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STATUTORY INSTRUMENTS

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**2018 No. 345**

**The Branded Health Service  
Medicines (Costs) Regulations 2018**

**PART 3**

**INFORMATION REQUIREMENTS**

**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);
- [<sup>F1</sup>(fa) with respect to the net sales income received in respect of the supply of an item of presentation under a contract with a contracting authority based on a framework agreement to which a payment percentage is determined in accordance with regulation 3(5A), details of the contract with the contracting authority, the framework agreement on which that contract is based and the item of presentation so supplied;
- (fb) with respect to the net sales income received in respect of the supply of an item of presentation under a public contract to which a payment percentage is determined in accordance with regulation 3(5A), details of the public contract and item of presentation so supplied;
- (fc) the total of the net sales income received in respect of the total supply of all of the items of presentations referred to in sub-paragraphs (fa) and (fb);]
- (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;

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*Changes to legislation: There are currently no known outstanding effects for the The Branded Health Service Medicines (Costs) Regulations 2018, Section 21. (See end of Document for details)*

- (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) [<sup>F2</sup>to the extent not already required by paragraph (b),] 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.

**Textual Amendments**

- F1** Reg. 21(1)(fa)-(fc) inserted (1.1.2019) by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 (S.I. 2018/1255), regs. 1, **2(5)(a)**
- F2** Words in reg. 21(1)(n) inserted (1.1.2019) by The Branded Health Service Medicines (Costs) (Amendment) Regulations 2018 (S.I. 2018/1255), regs. 1, **2(5)(b)**

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