STATUTORY INSTRUMENTS

2018 No. 345

The Branded Health Service Medicines (Costs) Regulations 2018

PART 3

INFORMATION REQUIREMENTS

Provision of information for payment scheme

18.—(1) A manufacturer or supplier required to make payments under regulation 3 or under a direction given under regulation 4(2)(b), must record and keep for a period of six years the information required under Schedule 1 and provide that information to the Secretary of State in accordance with Schedule 1.

(2) This regulation does not apply to a small manufacturer or supplier or a new manufacturer or supplier.

New manufacturer or supplier

19.—(1) A new manufacturer or supplier required to make payments under regulation 3 or under a direction given under regulation 4(2)(b) must record and keep for a period of six years the information required under Schedule 3 and provide that information to the Secretary of State in accordance with Schedule 3.

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

Small manufacturer or supplier

20.—(1) A small manufacturer or supplier must record and keep the information required under Schedule 2 and provide that information to the Secretary of State in accordance with Schedule 2.

(2) Where a manufacturer or supplier has provided information in accordance with paragraphs 4 or 5 of Schedule 2, 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.

(3) A request under paragraph (2)—

(a) must be made within 12 months of receipt of the information provided in accordance with paragraphs 4 or 5 of Schedule 2;

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

(c) must not require the audited sales report to be provided before the completion of the first 9 months following the last day of the manufacturer's or supplier's financial year.

Sales report

21.—(1) Where a manufacturer or supplier is required to provide the Secretary of State with a "sales report" by these Regulations, the sales report must be provided via the relevant NHS BSA online gateway and must set out—

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

(b) the total of the net sales income received for the total supply of all presentations in respect of which that manufacturer or supplier is required to make a payment under regulation 3 and any direction given under regulation 4;

(c) the total payments required from the manufacturer or supplier in accordance with regulation 3 and any direction given under regulation 4;

(d) with respect to a contract with a contracting authority based on a framework agreement under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(i), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;

(e) with respect to a public contract under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(ii), details of the public contract and the item of presentation so supplied;

(f) the total of the net sales income received in respect of the total supply of all of the items of presentations in sub-paragraphs (d) and (e);

(g) the items of low cost presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(h) the items of parallel distribution presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(i) the items of voluntary scheme presentation supplied and the total of the net sales income received in respect of the total supply of all of those presentations;

(j) information which verifies that the items of presentation in sub-paragraph (i) are items of voluntary scheme presentation;

(k) the products other than medicinal products supplied and the total of the net sales income received in respect of the total supply of all of those products;

(l) the Non United Kingdom medicinal products supplied and the total of the net sales income received in respect of the total supply of all of those products;

(m) except the medicinal products listed at sub-paragraphs (o) and (p), the medicinal products supplied for purposes other than for health service use and the total of the net sales income received in respect of the total supply of all of those medicinal products;

(n) the unbranded generic health service medicines supplied and the total of the net sales income received in respect of the total supply of all of those unbranded generic health service medicines;

(o) the medicinal products subject to general sale supplied and the total of the net sales income received in respect of the total supply of all of those medicinal products; and

(p) the pharmacy medicines supplied and the total of the net sales income received in respect of the total supply of all of those pharmacy medicines.

(2) Paragraph (3) applies where it is not possible to distinguish, in information relating to net sales income, between—

(a) medicinal products that are or were for health service use and medicinal products that are not or were not for health service use;

(b) medicinal products that are or were for use outside the United Kingdom and medicinal products that are not or were not for use outside of the United Kingdom.

(3) Where this paragraph applies, a manufacturer or supplier must provide information on the basis of a best estimate of the net sales income for medicinal products that are or were likely to be for health service use, or that are or were for use outside of the United Kingdom, as the case may be, but only if, when it provides the information to the Secretary of State, the producer explains to the satisfaction of the Secretary of State—

(a) the method of calculating the best estimate; and

(b) why the information could only be provided on the basis of a best estimate of the net sales income for medicinal products that are likely to be for health service use or that are likely to be for use outside of the United Kingdom, as the case may be.

(4) In this regulation—

"medicinal products subject to general sale" is to be construed in accordance with regulation 5 of the 2012 Regulations;

"Non United Kingdom medicinal products" means a medicinal product—

(a) which is a branded medicine;

(b) which is a prescription only medicine; and

(c) which is for use outside of the United Kingdom; and

"pharmacy medicines" is to be construed in accordance with regulation 5 of the 2012 Regulations.

Presentation report

22. Where a manufacturer or supplier is required to provide the Secretary of State with a "presentation report" by these Regulations, the presentation report must be provided via the relevant NHS BSA online gateway and, with respect to each presentation, separately set out—

(a) the name of each presentation supplied;

(b) except in relation to the supply of items of presentation specified in regulation 3(4), the quantity of each presentation supplied to—

(i) wholesalers,

(ii) primary medical services providers,

(iii) NHS chemists,

(iv) relevant UK hospitals, and

(v) any other persons or bodies;

(c) except in relation to the supply of items of presentations specified in regulation 3(4), the total gross sales income and total net sales income received for the supply of each presentation to each of the categories listed in paragraph (b);

(d) with respect to a contract with a contracting authority based on a framework agreement under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(i), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;

(e) with respect to a public contract under which the item of presentation supplied is excluded from the calculation of net sales income in accordance with regulation 3(4)(a)(ii), details of the public contract and the item of presentation so supplied;

(f) the quantity supplied and the total gross sales income and total net sales income received for 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 before the date of coming into force of these Regulations or was entered into following a tender which closed on or before the date of coming into force of these Regulations, and

(ii) each presentation which was supplied under a public contract 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 the date of the coming into force of these Regulations;

(g) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each low cost presentation;

(h) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each parallel distributed presentation;

(i) the quantity supplied and the total gross sales income and the total net sales income received for the supply of each voluntary scheme presentation; and

(j) for the purposes of paragraph (i), information which verifies that the relevant presentation is a voluntary scheme presentation.

Audited information

23.—(1) Any information required to be audited by these Regulations, including an audited sales report, must be prepared and approved by the manufacturer or supplier and audited by a qualified independent auditor and must be accompanied by—

(a) a statement from the qualified independent auditor that the audited sales report or audited information has been audited in accordance with applicable auditing standards;

(b) details of the specific applicable auditing standards relied on by the qualified independent auditor;

(c) a report by the qualified independent auditor and signed by the qualified independent auditor which provides a reasonable assurance (as provided for in the applicable auditing standards) that the information in the audited sales report or audited information has not been materially misstated; and

(d) the final audit plan prepared in accordance with the applicable auditing standards.

(2) In this regulation—

"applicable auditing standards" means any relevant International Standard on Auditing and related Statements or Standards produced by the Financial Reporting Council Limited(**1**); and

"qualified independent auditor" means the auditor of the manufacturer's or supplier's statutory audited accounts, or with the agreement of the Secretary of State, another suitably qualified auditor.

Written declaration of approval

24.—(1) Where a manufacturer or supplier is required to provide any information by these Regulations the information must be accompanied by a written declaration of approval from—

(**1**) Registered Number 02486368. Copies of the relevant statements and standards can be obtained from the Financial Reporting Council Limited, 8th Floor, 125 London Wall, London, EC2Y 5AS or at https://www.frc.org.uk/auditors/audit-assurance/standards-and-guidance.

(a) the director of the manufacturer or supplier; or

(b) in the case of a small manufacturer or supplier, a designated senior official.

(2) For the purposes of paragraph (1)(b) a designated senior official cannot provide a written declaration of approval unless the director or the board of the manufacturer or supplier has provided written authority specifying that the designated senior official has authority to approve the information required by these Regulations.

(3) For the purposes of paragraph (1) a director or senior official of a manufacturer or supplier must not approve information unless they are satisfied that the information gives a true and fair account of the information required and must include a statement to that effect in the written declaration of approval.

Review

25.—(1) If on a review of any information provided to the Secretary of State under these Regulations the Secretary of State considers that a manufacturer or supplier has paid an amount different to the amount required by regulation 3 or by a direction given under regulation 4, the Secretary of State may—

(a) by way of issuing a notice to the manufacturer or supplier require that person to pay an additional amount; or

(b) pay an amount to the manufacturer or supplier.

(2) The Secretary of State is to determine the amount referred to in paragraph (1) by determining the difference between the amount the manufacturer or supplier should have paid had the payment been made in accordance with regulation 3 or a direction given under regulation 4 and the amount actually received by the Secretary of State.

(3) In determining the amount under paragraph (1) the Secretary of State may take into account any information on medicinal products, whether or not the Secretary of State obtained that information under these Regulations.

(4) A notice made under paragraph (1)(a) must be in writing and must specify—

(a) the period to which the amount to be paid relates;

(b) the amount to be paid referred to in paragraph (1);

(c) the period, which must not be less than 28 days from the date that the notice is issued by the Secretary of State, within which the payment must be made; and

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

(5) Where the Secretary of State considers that the information provided by a manufacturer or supplier under these Regulations does not reflect the information that is required to be kept and recorded by these Regulations, the Secretary of State may require that the manufacturer or supplier record and keep for a period of six years what the Secretary of State considers to be the correct information and provide that information or part of that information to the Secretary of State on request.

(6) In this regulation, "review of any information provided to the Secretary of State" includes review of estimated or audited information.

Penalties, demands and appeals

26.—(1) If the Secretary of State considers that the information provided by a manufacturer or supplier under this Part is incomplete, he may write to the manufacturer or supplier, and where appropriate by giving an information notice, to request complete information from the manufacturer or supplier be provided within a period of 30 days.

(2) In making a determination under paragraph (1), the Secretary of State may take into account any information on medicinal products, whether or not the Secretary of State obtained the information under these Regulations.

(3) Paragraph (4) applies where a manufacturer or supplier contravenes regulation 18, 19, 20, 21, 22, 23, 24 or 25 or paragraph (1) of this regulation.

(4) 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 paragraph (8) and (9), until the manufacturer or supplier complies with the relevant regulation (except to the extent that it is no longer possible to meet a deadline because the deadline has passed).

(5) Where a manufacturer or supplier is liable to pay a penalty, the Secretary of State may make a demand for payment from the manufacturer or supplier.

(6) A demand made under paragraph (5) must be made by way of issuing a written notice to that manufacturer or supplier and must state—

(a) the amount of the penalty calculated in accordance with paragraph (4) up to the date on which the demand is made;

(b) the date before which the penalty must be paid;

(c) the daily rate at which the penalty continues to accrue until the manufacturer or supplier complies with the relevant regulation (except to the extent that it is no longer possible to meet the deadline because the deadline has passed); and

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

(7) Where a manufacturer or supplier is liable to pay a penalty under regulation 6 and liable to pay a penalty under this regulation for failing to provide a sales report in respect of the same period in accordance with Schedule 1 or 3, as the case may be, the Secretary of State may make a demand for the payment of a penalty under regulation 7(3) or under paragraph (5) but not under both.

(8) 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(**2**), in respect of a demand made under paragraph (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 the manufacturer or supplier contravenes regulation 18, 19, 20, 21, 22, 23, 24 or 25 or paragraph (1) of this regulation, as the case may be.

(9) For the purposes of calculating the amount of penalty by reference to a number of days, the day on which the manufacturer or supplier starts to comply with the relevant regulation, does not count towards the calculation of that number of days.

(**2**) S.I. 2000/124 amended by S.I. 2000/870 and 2007/1898.