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THE SCOTTISH OFFICE

National Health Service in Scotland
Management Executive

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Dear Colleague

NEW EUROPEAN STANDARD FOR CONDOMS AND IMPACT OF THE MEDICAL DEVICES REGULATIONS

Summary

1. This letter gives information about the planned introduction of a new European Standard for condoms and the impact from 1 January 1995 of the Medical Devices Regulations on the supply of condoms within the European Economic Area.

Action

2. With effect from 1 January 1995 condoms came within the scope of the Medical Devices Regulations and during a transitional period to 13 June 1998 manufacturers or suppliers will be able to choose either:

- to conform to the requirements of the Regulations, and put the 'CE' marking of conformity on the packaging of condoms which meet the appropriate essential requirements and quality system requirements of the Regulations; or

- continue to follow any relevant national law in force on 31 December 1994.

3. General Managers and Trust Chief Executives are asked to ensure that the contents of the Annex are drawn to the attention of all appropriate managers and staff.

Yours sincerely

DAVID R STEEL
Director of Corporate Affairs

For Action

General Managers,
Health Boards
Chief Executives, NHS
Trusts
General Manager, State
Hospitals Board for
Scotland

For Information

General Manager,
Common Services
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General Manager,
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1. One means by which manufacturers will be able to demonstrate that their product meets the essential requirements referred to above will be to show that it complies with the technical requirements of a European Standard for condoms, which is currently at a draft stage. It is hoped that the standard will be published later this year, when it will become a national standard in all of the member states of the European Economic area.

2. The Regulations do not rule out the addition to a condom's packaging of marks other than the CE marking, provided that such additional marks are not likely to mislead third parties with regard to the meaning or graphics of the CE marking or reduce its visibility or legibility. Anyone involved in sexual health promotion must therefore take account of the possibility that some manufacturers may decide to market condoms which are both CE marked and 'Kitemarked'.

3. Accordingly condoms which the Department now consider to be acceptable for purchase are those labelled with:

- the CE marking or

- the CE marking and the BSI 'Kitemark'.

During the transitional period to 13 June 1998, in those instances where condom packaging does not bear the CE mark, condoms labelled with the BSI 'Kitemark' should continue to be purchased.

4. It is essential that any information or publicity material you issue about condoms during the transitional period advises the use of products carrying either the European CE marking or the BSI 'Kitemark' or even both.

5. After the transitional period ends, it will be illegal to supply condoms in any state in the European Economic Area unless the packaging bears the CE marking.