STATUTORY INSTRUMENTS

2018 No. 345

The Branded Health Service Medicines (Costs) Regulations 2018

PART 2

MAXIMUM PRICES

Maximum price

8.—(1) Subject to paragraphs (2) and (4), the maximum price which may be charged by a manufacturer or supplier for the supply of each item of a presentation is the maximum price set out in the most recent direction given under paragraph (3) or regulation 9(5), (7), 10(1), 11(2), 12(2) or 13(1) in respect of that presentation.

(2) Where, in respect of a presentation, there is no direction as referred to in paragraph (1), the maximum price which may be charged by a manufacturer or supplier for the supply of each item of a presentation is—

(a) where a presentation was on sale for health service use before 1st December 2013—

(i) the price, as determined by the Secretary of State, at which an item of that presentation was on sale for health service use without regard to any discount or variation of that price which did not have general application on that date, or

(ii) where the Secretary of State specified an increase in the price of an item of presentation in accordance with regulation 6 of the 2008 Regulations, the specified increased price;

(b) where the presentation was first made available for sale for health service use on or after 1st December 2013—

(i) the price, as specified by the Secretary of State in accordance with regulation 3 of the 2008 Regulations, or

(ii) where the Secretary of State specified an increase in the price of an item of presentation in accordance with regulation 6 of the 2008 Regulations, the specified increased price.

(3) Where the price of a presentation first made available for sale for health service use on or after 1stDecember 2013 was not specified by the Secretary of State as set out in paragraph (2)(b)(i), the Secretary of State may specify the maximum price which may be charged by a manufacturer or supplier for the supply of each item of that presentation by direction to a specific manufacturer or supplier.

(4) Subject to paragraph (5), with respect to the supply of any item of presentation supplied under a contract with a contracting authority based on a framework agreement or supplied under a public contract—

(a) paragraph (1) does not apply where the framework agreement or public contract was entered into before the date that the direction under paragraph (3) or regulation 9(5), (7),

10(1), 11(2), 12(2) or 13(1) was given, or was entered into following a tender which closed on or before that date;

(b) paragraph (2) does not apply where the framework agreement or public contract was entered into before the date of the coming into force of these Regulations or was entered into following a tender which closed on or before that date.

(5) Paragraph (4) does not apply to any item of presentation added to a framework agreement or public contract after the date referred to in each corresponding sub-paragraph of paragraph (4).

New presentation

9.—(1) A manufacturer or supplier intending to place on the market a new presentation must record and keep for a period of 6 years information required under this regulation.

(2) At least 60 days prior to the proposed date on which a manufacturer or supplier is intending to place on the market a new presentation, the manufacturer or supplier must notify the Secretary of State of its intention to do so.

(3) A notification under paragraph (2) by a manufacturer or supplier to the Secretary of State must be made in writing and must—

(a) specify the presentation in respect of which the notification is made;

(b) include the summary of product characteristics;

(c) specify the proposed date for placing on the market the new presentation;

(d) specify the proposed maximum price; and

(e) include any relevant information relating to the factors set out under paragraphs (8)(a) to (g).

(4) Within 28 days of receiving a notification in accordance with paragraph (3), the Secretary of State must give the manufacturer or supplier an information notice specifying the information required in relation to any of the relevant factors set out under paragraphs (8)(h) and (i).

(5) Unless further information relating to the factors listed at paragraph (8) is requested, the Secretary of State must specify the maximum price at which that new presentation may be supplied by direction to the manufacturer or supplier within a period of 28 days of receiving the information under paragraph (4).

(6) Where further information relating to the factors listed at paragraph (8) is required, the Secretary of State must within 28 days of receiving the information under paragraph (4), notify and where appropriate, by giving an information notice, the manufacturer or supplier that further information is required, and inform the manufacturer or supplier of the maximum price within 28 days of receiving that further information.

(7) Where a manufacturer or supplier fails to notify the Secretary of State of its intention to place the presentation on the market within the 60 day period referred to in paragraph (2) or provide the Secretary of State with the information that the Secretary of State requires to determine the maximum price, the Secretary of State may, by direction, specify the maximum price of that presentation.

(8) The maximum price for an item of a new presentation to which this regulation applies may be determined by the Secretary of State, having regard to, among other factors, the following factors—

(a) the clinical need for the new presentation at the time that the notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(b) the price and associated operational costs of therapeutically equivalent or comparable medicines to that new presentation at the time that the notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(c) the price and associated operational costs of the new presentation in the European Economic Area and any other markets if it is available elsewhere in the world at the time that notification under paragraph (2) is made and during the period that the notification is being considered by the Secretary of State;

(d) whether the presentation contains a new active substance;

(e) the date on which the patent protection period for each indication of the new presentation expires;

(f) the total profit of the manufacturer or supplier before interest charges and taxes for their previous accounting reference period as set out in the manufacturer's or supplier's individual accounts;

(g) the estimated total quantity to be supplied and estimated total net sales income of the new presentation over the period of the first five financial years of the manufacturer's or supplier's sales of the new presentation, or where the patent protection period expires before the end of the first five financial years, the period until the date of the expiration of the patent protection period;

(h) the reasonableness of the estimated costs of the presentation over the period of the first five financial years of the manufacturer's or supplier's sales of the new presentation, or where the patent protection period expires before the end of the first five financial years, the period until the date of the expiration of the patent protection period, including—

(i) manufacturing and supply costs,

(ii) research and development costs,

(iii) operational costs, and

(iv) any other costs;

(i) the price at which the manufacturer's or supplier's reasonable costs for that presentation, as determined by the Secretary of State would be met.

(9) For the purposes of this regulation, where there is more than one patent protection period, the patent protection period which expires on the latest date will apply.

(10) For the purposes of paragraph (8)(d) a presentation will only be considered to contain a "new active substance", where—

(a) the European Public Assessment Report published by the European Medicines Agency [M1] 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 confirms that the presentation contains a new active substance; or

(b) the Assessment Report published by the licensing authority in relation to the presentation in accordance with Article 21 **[**[F1]or regulation 64(6) of the 2012 Regulations**]** of the Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use [M2] confirms that the presentation contains a new active substance.

(11) In these Regulations "new presentation" means a presentation which at the time the notification under paragraph (3) must be made, is not subject to a maximum price under regulation 8(2) or under a direction made under regulation 8(3), 10(1), 11(2), 12(2), or 13(1).

(12) In this regulation—

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

"summary of product characteristics" is to be construed in accordance with regulation 8(1) of the 2012 Regulations.

Textual Amendments

F1 Words in reg. 9(10)(b) inserted (31.12.2020) by S.I. 2019/775, **Sch. 8 para. 16(4)(a)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(iv)**); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M1 As established under Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 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 (OJ No L 136, 30.04.2004, p 1).

M2 OJ No L 311, 28.11.2001, p.67; article 21 was amended by Directive 2011/62/EU of the European Parliament and of the Council of 15 December 2010 (OJ No. L 348 31.12.2010, p 74).

Temporary exemptions

10.—(1) The Secretary of State may by direction, exempt for such temporary period as the Secretary of State may determine a presentation from the effect of regulation 8(1) or (2) where the Secretary of State considers that a temporary exemption is necessary to ensure adequate supplies of that presentation for health service purposes.

(2) The Secretary of State must specify in any direction given under paragraph (1)—

(a) the new temporary maximum price at which an item of presentation may be supplied for health service use; and

(b) the period during which the new temporary maximum price will apply.

(3) The power to issue a direction under paragraph (1) may be exercised on application by a manufacturer or supplier of a presentation or on the Secretary of State's own motion.

Increases

11.—(1) A manufacturer or supplier intending to make an application for a price increase under this regulation must record and keep for a period of six years the information required for such an application under this regulation.

(2) Subject to paragraph (3), the Secretary of State must within a period of 90 days, following an application made under paragraphs (4) to (6), confirm or increase the maximum price of a presentation by direction to that manufacturer or supplier.

(3) Where the number of applications received by the Secretary of State under this regulation makes it impracticable for the Secretary of State to confirm or increase the maximum price, the Secretary of State may extend that period for a further 60 days and must notify the manufacturer or supplier if this is the case within the 90 day period.

(4) A request by a manufacturer or supplier to the Secretary of State for an increase of the maximum price of a presentation must be made in writing and must—

(a) specify the presentation in respect of which the request is made;

(b) state the reasons for the request;

(c) specify the proposed increased maximum price; and

(d) include any relevant information relating to the factors set out under paragraphs (8)(a) to (e), (f)(i), (f)(ii), (g)(i), (g)(ii) and (h).

(5) Within 28 days of receiving the information set out at paragraph (4), the Secretary of State must give the manufacturer or supplier an information notice specifying the information required in relation to any of the relevant factors set out under paragraph (8)(f)(iii), (f)(iv), (g)(iii) and (g)(iv).

(6) Where further information relating to factors listed at paragraph (7) is required, the Secretary of State must within 28 days of receiving the information under paragraph (5) notify, and where appropriate, by giving an information notice, the manufacturer or supplier that further information is required.

(7) In determining whether to increase the maximum price for a presentation under this regulation, the Secretary of State may have regard to, amongst other factors, the following factors—

(a) the clinical need for the presentation at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(b) the price and associated operational costs of therapeutically equivalent or comparable medicines to that presentation at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(c) the price and associated operational costs of the presentation in the European Economic Area and any other markets if it is available elsewhere in the world at the time that the application under paragraph (4) is received by the Secretary of State and during the period that the application is being considered by the Secretary of State;

(d) the date on which the patent protection period for each indication of the presentation expires;

(e) the total profit of the manufacturer or supplier before interest charges and taxes for their previous accounting reference period as set out in the manufacturer's or supplier's individual accounts;

(f) in respect of the presentation—

(i) for the latest complete financial year, or where the application is made by a new manufacturer or supplier, up to the latest complete month in the current financial year, the total quantity of items supplied and the total net sales income,

(ii) for the three financial years which follow the most recent one referred to in sub-paragraph (f)(i), estimates of the total quantity to be supplied and the total net sales income,

(iii) the reasonableness of the estimated costs for the latest complete financial year, or where the application is made by a new manufacturer or supplier, the reasonableness of the estimated costs up to the latest complete month in the current financial year, including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs,

(iv) the reasonableness of the estimated costs over the period of the first three financial years which follow the most recent one referred to in sub-paragraph (f)(iii), or where the patent protection period expires before the end of the three financial years, the period until the date of the expiration of the patent protection period from the first financial year following the most recent one referred to in subparagraph (f)(iii), including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs;

(g) in respect of all of the manufacturer's or supplier's presentations—

(i) for the latest complete financial year, or where the application is made by a new manufacturer or supplier, until the end of the latest complete month in the current financial year, the total quantity of items supplied and the total net sales income,

(ii) for the first three financial years which follow the most recent one referred to in sub-paragraph (g)(i), estimates of the total quantity of items to be supplied and the total net sales income,

(iii) the reasonableness of the estimated costs for the latest complete financial year, or where the application is made by a new manufacturer or supplier, the reasonableness of the estimated costs up to the latest complete month in the current financial year, including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs,

(iv) the reasonableness of the estimated costs over the period of the first three financial years which follow the most recent one referred to in sub-paragraph (g)(iii), or where the patent protection period of the presentation with respect to the presentation that the application is made under this regulation expires before the end of the three financial years, the period until the date of the expiration of the patent protection period from the first financial year following the most recent one referred to in paragraph (g)(iii), including—

(aa) manufacturing and supply costs,

(bb) research and development costs,

(cc) operational costs, and

(dd) any other costs;

(h) the price at which the manufacturer's or supplier's reasonable costs for the presentation, as determined by the Secretary of State would be met;

(i) the estimated total net sales income after deduction of reasonable costs as determined by the Secretary of State over the most recent complete financial year, or where the application is made by a new manufacturer or supplier, until the end of the latest complete month in the current financial year, and the following three financial years—

(i) if the presentation was supplied at its current maximum price, and

(ii) if the presentation was supplied at the proposed increase in maximum price.

(8) For the purposes of this regulation, where there is more than one patent protection period with respect to the presentation that the application under this regulation is made, the patent protection period which expires on the latest date will apply.

Decreases

12.—(1) A manufacturer or supplier intending to make an application for a price decrease under paragraph (4) must record and keep for a period of six years the information required for such an application under this regulation.

(2) Subject to paragraph (3), the Secretary of State must within a period of 28 days, on receipt of all of the information required as part of an application made by a manufacturer or supplier in accordance with paragraph (4), confirm or decrease the maximum price of a presentation by direction to that manufacturer or supplier.

(3) Where the number of applications received by the Secretary of State under this regulation makes it impracticable for the Secretary of State to reply to all or any of the applications within the 28 day period, the Secretary of State may extend that period for a further 28 days and must notify the manufacturer or supplier if this is the case within the 28 day period.

(4) A request by a manufacturer or supplier to the Secretary of State for a reduction of the maximum price of an item of presentation must be made in writing and must—

(a) specify the presentation in respect of which the request is made;

(b) state the reasons for the request; and

(c) specify the proposed reduced maximum price.

Former voluntary scheme members

13.—(1) Where these Regulations apply to a manufacturer or supplier after they have left a voluntary scheme the maximum price which may be charged for an item of presentation by a manufacturer or supplier will be the price as determined by the Secretary of State by direction.

(2) When making a direction under paragraph (1) the Secretary of State may take into account the following factors—

(a) any permanent reductions of price under the relevant voluntary scheme;

(b) any permanent increases of price under that scheme; and

(c) any other relevant factors.

Recoverable sum

14.—(1) Paragraph (2) applies where a manufacturer or supplier supplies an item of presentation at a price in excess of the maximum price permitted by regulation 8.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a recoverable sum, calculated in accordance with Schedule 4, until the maximum price that the manufacturer or supplier charges for an item of the presentation is the maximum price permitted by regulation 8.

Interest payable on late payment of the recoverable sum

15.—(1) Paragraph (2) applies where any amount of the recoverable sum notified to the manufacturer or supplier under regulation 17 is not paid in accordance with that notice and so is overdue.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State interest, calculated in accordance with paragraph (3) read with regulation 1(4) and 17(5), on the amount of the recoverable sum which is overdue until that sum is paid.

(3) The interest payable under paragraph (2) shall be simple interest calculated from day to day at a rate of 2.5 per cent per annum over the Bank of England base rate as it may be from time to time applied to any amount outstanding on that day.

(4) For the purpose of this regulation the "Bank of England base rate" means—

(a) the rate announced from time to time by the Monetary Policy Committee of the Bank of England as the official dealing rate, being the rate at which the Bank is willing to enter into transactions for providing short term liquidity in the money markets; or

(b) where an order under section 19 of the Bank of England Act 1998 (reserve powers) is in force, any equivalent rate determined by the Treasury under that section.

Penalties

16.—(1) Paragraph (2) applies where a manufacturer or supplier supplies an item of presentation at a price in excess of the maximum price permitted by regulation 8.

(2) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a penalty, calculated on a daily basis in accordance with Schedule 5 read with regulation 17(5) and (6), until the maximum price that the manufacturer or supplier charges for an item of that presentation is the maximum price permitted by regulation 8.

(3) Paragraph (4) applies where a manufacturer or supplier contravenes regulation 9(2).

(4) Where this paragraph applies, the manufacturer or supplier is liable to pay to the Secretary of State a single penalty not exceeding £100,000.

(5) The level of penalty referred to in paragraph (4) is to be determined by the Secretary of State, having regard to, among other factors, the following factors—

(a) whether the manufacturer or supplier has previously contravened regulation 8;

(b) the total net sales income of the manufacturer or supplier;

(c) the estimated quantity of supply of the presentation; and

(d) the difference between the gross sales income that the manufacturer or supplier received for the supply of the presentation prior to the determination of the maximum price by the Secretary of State and the maximum price as determined by the Secretary of State.

Demands and appeals

17.—(1) Where a manufacturer or supplier is liable to pay a recoverable sum under regulation 14(2) the Secretary of State may make a demand for payment from the manufacturer or supplier.

(2) A demand made under paragraph (1) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) the amount of the recoverable sum calculated up to date on which the demand is made;

(b) the date before the end of which the recoverable sum must be paid;

(c) the daily rate at which the interest, calculated in accordance with regulation 15(2) and payable once the recoverable sum is overdue, is to accrue for as long as the recoverable sum continues to be overdue; and

(d) the manufacturer's or supplier's appeal rights.

(3) Where a manufacturer or supplier is liable to pay a penalty under regulation 16(2) or (4), the Secretary of State may make a demand for payment of the penalty from the manufacturer or supplier.

(4) A demand made under paragraph (2) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) either or both of the following—

(i) the amount of penalty calculated in accordance with regulation 16(2) up to the date on which the demand is made,

(ii) the amount of penalty determined by the Secretary of State in accordance with regulation 16(5);

(b) the date before which the amounts referred to in sub-paragraphs (a) or (b) must be paid;

(c) with respect to a penalty calculated in accordance with regulation 16(2) the daily rate at which the penalty continues to accrue until the maximum price that that manufacturer or supplier charges for an item of the presentation is the maximum price permitted by regulation 8;

(d) the manufacturer's or supplier's appeal rights.

(5) If a manufacturer or supplier sends a notice of an appeal to the Tribunal in accordance with regulation 4 of the Health Service Medicines (Price Control Appeal) Regulations 2000, in respect of a demand issued by way of a notice under paragraph (2) or (4), the period beginning on the date that the notice is received by the Tribunal to the date on which the appeal is finally determined or is withdrawn is discounted for the purposes of the calculation of the number of days in respect of which—

(a) the recoverable sum is overdue; or

(b) the manufacturer or supplier supplies an item of presentation in excess of the maximum price permitted by regulation 8.

(6) For the purposes of calculating the amount of penalty by reference to a number of days, the day on which the manufacturer or supplier charges the maximum price permitted by regulation 8 for that presentation does not count towards the calculation of that number of days.

Changes to legislation:
There are currently no known outstanding effects for the The Branded Health Service Medicines (Costs) Regulations 2018, PART 2.