EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations contain measures relating to arrangements underpinning the safe management and use of controlled drugs in England and Scotland.

Part 1 outlines preliminary matters.

Part 2 relates to accountable officers. A number of health care bodies are prescribed as designated bodies (regulation 3), and these are required to appoint accountable officers (regulation 4). There are limitations on who may act as accountable officers (regulation 5) and a duty on designated bodies to establish arrangements for their removal from office in specified circumstances (regulation 6). Designated bodies are required to ensure that their accountable officers are sufficiently resourced (regulation 7).

Accountable officers are given a number of functions relating to the safe management and use of controlled drugs. Essentially, these require the establishment by the accountable officer of a number of sets of arrangements which relate to the safe management and use of controlled drugs. As well as the basic arrangements (regulation 9), these include safe disposal arrangements (regulation 10) and auditing arrangements (regulation 11). As well as being given functions in relation to their own designated bodies, accountable officers are given functions in relation to health care professionals and others whose work involves the management and use of controlled drugs, for which their designated body is responsible. These responsibilities include maintaining records of and investigating concerns (regulations 15 and 16), and taking appropriate action where there are well-founded concerns (regulation 17). Accountable officers for Primary Care Trusts and Health Boards also have particular responsibilities for setting up local intelligence networks, relating to the management and use of controlled drugs, for their area (regulation 18).

Part 3 contains arrangements in relation to periodic inspections of premises used for the management and use of controlled drugs, where these issues would not be dealt with as part of other health and social care inspections, and other measures in relation to powers of entry.

Part 4 deals with co-operation between a number of listed health care bodies and other organisations (regulation 22), and in particular contains detailed arrangements with regard to the disclosure of information between the bodies that are required, by the Regulations, to co-operate with each other in connection with the identification of cases where action may need to be taken against individuals (regulations 24 to 27). There are record keeping requirements (regulation 28), and duties with regard to occurrence reports, which are quarterly statements that accountable officers must make about details of concerns that their designated body has (regulation 29). Accountable officers have duties to take action with regard to concerns that they have (regulation 30), and persons acting in good faith under the arrangements for sharing information under this Part are protected from damages claims (regulation 31).

A regulatory impact assessment relating to the effect that this instrument will have is available from the Department of Health, Skipton House, 80 London Road, London SE1 6LH. Copies of the assessment have been placed in the libraries of both Houses of Parliament.