These notes refer to the Health Act 1999 (c.8) which received Royal Assent on 30 June 1999

HEALTH ACT 1999

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part I - the National Health Service

Sections 33 to 38: Control of prices of medicines and profits

242. Pharmaceutical companies' profits from the sale of branded prescription medicines to the NHS are at present controlled by the Pharmaceutical Price Regulation Scheme (PPRS). The current PPRS is a voluntary, non-statutory agreement between the Government, represented by the Department of Health, and the industry represented by the Association of the British Pharmaceutical Industry (ABPI). It has operated in various forms since 1957. The current agreement commenced on 1st October 1993 and will continue until one side gives six months notice. Not all companies comply fully with the current scheme. Negotiations are taking place between the Government and ABPI with the objective of agreeing a successor agreement.

243. Section 57 of the 1977 Act enables the Secretary of State by order to control maximum prices for medical supplies. The provision does not provide power to regulate profits. Accordingly it cannot be used to ensure compliance by companies with all elements of the current PPRS or a similar successor scheme. In addition, breach of any Order which sets a maximum price or change thereto is a criminal offence.

244. Branded medicines are specialised products, the development of which incurs considerable research and development costs. The products have limited inter-changeability in many circumstances, and new medicines are subject to patent protection. This gives companies a period of market exclusivity. In this context, the Government is taking powers to ensure that prices are fair and reasonable to the NHS and to companies.

245. *Section 33* enables the Secretary of State, after making a scheme with the industry body (in practice the ABPI), to make regulations or issue directions to secure compliance with certain key elements of that scheme. This scheme (with additions or modifications agreed in individual cases) would apply only to those companies who consent (subsection (2)). Subsections (4) and (5) provide for the Secretary of State to give notice to a manufacturer or supplier that the scheme is no longer to apply to him. This can be done where the acts or omissions of the manufacturer or supplier have shown the scheme is ineffective in his case. Subsection (7) read with section 38 gives the Secretary of State power by regulations or direction to require any manufacturer or supplier to record and keep information, and to provide information to the Secretary of State.

246. Section 33(8) read with section 38 enables the Secretary of State by regulations or directions to prohibit any manufacturer or supplier to whom the scheme applies from increasing the prices of medicines provided to the health service without the Secretary of State's approval and, where this is breached, provides for payment of any excesses representing the increase to the Secretary of State within a specified period.

247. In addition to powers to secure compliance with a voluntary scheme, the Act provides powers to control maximum prices of health service medicines in other circumstances and to provide for a statutory scheme.

248. *Section 34* read with section 38 provides for the Secretary of State, after consultation with the industry body, by regulations or direction, to limit any price which may be charged by any manufacturer or supplier and for payment of the excess to the Secretary of State within a specified period. This power is only exercisable in relation to companies who are not "scheme members" as defined in section 33(4). This section replaces section 57 of the NHS Act 1977 with respect to controlling the maximum price of health service medicines. Section 38(5) therefore provides that section 57 shall cease to have effect in relation to health service medicines but this does not affect any other powers of the Secretary of State to control profits or prices.

249. *Section 35* read with section 38 enables the Secretary of State, after consultation with the industry body, by regulations or direction to make a statutory scheme for the purpose of limiting prices or profits of manufacturers or suppliers of health service medicines. Section 35(3) provides that such a scheme may in particular require any manufacturer or supplier to whom it applies to record and keep information and provide information to the Secretary of State. Section 35(5) provides for payment to the Secretary of State of profits in excess of the limits determined under the scheme. Section 35(6) enables the Secretary of State to prohibit any manufacturer to whom the scheme applies from increasing prices without his approval and to require a sum representing the amount of that excess to be paid to him. Section 35(7) excludes "scheme members" from any statutory scheme.

250. *Section 36* read with section 38 gives the Secretary of State power after consultation with the industry body to make supplementary regulations or directions enabling or facilitating the introduction of a statutory scheme.

251. *Section 37* provides for enforcement. Section 37(1) enables the Secretary of State to make regulations providing for the payment of penalties by a person who contravenes any provision of regulations or directions made under sections 33 to 36. Section 37(2) provides that the maximum single penalty for which provision can be made is £100,000 and the maximum daily penalty is £10,000. Section 37(3) provides that amounts payable to the Secretary of State in respect of excessive prices can be increased by up to 50%. Section 37(4) enables the Secretary of State to provide that the amount payable to him will carry interest at a rate specified or referred to in the regulations. Sums payable to the Secretary of State are recoverable through the civil courts.

252. Section 37(5) enables provision to be made by regulations conferring on suppliers and manufacturers a right of appeal against enforcement decisions. Section 37(7) defines the enforcement decisions against which a supplier or manufacturer may appeal. The decisions are those made by the Secretary of State to (a) require a specific manufacturer or supplier to provide information to him, (b) limit, in respect of any specific manufacturer or supplier, any price or profit, (c) refuse to give his approval to a price increase made by a specific manufacturer or supplier, or (d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him.

253. Section 37(8) provides that any requirement, prohibition or limit under sections 33 to 35 may only be enforced under this section and not relied on in any other proceedings. Section 37(9) requires the Secretary of State to consult the industry body before making regulations under the section 37. Section 37(10) provides for the maxima set out in section 37(2) to be increased by order, subject to the affirmative resolution procedures as provided for in section 62(8).

254. *Section 38* deals with supplementary matters. In particular section 38(1) provides how the powers in sections 33(6) to (8) and 34 to 36 may be exercised, namely by regulations or, in the case of a particular manufacturer or supplier, by directions, and that regulations

may give power to give directions in such particular cases. Section 38 provides that the power to control prices and profits may be exercised only with a view to limiting them to what is fair and reasonable and for the purposes of the health service. The Secretary of State and any other person must bear in mind the need for medicinal products to be available to the health service on reasonable terms and the costs of research and development.

255. The provisions in sections 33 to 38 enable the Secretary of State to make regulations in respect of England, Scotland, Wales and Northern Ireland. The operation of a pharmaceutical price regulation scheme in respect of Northern Ireland is a transferred matter under the Northern Ireland Act 1998. In practice, therefore, the Secretary of State will only make regulations which extend to Northern Ireland with the consent of the Northern Ireland Assembly.