
25%	10%
26%	9%
27%	8%
28%	7%
29%	6%
30%	5%
31%	4%
32%	3%
33%	2%
34%	1%
35% or more	0%

(2) Subject to paragraphs (3) and (4), the observed price decline for a relevant supply made by a manufacturer or supplier of an item of presentation that is an older presentation, where the average presentation selling price for the relevant period is lower than the reference price, is one minus the quotient of the average presentation selling price for that relevant period divided by the reference price expressed as a percentage rounded to the nearest whole number.

(3) If the average presentation selling price of an item of presentation that is an older presentation is higher than the reference price for a relevant period, the observed price

decline for that relevant period is to be 10% or less and the corresponding payment percentage in the second column of the table in paragraph (1) is to apply to the net sales income of the presentation for the relevant period.

(4) Where—

(a) there is a commercial relationship in relation to an item of presentation that is an older presentation supplied by a manufacturer or supplier who is not an originator, originator licensee, vaccine originator or vaccine originator licensee; and

(b) that commercial relationship is between that person and a manufacturer or supplier who is an originator, originator licensee, vaccine originator or vaccine originator licensee,

the payment percentage in Table 1 applicable to the relevant item of presentation supplied by the manufacturer or supplier in accordance with regulation 3(1AA) is to be no less than that which would apply to the originator, originator licensee, vaccine originator or vaccine originator licensee had they made the supply.

(5) The "relevant period" in relation to the supply of an item of presentation that is an older presentation is the calendar year in which the supply is made except if, part way through the calendar year—

(a) the presentation becomes an older presentation, in which case the relevant period is to be from the start of the next calendar quarter following the day on which the item of presentation ceased to be a newer presentation and runs to the end of that calendar year then (subject to any further application of this paragraph) each subsequent calendar year thereafter;

(b) the supply is the first relevant supply by a manufacturer or supplier who is not an originator, originator licensee, vaccine originator or vaccine originator licensee, in which case the relevant period starts on the day of the first relevant supply of the item of presentation and runs to the end of the calendar year then (subject to any further application of this paragraph) is each subsequent calendar year thereafter; or

(c) the manufacturer or supplier becomes liable to make a payment in accordance with regulation 3 for the first time, in which case the relevant period starts on the day after the manufacturer or supplier becomes liable to make a payment and runs to the end of that calendar year then (subject to any further application of this paragraph) is each subsequent calendar year thereafter.

(6) In this regulation—

"average presentation selling price" means, in relation to the supply of an item of presentation by a manufacturer or supplier during a relevant period, the quotient of the total net sales income during the relevant period divided by total quantity supplied during the relevant period (the calculation is to be based on information in the relevant presentation report, provided that the Secretary of State considers that information is accurate);

"commercial relationship" means a contractual or other business relationship, whether or not legally enforceable, regarding the manufacturing or supplying of an item of presentation including, but not limited to, licensing;

"reference price" has the meaning given to it in regulation 3C(9).".

Insertion of new regulation 3B

6. After regulation 3A (older presentation additional payments) insert—

"Meaning of newer presentation and older presentation

3B.—(1) Paragraphs (2) and (3) set out different conditions for items of presentation that are combination medicines and vaccines, but subject to those paragraphs, a newer presentation is an item of presentation supplied for health service use by a manufacturer or supplier who is an originator or originator licensee in respect of that presentation—

(a) during the period of time there is an extant supplementary protection certificate for the active ingredient of any relevant medicine with the same relevant virtual therapeutic moiety as the presentation; or

(b) where no supplementary protection certificate has been granted in respect of the active ingredient of any relevant medicine with the same relevant virtual therapeutic moiety as the presentation, during the period of 12 years beginning on the date on which the first marketing authorisation was granted for any relevant medicine supplied for health service use that contains the active ingredient with the same relevant virtual therapeutic moiety as the presentation.

(2) A presentation that is a combination medicine is a newer presentation when that item of presentation is supplied for health service use by a manufacturer or supplier who is an originator or originator licensee in respect of that presentation and—

(a) during the period of time there is at least one extant supplementary protection certificate for the same combination of active ingredients as the unique virtual therapeutic moiety for that combination medicine; or

(b) where no supplementary protection certificate has been granted in respect of the combination medicine—

(i) during the period of time there is an extant supplementary protection certificate for a relevant medicine that is supplied for health service use containing a constituent active ingredient or combination of constituent active ingredients of the combination medicine, or

(ii) where no supplementary protection certificate has been granted for a constituent active ingredient or combination of constituent active ingredients of the combination medicine, during the period of 12 years beginning on the date on which the latest presentation (P1) containing any of those constituent active ingredients was granted a marketing authorisation (that marketing authorisation being the first marketing authorisation granted for a presentation containing it or them), a relevant medicine of P1 also being the first with a marketing authorisation for the virtual therapeutic moiety of that active ingredient.

(3) A presentation that is a vaccine is a newer presentation when that item of presentation is supplied for health service use by a manufacturer or supplier who is a vaccine originator or vaccine originator licensee in respect of that presentation—

(a) during the period of time there is at least one extant supplementary protection certificate for the vaccine;

(b) if no supplementary protection certificate has been granted in respect of an active ingredient of the vaccine and—

(i) the vaccine was the first presentation for the relevant virtual therapeutic moiety to be granted a marketing authorisation, during the period of 12 years beginning on the date the first marketing authorisation is granted for the presentation, or

(ii) the licensing authority designates an active ingredient of the vaccine as a new active substance, for a period of 12 years from the date the vaccine is first placed on the market for health service use; or

(c) if it is a line extension of a presentation to which sub-paragraph (a) or (b) applies, during the period that sub-paragraph (a) or (b) applies to the relevant presentation.

(4) An older presentation is any item of presentation that is not a newer presentation.

(5) A newer presentation becomes an older presentation on the day after that presentation is no longer capable of satisfying the conditions for being a newer presentation in accordance with paragraphs (1), (2) or (3).

(6) Where a presentation is a newer presentation because paragraph (1)(a), (2)(a), (2)(b)(i) or (3)(a) applies, if the relevant supplementary protection certificate—

(a) is invalidated for any reason, paragraph (5) applies from the day following the day on which it would have ceased to satisfy the conditions for being a newer presentation in accordance with paragraphs (1), (2) or (3) otherwise than in reliance on the invalidated supplementary protection certificate;

(b) lapses as a consequence of the marketing authorisation to which that supplementary protection certificate relates being withdrawn, paragraph (5) applies for the period beginning on the day following the day on which the relevant marketing authorisation was withdrawn and ending on the day before the day on which the relevant marketing authorisation or supplementary protection certificate is reinstated (and so the presentation becomes a newer presentation); or

(c) is surrendered, paragraph (5) applies from the day following the day on which the relevant supplementary protection certificate is surrendered.

(7) The Secretary of State may, by giving an information notice, require a manufacturer or supplier to provide information to evidence that a presentation has been correctly classified as a newer presentation, older presentation or combination medicine in accordance with this regulation, including to provide any supplementary protection certificate and marketing authorisation data.

(8) For the purposes of these Regulations, a combination medicine is a relevant medicine containing two or more active ingredients—

(a) that has a unique virtual therapeutic moiety that is distinct from all other virtual therapeutic moieties of any of the constituent active ingredients of the relevant medicine; or

(b) in respect of which there is no unique virtual therapeutic moiety specified in the medicines information standard, but the Secretary of State determines, by direction, the relevant medicine is a combination medicine despite not satisfying sub-paragraph (a) for the purpose of determining payments due or other pricing matters in connection with these Regulations to a manufacturer or supplier who supplies the presentation for health service use.

(9) In this regulation—

"period of time" in relation to a supplementary protection certificate, means the period of time beginning on the day on which the supplementary protection certificate came into force and ending on the day on which the certificate lapses or is surrendered or is invalidated for any reason;

"relevant virtual therapeutic moiety" means—

(a) the virtual therapeutic moiety associated with an active ingredient, combination of active ingredients or combination medicine, as applicable, for a particular presentation; or

(b) where there is no suitable virtual therapeutic moiety in the medicines information standard for the active ingredient or combination of active ingredients for a particular presentation, the Secretary of State may, by direction, give an approximation of a virtual therapeutic moiety for the purpose of determining payments due or other pricing matters in connection with these Regulations to a manufacturer or supplier who supplies the presentation for health service use.

(10) This regulation does not apply to a small manufacturer or supplier.".

Insertion of new regulation 3C

7. After regulation 3B (meaning of newer presentation and older presentation) insert—

"Reference prices for older presentations

3C.—(1) The Secretary of State must, by direction, determine the reference price of each older presentation to the manufacturer or supplier who has supplied that item of presentation and is liable to make a payment in accordance with regulation 3(1AA).

(2) Whether or not the Secretary of State has received a request under paragraph (3)—

(a) the Secretary of State may, by direction, to the manufacturer or supplier who has supplied the item of presentation, change or alter a reference price if the Secretary of State considers it is reasonable to do so; and

(b) the changed or altered reference price is to apply, unless stated otherwise in the direction, from the date of the relevant direction.

(3) Except where a direction under paragraphs (1) or (2) has previously been given to the manufacturer or supplier, a manufacturer or supplier who may be required to make a payment under regulation 3 during a relevant period must make a request to the Secretary of State for a reference price for each older presentation—

(a) where the circumstances in regulation 9(1) apply, at the same time as they are required to make a notification under regulation 9(2); or

(b) in any other circumstance where the manufacturer or supplier does not have a direction specifying the reference price for a particular older presentation, within 30 days of the manufacturer or supplier becoming aware they may be liable to make a payment under regulation 3(1AA) in respect of the presentation.

(4) A request made under paragraph (3) must—

(a) be made in writing;

(b) specify the details of the presentation in respect of which the request is made; and

(c) include any relevant information relating to the factors set out in regulation 3D(5).

(5) Subject to paragraph (6), the Secretary of State must, by direction, within a period of 90 days following receipt of the information to be included in a request under paragraph (3) or paragraph (7), determine the reference price of the item of presentation to the relevant manufacturer or supplier.

(6) Where the number of requests received by the Secretary of State under paragraph (3) makes it impracticable for the Secretary of State to determine the reference price to a

manufacturer or supplier in accordance with paragraph (5), or insufficient information has been provided, the Secretary of State may extend that period for a further 60 days and must notify the manufacturer or supplier within the 90 day period.

(7) Within 28 days of receiving the information to be included in a request under paragraph (3), where further information is required in order to determine the reference price, the Secretary of State must give the manufacturer or supplier an information notice specifying the further information that is required.

(8) The Secretary of State may, by giving an information notice, require a manufacturer or supplier to provide information—

(a) to assist in the determination of a reference price under paragraph (1) or (2) in accordance with regulation 3D;

(b) within 28 days of receiving the information under paragraph (7) where the Secretary of State considers that further information is required to determine the reference price for a presentation; or

(c) where the Secretary of State considers that the average selling price, maximum price or other relevant pricing information of any relevant medicine has been altered or otherwise manipulated solely or mainly for the purpose of affecting the reference price that may be applied to an older presentation.

(9) In this regulation and regulation 3D—

"reference price" means the price assigned to an item of presentation in a direction given in accordance with paragraph (1), (2)(a) or (5);

"relevant period" has the meaning given to it in regulation 3A(5);

"relevant virtual therapeutic moiety" has the meaning given to it in regulation 3B(9).".

Insertion of new regulation 3D

8. After regulation 3C (reference prices for older presentations), insert—

"Determination of reference prices

3D.—(1) The Secretary of State must determine the reference price for an older presentation in accordance with this regulation.

(2) The reference price for a presentation that was an older presentation on or after 1st January 2015 and is supplied for health service use by a manufacturer or supplier who is an originator, originator licensee, vaccine originator or vaccine originator licensee or a person who is in the same group as the originator, originator licensee, vaccine originator or vaccine originator licensee in relation to that presentation, where it was first made available for health service use—

(a) before the reference anchor date, is the average selling price of the presentation during the full calendar year before the presentation became an older presentation; or

(b) on or after the reference anchor date, is the average selling price during the full year before the presentation became an older presentation of the most relevant comparator with the same virtual therapeutic moiety as the presentation that was first made available for health service use on or before the reference anchor date.

(3) The reference price for a presentation which was an older presentation before 1st January 2015 and is supplied for health service use by a manufacturer or supplier who is an originator, originator licensee, vaccine originator or vaccine originator licensee or by a

person in the same group as the originator, originator licensee, vaccine originator or vaccine originator licensee in relation to that presentation, where it was first made available for health service use—

(a) before the reference anchor date, is the maximum price of the presentation on the reference anchor date reduced by 12.5%; or

(b) on or after the reference anchor date, is to be determined based on the maximum price of the most relevant comparator for the same virtual therapeutic moiety as the presentation that had been made available for sale for health service use on or before the reference anchor date, reduced by 12.5%.

(4) The reference price for a presentation which is an older presentation and is supplied for health service use by a manufacturer or supplier who is not an originator, originator licensee, vaccine originator or vaccine originator licensee or a person in the same group as the originator, originator licensee, vaccine originator or vaccine originator licensee in relation to that presentation, where it was first made available for sale for health service use—

(a) before the reference anchor date and—

(i) there is an alternate presentation with the same virtual medicinal product pack available before the reference anchor date which was supplied for health service use by an originator, originator licensee, vaccine originator or vaccine originator licensee, is the maximum price of the alternate presentation on the date the presentation was first made available for sale for health service use, reduced by 12.5%, or

(ii) there is no alternate presentation with the same virtual medicinal product pack supplied for health service use by an originator, originator licensee, vaccine originator or vaccine originator licensee on or before the reference anchor date, is to be determined based on the most relevant comparator maximum price with the same virtual therapeutic moiety as the presentation on the date the presentation was first made available for sale for health service use, reduced by 12.5%; or

(b) on or after the reference anchor date and—

(i) there is an alternate presentation with the same virtual medicinal product pack available before the reference anchor date which was supplied for health service use by an originator, originator licensee, vaccine originator or vaccine originator licensee, is the maximum price of the alternate presentation on the reference anchor date reduced by 12.5%, or

(ii) there is no alternate presentation with the same virtual medicinal product pack supplied for health service use by an originator, originator licensee, vaccine originator or vaccine originator licensee before the reference anchor date, is to be determined based on the maximum price of the most relevant comparator with the same virtual therapeutic moiety as the presentation that had been made available for sale for health service use on or before the reference anchor date, reduced by 12.5%.

(5) When determining the reference price the Secretary of State may have regard, among other factors, to any one or more of the following—

(a) available presentations or maximum prices for presentations supplied by the manufacturer or supplier of the applicable presentation;

(b) available presentations or maximum prices for presentations supplied by a different manufacturer or supplier;

(c) the active ingredients, strength, excipients, pack size, method of administration or formulation of an applicable presentation;

(d) the virtual therapeutic moiety or the virtual medicinal product pack, as applicable, of an applicable presentation;

(e) the similarities and differences between applicable presentations to be compared; and

(f) the period an applicable presentation has been made available for health service use before or after the relevant reference anchor date.

(6) Where there is no or incomplete average selling price or maximum price information available for a relevant date or period for an applicable presentation, the Secretary of State may rely on any available information the Secretary of State considers appropriate for comparison purposes, including—

(a) the closest available data for calculating average selling prices for the applicable calendar year; and

(b) the maximum price that is the closest in date to the 1st January of the relevant calendar year as published in the medicines information standard.

(7) In this regulation—

"applicable presentation" means the presentation for which a reference price is to be applied or an alternate presentation to be relied on as a comparator, as the case may be;

"reference anchor date" means in relation to—

(a) an older presentation supplied by a manufacturer or supplier who is an originator, originator licensee, vaccine originator or vaccine originator licensee of that presentation, is the 1st January of the year before that presentation finally ceased to be a newer presentation in accordance with regulation 3B; or

(b) an older presentation supplied by a manufacturer or supplier who is not an originator, originator licensee, vaccine originator or vaccine originator licensee of that relevant medicine, is the 1st January of the year before the earliest supply of a presentation for health service use by an originator, originator licensee, vaccine originator or vaccine originator licensee with the same relevant virtual therapeutic moiety as the presentation which has finally ceased to be a newer presentation; and

"virtual medicinal product pack" means an abstract representation of a relevant medicine as formulated in the medicines information standard which has any one or more of the characteristics of active ingredients, strength, excipients, pack size, method of administration or formulation in common with similar presentations which have been placed on the market for health service use by any manufacturer or supplier.".

Amendment to regulation 4

9. In regulation 4 (direction to make a payment)(**a**), in paragraph (1), for "regulation 3" substitute "regulation 3 or 3A".

(**a**) Regulation 4 was amended by S.I. 2018/1255 and 2023/1307.

Amendments to regulation 21

10.—(1) Regulation 21 (sales report)(**a**) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (b), insert—

"(ba) the total of the net sales income received for the total supply of presentations which are newer presentations and older presentations in respect of which that manufacturer or supplier is required to make a payment in accordance with regulation 3 and any direction given under regulation 4;";

(b) after sub-paragraph (c), insert—

"(ca) the total payments for newer presentations and older presentations required to be paid by the manufacturer or supplier in accordance with regulation 3 and any direction given under regulation 4;"; and

(c) after sub-paragraph (g), insert—

"(ga) each item of new active substance presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(gb) each item which is a line extension to which regulation 3(4)(f) applies that is supplied and the total of the net sales income received in respect of the total supply of all those presentations;

(gc) each item of exceptional central procurement presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(gd) each item of centrally procured vaccine presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(ge) each item of presentation of plasma derived medicinal products supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(gf) each item of presentation to which regulation 3(4A)(b) applies that is supplied and the total of the net sales income received in respect of the total supply of all of those presentations;".

(3) After paragraph (1), insert—

"(1A) Each manufacturer or supplier must provide information in a manner that supports a best estimate calculation of any payments due under regulation 3(1AA) for the period a sales report covers and an explanation to the satisfaction of the Secretary of State of the method of calculating that best estimate with the relevant sales report.".

Amendments to regulation 22

11. In regulation 22 (presentation report)(**b**)—

(a) in paragraph (a), after "supplied" insert "and whether it is a newer presentation or an older presentation";

(**a**) Regulation 21 was amended by S.I. 2018/1255.
(**b**) Regulation 22 was amended by S.I. 2018/1255.

(b) in paragraphs (b) and (c), for "regulation 3(4)" substitute "regulation 3(4)(a), (b), (c), (d), (g) and (h)"; and

(c) after paragraph (g), insert—

"(ga) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item of new active substance presentation supplied;

(gb) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item which is a line extension to which regulation 3(4)(f) applies that is supplied;

(gc) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item of exceptional central procurement presentation supplied;

(gd) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item of centrally procured vaccine presentation supplied;

(ge) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item of presentation of plasma derived medicinal products;

(gf) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each item of presentation to which regulation 3(4A)(b) applies that is supplied;".

Amendments to regulation 23

12. In regulation 23 (audited information), after paragraph (1), insert—

"(1A) Where a manufacturer or supplier has provided information under regulation 21 or 22, the Secretary of State may, for the purposes of verifying the information provided, request the manufacturer or supplier to provide that information in an audited form.

(1B) A request made under paragraph (1A)—

(a) must be made within 12 months of receipt of the information provided in accordance with the relevant report; and

(b) must require the audited report to be provided within a period of not less than 3 months and not more than 12 months from the date on which the Secretary of State makes the request.".

Amendments to regulation 26

13. In regulation 26 (Penalties, demands and appeals), in paragraph (1), for "by a manufacturer or supplier under this Part is incomplete," substitute "or to be provided by a manufacturer or supplier under regulation 3B(7) or 3C(3) or (7) or this Part is incomplete ("incomplete" includes circumstances where no information has been provided, notwithstanding the obligation to provide it),".

Amendments to Schedule 1

14.—(1) Schedule 1 (general provisions for payment scheme) is amended as follows.

(2) In paragraph 1 (payment scheme requirement)—

(a) for "regulation 3" substitute "regulation 3(1)"; and

(b) for "paragraphs 3 to 7" substitute "paragraphs 3 to 9".

(3) After paragraph 1, insert—

"1A. Any payment required to be made under regulation 3(1AA) by a manufacturer or supplier to whom this Schedule applies must—

(a) be paid annually at the same time as the relevant presentation report is due;

(b) be paid by electronic transfer no later than the last day of the period within which the payment must be made; and

(c) be calculated, where relevant, in accordance with the rules in paragraphs 3 to 9.".

(4) In paragraph 2 (information requirements)—

(a) in sub-paragraph (b), for "paragraphs 3 to 7" substitute "paragraphs 3 to 9";

(b) in table 2, in the third row—

(i) in the first column, for "financial" substitute "calendar", and

(ii) in the third column, for "2 months" substitute "3 months" and for "financial" substitute "calendar".

(5) In paragraphs 4 and 5 (which relate to calculations of payments and provisions of reports), after "regulation 3(1) or" in each place where it occurs (six times) insert "(1AA) or".

(6) After paragraph 7, insert—

"8. A manufacturer or supplier whose financial year does not end on 31st December must, in addition to the reports required to be provided in table 1, provide two or more audited sales reports or presentation reports to cover the period of 1st January to the last day of the relevant accounting reference period and from the first day of the subsequent accounting reference period to the end of 31st December of that calendar year so that, when taken together, the separate reports cover the entire calendar year.

9. A manufacturer or supplier must provide two or more separate sales reports, audited sales reports or presentation reports for the period the applicable report covers in which a change to the payment percentages under regulation 3 or 3A occurs so that information concerning supplies of presentations made before and after that change are contained in separate reports and, when taken together, those reports cover the entire calendar quarter, financial year and, where paragraph 8 applies, the calendar year, as applicable.".

Amendments to schedule 2

15. In Schedule 2 (small manufacturer or supplier), in paragraph 3 (which relates to determinations of small manufacturers and suppliers), in Table 1 and Table 2, for "£5 million", in each place where it occurs (six times), substitute "£6 million".

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

Karin Smyth
Minister of State
3rd December 2024 Department of Health and Social Care

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 amendments update the payment percentages and introduce a new approach for calculating the amount of the net sales income manufacturers and suppliers subject to the Statutory Scheme Regulations will pay to the Secretary of State based on whether the supplies of the presentations are of newer presentations or older presentations.

Regulation 3 makes provision to amend regulation 1(2) of the Statutory Scheme Regulations to introduce new defined terms relevant to the amendments made by these Regulations.

Regulation 4(2) makes provision to replace the payment percentages in regulation 3(1) of the Statutory Scheme Regulations with new payment percentages for net sales income of newer presentations and older presentations payable by manufacturers and suppliers subject to the Statutory Scheme Regulations from the 1st January 2025.

Regulation 4(3) inserts a new regulation 3(1AA) in the Statutory Scheme Regulations which makes provision for additional amounts to be payable on the net sales income of manufacturers and suppliers who supply older presentations.

Regulation 4(4) amend regulation 3(4) and regulation 4(5) inserts a new regulation 3(4A) into the Statutory Scheme Regulations to make provision that exempts supplies of certain presentations from the requirement to make payments under regulation 3(1) or the additional payment under new regulation 3(1AA).

Regulations 5 to 9 insert new regulations 3A to 3D in the Statutory Scheme Regulations which make provision for calculating the additional payments on older presentations, determining which are newer presentations and older presentations and for the Secretary of State to determine and issue reference prices for older presentations that are relevant to calculating the additional payments due under new regulation 3(1AA).

Regulation 9 makes consequential amendments to regulation 4 of the Statutory Scheme Regulations.

Regulations 10, 11 and 12 make amendments to the Statutory Scheme Regulations requiring manufacturers and suppliers to collect, audit and provide to the Secretary of State certain information concerning the supply of branded health service medicines in sales reports and presentation reports.

Regulation 13 amends regulation 26 of the Statutory Scheme Regulations to make provision to allow the Secretary of State to impose sanctions on a manufacturer or supplier who fails to comply with the requirements to provide relevant information.

Regulation 14 amends Schedule 1 of the Statutory Scheme Regulations to make provision for manufacturers and suppliers to make the additional payments required by new regulation 3(1AA) and associated reporting obligations.

Regulation 15 amends Schedule 2 to increase the threshold for qualification as a small manufacturer or supplier under the Statutory Scheme Regulations from £5 million to £6 million.

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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