

WG24-17

**NATIONAL HEALTH
SERVICE (WALES) ACT 2006**

**THE DIRECTIONS TO LOCAL
HEALTH BOARDS AND NHS
TRUSTS IN WALES 2003 AND
THE MANAGED
INTRODUCTION OF NEW
MEDICINES INTO THE
NATIONAL HEALTH SERVICE
IN WALES DIRECTIONS 2009
(AMENDMENT) (WALES)
DIRECTIONS 2024**

Made 29 April 2024

Coming into force 1 May 2024

The Welsh Ministers, in exercise of the powers conferred on them by sections 12(3), 19(1), 174(10) and 203(9) and (10) of the National Health Service (Wales) Act 2006(1), give the following Directions.

Title, commencement, application and interpretation

1.—(1) The title of these Directions is The Directions to Local Health Boards and NHS Trusts in Wales 2003 and the Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009 (Amendment) (Wales) Directions 2024.

(2) These Directions come into force on 1 May 2024 and apply in relation to every Local Health Board and NHS Trust in Wales.

(3) In these Directions —

“the 2003 Directions” (“*Cyfarwyddydau 2003*”) means The Directions to Local Health Boards and NHS Trusts in Wales, dated 23 October 2003, as amended⁽¹⁾;

“the 2009 Directions” (“*Cyfarwyddydau 2009*”) means The Managed Introduction of New Medicines into the National Health Service in Wales Directions 2009⁽²⁾;

“AWMSG” (“*GSFCCG*”) means the All Wales Medicines Strategy Group;

“Final Appraisal Determination” (“*Penderfyniad Gwerthuso Terfynol*”) means the National Institute for Health and Care Excellence’s final draft guidance about using a health care intervention in the National Health Service, issued in accordance with the National Institute for Health and Care Excellence’s published procedures;

“NICE” (“*NICE*”) means the National Institute for Health and Care Excellence.

Amendment of the 2003 Directions

2.—(1) The 2003 Directions are amended in accordance with subparagraph (2).

(2) After paragraph 2B(2) insert—

“(3) The requirement in paragraph 2 to make a healthcare intervention available within a 2 month implementation period will not apply if one or more of the following circumstances apply—

(a) NICE extends the implementation period as confirmed in the Final Appraisal Determination, or

(b) the Welsh Ministers make a determination to extend the implementation period.

(4) If one of the circumstances listed in paragraph 2B(3) apply, the usual 2 month implementation period for introduction of the health care intervention will be replaced with the extended period recommended by NICE or the Welsh Ministers.”

Amendment of the 2009 Directions

3.—(1) The 2009 Directions are amended in accordance with subparagraph (2).

(2) After paragraph 2A(2) insert—

⁽¹⁾ The 2003 Directions were amended by The Directions to Local Health Boards and NHS Trusts in Wales dated 23 December 2003, 4 March 2004, 8 February 2005, 3 April 2006, 25 October 2006, 19 March 2009, 10 March 2010 and 26 April 2017.

⁽²⁾ 2009 No. 9 amended dated 26 April 2017.

“(3) The requirement in paragraph 2 to make a medicine available within a 2 month implementation period will not apply if one or more of the following circumstances apply—

(a) AWMSG has recommended the implementation period is extended, or

(b) the Welsh Ministers make a determination to extend the implementation period.

(4) If one of the circumstances listed in paragraph 2A(3) apply, the usual 2 month implementation period for introduction of the medicine will be replaced with the extended period recommended by AWMSG or the Welsh Ministers.”



Andrew Evans
Chief Pharmaceutical Officer, under the authority of
the Cabinet Secretary for Health and Social Care, one
of the Welsh Ministers

29 April 2024