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Department of
**Health, Social Services
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An Roinn

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

www.dhsspsni.gov.uk

To: The Chief Executive of each Health and Social Services Board
The Chief Executive of each Health and Social Care Trust
The Chief Executive of the Central Services Agency

Cc: Deputy Secretary's DHSSPSNI
Chief Professional Officers, DHSSPSNI
David Sissling, Chief Executive Designate Health and Social Care
Authority
Directors DHSSPSNI

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Dear Colleague

PATIENT MOBILITY – PRELIMINARY ADVICE ON HANDLING REQUESTS FOR HOSPITAL CARE IN OTHER EUROPEAN COUNTRIES

1. Introduction

- 1.1 This circular sets out guidance to help Health and Social Services Boards handle requests from the public to go to certain other European countries for treatment, which in Northern Ireland, is provided in hospitals.
- 1.2. Along with reminding Boards of the arrangements that already exist for handling such requests it also explains the implications of recent rulings by the European Court of Justice (ECJ) in the Watts and other related cases. It advises Boards that they must have systems in place for handling requests to go abroad for treatment in hospitals, and gives some practical advice on how to handle these requests.
- 1.3. The area of cross-border healthcare, including patient mobility, is currently the focus of discussions on possible EU action on health

services. There is a possibility that a Directive may be proposed in this area. Given this, Boards should bear in mind that there may be a need to alter the sorts of systems discussed in this guidance at some point over the next three or four years in order to take account of these developments.

1.4. This preliminary guidance, and the Watts case, deals with requests to go abroad for treatment in hospital. There are related judgments from the European Court on treatment outside hospitals: Annex 2 to this guidance provides some details about how the Boards could handle these requests.

1.5. Though this guidance is detailed to help Boards manage requests effectively, there are a small number of relatively simple principles which if followed will allow commissioners to meet the main EU requirements. These principles are:

- Boards can (and should) set up systems for considering requests from patients for authorisation to go abroad for treatment which in the UK is provided in hospitals; these systems are different from the current E112 referral arrangements;
- A Board is entitled to refuse to pay for healthcare services that are available in other Member States but that it does not offer to patients in Northern Ireland. **A Board is entitled to refuse to authorise a request for treatment that it does not fund, even if that treatment is funded elsewhere in Northern Ireland;**
- If a Board agrees that a patient should be offered treatment on the health service, and if that treatment is not available without “undue delay” in the health service, then the patient is legally entitled to go elsewhere in the EU for that service, and can request either E112 or Article 49 authorisation;
- Under the case law developed by the European Court in the Watts case (**Article 49**), Boards are only required to refund up to the costs of treatment in Northern Ireland: if treatment costs elsewhere in the EU are higher than those in Northern Ireland, then the patient needs to pay the difference

2. The difference between requests to go abroad and commissioning services abroad

This guidance is about handling requests from individual patients to go to other European countries for treatment. It does not affect other commissioning activities, such as contractual arrangements that Boards may have made with healthcare providers overseas (for example for

treatment for rare conditions, or because of capacity constraints in the health service). Suggested guidelines to facilitate this process have been produced in discussions between the EU Member States and the European Commission and are available at:

<http://www.dh.gov.uk/PolicyAndGuidance/International/OverseasTreatmentGuidanceForNHS/fs/en>.

3. Countries covered by this guidance

This guidance only relates to the European countries listed at Annex 1. References in this guidance to “Europe” and “European” should be understood accordingly. EU requirements do not give patients any rights to be refunded for treatment received outside the countries on this list.

4. Existing arrangements and recent case-law from the European Court of Justice

- 4.1 There are long-standing arrangements, under European law, to handle requests from patients for hospital treatment in other parts of the EU. Under European legislation (Regulation 1408/71¹), patients can apply for an E112 authorisation, which the Department issues, after receiving confirmation that the relevant Board is willing to fund the treatment. Under this pre-existing system, patients are entitled to go elsewhere in Europe for treatment offered by their home health system, if they face “undue delay”, although they need to be issued with an E112 authorisation before leaving the UK. E112 authorisations can also be issued where there is no formal entitlement. This system has not been altered by the ECJ ruling in the Watts case.
- 4.2 In the Watts judgment², the ECJ ruled that its case law relating to patients seeking hospital treatment in another European country applies to UK patients. This case law takes as its starting point the principle that any action that restricts patients’ rights to receive treatment within Europe curtails the Single Market. However, the Court has accepted that health systems can justify the use of systems of “prior authorisation” before patients go abroad for treatment in hospitals. The Court has also confirmed that authorisation cannot be refused (and healthcare costs must be refunded) when the home health system cannot offer the service without “undue delay”. Boards must therefore base their decision about what “undue delay” means on a clinical assessment of the individual circumstances of the patient; this

¹ Council Regulation (EC) No 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community, see http://europa.eu/eur-lex/en/consleg/main/1971/en_1971R1408_index.html

² Judgment of the European Court of Justice, 16 May 2006, Case C-372/04, The Queen (on the application of Mrs. Yvonne Watts) v Bedford Primary Care Trust and the Secretary of State for Health, see <http://www.curia.eu.int/>

assessment needs to be kept under review while the patient is waiting for treatment.

- 4.3 The ECJ criticised the UK for not having clear criteria for managing its prior authorisation systems, the rest of this guidance gives advice about how Boards can put effective processes in place.
- 4.4 In managing requests, Boards should bear in mind that there are now two different routes for treatment in other European countries under EU legislation, the **E112 authorisation** route and the **Article 49** route, [Article 49 is the Article of the Treaty which guarantees the rights of service users to access services (and the rights of service providers to provide services) in the Single Market]. Further details about which route is appropriate are given in paragraphs 7-8.

5. Action

- 5.1 Boards must ensure that their arrangements for handling requests to go to other European countries for hospital treatment are managed in accordance with the requirements set out in the Watts case. As an aid, a flowchart for assessing requests to go abroad for treatment is set out at Annex 3.
- 5.2 The Department believes that it is in the financial and the clinical interests of both patients and Boards to sort out the arrangements that will apply to treatment abroad **before** the patient goes for treatment. Where Boards have "prior authorisation" processes in place for handling requests, they can normally refuse to refund treatment costs to patients who go abroad for treatment without seeking prior approval, except where the patient faces undue delay (see paragraph 6.4).

6. Specific points relevant to handling requests for treatment in other European countries

The following points are worth highlighting in the process.

Does the Board offer the service?

- 6.1 European case law respects the responsibility of Member States to decide, and prioritise, the services that they offer their populations, so long as this is done in an objective and transparent manner. This means that a Board is entitled to refuse to authorise a request for treatment that it does not fund, even if that treatment is funded elsewhere in the UK.
- 6.2 There may be exceptional circumstances where Boards will be prepared to agree to a request for a service that is not otherwise

funded: this must be determined on a case-by-case basis. In these circumstances, it is unlikely that “undue delay” will, in practice, be a consideration.

Undue delay

- 6.3 The question of whether the patient faces “undue delay” is the other factor that determines whether a patient is entitled to go elsewhere in Europe for treatment. Where the patient does not face “undue delay”, there is no requirement to authorise treatment outside the UK. However, best practice is for Boards to consider the best interests of the patients; Boards should also bear in mind that an unjustified refusal in these circumstances might constitute an infringement of EU law and Boards should consider requests on a case-by-case basis.
- 6.4 In arriving at a decision about what “undue delay” means, the ECJ has stressed that this must be based on a clinical assessment of what is a medically acceptable period for the individual clinical circumstances of the patient, and that this assessment needs to be kept under review while the patient is waiting for treatment. Therefore Boards need transparent systems for showing that assessments are kept under review separately from current waiting lists. Specifically, the ECJ has said that offering treatment within a national waiting time target does not necessarily avoid “undue delay”.
- 6.5 Boards should be aware that “undue delay” may be relevant to the decision of whether to refund treatment costs to patients who have gone abroad without first seeking prior authorisation. Normally, if Boards have systems of prior authorisation in place, they can refuse to refund payment to patients who go abroad without first seeking authorisation. However, if the Board decides that “undue delay” applied to the individual circumstances of the patient in this situation, they should consider whether they should refund the patient. Given the recent substantial decrease in waiting times in the health service, the number of situations where the patient is likely to face “undue delay” has reduced significantly in recent years.

Which route, E112 authorisation or Article 49?

- 6.6 Below are the main practical differences between the two routes:
- E112 authorisations are issued currently by the Department, although the decisions about whether to offer the service and about the patients’ clinical needs are based on the advice of a health service Consultant. The Board is liable to pay the full cost of treatment (if free to the patient in the country of treatment) or the amount reimbursed by the state system (if treatment is not free to the patient), even if these costs are greater than in Northern

Ireland. Where co-payments are charged, the Board is also liable to pay any difference between costs reimbursed in the country of treatment and cost of treatment in Northern Ireland (where higher). The Department reserves the right to confirm that Boards agree to pay the costs of treatment under the E112 system before granting approval.

- Prior authorisation under Article 49 is handled locally, including the arrangements for refunding the patient, who will normally pay the hospital abroad directly for the treatment received. Boards are only liable to pay costs equivalent to those of treatment in Northern Ireland, or the actual cost of treatment, whichever is the lower.

6.7 If the patient wishes to be treated in a hospital which is not part of a state system, then the EU regulations do not allow an E112 authorisation to be used: the Article 49 route must be used.

6.8 In other circumstances, either route can, in principle, be used. However, in circumstances where undue delay does not apply, the Department may seek justification from Boards that the use of an E112 authorisation represents effective value for money for the health service, if use of the E112 route results in greater expenditure by the health service than would be the case if the Article 49 route (which restricts the amounts paid to the costs of treatment in the health service) were used. Where undue delay applies, the patient may be able to insist on the referral route.

7. The prior authorisation agreement [(Article 49 route)]

7.1 On request, the Board should write to the patient, setting out the exact terms of the prior authorisation and related arrangements. This is for the benefit of both parties, and is the way in which the patient can be certain of the financial and clinical care arrangements that will apply.

7.2 It is also the opportunity to ensure that the patient is aware that the responsibility for ensuring the quality of the care that the patient receives is that of the health system in the country of treatment. It is important that patients understand that the health service cannot vouch for the quality of providers that the HPSS neither oversees nor regulates. The letter also provides an opportunity to set out what care arrangements the patient can expect when they return to Northern Ireland. Specifically the letter will allow Boards to set out that authorisation will not make the health service liable for any clinical negligence and that any liability of the provider would have to be established in accordance with the legislation of the host state.

7.3 Practically, the prior authorisation letter should include at least the following:

- financial arrangements: who will pay what to whom and when (reimbursements will be retrospective); the health service tariff for the treatment (where this is relevant); the total cost of the treatment abroad and payment mechanisms.
- any travel and subsistence costs, the health service is only required to pay these where patients would have been eligible, on a means-tested basis, to receive reimbursement for such costs if treatment had been provided in Northern Ireland;
- an explanation that the health service is not responsible for the quality of the care that will be provided in the country of treatment;
- an explanation that legal liability will be decided in accordance with the law of the host state, including (where appropriate) an explicit statement that the patient is not covered by the Clinical Negligence Pre-Action Protocol, and the need to insure themselves against negligence (and other risks, such as the cost of repatriation);
- clinical arrangements: in particular arrangements for continued care when the patient returns to Northern Ireland.

8. What happens if patients disagree with decisions taken by the Boards?

- 8.1 Boards need to ensure that patients can appeal against decisions made on requests for treatment in other European countries. Currently, the only means of challenging such a refusal is by way of judicial review. Boards therefore may wish to put in place an internal system for review of their decisions (either refusals to make recommendations to the Department under the existing E112 system or refusals to authorise under Article 49). This can be done, for example, through the standard processes that Boards will already have in place to deal with appeals against their decisions about domestic commissioning. However, patients would not be obliged to use such a system and must be told of their rights to seek judicial review of adverse decisions.

9. Planning and Financial Stability:

- 9.1 The European requirements about dealing with requests to be treated elsewhere in Europe are intended to respect the responsibilities that Boards have for planning, organising and managing healthcare services. If the volume of requests for treatment in Europe increases to an extent that may damage planning etc of healthcare services, it may be possible to reconsider the criteria for granting authorisation. Boards should alert the Department if the number of authorisations granted increases significantly.

Annex 1

List of the countries where patients can ask to be treated under EU requirements

EU Member States (other than UK)

Austria	Germany	Netherlands
Belgium	Greece	Poland
Bulgaria	Hungary	Portugal
Cyprus	Ireland	Romania
Czech Republic	Italy	Slovakia
Denmark	Latvia	Slovenia
Estonia	Lithuania	Spain
Finland	Luxembourg	Sweden
France	Malta	

Non-EU Member States

Norway
Iceland
Liechtenstein
Switzerland (E112 route only)

Annex 2

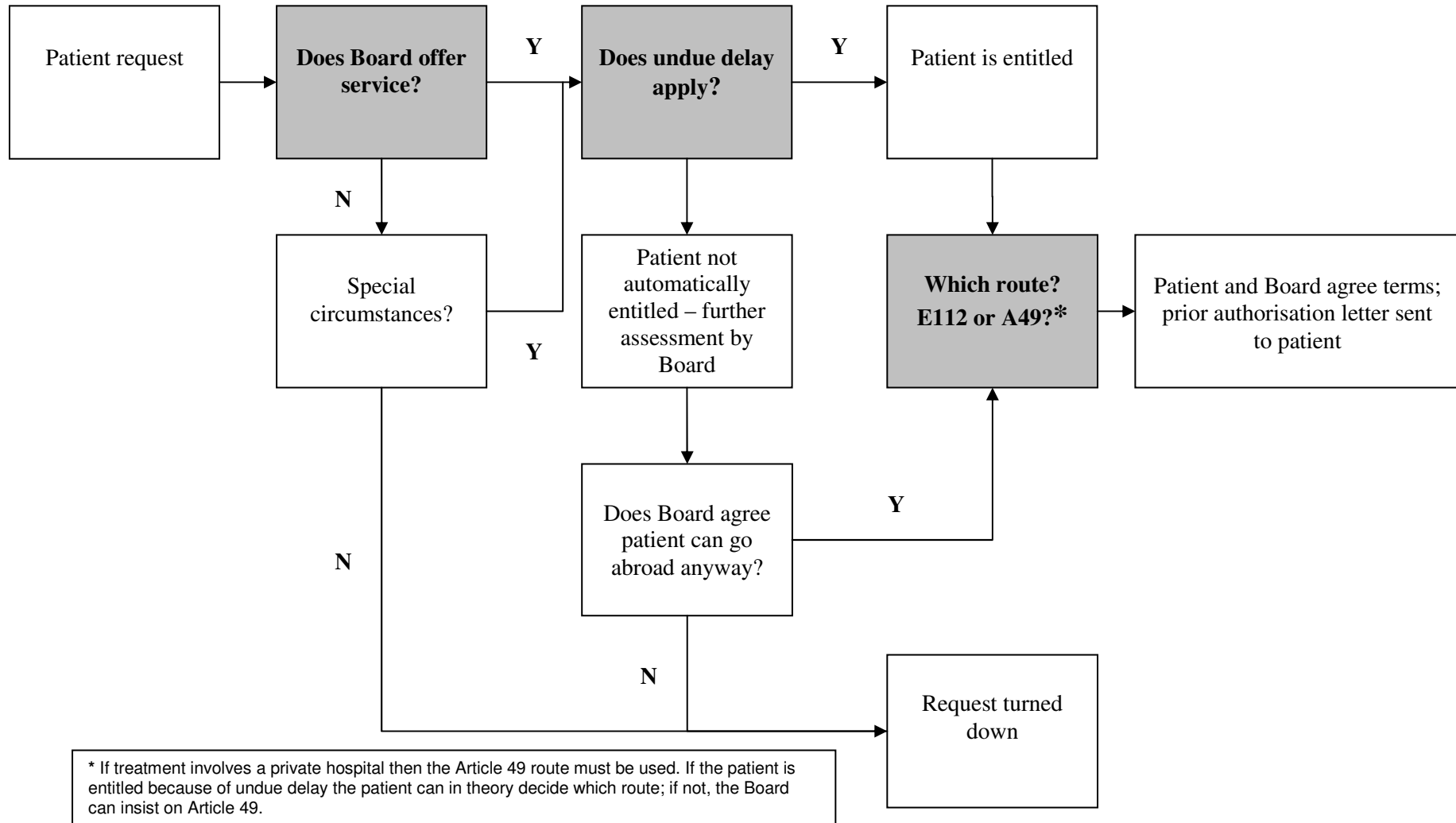
Handling Non-Hospital Services

1. This annex sets out the guidance as to how the health service should handle requests to go to other European countries for non-hospital care.
2. The ECJ is sceptical of the need for health systems to have prior authorisation systems for patients who want to go to other European countries for non-hospital care, because this may unjustifiably restrict the Single Market. However, prior authorisation may be justifiable if it is necessary to protect the financial stability of health systems and to allow for effective planning, particularly of services or treatments whose individual unit costs are high. The Court has also shown itself sympathetic to the idea of having a 'gatekeeper' function.
3. The view of the Department is that it is important, in the case of non-hospital services, for Boards to distinguish between:
 - a. services for which it is not necessary for Boards to put in place prior authorisation processes for patients that wish to access these services in other parts of Europe. These might include simple GP consultations, optometry, pharmacy and some dental treatments; and
 - b. a range of services that are not provided in hospitals in Northern Ireland whose complexity and cost makes them more similar to services provided in hospitals than other primary care services: mostly these are services subject to referral or which are part of complex patient pathways. Here, Boards may consider that there are justifications for having a requirement for prior authorisation in place before patients access these services elsewhere in Europe. In particular this justification would be based on issues such as:
 - i. the high unit costs of treatment, especially in the context of the direction of travel set out in the Primary Care White Paper, of getting services out of hospitals into more local settings;
 - ii. the need to ensure effective clinical governance of complex patient pathways, especially for complex chronic conditions, where treatment is not being sought on a "one-off" basis;
 - iii. circumstances where it is in the patient's own interest to be aware of issues such as the costs that the health service will refund, the arrangements for aftercare when the patient returns to Northern Ireland, and the arrangements that apply for clinical liability.

In respect of these latter services, Boards should ensure that they have processes in place to agree with the patient the conditions that apply to accessing such treatment in other EU countries, along the lines set out in paragraph 8 of the hospital guidance. They should also make sure that their local populations are aware of any prior authorisation requirement.

4. Particular care is needed in handling requests for dental care abroad since it is difficult for Boards to establish after the event whether any treatment undertaken abroad was clinically necessary and therefore of a sort that would have been provided by the health service. Boards are advised to introduce a voluntary gateway system, under which they would reimburse patients only if:
 - a. a health service Treatment Plan, or similar form, was completed prior to the patient going abroad for treatment; or
 - b. if such a form was not completed prior to treatment, the patient could present evidence (eg patient records, x-rays) to satisfy the Board that the treatment received was clinically necessary. Boards might consider asking the Dental Referral Service in the Department to carry out post-treatment assessments in the case of particularly expensive claims.
5. Boards will wish to ensure that the level of reimbursement in each case is kept to a reasonable minimum. This would limit reimbursement to the average cost paid by Boards for the equivalent health service course of treatment, or the actual cost of treatment overseas if this was lower. Patient charges that would have been paid should, naturally, be deducted from any refund.
6. The logic of the ECJ's rulings is that requests for treatment elsewhere in Europe should be subject to the same conditions as attached to treatment on the health service and should not cost the health service more than it would have spent treating the patient in the health service. The Department stresses, therefore, that:
 - a. even in circumstances where prior authorisation is not required, patients cannot insist that they are reimbursed for healthcare products and services that Boards do not offer in the health service;
 - b. where a service is available in the health service on referral, patients will need to validate with their Board any referral that might arise from a non-hospital contact in another European health system.

Annex 3 Flow chart to show process for assessing request to go abroad for treatment



10 Action

10.1 You are asked to note the enclosed guidance, bring its contents to the attention of all relevant staff and take any appropriate action required.

11. Queries

11.1 Any queries regarding this Circular, or requests for further copies, should be addressed to:

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Yours sincerely

JOHN FARRELL

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