EXECUTIVE NOTE

DRAFT SSI: THE NATIONAL HEALTH SERVICE (REIMBURSEMENT OF THE COST OF EEA TREATMENT) (SCOTLAND) REGULATIONS 2010 (S.S.I 2010/)

1. The above instrument will be made in exercise of the powers conferred under section 2 (2) of the European Communities Act 1972. The instrument is subject to affirmative resolution procedure.

Policy Objectives

2. The purpose of the instrument is to give effect to the judgement of the European Court of Justice in Case C-372/04 *The Queen, on the application of Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* (which held that the obligation under article 49 of the EC Treaty (now article 56 of the Treaty on the Functioning of the European Union which provides for the freedom to provide and receive services in another member state of the European Union) to reimburse the cost of hospital treatment provided in another member state also applies to a tax funded national health service, such as in Scotland, which provides treatment free of charge. These Regulations also cover non-hospital treatment.

3. The ECJ, in the *Watts* judgment, found that patients have rights under what is now Article 56 to receive medical services in another Member State and to be reimbursed the costs of those services by their home health system and that these rights apply equally to NHS patients. These, and other healthcare-related Treaty rights accorded to citizens as determined by the ECJ in its judgments, will in due course be codified and clarified within a European Directive, which is currently in the process of negotiation between Member States.

4. The ECJ made clear that national systems may impose a requirement for patients to obtain approval from their local healthcare commissioners and that such a restriction can be justified. The Court has also ruled that prior authorisation should always be granted if their home health service cannot make the required service available to the patient "without undue delay". The ECJ identified certain factors that should be considered in assessing whether or not the service can be provided without undue delay. These factors are reflected in this instrument.

5. The policy objectives of the instrument are to provide certainty and transparency following the Watts judgment, in relation to arrangements for:

- reimbursement of cost;
- the circumstances in which prior authorisation is required; and
- when prior authorisation must be granted.

Consultation

6. NHS Boards; the General Medical Council (Scotland); and the British Medical Association (Scotland) have been consulted during the preparation of the instrument. Moreover, a full public consultation exercise was carried out in Scotland at the end of 2008, following the publication of the European Commission's proposals for a cross border healthcare directorate in July 2008. The draft directive contained, amongst other things, the policy objectives of the above-named Regulations.

Financial Effects

7. The instrument has nil or negligible financial effects on the Scottish Government, local government or on business. The effect on Scottish NHS Boards will also be negligible.

Impact

8. A Regulatory Impact Assessment has not been prepared for this instrument. The impact on business (the legislation does not apply to small business) charities, voluntary bodies or the public sector, including NHS Scotland, is estimated to be nil or minimal. Scottish NHS Boards should already have mechanisms in place to deal with applications from patients wishing to travel to another EEA country for treatment under the long established E112 scheme or under Article 56 (formerly Article 49) following the aforementioned ECJ judgement, when interim guidance was provided by the Scottish Government to NHS Boards in October 2007.

Guidance

9. Detailed guidance to accompany the Regulations will shortly be made available to NHS Scotland. Copies of the draft guidance have been placed in the Scottish Parliament Information Centre (SPICe)

Monitoring & review

10. This instrument aims to ensure that NHS Scotland is complying with European case law. Scottish Government Patient Support and Participation Division will keep the effect of these regulations under review, pending the agreement of a wider and more comprehensive EU Directive on patient mobility currently being negotiated between EU Member States.

Scottish Government Healthcare Policy & Strategy Directorate
Patient Support & Participation Division
26 May 2010