

**ACQUISITION BY COLOPLAST A/S OF THE CONTINENCE CARE BUSINESS OF  
SSL INTERNATIONAL PLC**

**UNDERTAKINGS GIVEN BY COLOPLAST A/S, COLOPLAST LIMITED AND  
4C HEALTH LIMITED TO THE SECRETARY OF STATE FOR TRADE AND  
INDUSTRY UNDER SECTION 88(2) FAIR TRADING ACT 1973**

**WHEREAS** on 29 September 2001 Coloplast A/S acquired the continence care business of SSL International plc and on 14 January 2002 the Secretary of State referred the resulting merger situation to the Competition Commission under sections 64 and 69(2) of the Act;

**WHEREAS** the Report presented to Parliament in June 2002 by the Secretary of State sets out such conclusions as are mentioned in section 73(1) of the Act;

**WHEREAS** the Secretary of State required the Companies to negotiate with Mentor to secure either divestment of the 'Clear Advantage' brand (leaving the Companies with the right to source silicon Sheaths from Mentor or any other person but supply them under a different brand name) or divestment of the 'Clear Advantage' brand and product;

**WHEREAS** undertakings arising were given by the Companies and 4C Health under section 88(2) of the Act and were accepted by the Secretary of State on 15 August 2002;

**WHEREAS** following the failure of the resulting negotiations, the Secretary of State sought further advice from the Director who advised that the undertakings needed to be varied or superseded by new undertakings;

**WHEREAS** pursuant to a request by the Secretary of State, the Director has consulted with the Companies with a view to obtaining from them the following undertakings to take action in accordance with section 88(1) of the Act;

**WHEREAS** the undertakings accepted on 15 August 2002 shall cease to have effect at the moment that the Secretary of State accepts the following undertakings;

**NOW THEREFORE** the Companies and 4C Health hereby give to the Secretary of State under section 88(2) of the Act the following undertakings to take action requisite for the purpose of remedying or preventing the adverse effects specified in the Report:

**Price cap for 'Clear Advantage' and 'Conveen Security Plus' Sheaths for supplies to NHS Hospitals**

1.- From 1 October 2003 until 31 March 2007 inclusive, the Companies and 4C Health or any one of them shall not directly or indirectly supply, agree or offer to supply or procure others to supply, agree or offer to supply to any NHS Hospital in the United Kingdom any 'Clear Advantage' branded Sheath or 'Conveen Security Plus' branded Sheath at prices higher than those prescribed by the Director, and

(a) on the day that these undertakings take effect and until otherwise prescribed by the Director pursuant to paragraph (b) below, those prices are as prescribed by the Director in his letter to the Companies of 4 March 2003, and

(b) on his own initiative or following an application by the Companies and having had regard to the cost information provided by them, the Director may prescribe such other prices as he sees fit.

**Non supply of Mentor branded Sheaths to NHS Hospitals and limited supply in the Community Sector**

2.- Subject to clause 3, after the expiry of the Mentor Agreement on 31 March 2007 or on such earlier termination date as may arise under it,

(a) the Companies shall not:

(i) directly or indirectly sell, distribute, handle, market, obtain orders for or otherwise deal in any Mentor branded Sheath (whether as principal, agent or otherwise) in the United Kingdom;

(ii) make any Agreement (whether with Mentor or any other person) to the like effect as the Mentor Agreement; or

(iii) where an Agreement (whether with Mentor or any other person) to the like effect as the Mentor Agreement has already been made, give effect to that Agreement or enforce or purport to enforce it;

(b) the Companies and 4C Health or any one of them shall not directly or indirectly supply, agree or offer to supply or procure others to supply, agree or offer to supply to any NHS Hospital in the United Kingdom any Mentor branded Sheath; and

(c) 4C Health shall not:

(i) make any exclusive distribution Agreement (whether with Mentor or any other person) to the like effect as the Mentor Agreement; or

(ii) where an exclusive distribution Agreement (whether with Mentor or any other person) to the like effect as the Mentor Agreement has already been made, give effect to that Agreement or enforce or purport to enforce it.

3.- Clause 2 above shall not prevent:

(a) the Companies or 4C Health from retailing Mentor branded Sheaths but only to the extent that such retailing is through a DAC Owned by the Companies to individual patients in the Community Sector on prescription on the basis of a listing in the Drug Tariff; or

(b) 4C Health from wholesaling Mentor branded Sheaths but only to the extent that:

(i) such wholesaling is to a Chemist;

(ii) it is a condition in any wholesale supply agreement arising that any resale by that Chemist shall be only to individual patients in the Community Sector on prescription on the basis of a listing in the Drug Tariff; and

(iii) to the best of 4C Health's knowledge and belief, that Chemist will comply with that condition.

#### **Furnishing of information to the Director**

4.- On the day that any tender is submitted to PASA or its equivalent bodies in Wales, Scotland and Northern Ireland in relation to the supply of 'Clear Advantage' branded Sheaths or 'Conveen Security Plus' branded Sheaths in the United Kingdom, the Companies shall furnish to the Director a copy of that tender demonstrating that the Companies and 4C Health have complied with clause 1 above.

5.- The Companies shall keep under review the prices prescribed by the Director under clause 1 above and:

(a) if any one of them has reasonable grounds to suspect that those prices would be, but for these undertakings, predatory within the meaning of the Chapter II prohibition in the Competition Act 1998, it shall furnish promptly to the Director such information as it considers necessary to demonstrate this; and

(b) on the last Working Day in November in each year, the Companies shall furnish to the Director a review, in a form specified by him, of the

year ending on the immediately preceding 30 September of those prices in the light of exchange rate and other cost changes.

6.- The Companies and 4C Health or any one of them shall furnish promptly to the Director such other information as he considers necessary to monitor these undertakings.

#### **Directions and compliance**

7.- The Companies and 4C Health or any one of them shall comply promptly with such written directions as the Director may give:

(a) to take such steps as may be specified or described in the directions for the purpose of carrying out or securing compliance with these undertakings; or

(b) to do or refrain from doing anything so specified or described which they might be required by these undertakings to do or to refrain from doing.

8.- (1) The Companies and 4C Health or any one of them shall procure that any member of the same Group of Interconnected Bodies Corporate as them shall comply with these undertakings as if it had given them.

(2) Where any Affiliate of the Companies or 4C Health is not a member of the same Group of Interconnected Bodies Corporate as them, the Companies and 4C Health or any one of them shall use their best endeavours to procure that any such Affiliate shall comply with these undertakings as if it had given them.

#### **Interpretation**

9.- The Interpretation Act 1978 shall apply to these undertakings as it does to Acts of Parliament.

10.- In these undertakings:

'4C Health' means 4C Health Limited, the company incorporated in Scotland with registration number SC120654 having as its registered address Unit 2, Oakbank Park Way, Mid Calder, Livingston, EH53 0TH;

'the Act' means the Fair Trading Act 1973;

an 'Affiliate' of a person is another person who satisfies the following condition, namely that any Enterprise that the first person carries on from time to time and any Enterprise that the second person carries on from time to time would be regarded as being under common control for the purposes of section 65 of the Act;

'Agreement' has the meaning given in section 137(2) of the Act and, includes a merger situation within the meaning of the Act;

'Chemist' for supply in England or Wales has the meaning given to it in regulation 2 of the National Health Service (Pharmaceutical Services) Regulations 1992, SI 1992 No. 662, or, for supply in Scotland or Northern Ireland, the equivalent meaning given in the equivalent enactment for Scotland or Northern Ireland respectively;

'"Clear Advantage" branded Sheaths' includes enhancements to such branded Sheaths and all Sheaths that succeed or replace such branded Sheaths;

'Coloplast A/S' means the company incorporated in Denmark with registration number 69749917 having as its registered address Hortedam 1, DK-3050 Humlebæk;

'Coloplast Limited' means the company incorporated in England & Wales with registration number 1094405 having as its registered address Peterborough Business Park, Peterborough, Cambridgeshire PE12 6FX;

'Community Sector', for the avoidance of doubt, excludes National Health Service and other hospitals;

'the Companies' means Coloplast A/S and Coloplast Limited or any one of them;

'"Conveen Security Plus" branded Sheaths' includes enhancements to such branded Sheaths and all Sheaths that succeed or replace such branded Sheaths;

'DAC' means dispensing appliance contractor being a person who is either:

(a) for supply in England or Wales:

(i) a retail supplier of appliances which are included in a list for the time being approved by the Secretary of State for Health or the National Assembly for Wales for the purposes of section 41 of the NHS Act; and

(ii) who is included in the list of a Primary Care Trust (being a body of that name established by the Secretary of State for Health under section 16A of the NHS Act) or a Health Authority (being a body of that name established by the National Assembly for Wales under section 8(1) of the NHS Act) made under section 42 of the NHS Act; or

(b) for supply in Scotland or Northern Ireland, an equivalent approved retail supplier of equivalent approved appliances under the equivalent enactment for Scotland or Northern Ireland respectively;

'a DAC Owned by the Companies' means a DAC who is:

(a) 4C Health, provided that the Companies retain at least the level of control held in 4C Health as they have at the time that these undertakings take effect; or

(b) any member of the same Group of Interconnected Bodies Corporate as the Companies.

'the Director' means the Director General of Fair Trading;

'the Drug Tariff' for supply in England or Wales has the meaning given to it in regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992, SI 1992 No. 662, or, for supply in Scotland or Northern Ireland, the equivalent meaning given in the equivalent enactment for Scotland or Northern Ireland respectively;

'Enterprise' has the meaning given in section 63(2) of the Act;

'Group of Interconnected Bodies Corporate' has the meaning given in section 137(5) of the Act;

'Mentor' means Mentor Corporation, the company incorporated in the State of Minnesota, United States of America with registration number 0000064892 having as its principal offices 201 Mentor Drive, Santa Barbara CA 93111, United States of America and any member of the same Group of Interconnected Bodies Corporate as it or any one of them;

'Mentor Agreement' means the distribution agreement with Mentor dated 29 September 2001 (and more particularly described in paragraphs 2.12-2.16 and 3.70-3.75 of the Report);

'Mentor branded Sheath' means a Sheath which has been branded by Mentor and includes 'Clear Advantage' branded Sheaths but only to the extent that they are branded;

'the NHS Act' means the National Health Service Act 1977;

'NHS Hospital':

(a) for England or Wales, has the meaning given in section 128(1) of the NHS Act to 'health service hospital';

(b) for Scotland, has the meaning given in section 108(1)] of the National Health Service (Scotland) Act 1978 to 'health service hospital';

(c) for Northern Ireland, means a hospital providing health services within the meaning of the Health and Personal Social Services Order 1972 SI 1972/1265 (NI 14); and

(d) for any part of the United Kingdom, includes such other similar public hospital as the Director may prescribe;

'PASA' means the Purchasing and Supply Agency, an executive agency of the Department of Health, or its successor body;

'the Report' means the report of the Competition Commission entitled *Coloplast A/S and SSL International plc – a report on the merger situation* (Cm 5522, June 2002);

'the Secretary of State' means the Secretary of State for Trade and Industry;

'Sheath' means incontinence sheath;

a 'Working Day' means a day which is not Saturday, Sunday or any other day on which the Office of Fair Trading is closed for business.

**FOR AND ON BEHALF OF COLOPLAST A/S**

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**Date**.....

**Name**.....

**Director**

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**Date**.....

**Name**.....

**Director/Secretary**

**FOR AND ON BEHALF OF COLOPLAST LIMITED**

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**Date**.....

**Name**.....

**Director**

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**Date**.....

**Name**.....

**Director/Secretary**

**FOR AND ON BEHALF OF 4C HEALTH LIMITED**

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**Date**.....

**Name**.....

**Director**

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**Date**.....

**Name**.....

**Director/Secretary**