



Llywodraeth Cymru
Welsh Government

GUIDANCE, DOCUMENT

New treatment fund: directions on the exemptions for health boards and trusts (WHC/2024/020)

What local health boards and NHS trusts must do to make medicines and other interventions available.

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Details

Issue date

29 April 2024.

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Compliance and action.

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Title

Exemptions for local health boards and NHS trusts to the requirement to implement recommendations made by the National Institute for Health and Care Excellence (NICE) or the All Wales Medicines Strategy Group (AWMSG) within the usual period, in specified circumstances.

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Until replaced or amended.

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For action by

Local health boards and NHS trusts.

Action required by

1 May 2024.

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Enclosures

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)

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Directions 2024.

Exemptions for local health boards and NHS trusts to the requirement to implement recommendations made by the National Institute for Health and Care Excellence or the All Wales Medicines Strategy Group within the usual period, in specified circumstances

Purpose

1. This circular describes amendments to the directions specifying the implementation period within which health boards and NHS trusts in Wales must make medicines and other interventions recommended in National Institute for Health and Care Excellence (NICE) technology appraisals and highly specialised technology assessments, and All Wales Medicines Strategy Group (AWMSG) recommendations, available coming into force from 1 May 2024.

Background

2. Since January 2017, the New Treatment Fund (the fund) has supported health boards and NHS trusts to introduce new, recommended medicines and other interventions faster and more consistently across Wales.

3. The fund ensures dedicated resource is available to support health boards and NHS trusts in making medicines and interventions recommended by NICE and AWMSG, available within no more than 2 months of the publication of a NICE technology appraisal or highly specialised technology assessment, and an

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AWMSG recommendation being endorsed by Welsh ministers.

4. The fund helps address the financial pressures that can be associated with the introduction of some new medicines, providing health boards with the time to plan to invest in future years. Occasionally however there are circumstances which mean it is not possible for the NHS to make a new medicine or intervention routinely available within the 2 months allowed for in directions.

Exemptions to the requirement to implement recommendations

5. 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 as amended (the principal directions), provide for a health board or NHS trust to notify the Welsh Government's Chief Medical Officer of situations in which it is unable to meet the 2 month implementation and for this period to be extended to a maximum total 3 month implementation period.

6. It was envisaged this flexibility would be used in a limited way and only where a health board or NHS trust had local extenuating circumstances warranting an extension.

7. In recent months, NICE has published technology appraisals which include a variation to the statutory implementation period that applies in England. These variations recognise that the scale or nature of service development required by the NHS to make the medicines or healthcare interventions routinely available may be significant or may have a lead time which exceeds the normal implementation period.

8. In these circumstances, it would not be appropriate to rely on the existing flexibilities in the principal directions. Instead, the 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 2024 (the amendment directions) enclosed with this circular, amend the principal directions to include a new exemption. The amendment directions exempt health boards and NHS trusts from the requirement to implement a NICE or AMWSG recommendation within 2 months where:

- NICE extends the implementation period as confirmed in the Final Appraisal Determination
- AWMSG has recommended the implementation period is extended
- Welsh ministers make a determination to extend the implementation period

9. There are no other situations in which health boards and NHS trusts are exempted from the requirement to implement NICE or AWMSG recommendations as required by the principal directions.

10. The amendments come into effect on 1 May 2024.

11. **The amendment directions are available on the Welsh Government website.**

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