

## SCHEDULE 2

Regulations 24, 31 and 32

### Small producers

#### General

1. This Schedule sets out the rules for determining whether a UK producer is a small producer for the purposes of regulation 24, 31 or 32.

#### Interpretation of Schedule 2

2.—(1) In this Schedule—

“net NHS sales income”, in relation to a producer, means the producer’s total income (in pounds sterling) from the supply of UK health service products—

- (a) excluding value added taxes, and
- (b) after the deduction of—
  - (i) all discounts and payments, and
  - (ii) the value of all payments or benefits in kind, given in connection with the supply of those products;

“pharmaceutical services remuneration”—

- (a) in relation to a Health Service chemist who is an English NHS chemist, means remuneration for the provision of pharmaceutical or local pharmaceutical services under Part 7 of the 2006 Act;
- (b) in relation to a Health Service chemist who is a Welsh NHS chemist, means remuneration for the provision of pharmaceutical services under Part 7 of the 2006 Wales Act;
- (c) in relation to a Health Service chemist who is a Scottish NHS chemist, means remuneration for the provision of pharmaceutical care services under section 2CA(1) of the 1978 Act;
- (d) in relation to a Health Service chemist who a Northern Ireland HS chemist, means remuneration for the provision of pharmaceutical services under Part 2 or 6 of the 1972 Order;

“qualifying Health service chemist” means a Health Service chemist who, in the relevant financial year, is paid pharmaceutical services remuneration of £5 million or less;

“qualifying NHS hospital purchaser” means a NHS hospital purchaser who, in the relevant financial year, has net NHS expenditure of £5 million or less.

(2) For the purposes of this Schedule, “the relevant financial year”—

- (a) in relation to a UK producer who receives a request under regulation 23, means the producer’s last complete financial year ending before the day on which the producer is given the request;
- (b) in relation to a UK producer who—
  - (i) is given a compliance notice relating to an original request given under regulation 23, or
  - (ii) is liable to pay a penalty under regulation 32(4) for failing to comply with such a notice,

means the producer’s last complete financial year ending before the day on which the producer was given the original request under regulation 23;

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- (c) in relation to a UK producer who is liable to pay a penalty under regulation 32(4)—
  - (i) for failing to comply with regulation 25(4), or
  - (ii) in connection with a compliance notice other than one mentioned in paragraph (b)(i), means the last complete financial year ending before the day on which the producer becomes liable to pay the penalty.

**UK primary medical providers who are small producers**

- 3. A UK producer who is a UK primary medical services provider is a small producer if—
  - (a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or
  - (b) the producer—
    - (i) is a medicines wholesaler or a medical supplies wholesaler, but
    - (ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

**Health Service chemists who are small producers**

- 4. A UK producer who is a qualifying Health Service chemist is a small producer if—
  - (a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or
  - (b) the producer—
    - (i) is a medicines wholesaler or a medical supplies wholesaler, but
    - (ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

**NHS hospital purchasers who are small producers**

- 5. A UK producer who is a qualifying NHS hospital purchaser is a small producer if—
  - (a) the producer is not also a medicines wholesaler or a medical supplies wholesaler, or
  - (b) the producer—
    - (i) is a medicines wholesaler or a medical supplies wholesaler, but
    - (ii) in the relevant financial year, has net NHS wholesale income of £5 million or less.

**Other UK producers who are small producers**

- 6.—(1) A UK producer who is not a UK primary medical services provider, a Health Service chemist or an NHS hospital purchaser is a small producer if—
  - (a) the producer has net NHS sales income of £5 million or less in the relevant financial year,
  - (b) the producer receives—
    - (i) a request under regulation 23 during the producer’s first accounting reference period,  
or
    - (ii) a compliance notice in connection with such a request, or
  - (c) the producer becomes liable to pay a penalty under regulation 32(4) during the producer’s first accounting reference period.
- (2) In this paragraph, “accounting reference period” had the meaning given in section 391 of the Companies Act 2006.