DIRECTIONS RELATING TO THE EXERCISE OF POWERS UNDER SECTION 7(2) AND (7A) OF THE HEALTH AND MEDICINES ACT 1988

In exercise of the powers conferred on the Secretary of State (a) by sections 17 and 18A(6) of the National Health Service Act 1977 (b) and section 5(9) of the National Health Service and Community Care Act 1990 (c), and of all other powers enabling him in that behalf, the Secretary of State makes the following Directions:-

Commencement, Application and Interpretation

- 1. -(1) These Directions shall come into force on 9^{th} September 2002.
 - (2) These Directions apply to the exercise of the powers in section 7(2) and (7A) of the 1988 Act (d) by
 - (a) a National Health Service trust all or most of whose hospitals, establishments and facilities are situated in England; or
 - (b) a Primary Care Trust established for an area of England.
 - (3) In these Directions –

"the 1977 Act" means the National Health Service Act 1977;

"the 1988 Act" means the Health and Medicines Act 1988;

"the 1990 Act" means the National Health Service and Community Care Act 1990;

"business case" means a document which relates to a proposal by a relevant body for the exercise by it of any of the powers in subsection (7A) of section 7 of the 1988 Act in relation to the company, in connection with the exercise by it of any of the powers in subsection (2) of that section, and which sets out –

- ^a Concerning NHS trusts, functions that are exercisable in relation to a cross-border body which by their nature cannot specifically be exercised in relation to Wales are exercisable concurrently by the Secretary of State see article 2(c) of the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672. Concerning Primary Care Trusts, the function of establishing such Trusts is conferred on the Secretary of State by section 16A of the 1977 Act. By virtue of article 2(a) of that Order, that function, so far as it is exercisable in relation to Wales, is transferred to the National Assembly for Wales.
- b 1977 c.49. Section 17 was substituted by section 12(1) of the Health Act 1999 (c.8); section 17 was amended by Schedule 5, Part 1, paragraphs 5(1) and (3), to the Health and Social Care Act 2001 (c.15); section 18A was inserted by section 5 of the Health Act 1999.
- c 1990 c. 19; section 5(9) was substituted by section 14 of the Health Act 1999 (c. 8).
- d Subsections (7A) and (7B) were inserted by section 5 of the Health and Social Care Act 2001 (c. 15); the powers referred to in subsection (7A) are expressed by that subsection to be powers included within the power in section 7(2)(g) of the 1988 Act.

- (a) how, in the view of the relevant body, the exercise of the powers in subsection (7A) will facilitate or be conducive or incidental to the exercise of the powers conferred by subsection (2), and the rationale for exercising the powers in subsection (7A), as opposed to taking other measures, in connection with the exercise of the powers conferred by subsection (2);
- (b) the projected income and expenditure for the company, in so far as is practicable and appropriate in the form described in sections 226 to 232 of the Companies Act 1985 (a) and any statutory modification or re-enactment thereof for the time being in force, over a period of at least 3 years, or the period during which the body proposes exercising the powers in subsection (7A), if less;
- (c) the projected income which it is anticipated will be made available for the improvement of the health service, through the activities of the company connected with the exercise of those subsection (7A) powers, over the period referred to in paragraph (b) above;
- (d) the commercial assumptions and operational plans in relation to the company's business which form the basis for the projections referred to in paragraphs (b) and (c) above; and
- (e) how the body proposes to manage any financial risks to it or to any other health service body which may arise from its exercise of the powers in subsection (7A) or from the activities of the company connected with the exercise of those subsection (7A) powers;

"the company" means the company in relation to which a relevant body proposes to exercise any of the powers in section 7(7A) of the 1988 Act;

"document" includes information transmitted using electronic communications;

"dormant company" means a company which has never traded;

"electronic communications" has the same meaning as in section 15 of the Electronic Communications Act 2000 (b);

"the proposal" means the document referred to in paragraph (a) of the Schedule to these Directions;

"relevant body" means a body specified in sub-paragraph 1(2).

(4) In these Directions, save where the contrary intention appears, any reference to a numbered paragraph is a reference to the paragraph which forms part of these Directions and which bears that number, and any reference, in a paragraph which forms part of these Directions, to a numbered sub-paragraph is a reference to the sub-paragraph of that paragraph which bears that number.

Proposal for the exercise of the powers in section 7(2) and (7A)

2. – (1) The Secretary of State directs that, save as otherwise allowed by him, a relevant body shall not exercise any of the powers in subsection (7A) of section 7 of the 1988 Act in connection with the exercise of any of the powers in subsection (2) of that section, unless it has submitted to the Secretary of State a proposal, and the other information and documents specified in the Schedule to these Directions and the Secretary of State has notified the body that he considers that the proposal—

^a 1985 c.6. These sections were inserted by sections 4 to 6 of the Companies Act 1989 (c.40). Section 228 was amended by S.I. 1992/3178, 1993/3246 and 1996/189 and by the Welsh Language Act 1993, section 30.

ь 2000 с. 15.

- (a) satisfies the tests specified in section 7(8) of the 1988 Act;
- (b) where the body is a Primary Care Trust, satisfies the criteria specified in section 18A(6)(a) of the 1977 Act;
- (c) where the body is a National Health Service trust, satisfies the criteria specified in section 5(9) of the 1990 Act; and
- (d) represents an appropriate exercise of the powers in subsection (7A) by the body, having regard in particular to the matters specified in sub-paragraph (2) below.

(2) The matters referred to are –

- (a) the financial risks for the health service and the financial benefits for the health service (in terms of greater income for improving the health service) which appear to him to be associated with the proposal;
- (b) where the proposal concerns the exercise of the powers in subsection (7A) in connection with the powers in subsection (2)(f) (ideas and intellectual property), the conditions on which the ideas or intellectual property may be made available to bodies established in countries outside England and Wales being bodies that are concerned with the delivery of health care in those countries, following the exercise of the powers in subsection (7A); and
- (c) where the proposal concerns the exercise of the powers in subsection (7A) in connection with the powers in subsection (2)(f) (ideas and intellectual property), the conditions on which the ideas or intellectual property may be made available for the purposes of the health service, following the exercise of the powers in subsection (7A).

Conditions applying to the exercise of the powers in section 7(2) and (7A)

- **3.** The Secretary of State directs that a relevant body which exercises any of the powers in subsection (7A) of section 7 shall, subject to any enactment, rule of law or any person's contractual or proprietary rights—
 - (a) save where otherwise allowed by the Secretary of State, and subject to sub-paragraph (b), exercise the powers in subsection (7A), and any powers in subsection (2) in connection with which the powers in subsection (7A) are exercised, in accordance with the proposal which has been the subject of a notification by the Secretary of State as referred to in paragraph 2(1) including the documents referred to in paragraph (a)(vii) and (viii) of the Schedule to this Order, but otherwise excluding any documents attached to the proposal;
 - (b) exercise the powers in subsection (7A) in accordance with any restrictions laid down by the Secretary of State at any time (being restrictions which do not have retrospective effect) relating to
 - (i) the amount of money or other property which the body may provide in connection with investment in the company, including any restrictions as to the amount which may be provided within a particular period or periods of time; and
 - (ii) the amount which may be provided to or in respect of the company by way of loans, guarantees or other financial provision, including any restrictions as to the amount which may be provided within a particular period or periods of time; and

(c) in exercising the powers in subsection (7A), and any powers in subsection (2) in connection with which the powers in subsection (7A) are exercised, have regard to any relevant guidance issued by the Secretary of State.

Information concerning the exercise of the powers in section 7(2) and (7A)

- **4.** The Secretary of State directs that, where the Secretary of State has notified a relevant body as referred to in paragraph 2(1), the relevant body shall supply the Secretary of State with such information in its possession, or to which it is entitled, concerning
 - (a) the exercise by it of any of the powers in section 7(7A) of the 1988 Act, and of any of the powers in section 7(2) of the 1988 Act in connection with which the powers in section 7(7A) are exercised; and
 - (b) the activities of the company connected with the exercise of those powers,

as the Secretary of State may request at any time.

Annual report

- 5. The Secretary of State directs that, where the Secretary of State has notified a relevant body as referred to in paragraph 2(1), the relevant body shall, no later than 30th September in each year, serve on the Secretary of State a report giving
 - (a) a summary by reference to the financial year ending on the preceding 31st March of how it has exercised the powers in section 7(7A) of the 1988 Act in relation to the company, and of how it has exercised any of the powers in section 7(2) of the 1988 Act in connection with which the powers in section 7(7A) were exercised;
 - (b) on the basis of the information in its possession, or to which it is entitled, a summary of the activities of the company connected with the exercise of those powers; and
 - (c) particulars of any changes to the Memorandum or Articles of Association of the company, and of any statutory returns made to the Registrar of Companies, during that year.

On behalf of the Secretary of State for Health

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5th September 2002.