

To: Business Committee
From: Brian Gibbons AM
Minister for Health & Social Services

EXPLANATORY MEMORANDUM

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

INCOME GENERATION POWERS OF SPECIAL HEALTH AUTHORITIES DIRECTIONS 2005

Summary

These Directions, which relate to England and Wales, make provisions in relation to the exercise of income generation powers as set out in section 7 of the Health and Medicines Act 1988 by cross-border Special Health Authorities.

Paragraph 2 provides that cross-border Special Health Authorities may exercise the income generation powers set out in section 7.

Paragraph 3 provides that in order to exercise powers relating to the establishment or investment in companies (formed to exploit intellectual property) under section 7(7A), a cross-border Special Health Authority must have submitted a written proposal to the Assembly and the Secretary of State and have received their approval in writing.

Paragraph 4 further provides that in order to exercise powers under section 7(7A) the Special Health Authority must have submitted a full business case, which also contains any additional relevant information requested by the Assembly and/or the Secretary of State.

Paragraph 5 allows the Assembly and the Secretary of State to lay down any conditions relating to the exercise of the powers under section 7(7A).

Paragraph 6 requires cross-border Special Health Authorities to have regard to any guidance issued by the Assembly and by the Secretary of State.

Paragraph 7 requires cross-border Special Health Authorities to submit reports on their exercise of any income generation powers under section 7 to the Assembly and the Secretary of State. They must also submit relevant documentation filed at Companies House where they have established or invested in a company under section 7(7A).

Paragraph 8 revokes existing directions to certain Special Health Authorities.

1. This Memorandum is submitted to the Assembly's Business Committee in relation to the Income Generation Powers of Special Health Authorities Directions 2005, in accordance with Standing Order 25 (section 3).
2. A copy of the Instrument is submitted with this Memorandum.

Enabling Powers

3. The powers enabling this Instrument to be made are contained in sections 16D(1), 17, 18(1) and (3) and 126(4) of the National Health Service Act 1977 and section 7(3), (4) and (5) of the Health and Medicines Act 1988. These powers have been transferred to the National Assembly for Wales and have subsequently been delegated to my portfolio as Minister for Health and Social Services.

Effect

4. Section 7 of the Health and Medicines Act 1988 allows income generation activities to be undertaken, including the ability to set up and invest in companies whose purpose is to exploit and market intellectual property generated within the NHS. Intellectual property refers to products of creativity or innovation, which can be given legal recognition of ownership as Intellectual Property Rights through, for example, patents, trademarks or copyrights. These powers are conferred on the Assembly by virtue of section 7(7A), which was inserted into section 7 by section 5 of the Health and Social Care Act 2001. By virtue of section 7(3) the Assembly may confer these functions on NHS bodies. The Assembly has already issued directions to NHS Trusts and Local Health Boards, which came into force on 15 October 2003. These directions, however, are being issued by the Secretary of State to English only Special Health Authorities and by the Assembly and Secretary of State, acting in combination, to cross-border Special Health Authorities.
5. The effect of the Directions will be to allow cross-border Special Health Authorities to take steps to exploit intellectual property arising out of research for the purpose of making additional income available in order to better perform their functions, as well as the ability to set up or invest in companies, which will exploit and market such intellectual property.
6. A safeguard has been built into the Directions imposing a requirement that cross-border Special Health Authorities must submit a business case before investing in or setting up a company, which must be approved by the Assembly in relation to Wales, and by the Secretary of State in relation to England.

Target Implementation

7. It is intended that the proposed Instrument be made by the Assembly on 8 March 2005 and subsequently be made by the Secretary of State with a coming into force date of 1 April 2005. The target date coincides with the first batch of restructuring of Special Health Authorities being effected as a result of the Arm's Length Body Review being undertaken by the Department of Health.

Financial Implications

8. There are no financial implications arising from these Directions, and cross-border Special Health Authorities will not incur any additional costs. The Directions simply confer additional powers on them, the purpose of which is to generate additional income. Neither are there any financial implications for the Assembly.

Regulatory Appraisal

9. As these Directions fall outside the definition of Assembly general subordinate legislation in section 58 of the Government of Wales Act 1998, a Regulatory Appraisal is not required to be undertaken.

Consultation

With Stakeholders

10. Having had regard to Assembly Guidance, I have concluded the Directions should not be subject to consultation, given the Directions have no costs associated with them, they simply confer additional income generation powers on a very small group of bodies constituting cross-border Special Health Authorities.

With Subject Committee

11. There has been no prior scrutiny of the proposed Instrument by the Health and Social Services Committee. However, they are to be included on the list of forthcoming legislation that is to be considered by the Health and Social Services Committee on 2 March 2005. They were not included on the list previously, because the draft Directions have only recently been prepared by the Department of Health and provided to the Assembly. The issuing of the Directions is, however, pressing due to the restructuring of a number of Special Health Authorities in the light of the Arm's Length Body review referred to in paragraph 7 above.

Recommended Procedure

12. Subject to the views of the Business Committee, I recommend that these Directions proceed to plenary under the Accelerated procedure because the Directions are not contentious and they simply confer additional income generation powers on a very small group of bodies. However, if the Subject Committee subsequently wants to consider the legislation in more detail on 2 March, I will schedule the legislation for debate in Plenary.

Compliance

13. This Instrument will (as far as is applicable):
- have due regard to the principle of equality of opportunity for all people (Section 120 Government of Wales Act 1998);
 - be compatible with the Assembly's scheme for sustainable development (Section 121);
 - be compatible with Community law (Section 106);
 - be compatible with the Assembly's human rights legislation (Section 107);
 - and
 - be compatible with any international obligations binding the UK Government and the Assembly (Section 108).

14. This Memorandum has been cleared by the Office of the Counsel General and by the Assembly Compliance Officer.

15. Drafting Lawyer - Neil Buffin ext. 1561.

16. Head of Division - Geraint Martin ext. 6793.

17. Policy Division contact - Susan Denman ext. 1535.

**BRIAN GIBBONS AM
MINISTER FOR HEALTH AND SOCIAL SERVICES**

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