

2017 No. 17

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

**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 2017**

Made 19 April 2017

Coming into force 26 April 2017

The Welsh Ministers, in exercise of the powers conferred on them by sections 12(3), 19(1), 174(10), 203(9) and (10) and 204(1) 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 2017.

(2) These Directions come into force on 26 April 2017 and apply 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” (“*GSFCC*”) means the All Wales Medicines Strategy Group;

“endorsed by the Minister” (“*wedi ei ar dystio gan y Gweinidog*”) means the acceptance by the Welsh Ministers of a recommendation made by the AWMSG;

“Technology Appraisal Guidance” (“*Canllawiau Gwerthuso Technoleg*”) means Technology Appraisal Guidance issued by the National Institute for Health and Care Excellence(3) in accordance with their published procedures.

Amendment of the 2003 Directions

2. The 2003 Directions are amended in accordance with paragraphs 3 to 5.

3. In paragraph 1(2)—

(a) in the definition “recommended by the Institute” (“*a gymeradwyir gan y Sefydliad*”), after “Technology Appraisal Guidance” insert “, Highly Specialised Technology Guidance or a Recommendation for Use Within the Cancer Drug Fund”;

(b) in the definition of “Technology Appraisal Guidance” (“*Canllawiau Gwerthuso Technoleg*”) for “Technology Appraisal Guidance” (“*Canllawiau Gwerthuso Technoleg*”) substitute “Technology Appraisal Guidance or Highly Specialised Technology Guidance” (“*Canllawiau Gwerthuso Technoleg neu Ganllawiau Technoleg Arbenigol Iawn*”); and

(c) in the appropriate places in the alphabetical order insert—

“Final Appraisal Determination” (“*Penderfyniad Gwerthuso Terfynol*”) means the Institute’s appraisal committee’s final draft guidance about using a health care intervention in the National Health

(1) As 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 and 10 March 2010.

(2) 2009 No. 9.

(3) Established pursuant to section 232 of the Health and Social Care Act 2012 (c. 7).

Service issued in accordance with the Institute's published procedures;"; and

"Recommendation for Use Within the Cancer Drugs Fund" ("*Cymeradwyaeth ar gyfer Defnydd o fewn y Gronfa Cyffuriau Canser*") means recommended for use within the Cancer Drugs Fund following appraisals conducted by the Institute in accordance with their published procedures since 29 July 2016;".

4. Save in the case of Technology Appraisal Guidance published before 26 April 2017 and for which paragraph 2 of the 2003 Directions will continue to have effect, paragraph 2 of the 2003 Directions is revoked.

5. Subject to paragraph 4, for paragraph 2 of the 2003 Directions substitute—

"2. Subject to paragraphs 2A, 2B and 3 and unless directed otherwise by the Welsh Ministers, a Local Health Board will in exercising those functions that it has been directed to exercise by the Welsh Ministers⁽¹⁾, apply such of those sums paid to it under section 174(1)(b) of the National Health Service (Wales) Act 2006 as may be required so as to ensure that a health care intervention that is recommended by the Institute in Technology Appraisal Guidance, Highly Specialised Technology Guidance or a Recommendation for use within the Cancer Drug Fund is available:

- (a) to be prescribed for any patient on a prescription form for the purpose of a patient's NHS treatment; or
- (b) to be supplied or administered to any patient for the purpose of the patient's NHS treatment,

as soon as reasonably practicable and, in any event, within two months of the publication by the Institute of the Final Appraisal Determination in relation to that health care intervention.

2A. For a healthcare intervention that is recommended by the Institute in Highly Specialised Technology Guidance or a Recommendation for Use within the Cancer Drugs Fund before 26 April 2017, the reference in paragraph 2 to "within two months of the publication by the Institute of the Final Appraisal Determination in relation to that

(1) The Local Health Boards (Directed Functions) (Wales) Regulations 2009 (S.I. 2009/1511) (W. 147).

healthcare intervention” is amended to “within two months of 26 April 2017.”.

2B.—(1) In exceptional circumstances, where the scale of service planning necessary to make a health care intervention available will take longer than two months, the reference in paragraph 2 to two months is amended to three months.

(2) Where a Local Health Board determines that the circumstances in sub-paragraph (1) are satisfied in relation to a health care intervention, it must, within 3 weeks of the publication by the Institute of the Final Appraisal Determination relating to that health care intervention, advise the Welsh Ministers, in writing, of its decision to provide the health care intervention within three months of the publication of the Final Appraisal Determination and its reasons for that decision.”

Amendment of the 2009 Directions

6. Save in respect of a medicine recommended by the AWMSG that has been endorsed by the Minister before 26 April 2017, and for which paragraph 2 to the 2009 Directions will continue to have effect, paragraph 2 of the 2009 Directions is revoked.

7. Subject to paragraph 6, for paragraph 2 of the 2009 Directions substitute—

“2. Unless directed otherwise by the Welsh Ministers, and subject to paragraph 2A, a Local Health Board must in exercising its functions, including those functions it has been directed to exercise by the Welsh Ministers(1), apply such amounts of the sums paid to it under section 174(1)(b) of the Act as may be required so as to ensure that a medicine recommended by the AWMSG and endorsed by the Minister is, as soon as reasonably practicable and, in any event, from a date not later than two months from the date of the Minister’s endorsement, available:

- (a) to be prescribed for any patient on a prescription form for the purpose of the patient’s NHS treatment; or
- (b) to be supplied or administered to any patient for the purpose of the patient’s NHS treatment.

2A.—(1) In exceptional circumstances, where the scale of service planning necessary to make

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a medicine available will take longer than two months, the reference in paragraph 2 to two months is amended to three months.

(2) Where a Local Health Board determines that the circumstances in sub-paragraph (1) are satisfied in relation to a medicine, it must, within 3 weeks of the date of endorsement by the Minister of that medicine, advise the Welsh Ministers, in writing, of its decision to provide the medicine within three months of the date of the Ministerial endorsement and its reasons for that decision.”

Signed

A handwritten signature in black ink, appearing to be 'F. Atherton', written over a horizontal line.

Frank Atherton, Chief Medical Officer, Welsh Government, under the authority of the Cabinet Secretary for Health, Well-being and Sport, one of the Welsh Ministers

Date 19 April 2017

