

SCHEDULE 5

Regulation 35(2)

Information about supply of unbranded generic health service medicines or special health service medicines: transitional provisions

General

1. This Schedule makes transitional provision in relation to—
 - (a) the recording, keeping and provision of information about the supply of unbranded generic health service medicines by members of Scheme M and Scheme W (see paragraphs 2 and 3), and
 - (b) the recording, keeping and provision of information about the supply of special health service medicines by members of the Specials MoU (see paragraphs 4 and 5).

Transitional provision: information about supply of unbranded generic health service medicines

- 2.—(1) A Scheme member is not required to comply—
 - (a) with regulation 7 or 8 in any month which falls within a transitional quarter, or
 - (b) with regulation 9 in respect of any transitional quarter.
- (2) But this paragraph is subject to paragraph 3.
- (3) In this paragraph and paragraph 3—

“Scheme end date” means—

 - (a) in the case of a member of Scheme M, the day on which Scheme M ceases to operate following notice of termination being given by the Secretary of State in accordance with that Scheme;
 - (b) in the case of a member of Scheme W, the day on which Scheme W ceases to operate following notice of termination being given by the Secretary of State in accordance with that Scheme;

“Scheme member” means a UK producer who, immediately before 1st July 2018, is a member of Scheme M or Scheme W;

“transitional quarter” means a quarterly period (as determined in accordance with regulation 9(2)) which—

 - (a) begins on or after 1st July 2018, but
 - (b) before the Scheme end date.

(4) For the purposes of this paragraph, it does not matter whether the Secretary of State gives notice of termination in accordance with Scheme M or Scheme W before, on or after 1st July 2018.

Circumstances in which transitional provision in paragraph 2 ceases to apply

- 3.—(1) This paragraph applies to a Scheme member—
 - (a) who does not provide the Scheme information to the Secretary of State for a Scheme quarter within the submission period, or
 - (b) who, before the Scheme end date, ceases to be a member of the Scheme.

Such a member is referred to in this paragraph as an “exiting member”.

(2) An exiting member must comply with regulation 7 or 8 (or both, as the case may be) on and after the exit date.

Status: This is the original version (as it was originally made).

(3) An exiting member must also comply with regulation 9 in respect of each transitional quarter which begins on or after the exit date.

(4) In addition, where the exit date falls during a transitional quarter, the exiting member must comply with regulation 9 in respect of the remaining part of that quarter.

(5) In this regulation—

“exit date”—

- (a) in relation to an exiting member to whom sub-paragraph (1)(a) applies, means the day after the day on which the submission period ends;
- (b) in relation to an exiting member to whom sub-paragraph (1)(b) applies, means the day on which the member ceases to be a member of the Scheme;

“Scheme information” means—

- (a) in the case of a member of Scheme M, the information which the member is required under Scheme M to provide to the Secretary of State for each Scheme quarter;
- (b) in the case of a member of Scheme W, the information which the member is required under Scheme W to provide to the Secretary of State for each Scheme quarter;

“Scheme quarter”—

- (a) in the case of a member of Scheme M, means a quarterly period—
 - (i) which is specified in that Scheme as a period for which Scheme information is to be provided, and
 - (ii) for which the submission period ends after 1st July 2018;
- (b) in the case of a member of Scheme W, means a quarterly period—
 - (i) which is specified in that Scheme as a period for which Scheme information is to be provided, and
 - (ii) for which the submission period ends after 1st July 2018;

“submission period” means the period within which Scheme information must be submitted following the end of a Scheme quarter.

Transitional provision: information about supply of special health service medicines

4.—(1) A Specials MoU member is not required to comply—

- (a) with regulation 11, 12 or 13 in any month which falls within a transitional quarter, or
- (b) with regulation 14 in respect of any transitional quarter.

(2) But this paragraph is subject to paragraph 5.

(3) In this paragraph and paragraph 5—

“Specials MoU end date” means the day on which the Specials MoU ceases to operate following notice of termination being given by the Secretary of State in accordance with the MoU;

“Specials MoU member” means a UK producer who, immediately before 1st August 2018, is a participating manufacturer for the purposes of the Specials MoU;

“transitional quarter” means a quarterly period (determined in accordance with regulation 14(2)) which begins—

- (a) on or after 1st August 2018, but
- (b) before the day on which the Specials MoU end date.

(4) For the purposes of this paragraph, it does not matter whether the Secretary of State gives notice of termination in accordance with the Specials MoU before, on or after 1st August 2018.

Circumstances in which transitional provision in paragraph 4 ceases to apply

5.—(1) This regulation applies to a Specials MoU member—

- (a) who does not provide the specials information to the Secretary of State for an MoU quarter within the submission period; or
- (b) who, before the Specials MoU end date, ceases to be a Specials MoU member.

Such a member is referred to in this paragraph as an “exiting member”.

(2) An exiting member must comply with regulations 11, 12 and 13 on and after the exit date.

(3) An exiting member must comply with regulation 14 in respect of each transitional quarter which begins on or after the exit date.

(4) In addition, where the exit date falls during a transitional quarter, the exiting member must comply with regulation 14 in respect of the remaining part of that quarter.

(5) In this regulation—

“exit date”—

- (a) in relation to an exiting member to whom sub-paragraph (1)(a) applies, means the day after the day on which the submission period ends;
- (b) in relation to an exiting member to whom sub-paragraph (1)(b) applies, means the day on which the member ceases to be a member;

“MoU quarter” means a quarterly period—

- (a) which is specified in the Specials MoU as a period for which specials information is to be provided, and
- (b) for which the submission period ends after 1st August 2018;

“specials information” means the information which a Specials MoU member is required under the Specials MoU to provide to the Secretary of State in respect of each MoU quarter;

“submission period” means the period within which the specials information must be provided to the Secretary of State following the end of the relevant MoU quarter.