EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Marketing Authorisation Etc.) Regulations 1994 ("the principal Regulations") to make further provision implementing Council Directive 92/27/EEC (O.J. No. L113 of 30.4.1992) ("the Directive") by requring necessary special warnings to be included on the packaging of relevant medicinal products containing paracetamol, and in package leaflets accompanying those products.

The new paragraph 5(1)(f) of Schedule 5 to the principal Regulations specifies the new warnings which must appear on the packaging of paracetamol products for adult use. The new paragraph 5(1)(g) specifies similar warnings in respect of products for paediatric use. Paragraph 5(2) of Schedule 5 to the principal Regulations is amended so that the required label warnigns must appear prominently and in a rectangle (regulation 3).

Paragraph 1 of the new Schedule 5A to the principal Regulations specifies the new warning which must appear in any package leaflet included in accordance with the Directive in the packaging of a paracetamol product for adult use, and paragraph 2 of the Schedule specifies the warning which must appear in any package leaflet included in accordance with the Directive in the packaging of a paracetamol product for paediatric use (regulation 4).

Consequential amendments are made to paragraphs 11 and 12 of Schedule 3 to the principal Regulations, making breaches of the new requirements offences (regulation 5).

A Regulatory Appraisal in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.