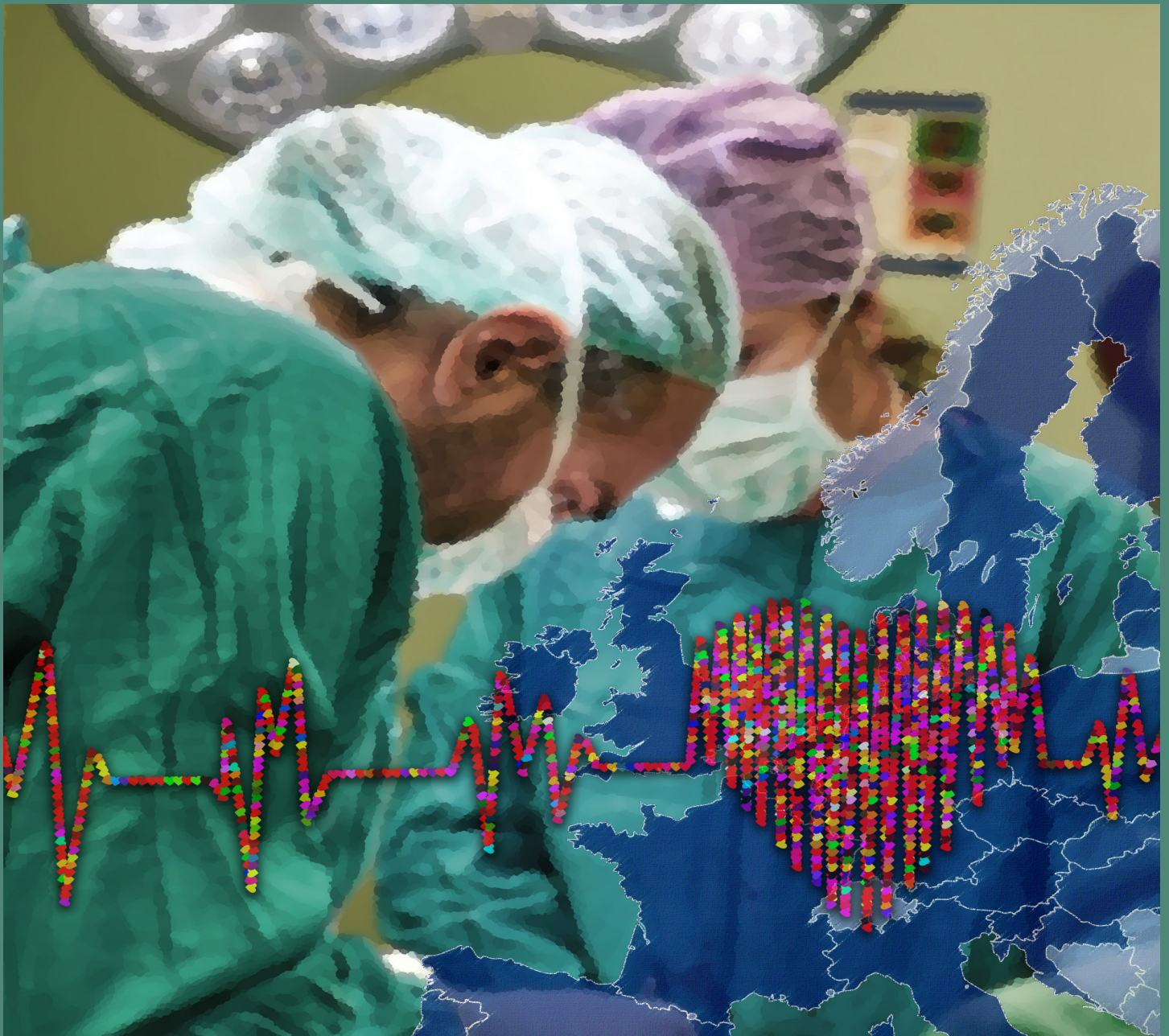


Treatment Abroad



Ombudsman

An investigation by the Ombudsman into the
administration of the Treatment Abroad Scheme
by the Health Service Executive (HSE)





Ombudsman

2018 Office of the Ombudsman

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Ombudsman

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An investigation by the Ombudsman into the administration of
the Treatment Abroad Scheme by the Health Service Executive (HSE)

(Under Section 4 of the Ombudsman Act 1980, as amended)

January 2018

Foreword

Many people who have suffered painful and debilitating illness will know the lengths to which they are prepared to go to find a remedy for their medical condition. For some, their journey through the Irish healthcare system does not always produce the outcome they need. While Ireland is renowned as a country whose healthcare services are among the best in the world, expertise in the treatment of some rare diseases and medical conditions is not as developed here as it is elsewhere, and there are logical reasons why this should be the case.

Compared to many countries in Europe, Ireland has a small population. It is not always feasible, from an investment and resource perspective, for Irish healthcare services to develop expertise and provide specialist treatments for illnesses and conditions which are very rare among our population. For specialists to maintain and develop cutting edge clinical expertise in rare and complex medical challenges they need to be working with a ‘critical mass’ of patients.

The Treatment Abroad Scheme (TAS) was introduced to ensure that all EU / EEA patients, including Irish patients, have access to the same level of medical expertise and treatments regardless of their state of residence. Where treatments and remedies they need are available in the EU / EEA, but not in Ireland, (or not available within a reasonable time-frame) Irish patients may apply for funding under the TAS to travel for the treatment.

My investigation into the TAS was prompted by a complaint I received from a patient who experienced significant difficulty and delay in accessing treatment abroad under the scheme. This resulted in his having to endure severe pain for several months longer than he should have. This in turn caused deep distress for him and his family. After conducting a preliminary examination of that complaint I decided to initiate a wider-ranging systemic investigation, under Section 4 of the Ombudsman Act 1980, as amended, of the actions of the HSE in administering the scheme and the processing of TAS referrals by Irish-based consultants.

Within the Irish healthcare system the proportion of patients who seek funding under the TAS is very small. This is a reflection that the highest standards of healthcare are generally available here. The HSE reports that for the vast majority of patients who seek treatment abroad under the scheme the application process works well. However, for a small number, the experience was extremely stressful and upsetting, and it really didn’t need to be.



TREATMENT ABROAD

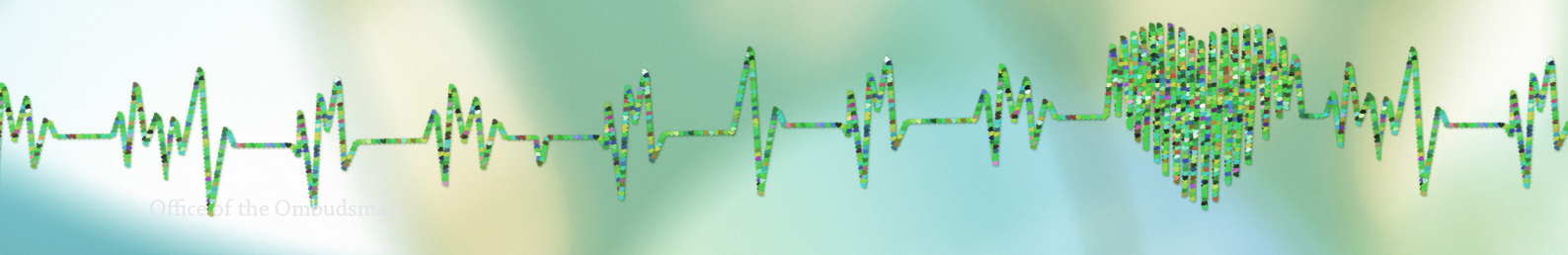
An Investigation by the Ombudsman into the administration of the Treatment Abroad Scheme by the Health Service Executive (HSE)

Patients who seek treatment abroad can be at a very low ebb in their lives as a result of their unresolved health problems. The possibility, that treatment abroad might resolve or bring relief to their health problem, is likely to raise feelings of new hope in them. A refusal of funding under the TAS scheme at this stage in their healthcare journey is therefore likely to have a devastating effect.

My recommendations for administrative improvements in the TAS scheme are intended to eliminate the possibility of this kind of devastating refusal. They are also intended to bring additional clarity for patients and consultants alike to what is a particularly complex scheme to understand.



**Peter Tyndall
Ombudsman
January 2018**



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Preface

The Treatment Abroad Scheme (TAS) is a European Union wide scheme. It was established under Council Regulation (EEC) No 1408/71 (and operated under Council Regulation (EEC) No 574/72), which essentially provides for the coordination of national medical and social support legislation to ensure the rights of EU citizens moving between states within the European Union are protected.

In effect the Treatment Abroad Scheme (TAS) ensures that all European Union (EU) / European Economic Area (EEA) public patients, including Irish patients, have access to the same level of medical expertise and treatments regardless of their state of residence. Where the treatments and remedies they need are available in the EU / EEA or Switzerland, but not in the patient's home state, (or not available within a reasonable time-frame) Irish patients may apply for funding under the TAS to travel for the treatment.

Because the highest standards in healthcare provision are comprehensively available in Ireland, with new exciting cutting edge treatments being developed here on an ongoing basis, the numbers of patients who need a referral abroad for treatment which is not available in this country, is always going to be very small. There were fewer than 800 applicants in each of the past four years. The expenditure for the scheme averaged approximately €9 million for those years. The annual healthcare budget in 2017 was some €13 billion.

It should also be noted that patient traffic is not just one way. Patients residing in other EU / EEA states travel to Ireland to receive certain specialist treatments not available in their own home states.

As the development of specialist expertise in clinical techniques and medical care continues throughout Europe more and more centres of expertise are being established.

In the case of rare diseases, centres of expertise are becoming recognised and registered as European Reference Networks (ERNs). ERNs create a clear governance structure for knowledge sharing and networking of centres of expertise across Europe. It is their mission to improve the overall quality and management of care for patients with rare diseases. There are currently 24 European Reference Networks. Irish healthcare providers are represented as full members on three of these networks. In July 2015, the HSE established a National Rare Diseases Office and appointed a National Clinical Lead as head of the office. These are all welcome developments.

Over the years, Regulation 1408/71 was amended and updated on numerous occasions to take account of developments in the European Union as well as judgements of the Court of Justice and changes in legislation at national level. Regulation 1408/71 was later replaced by Regulation (EC) No 883/2004.

In Ireland the Health Service Executive (HSE) is the public body with responsibility for the administration of the TAS scheme. The HSE assesses applications from public patients, who are referred by their Irish-based treating consultant for treatment in another EU / EEA member state or Switzerland, against the eligibility criteria set out in the scheme. Prior to 2012, applications for TAS

funding were processed in local HSE offices throughout the country. In 2012, the HSE completed the centralisation of the assessment and processing administration for TAS applications in St Canice's Hospital, Kilkenny.

Where an application under the TAS scheme is approved, the HSE provides the costs of treatment and healthcare, and in certain circumstances it also approves travel costs.

An Irish-based consultant interviewed during this investigation described treatments for patients as falling into two broad categories –

- Surgical ... when patients require a 'point in time' surgical response, and
- Medical ... which includes the treatment of chronic diseases and illnesses

The HSE told us that the vast majority of consultants' referrals under the TAS scheme are for a surgical intervention at a point in time, and that the majority of these referrals are for specialist surgical treatments which are clearly not available in Ireland. Paediatric patients are among the largest cohorts of patient for whom TAS referrals are made.

The HSE reported that over the past five years some 95% of TAS applications were processed and approved in a timely manner. The HSE aims to provide a decision on an application within 15 to 20 working days. While the investigation did not examine approved applications the Ombudsman acknowledges that for the majority of applicants the TAS scheme appears to work well.

As the majority of TAS applicants require surgical treatment, determining whether a treatment specified in an application falls within the scope of the TAS scheme is generally straightforward. The investigation focused more on the processes involved in deciding applications from patients who need 'medical' treatment and support, particularly where referring consultants cannot 'specify the treatment' their patients need. Examples of this include the referral of patients to centres abroad where a higher level of expertise has been developed and the consultant wishes to obtain a second or specialist opinion on a care and treatment plan which will alleviate the patient's acute or complex symptoms.

This investigation was initially prompted by a complaint received by the Ombudsman from a patient with a rare, debilitating and painful hereditary disease. The examination of that complaint identified significant shortfalls and weaknesses in the TAS application process, which resulted in unnecessary distress and delay for the patient and his family. A wider ranging investigation of the TAS application and assessment process identified administrative weaknesses, which left unchecked, have the potential to cause similar delay and distress for others.



Executive Summary

Public sector bodies must embody certain essential values. These include clarity of information; openness; transparency; respect; dignity; helpfulness; fair process and the right of appeal.

Best practice in public administration demands that for every public services scheme, there should be access to sufficient information and explanatory documentation so that applicants can easily understand -

- (i) how the scheme works;
- (ii) their entitlements under the scheme;
- (iii) the conditions governing their entitlement;
- (iv) the application process, and
- (v) how to seek an independent appeal / review should their application be refused

It is also a principle of best practice for public services providers to ensure that their administrative systems for accepting and processing applications are -

- (i) clear and simple;
- (ii) easily accessed;
- (iii) operated in a helpful and timely manner;
- (iv) free from barrier and bias;
- (v) transparent, and
- (vi) fair

This investigation by the Office of the Ombudsman-

- (i) looks at the qualifying conditions for the Treatment Abroad Scheme;
- (ii) examines the application process including the assessment of applications;
- (iii) examines the appeals process and
- (iv) reveals examples where unnecessary difficulties and delays were experienced by patients, because of an inappropriate administrative structure for processing funding applications

The names of patients who complained to the Ombudsman about their experiences have been changed to protect their identity.

The key findings are set out in this section along with recommendations to address administrative weaknesses and barriers.

Key findings and recommendations

1. Consultant TAS Referrals

The current administrative process for considering applications for TAS funding requires a patient to request an application form which they then must submit to the central HSE TAS Office in Kilkenny, fully completed and signed by both the applicant and their Irish based referring consultant.

The patient's referring consultant (who must be an Irish based public healthcare consultant) is not authorised to approve or refuse TAS funding applications. In effect, the referring consultant joins with the applicant in seeking approval for funding for the patient to travel abroad for treatment identified by the consultant, which is not available in Ireland (or available within a reasonable time-frame).

Insofar as possible a consultant should not initiate a TAS referral which does not meet the conditions for approval of funding under the TAS scheme. Refusals of funding applications are likely to be very distressing for patients and their families.

Before a patient is informed by a consultant that they propose to refer them abroad for treatment, the consultant (or their team) should ensure that the referral meets the conditions set out in the TAS scheme for eligibility.

When a referring consultant has established that his or her patient needs treatment abroad, which is not available in Ireland, and which meets the conditions for approval under the TAS scheme, there should be no need for further assessment within the HSE's TAS application process.

Essentially, the consultant's role in referring a patient for treatment under the TAS scheme should be no different to his or her role in referring a patient for treatment to another consultant based in Ireland. There should be no administrative impediment restricting consultants in their exercise of care and treatment decisions or choosing a medical care pathway for their patients.

Updated guidance in regard to treatment abroad with particular reference to EU law, issued by the Department of Health in September 2008 states, inter alia, *"The HSE should also be cognisant of the fact that criteria for assessment of requests for treatment abroad should not be more rigorous than those imposed for treatment at home. It is only on the basis that these criteria apply equally to all treatment provided by the HSE that they are acceptable under European Law in relation to cross-border treatment"*.

Recommendation 1

Before an Irish based referring consultant initiates a TAS referral for treatment abroad he / she should carry out a 'pre-referral check' with an appropriate national contact point to ensure that the qualifying conditions for approval of funding under the TAS scheme are met. The input of National Clinical Leads, other specialists and European Reference Networks is envisaged in the pre-referral check process.

Only after a patient's eligibility under the TAS scheme has been established by the consultant should the patient be invited to complete an application form (E112) for TAS funding.



2. Guide to TAS for consultants

There are and will continue to be occasions when consultants may not be fully familiar with the extent to which tertiary services are available in Ireland or elsewhere in the EU / EEA member states. An example of this might be when a consultant is treating a patient with a rare disease or medical condition.

In considering whether to refer a patient for treatment abroad a consultant must have recourse to a comprehensive suite of information on the availability of expert treatments and healthcare both in Ireland and the EU / EEA for a presenting medical challenge.

In the course of their deliberations consultants should have access to the HSE's National Clinical Leads or other designated national contact point, for advice and guidance on the availability of relevant tertiary services in Ireland. In the event that appropriate treatment is not available here, National Clinical Leads should advise consultants about potential TAS appropriate healthcare solutions in other EU/ EEA member states, and elsewhere, where these are available.

Consultants and their teams also need to fully understand the conditions for patient eligibility under the TAS scheme and how to access TAS funding efficiently and effectively. While the HSE posts guidance for consultants on referring patients for funding under the TAS scheme this guidance inadequately addresses the complexities that arise in referrals and applications.

Recommendation 2

- (i) A comprehensive guide to the TAS scheme needs to be developed and maintained online, in support of the introduction of a 'pre-referral check system' by consultants, before they initiate referrals abroad and before they advise patients to submit TAS applications.
- (ii) The guide should set out the steps consultants must follow to enable decision makers to consider whether the proposed referral abroad meets the conditions for approval of TAS funding.
- (iii) It should comprehensively explain the qualifying conditions for TAS funding.
- (iv) It should set out the steps consultants should follow when they need information or guidance regarding medical criteria for eligibility under the scheme.
- (v) It should set out the administrative process for activating and recording referrals.

3. TAS Medical Advice

Over the past few years the TAS administration office in Kilkenny invited a number of medical practitioners to become ‘medical advisors’ to that office where it has reason to doubt the medical appropriateness of a referral abroad under the TAS scheme. An ad hoc panel of largely voluntary medical advisors has been established for this purpose. The names of medical advisors on the panel are not published.

Applications being considered by the TAS office for approval under the scheme are referred to a medical advisor for an opinion on matters such as –

- Is the treatment available in Ireland?
- Is the treatment a proven form of treatment?
- Have all avenues for treatment in Ireland been exhausted?

If in the opinion of a medical advisor a referral abroad may not be appropriate or necessary the application for TAS funding is refused. There is no formal provision in the TAS administrative process, for a referring consultant or a patient to challenge the advice provided by a medical advisor which has resulted in the refusal of the TAS application. Neither is there any provision for a patient or consultant to appeal the decision to an independent / impartial medical expert.

This kind of assessment process does not conform to the standards of transparency and fairness required today in public administration.

The TAS administration office itself has expressed concerns about equity and transparency in relation to due diligence with regard to certain medical advice in the assessment of TAS applications.

Recommendation 3

Medical advice, where required, on the appropriateness of a TAS referral should be sought by the referring consultant from the relevant National Level Clinical Specialist.

4. Proven Form of Treatment

One of the qualifying conditions which must be met for an applicant to be deemed eligible for TAS funding is that treatment for which a patient is being referred is a ‘proven form of treatment’. The scheme does not fund patients for treatment abroad which is considered to be experimental.

However, there may be cutting edge treatments which are considered to be ‘proven forms of treatment’ in other EU member states but not in Ireland. This presumption is based on the fact that some new treatments are provided to patients in other EU states through their national healthcare system which may not be considered as ‘proven forms of treatment’ in Ireland.



An example of one such treatment is lung volume reduction treatment (LVRT), which is available for patients with chronic obstructive pulmonary disease (COPD) in Germany.

In a complaint to the Ombudsman a patient who applied for funding under the TAS scheme for LVRT treatment in Germany was refused on the basis that the treatment was 'not a proven form of treatment'. TAS administration in Kilkenny based the refusal on medical advice it received from a medical advisor to that effect.

This raised a question for the Ombudsman. Is there a comprehensive list anywhere in Ireland or the EU / EEA area of 'proven forms of treatment'?

The TAS scheme provides for patients to travel abroad to receive treatment which is not available in Ireland (or available within a reasonable timeframe). There are several other conditions also including –

- (i) The treatment must be among the benefits provided for by Irish legislation.
- (ii) It is not considered to be an 'illegal treatment' under Irish legislation.
- (iii) The treatment must be medically necessary and will meet the patient's needs.
- (iv) The referral pathway must be public healthcare in Ireland to public healthcare abroad.

A Department of Health letter (16 September 2008) with "Updated guidance regarding treatment abroad, with particular reference to EU law" states, inter alia, "*E112 arrangements have traditionally provided scope for referring patients for medically necessary procedures or treatments that because of their highly specialised nature, are not available in Ireland, and this approach should be continued.*"

Clearly, considering applications in which these questions arise is complex for the TAS assessment office, not least as the referring consultant may have confirmed that the treatment for which the patient is being referred meets all the qualifying conditions. The current practice whereby the view of a medical advisor may be sourced and relied upon to be the deciding factor in decisions of such importance is not sustainable.

Recommendation 4

- (i) In the event that a referring consultant is uncertain whether a treatment for which he / she is referring a patient is a 'proven form of treatment' he / she should obtain the views of the relevant National Level Clinical Specialist.
- (ii) In the event that there is a difference of opinion between the referring consultant and the National Level Clinical Specialist the matter should be referred to a European Reference Network or other relevant European specialist centre with a view to reaching a final decision.
- (iii) In the interest of fairness and transparency for patients being referred the process for selecting specialists to consider the balance of merit in opinions held by a referring consultant and the National Level Clinical Specialist must ensure independence and impartiality.

5. Decision Notification

The HSE reported that over the past five years, approximately 95% of TAS funding applications were approved in an effective and timely manner.

The vast majority of TAS applications are for specified ‘surgical treatments’, which are not available in Ireland and there is no ambiguity about whether they are covered by the TAS scheme. For many of these procedures the HSE has established a list it considers as a ‘pre-approved list’. The TAS office does not require an opinion from a medical advisor on its panel of advisors when processing applications for pre-approved treatments.

Processing applications for TAS funding for ‘medical treatments’ abroad, including referrals for second or expert opinion is more complex. This investigation revealed that where TAS applications did not meet all of the criteria for approval, or where application forms were not fully completed, the applications were deemed to be ‘invalid’ rather than refused. Examples of reasons for declining an application as ‘invalid’ included – referrals for second or specialist opinion; not a proven form of treatment; referral pathway is not public healthcare in Ireland to public healthcare abroad; and more.

When an application is deemed to be invalid the HSE considers that the application was not refused and therefore the applicant has no right of appeal. Applicants who have submitted an application for TAS funding are entitled to receive a formal refusal, setting out the basis for the refusal and informing them they have a right to appeal the decision in every case. The practice of informing applicants that their application was invalid and therefore they have no right of appeal should be terminated.

The 95% approval rate for TAS applications provided by the HSE excludes applications which were deemed to be ‘invalid’ applications.

Recommendation 5

- (i) All TAS applicants not approved for funding should receive a formal decision setting out the basis on which their application was refused. The decision notification should include clear information about how to submit an appeal.
- (ii) Applicants who are refused funding under the TAS scheme should be informed about their right to complain to the Ombudsman’s Office.

6. Appeals

The present administrative structure for processing and deciding applications for TAS funding is managed by the TAS central processing office in Kilkenny. When a patient is unhappy with a decision refusing their application they have a right to appeal that decision to the Assistant National Director for HSE Contracts, who has overall management responsibility for the TAS scheme as well.

Indeed, under the present administrative structure an Irish based consultant may also be unhappy that a referral has not been supported.

An appeals structure should offer applicants a right to have the basis for their refusal considered in an informed, impartial, meaningful and fair manner. But where a patient's application is refused on the grounds that – the treatment is not specified; or the treatment is not a proven form of treatment; or the treatment is available elsewhere in Ireland; it is not possible for applicants to appeal such decisions in an informed and meaningful manner.

In these circumstances one might consider that it should be the consultant who makes the appeal, as only the consultant is qualified to present an informed argument. However, as the consultant and the TAS deciding officer are both employees of the HSE there is no formal process through which a consultant can appeal an administrative decision refusing an application. Under the recommended revised procedure whereby consultants will carry out 'pre-referral checks' to ensure a TAS referral will not be refused after a formal TAS application has been submitted, refusals of this nature should not occur.

In some circumstances patients themselves may discover a treatment abroad they believe will help or resolve their medical condition and ask their consultant to arrange for a TAS referral. There will be circumstances where the consultant is not in agreement with the patient and refuse to initiate a referral. Under the EU regulation governing the TAS scheme patients have a right to apply for treatment abroad and to have their application fully considered. In the event that their request for a referral abroad under the TAS scheme is refused by their consultant they have a right to appeal that refusal.

Recommendation 6

The HSE should establish an appeals process, which is independent of the original decision makers and which has the necessary expertise and competence to arbitrate on any clinical and non-clinical matters under appeal.

7. TAS Information and Guidance

The governing legislation for the Treatment Abroad Scheme was founded in Regulation (EEC) 1408/71. This regulation was amended many times and eventually replaced by Regulation (EC) 883/2004. These regulations are largely concerned with the freedom of movement of citizens between EU member states and how their social and medical support entitlements are governed, preserved and potentially enhanced by virtue of being members of the European Union or the EEA.

The HSE's conditions for Irish patients who wish to avail of the Treatment Abroad Scheme are largely derived from the EU (formerly EEC and EC) Regulations. However, they also derive from European case law and Department of Health Guidelines on interpretations and administrative necessities.

The plethora of EU Regulations, amendments, court cases and guidelines relating to a patient's eligibility for funding to travel abroad for treatment are too numerous and complex for the average patient and consultant to navigate. They rely on the HSE to provide clear and simple information in documentary or web based format to help them to understand their rights and opportunities under the TAS scheme. Patients who research possible solutions for their unresolved medical conditions must also navigate the online labyrinth of international medical and surgical treatments.

It is incumbent on the HSE to provide clear, simple and comprehensive information for patients (and consultants) about how to access specialist treatment and medical care abroad that may not be available in Ireland, or available within a reasonable time-frame. The HSE's information currently available online and in documentary format is inadequate, and in some regards, misleading. Examples of this are illustrated later in this report.

Recommendation 7

The HSE should develop new guidance on the TAS for patients and consultants which is accurate, comprehensive and easy to understand for patients and consultants alike.



8. Assisting Applicants

Section 4a of the Ombudsman Act 1980, as amended, obliges reviewable agencies in the performance of administrative functions, to provide ‘reasonable assistance’ to applicants wishing to avail of a “*right, privilege or other benefit to which an eligible person is or may be entitled...*”.

This investigation did not examine in detail the steps the HSE has taken to ensure that applicants for TAS funding are given ‘reasonable assistance’ in their pursuit of treatment or medical care abroad.

The current assessment process for determining eligibility for TAS funding falls to the TAS administration office in Kilkenny. Applications are considered and may be refused for many reasons including – ‘the treatment is available in Ireland’; ‘the treatment is not a proven form of treatment’; ‘the treatment was not specified’; and many more. The investigation considered whether the TAS administrative office had been sufficiently helpful in informing applicants where the treatment is available in Ireland; or why the treatment was considered not to be a proven form of treatment; or if the treatment was not specified that there are circumstances when the treatment does not need to be specified for a funding application to be approved.

In some cases a patient may not qualify for funding under the TAS scheme, but may be entitled to funding support under the Cross Border Directive. The obligation to provide reasonable assistance to applicants requires TAS officials to inform unsuccessful applicants about any possible alternative routes to the medical care they are seeking. In complaint cases examined by the Ombudsman it is evident that ‘reasonable assistance’ may not have been provided.

Providing advice and assistance to patients rather than simply refusing an application as ‘invalid’ or ‘incomplete’ would also help to avoid causing distress and delay for patients who may already be at a very low ebb.

A culture of providing advice and assistance for patients seeking access to treatment abroad should be actively fostered.

Recommendation 8

- (i) A guideline or protocol for staff on the provision of reasonable assistance in the administration of the TAS should be drafted.
- (ii) Training should be provided for staff on the provision of reasonable assistance to applicants.

9. Publicising the TAS scheme

Key to success in delivering health services is health promotion. An obvious value of the Treatment Abroad Scheme for Irish public patients is that it gives them access to specialist expertise which may not be available in Ireland, but which is available in the EU / EEA. However, many patients will be unaware of this possible treatment pathway.

Recommendation 9

In order to maximise the value of this healthcare pathway for Irish patients, the HSE should actively advise patients and clinicians about the TAS scheme as a possible access route to expert treatment abroad for certain patients.

10. TAS Protocols

In recent years the TAS central office compiled a suite of protocols to assist consultants who may be considering a patient referral under the TAS scheme. These protocols explain the TAS administrative processes as well as particular considerations relating to certain medical conditions. The protocols are also used as a guide for administrative staff assessing TAS funding applications.

The principle of drafting protocols for the purpose of bringing clarity and efficiency to the TAS application process is sound. However, there is insufficient information and clarity in some protocols which may lead to incorrect refusals of TAS applications.

Many of the TAS protocols are not available on the HSE's website or in documentary format for consideration by patients or consultants.

Recommendation 10

- (i) There should be a thorough review of protocols to ensure they are clear, comprehensive and fully informative.
- (ii) Additional protocols should be drafted where possible to bring further clarity and guidance for consultants and patients about the TAS scheme.
- (iii) In the interest of transparency and fairness all protocols should be published on the HSE's website and in information leaflet format.



11. Implementation Plan

In responding to the Ombudsman the HSE welcomed the investigation report, saying that it values external reviews on the various services and schemes within its remit. Reviews of this kind bring new perspectives and fresh thinking to what are often complex areas of healthcare which directly impact on the lives of citizens. The HSE acknowledged that the Ombudsman's reviews have contributed in no small measure to improvements in the administration of these services and schemes in terms of transparency, administrative fairness and client centredness.

The HSE stated that while some of the recommendations in this report may be challenging for it, it is committed to achieving the best possible standards in providing accurate, helpful information for the public and clinicians, and to provide the maximum assistance possible to patients in terms of accessing health services, whether in Ireland or in other EU jurisdictions where this is necessary. The HSE has committed to working closely with the Ombudsman in this regard.

Recommendation 11

- (i) The HSE should respond to the findings and recommendations in this report by the end of February 2018, with details of an implementation plan, to include a time-frame for the completion of its implementation of the recommendations.
- (ii) The HSE should contact the Ombudsman with a view to agreeing a schedule of meetings to discuss the implementation of recommendations.
- (iii) On the last day of March 2018 and on the last day of each month thereafter, the HSE should provide a progress report to the Ombudsman on the implementation of the recommendations in this report until they have been fully incorporated.

Chapter 1

Methodology

Methodology

Complaints received by the Ombudsman revealed systemic weaknesses in the administration of the TAS scheme, which led to unnecessary delay in patient care and deep distress for the complainants. The Ombudsman initiated a wide ranging investigation into the administrative processes patients and their referring consultants must negotiate when seeking approval for TAS funding.

The Ombudsman nominated an investigator to lead the investigation. The Department of Health and the HSE each nominated senior staff to assist with the Ombudsman's investigation.

The Ombudsman conducted a review of the following documentation –

- Complaints submitted to the Ombudsman from applicants for the TAS
- HSE web based and documentary information relating to the TAS
 - Patient information and guidelines
 - Irish based referring consultant's information and guidelines
 - TAS application form
 - A random selection of TAS application files
 - A selection of management, statistical and financial information
- Underpinning TAS legislation and supporting guidelines

The investigation did not examine the legislative provisions underpinning the scheme. Nor did it consider the role of consultants in their execution of clinical judgement when deciding on appropriate patient care treatments or pathways abroad.

The Ombudsman did not invite members of the public to comment on their own experiences in seeking funding under the TAS.

The investigation did not test the satisfaction rate of TAS applicants who were approved for funding under the scheme.

The following agencies and persons were contacted and interviewed in the course of the investigation.

Patients, families and representatives of patients who complained to the Ombudsman

- The National Director, Primary Care, HSE, (Responsible for the administration of the TAS)
- The National Director, Quality Improvement, HSE
- The National Director, Acute Hospitals, HSE

- The Assistant National Director, National Contracts Office, HSE, (Management responsibility for the TAS and TAS Appeals Officer)
- The General Manager, TAS, HSE, (Operational responsibility for the TAS)
- The National Lead, Rare Diseases Clinical Programme
- The Programme Manager, Rare Diseases, Clinical Programme
- Assistant Principal, Department of Health
- Two Irish based Consultants
- The President and Secretary General, Irish Hospital Consultant's Association
- The CEO and a Patient Advocate, Patient Focus

Chapter 2

TAS Qualifying Conditions

TAS Qualifying Conditions

*The **Treatment Abroad Scheme** (TAS) is a European Union wide scheme. It was established by Council Regulation (EEC) No 1408/71, (and operated in accordance with Council Regulation (EEC) No 574/72). This Regulation was amended and updated on numerous occasions to take account of developments in the Community as well as judgements of the Court of Justice and changes of legislation at national level. The Regulation was later replaced by Regulation (EC) No 883/2004.*

An EU Regulation is a legal act of the European Union that becomes immediately enforceable as law in all member states simultaneously. EU Regulations are self-executing and do not require any implementing measures. They can be compared to acts of the Oireachtas insofar as they have binding legal force. However, EU Regulations override national laws dealing with the same subject. National legislation must be consistent with EU Regulations.

There are pathways other than the TAS for accessing medical treatment abroad, all of which have their own conditions for eligibility. These include the Cross Border Directive (CBD), the European Health Insurance Card (EHIC) and for those with private health insurance policies, treatment abroad may be included in their insurance cover. While these medical treatment pathways are broadly outlined in the appendices to this report for the sake of comparison, the investigation was confined to the Treatment Abroad Scheme alone.

EU Directives differ from EU Regulations insofar as they require member states to achieve a particular result without specifying in detail the means of achieving that result. EU Directives leave member states with some leeway with regard to how they are implemented. EU Directives must be incorporated by EU member states into national legislation.

Conditions for eligibility

The Ombudsman recognises the importance of attaching strict qualifying conditions to the TAS scheme. With the increasing availability of information on the internet, relating to all medical conditions and illnesses, new hopes can be instilled in patients whose medical treatment has not cured their illness or eliminated their pain. Resourceful patients can often find articles which purport to show evidence of miracle cures in patients abroad suffering from the same illnesses and symptoms as themselves. Understandably such patients can try to pressurise their treating consultants into referring them for a treatment abroad that may not be a proven form of treatment or even provided by a qualified physician.

A review of qualifying conditions for the TAS might give the impression that they seem simple enough to understand and are few in number. Indeed the HSE maintains that for the vast majority of applicants availing of the Treatment Abroad scheme is a simple and smooth process. However as the vast majority of applications submitted for TAS funding relate to defined surgical treatments not available in Ireland and which clearly satisfy the qualifying conditions for TAS approval the Ombudsman expects that the application process should be simple and work satisfactorily for these patients.

However, the investigation illustrates that for certain categories of applicant navigating the application process and satisfying the qualifying conditions for funding was anything but simple. Patients complained that the process caused them severe distress, delay and pain.

In general, these patients were not seeking (i) 'clearly specified surgical treatment', (ii) which is an approved form of treatment, (iii) not available in Ireland, and (iv) in a recognised medical care facility abroad. By and large these patients were seeking either 'medical treatment'; or 'specialist opinion'; or perhaps 'treatment not regarded to be an approved form of treatment'; and suchlike. These applications require a more complex assessment process and many of the questions are outside the patient's capacity to answer.

The TAS scheme also provides for the approval of funding for patients seeking 'medical treatment and specialist opinion' abroad, subject to certain conditions. The qualifying conditions and the assessment criteria in these circumstances are not straightforward, and the HSE's information for both patients and consultants about how to satisfy the conditions is inadequate, unclear and even misleading. The full range of qualifying conditions which must be satisfied for approval of TAS funding needs to be comprehensively published and properly explained by the HSE on its website and in documentary format. The HSE must also explain to applicants seeking TAS funding how the assessment is conducted and what factors are considered. When an applicant does not qualify for TAS the HSE should clearly explain the basis for the refusal, and where relevant, pointing to any possible alternative care pathways.

Applicants for TAS funding must satisfy the following conditions:-

1. That the referral pathway is public healthcare patient in Ireland to public healthcare service in the EU / EEA / Switzerland
2. That the treatment is not available in Ireland, or not available within a reasonable timeframe
3. That the treatment in question is among the benefits provided for by Irish legislation
4. That a referral for treatment abroad must be made by the patient's Irish based treating consultant
5. That the treatment for which the patient is being referred abroad to receive must be specified
6. That a clinical assessment has been carried out to demonstrate that the treatment is medically necessary and will meet the patient's needs
7. That the treatment for which the patient is being referred is a proven form of treatment and is not an experimental or test treatment
8. That the hospital or other institution providing the treatment is recognised and is under the control of a registered medical practitioner

Obviously the patient, who is the applicant for the TAS, cannot satisfy the HSE with regard to any of these conditions. The application process requires that the patient must ask their consultant to certify that these conditions are met before an application can be submitted for consideration. In effect therefore the consultant and the patient become joint applicants in the HSE's assessment process for the approval or refusal of the TAS application.

Condition 1: Referral pathway must be public healthcare patient in Ireland to public healthcare service in the EU / EEA / Switzerland

A preliminary condition applicants must satisfy for approval under the Treatment Abroad Scheme is that the referral pathway must be within the parameters of public health service provisions. In other words the patient must be a public patient, referred by an Irish based consultant in the public health services, for treatment abroad, which also must be available through that country's public health services. A referring consultant must confirm that this condition is being met on the TAS application.

Patients being treated by their consultants in a private capacity, who are likely to be receiving healthcare treatment through their private health insurance, fall outside the scope of the TAS.

It should be noted however that a private patient is entitled to opt for public healthcare and seek a TAS referral from a consultant in the public health services. In cases where an application is being refused on the basis that the referral pathway is not public to public the refusal information should explain to patients how they may be able to access TAS funding by opting for public treatment.

Whereas the TAS scheme makes provisions for funding public patient treatments in the EU / EEA states and Switzerland, patients may apply to the HSE for funding for unique treatments available only outside the EU / EEA, and which may only be provided in private healthcare facilities. All such applications must be considered by the HSE on their individual merits. Department of Health guidance in 2008 states – *“Any arrangement for treatment abroad outside European countries covered are at the discretion of the HSE and are not subject to the criteria set out in this guidance”*.

Recommendation

The HSE should advise patients, who receive a refusal of funding under the TAS scheme because they do not satisfy this condition, to discuss with their consultant the possibility of accessing treatment abroad under the HSE's discretionary provisions.

Condition 2: That the treatment is not available in Ireland or available in a reasonable time-frame

Consultants, having exhausted all avenues of treatment known for them in Ireland, may deem it necessary to refer a patient abroad to receive treatment which is not available here. The majority of TAS applications involve specialised surgical treatments which, because of their low volume and highly specialised nature, are not available in Ireland.

In exceptional cases where a treatment is available in Ireland, consultants may deem it necessary to refer a patient for treatment abroad, because the patient's need is of such urgency that they cannot wait until their turn comes around on the waiting list.

But consultants also refer patients abroad for 'medical assessments' and 'specialist opinion' to centres which have developed a higher level of expertise in their specialist areas of medicine than is available in Ireland. Examples of this include patients with rare diseases or illnesses, who may be experiencing unusual symptoms outside the referring consultant's area of specialist expertise.



TREATMENT ABROAD

An Investigation by the Ombudsman into the administration of the Treatment Abroad Scheme by the Health Service Executive (HSE)

The Ombudsman acknowledges the establishment of the National Rare Diseases Office and the appointment of a National Clinical Lead for rare diseases as a welcome resource for patients and consultants. The role of the National Clinical Lead and her team in the coordination and dissemination of up to date, quality assured information on rare diseases, centres of expertise (CoEs) at home and abroad, European Reference Networks (ERNs) and hosting the Orphanet portal, which is the HSE's repository of rare diseases information, is an excellent model for all specialist healthcare providers.

Consultants may also be aware of other specialists, both in Ireland and abroad, who are renowned as experts in their areas of speciality. They may not necessarily be located in a registered 'centre of expertise or excellence'. A treating consultant may feel that their patient needs an assessment or an opinion from one of these specialists. There is nothing preventing a consultant from referring a patient to another specialist in the Irish public healthcare system. But if the consultant wishes to refer a patient abroad under the TAS scheme they will be required to confirm that the level of expert opinion they are seeking is not available in Ireland first. Applications for second or expert opinion abroad can be problematic for patients and consultants.

Under the present assessment process the TAS assessment office obtains its own medical advice regarding whether a 'treatment' or 'opinion' being sought is available in Ireland. It may receive advice from a medical advisor which differs from that of the referring consultant. In light of evidence from complaints examined it appears that the medical advice provided to the TAS office by its own medical advisors is accepted as the deciding factor in the refusal of such applications. There is no formal process within the TAS scheme to resolve differences of opinion between referring consultants and medical advisors in these circumstances.

This is illustrated in a complaint currently being examined by the Ombudsman. The patient stated that her health had been deteriorating without obvious cause. She had been seen by several physicians and consultants, as a public healthcare patient, over several years, but her medical condition continued to worsen. Her medical support team were of a view that her underlying medical problems stemmed from a rare hereditary disease known as Ehlers-Danlos Syndrome (EDS). She was supported in making an application under the TAS scheme to travel abroad, (to a centre where expertise in EDS was developed to a higher level than anywhere in Ireland), for an assessment and a diagnosis, and where a tailored care and treatment plan could be designed for her. Her application was refused.

In a similar complaint case, a patient, who was experiencing severe pain because of the same very rare hereditary disease (EDS), was referred to a specialist centre abroad for assessment and management of his symptoms.

In both these cases the referring consultants were aware that expertise had been developed abroad to a standard not available in Ireland. But the applications for TAS funding were refused on the basis that the treatment was available in Ireland.

Under the HSE's TAS application and assessment process a referring consultant's role is a recommending one only. It is a function of the TAS office, which has been centralised since 2012, to assess and approve or refuse TAS applications.

When an application is received by the TAS processing office, it is considered by administrative staff. They may seek an opinion on the application from the National Clinical Lead or one of 'a panel of medical experts' established to provide medical advice and information relating to referrals. If the TAS office then receives advice that the treatment sought is in fact available in Ireland, or that all avenues of

treatment may not have been exhausted in Ireland, the application is refused.

One consideration for the assessment staff is whether the referring consultant is a 'tertiary care consultant' in the field for which he or she has been treating the patient. In other words, is the referring consultant sufficiently expert and well enough informed to certify that the treatment being sought is not available in Ireland? In cases where the referring consultant is not a tertiary care consultant the TAS office generally requires that the patient is assessed by such a consultant before a referral abroad under the TAS scheme will be approved.

It can of course be the case that a referring consultant is new in their position or even newly arrived in Ireland, and may not be aware that a particular treatment or remedy is available in Ireland. Alternatively, it may be the case that the medical advice received by the TAS office is inaccurate. Whatever the case patients will feel justifiably aggrieved that their application has fallen foul of a difference of opinion between their consultant and the TAS processing office; both of which are HSE service providers.

The process for deciding whether a treatment is available in Ireland or available within a reasonable time frame, should be established by referring consultants before a patient is invited to complete an application for funding under the TAS scheme.

The following case illustrates how a patient was adversely affected when the TAS office inappropriately refused an application on the grounds that the treatment was available in Ireland.

Ms F complaint

Ms F is a cancer patient who needed specialised and intensive lymphedema treatment for her condition. She applied for TAS funding to obtain the treatment in Germany. Her consultant confirmed that the treatment for which she was referred is not available in Ireland. In refusing her application (and based on the medical advice it received), the TAS office explained that the treatment she sought is available at numerous centres in Ireland. This came as a shock to the woman as her consultant informed her that it wasn't and she had received TAS funding for two previous trips abroad for the same treatment.

In this case the TAS office informed the woman that it was not actually refusing her TAS application. It informed her that as the treatment was available in Ireland her application would not satisfy that condition. It advised her that she should not have applied for treatment under the TAS scheme, but if she wished to obtain the specified treatment in Germany she could apply for funding under the Cross Border Directive and that her application would be approved. While she could have qualified for treatment under the Cross Border Directive, that scheme requires that the patients must pay for their treatment up front and seek reimbursement later. Also by deeming Ms F's application for TAS funding 'invalid' rather than 'refused' the patient was effectively denied access to her right of appeal. The appeals aspect of TAS administration is dealt with in more detail later in this report.

Unable to submit an appeal to the HSE as she had not received a formal refusal, the woman complained to the Ombudsman. In the course of the examination the Ombudsman learned that the treatment Ms F's consultant had referred her to receive was for 'intensive in-patient lymphedema treatment', which was not available anywhere in Ireland.

The Ombudsman also learned that in 2012, the TAS office introduced a protocol requiring it to seek a medical assessment in cases of treatment abroad applications for primary lymphedema. This involved seeking the advice of a named medical expert. No evidence was presented to the Ombudsman that any medical advice was sought in processing this application. If the TAS office had applied its own protocol it is likely that the correct information regarding the availability of the treatment for this condition would have been established, and the delay and upset caused in this case, avoided. On foot of the Ombudsman's examination the application was retrospectively approved.

To access treatment abroad a patient relies on two individual arms of the HSE to work in tandem; (i) the patient's Irish based treating public consultant (who is employed by the HSE) and (ii) TAS administration (also staffed by HSE employees). There should have been a communication pathway between these key actors to ensure that any questions arising could be resolved without any need for the patient to become involved. Indeed where any difference of opinion arises, ideally there should be no need for the patient to be even aware of it.

The HSE states that one of the most common reasons for declining a TAS application is that the treatment or an equivalent treatment is available in Ireland.

Recommendation

- (i) Before a patient is asked to complete a TAS application form consultants should ensure that the treatment for which they wish to refer their patient is covered by the TAS scheme.
- (ii) It follows that TAS applicants should not receive refusals of TAS funding on the basis that the treatment is available in Ireland.
- (iii) There should be a clear process for consultants to establish whether a suitable treatment or alternative pathway in their continuing care of a patient is available in Ireland.

Condition 3: That the treatment is among the benefits provided for by Irish legislation

An obvious reason for this condition is to ensure that Irish patients are not funded under the TAS scheme to travel abroad for treatments which are illegal in this country.

However, interpreting other intentions behind the HSE and Department of Health's guidance on this condition is somewhat more difficult.

In the Department of Health's 'Updated guidance in regard to treatment abroad, with particular reference to EU law' which issued in September 2008, it states, inter alia – "... *there can be no entitlement to receive a particular treatment in another European country at the cost of the HSE unless the patient is eligible for the same or similar treatment within the Irish public healthcare system*".

It also states – *“In general, if the treatment is available to public patients in the Irish public health system, then it must be considered that the treatment is among the benefits provided for by Irish legislation. However, the fact that the treatment is not available to public patients in the Irish public health system should not automatically mean that the treatment is not among the benefits provided for by Irish legislation. E112 have traditionally provided scope for referring patients for medically necessary procedures or treatments that, because of their highly specialised nature, are not available Ireland and this approach should continue.”*

It goes on to state – *“At the same time, E112 arrangements should not be used to fund a treatment solely on the grounds that it is taking place in another European country; the fact that a treatment is part of the public system in another European country does not of itself mean that the patient is eligible for the same or similar treatment within the Irish public healthcare system”.*

A number of questions arise out of this guidance.

Firstly, it is a condition for funding under the TAS scheme that the ‘treatment is not available in Ireland’. The reference in the above guidance to the effect that the same or similar treatment must be available in Ireland is confusing.

Secondly, if a consultant refers a patient for treatment which is available in the public healthcare system of another EU state, and it is not considered ‘experimental’ treatment in that state, what is the process for deciding whether the funding application should be approved?

The Ombudsman received a complaint from a patient which centred on these questions.

Mr B complaint

Mr B complained to the Ombudsman that he applied for TAS funding to enable him to avail of treatment provided in Germany which was not available in Ireland. The man suffered from chronic obstructive pulmonary disease (COPD) and his condition had been worsening over the preceding years. The treatments he had been receiving in Ireland were largely reactive treatments and were not improving his health.

The man had been seeing two consultants, one in a private capacity whom he hoped might find a long-term medical solution for his debilitating condition. He saw the second consultant more often due to the frequency of his emergency admissions at a different hospital for urgent medical treatment.

Mr B stated that given the severity of his medical condition, both consultants were in agreement that there were two treatments which would possibly reduce his reliance on emergency treatment in hospital and improve his health. One was called the ROX procedure and the second - LVRC (Lung Volume Reduction Coil) procedure, neither of which were available in Ireland.

In 2013, the man received TAS approval and funding to travel to Germany for the ROX procedure. However upon his arrival final tests were carried out and it was decided that his health had deteriorated to the extent that the ROX procedure was unsuitable.

Later in 2013, the man visited both consultants again. He stated they both agreed that the LVRC procedure was still an option for him. Having obtained a referral from his public based consultant he submitted an application for TAS funding to avail of the LVRC treatment in Germany.



Initially Mr B's application was refused on the basis that he had been seeing his consultant in a private capacity and not as a public patient. He appealed the refusal on the grounds that he received the TAS referral from his public healthcare consultant, as a public patient. However, as he had previously been a private patient of his other consultant his referral as a public patient was not seen to be within the 'spirit of the scheme' and his appeal was denied. The TAS office then added that he was also ineligible for TAS funding on the basis that "the treatment requested is not a proven form of treatment".

Mr B appealed the refusal a second time and received a further letter stating that treatment was available appropriate to his condition in two Dublin hospitals.

It is not a matter for the Ombudsman's office to determine whether a treatment should be considered to be among the benefits provided for by Irish legislation. Nor can the Ombudsman decide whether a treatment should be considered a proven form of treatment or experimental treatment. But it is within the Ombudsman's remit to consider whether the process through which these questions can be addressed is transparent, fair and simple to access.

1. It emerged that medical advice relied upon by the TAS processing office in refusing Mr B's application was a record of a phone call with a specialist who regarded the LVRC treatment as an unproven treatment.
2. Despite the fact Mr B's referring consultant confirmed that the treatment is a proven form of treatment, TAS administration accepted the other medical advice it received without further consideration.
3. There does not appear to be a fair and transparent process for an applicant or a referring consultant to challenge the medical advice or opinion TAS administration receives and relies upon in the course of reaching decisions on TAS applications.
4. There appears to be an absence of clarity about how a 'proven form of treatment' is determined. This needs to be clarified for patients and consultants generally, as it is a key qualifying condition for TAS funding.
5. Mr B had been attending two separate consultants for his medical condition. One he was seeing as a private patient; the other as a public patient. His public based consultant initiated the referral for treatment abroad. However, because he was seeing another consultant as a private patient this was cited as a factor in refusing his application.

This complaint is currently being examined by the Ombudsman's office and is under active consideration by the HSE. Although it has not yet been concluded it highlights some of the complexities that can arise for patients. It also raises significant concerns about the absence of transparency in the assessment process for TAS funding under the present administrative structure.

Condition 4: That a referral for treatment abroad must be made by the patient's Irish based treating consultant

It is a HSE condition for funding under the TAS scheme that the patient's consultant is an Irish based public healthcare consultant and that only such consultant's referrals will be considered for approval. The HSE advises consultants that it will not consider referrals initiated by them based on requests by patients, parents of patients, advocates, or hospitals abroad. The referral must be based solely on the consultant's decision as an integral part of the provision of care to their patient.

In the course of this investigation we spoke with consultants who were of the view that consultants generally only refer a patient for treatment abroad as a last resort. This pathway is typically chosen when the treatment needed is not available in Ireland or when a patient's treatment plan has not been producing the desired result.

In some cases a patient's treating consultant may not be a specialist in a particular symptom being experienced by their patient at a point in time. In these circumstances it is normal practice for treating consultants to confer with their colleagues and other experts / specialists in the relevant medical or surgical specialist area, to see if solutions are available in Ireland before a referral abroad is considered. In some cases, the decision to refer a patient for treatment abroad is made after a lengthy period of treatment in Ireland. In others, the decision to refer may be obvious and urgently required. Whatever the circumstances the consultant must first inform the patient of all the possibilities associated with a referral for treatment abroad and obtain the patient's agreement to pursue such a remedy. At this time it is the patient who must make the decision whether they want to travel abroad for treatment or not. If a patient chooses to avail of treatment abroad under the scheme they must give their consent for the consultant to initiate a referral to the appropriate centre abroad.

At this point in their healthcare journey many patients will be at a very low ebb as a result of unresolved health problems. The possibility that treatment abroad might resolve or bring relief to their health problem is likely to raise feelings of new hope in them. Patients who consent to treatment abroad are likely to believe that completing an application form is merely a formality. After all why would a consultant raise their hopes by suggesting treatment abroad and initiating the referral process if there was any possibility that funding might be denied. A refusal of funding under the TAS scheme at this stage in their healthcare journey is therefore likely to have a devastating effect for many of these patients. It is the Ombudsman's view that the TAS application process should be amended so as to eliminate the possibility of this kind of refusal.

In the Ombudsman's view the referring consultant's role should not be simply that of a 'co-applicant' with the patient in the application and administrative process of the TAS scheme.

Irish based public consultants are employees of the HSE. Their role in patient healthcare is of paramount importance. It is vital that patients' confidence in their consultants is not undermined because of an administrative decision which refuses TAS funding for a referral abroad. To prevent the undermining of confidence in consultants in this manner consultants should carry out a 'pre-referral check' to ensure that the patient referral satisfies all the qualifying conditions under the TAS scheme before raising the patients hope and expectations of funding for expert treatment abroad. When it is confirmed to the consultant that the full range of circumstances in the case, as identified by the consultant, meet the conditions for TAS approval, only then should a patient be invited to complete an application for TAS funding.



Essentially, the consultant's role in referring a patient for treatment under the TAS scheme should be no different to his/her role in referring a patient for treatment to another consultant based in Ireland. There should be no administrative impediment restricting consultants in their exercise of care and treatment decisions or choosing a medical care pathway for their patients.

Updated guidance in regard to treatment abroad with particular reference to EU law, issued by the Department of Health in September 2008 states, inter alia, *"The HSE should also be cognisant of the fact that criteria for assessment of requests for treatment abroad should not be more rigorous than those imposed for treatment at home. It is only on the basis that these criteria apply equally to all treatment provided by the HSE that they are acceptable under European Law in relation to cross-border treatment"*.

Condition 5: That the treatment for which the patient is being referred abroad to receive must be specified

This is a condition in the assessment of TAS applications which has caused significant difficulties for TAS applicants and which, left unclarified, has the potential to cause delay and distress for many others.

In the case of surgical treatment 'specifying the treatment' is normally quite straightforward. A referring consultant being aware that the surgical procedure being sought is not available in Ireland can 'specify the treatment' as required in the E112 application form.

However, if a medical, rehabilitative or non-surgical remedy is being sought it is not always possible for a referring consultant to 'specify the treatment'. A consultant may be referring a patient to a centre of expertise, because he / she has exhausted all avenues of treatment known to them in Ireland without finding a resolution to the presenting healthcare problem. In many cases it is precisely for the identification of a treatment that the consultant may be referring their patient to the centre of expertise. So what happens in cases such as this?

Complaints from patients and a review of HSE information on the TAS scheme indicate that unless a 'treatment is specified' by a referring consultant the TAS application will fail. Many applications were refused or deemed 'invalid' by the TAS central office on the grounds that the treatment was not specified. But should these applications have failed for this reason?

When conducting examinations of complaints the Ombudsman learned that this condition for eligibility is not a mandatory condition. There are circumstances in which a patient's TAS application can be approved even though the **treatment is not specified**. This however, is not routinely explained to patients by the TAS office and there is nothing in patient information documentation or on the HSE's website explaining the circumstances in which this condition does not need to be met.

Take for example a patient with a rare disease or a patient manifesting a rare symptom in their illness because of an underlying medical condition. It may be the case that unique expertise has been developed at a particular specialist centre in another TAS member state. Irish based consultants may wish to refer their patient to one of these centres for second or expert opinion; or for guidance on a care and treatment plan to be implemented when the patient returns to Ireland. These, of course, are legitimate reasons for a consultant to refer a patient to another specialist centre and such referrals fall within the scope of the TAS scheme, even though the referring consultant cannot 'specify the treatment'.

The HSE explained to the Ombudsman that in cases such as these if the referring consultant is not a tertiary based consultant (i.e. a specialist in a national specialist treatment centre) for the rare disease, illness or the presenting symptom, then the consultant should refer the patient to a tertiary based consultant in Ireland for advice and / or assessment, and / or treatment, before the TAS office will approve applications for an intervention abroad. In the absence of sufficient knowledge about a rare disease, illness or symptom an Irish based treating consultant should seek advice from the National Clinical Lead about the availability of possible solutions in Ireland before referring a patient abroad under the TAS scheme.

The following extract, from a complaint examined by the Ombudsman, illustrates how such a case was dealt with and the HSE's incorrect interpretation of the condition that the 'treatment must be specified'.

Mr A Complaint

Mr A's referring consultant was an Orthopaedic Surgeon and Upper Limb Specialist. As his patient's symptoms were severe and worsening, and as his treatment was not having the desired effect, the consultant felt he had no option but to refer him for expert assessment and opinion stating *"it is likely that the specialist unit in Stanmore, under the care of [X] will significantly improve his situation so that his Emergency Department attendance is greatly reduced."*

During the Ombudsman's examination of Mr A's complaint the HSE stated –

"Mr A's application does not specify the treatment therefore it is invalid as it cannot be processed to examination as to whether the treatment is available in Ireland and thus it meets the criteria for the Scheme"

"The TAS does not have remit to fund second or specialist opinions. Where a consultant refers a patient to the TAS for such funding, the National Clinical Lead's opinion will be sought as to what service could provide a second opinion in Ireland".

"If the treatment is not identified it is not possible to examine the application against the criteria and therefore the application would be deemed invalid, as happened in this case".

"It is incumbent on Mr A's consultant to exhaust the services available for his patient in Ireland in the first instance before seeking to refer abroad."

After the application was originally deemed 'invalid' the referring consultant wrote to the TAS office stating –

"Mr A has been seen by every upper limb specialist in Ireland. His case was discussed at a shoulder conference held in Beaumont several years ago... There is no other upper limb specialist in Ireland with experience of this problem. Because of the rarity of the condition, only certain centres have built up an expertise in the management of this hereditary soft tissue problem."

Further representations were made to the TAS office on the patient's behalf by his mother, a local TD, Patient Focus, and other staff of the HSE. A separate consultant orthopaedic surgeon in the National Orthopaedic Hospital wrote to the public representative stating – *"Mr A is well known to me. The most appropriate place for him to be treated is a unit at Stanmore Hospital in London. Currently there is no unit that provides this kind of treatment in this country. I would endorse his application for further treatment at Stanmore."* This endorsement was brought to the attention of the TAS office.



Despite this, and the submission of three further applications for TAS funding by the patient which were endorsed by his referring consultant it was only when a third consultant, (a tertiary services consultant), assessed Mr A and wrote a letter to TAS central office stating –

“I agree with the opinion of [two named consultants] that the RNOH is the only centre on these Islands with the necessary specialist expertise to manage Mr A’s condition effectively”.

The application was then approved, but it was 14 months after the patient’s first application was submitted.

This complaint to the Ombudsman illustrated a series of shortfalls and failure on the HSE’s part in processing Mr A’s application for treatment abroad.

So what went wrong and what can be done to stop it happening again?

Once the application form was properly completed by the patient there was nothing more he could do to influence the decision.

The principal roles in the application process were those of the Irish based referring consultant and the TAS central processing office, both of which are performed by the HSE.

The referring consultant did not ‘specify the treatment’ for which he was referring his patient. This became the first major stumbling block as the TAS processing office considered that the absence of specified treatment invalidated the application. The second was that the TAS office considered that the patient should be referred to tertiary services in Ireland for a second or specialist opinion.

The consultant followed up on the refusal by writing to the TAS office, on a number of occasions, explaining that all available avenues for tertiary care in Ireland were exhausted. He explained that the patient suffers from a rare condition namely EDS (Elhers Danlos Syndrome); a lifelong condition; had been receiving treatment for several years, including in Stanmore where he had previously shown good progress; his condition was deteriorating; he was experiencing severe disability and pain; he required emergency surgical interventions almost weekly to re-set his shoulder; his treatment in Stanmore would significantly improve his situation so that ER attendance would be greatly reduced; and that the patient needs “super specialist opinion” which is not available in Ireland.

The consultant invited the TAS processing office to communicate with him directly in an attempt to provide whatever further clarification might be required in order for the TAS application to be approved. The TAS did not respond to his invitation for direct engagement with him. It reiterated its position that the TAS scheme does not fund second or specialist opinion and made reference to a HSE protocol which provides that “Consultants may reapply where they have shown to have sought and obtained specialist or expert opinion within Ireland... at which stage the TAS office will forward the application to the Medical Assessors to examine”. The refusal stood.

Under sustained pressure from the patient’s family, the TAS office eventually decided to arrange for the patient to be assessed by a tertiary based consultant orthopaedic surgeon who supported the treating consultant’s original referral by reporting - *“I agree with the opinion of [two named consultants] that the RNOH is the only centre on these Islands with the necessary specialist expertise to manage Mr A’s condition effectively”.* The treatment specified for the purposes of compliance with the E112 form stated – *“Multi and interdisciplinary intervention for management of complex bone disorder and recurrent shoulder dislocation*

at RNOH, Stanmore”. This is what Mr A’s consultant had been seeking approval for from the time of his initial referral. It should be noted that it is not normal practice for the TAS office to arrange for patient assessments in the course of considering applications.

The dispute between the TAS processing office and the patient’s referring consultant resulted in considerable delay in the patient’s treatment. The absence of communication between the TAS office and the referring consultant, despite the consultant’s attempts at engagement, was not explained. The intractable position adopted by the TAS office, over a period of 14 months, to insist on receiving a further medical report in the knowledge that the patient’s care and treatment plan revolved around emergency hospital admissions for surgical treatment on a weekly or fortnightly basis to reset his shoulder, was entirely unjustifiable.

The Ombudsman informed the HSE that the outcome from his complaint examination was to ‘uphold’ the complaint. In response the HSE stated – *“I believe all of the people in this case were genuinely attempting to do the best they could to meet the complex needs of Mr A within the context of their roles, competences and the parameters that they are each required to work within. That being said it must also be acknowledged that in this particular case our systems and processes in both the clinical and non-clinical domains were not sufficiently aligned so as to optimise this man’s journey through what is a complex and often daunting care system for patients and their families.”*

Arising from the examination of this complaint a number of improvements were agreed by the HSE.

- The HSE committed to bringing managers in the clinical and non-clinical functions of the TAS scheme administration together with a view to *“identifying the challenges and leveraging the learning points that arise on a whole system basis”*.
- In the case of incomplete applications the TAS office routinely closed them as ‘invalid applications’. Patients were therefore denied a right of independent appeal. The HSE agreed to close incomplete applications as ‘refused’ and inform patients of their right of appeal, and of their right to bring a complaint to the office of the Ombudsman.
- The HSE also agreed to introduce a quality assurance measure whereby on a quarterly basis a random sample of closed cases would be reviewed.

This investigation identifies that there is an absence of clarity for referring consultants about the TAS scheme and the processes involved in referring patients abroad under the scheme. There is insufficient guidance for consultants and the guidance available on the HSE’s website and in documentary format is not sufficiently clear or comprehensive.

During this investigation consultants expressed the view that when consultants treating a patient find that a treatment or care plan is not producing the required medical outcome, that referring a patient for a ‘second or specialist opinion’ or for an ‘assessment and guidance with the identification of a care and treatment plan’, is an intrinsic component of ‘treatment’ for that patient. If the expert opinion, assessment and guidance is available in Ireland it should be sourced in Ireland. If it is not available in Ireland it should be sourced abroad under the TAS scheme, as appropriate.

In October 2011, the HSE’s National Director for Clinical Strategy and Programmes and National Director for Quality and Patient Safety issued a circular to National Clinical Leads about the TAS scheme. The circular stated, inter alia, -



“Second or Specialist opinion: The TAS does not have a remit to fund application for second or specialist opinions. Where a Consultant refers a patient to the TAS for such funding, the National Clinical Lead’s opinion will be sought as to what service could provide a second opinion in Ireland”

Notwithstanding the above circular, the TAS office has a suite of protocols for consideration in processing TAS applications. The protocol relating to ‘second or specialist opinion’ dated September 2011, appears less restrictive on such referrals than the October 2011 circular to National Clinical Leads. However, it requires referring consultants to contact the National Clinical Lead for advice on the referral abroad and potential alternatives in Ireland.

In the main, second or specialist opinion will be available in specialist and tertiary care services in Ireland, for most medical conditions, but not all. The TAS scheme clearly provides for Irish patients to have access to specialist expertise which is not available in Ireland, but is available abroad.

Recommendation

- (i) A revised guideline and protocol should be drafted which explains how TAS funding can be accessed in cases of referral where the treatment cannot be clearly specified.
- (ii) Patients should never be caught in the middle of a dispute between HSE medical and non-medical domains which impacts on patients who are seeking to access treatment.
- (iii) A revised TAS application process whereby the referring consultant conducts a ‘pre-referral check’ to ensure their patients qualify for funding under the TAS scheme before initiating a TAS referral should be introduced.
- (iv) A clearly defined system of information and support for consultants who wish to consider referring patients for treatment abroad should be introduced.

Condition 6: That a clinical assessment has been carried out to demonstrate that the treatment is medically necessary and will meet the patient’s needs

Referring consultants are required to conduct a clinical evaluation of their patient’s medical needs within two weeks or thereabouts of completing a TAS referral form for treatment abroad.

Consultants are also required to certify, that the treatment for which they are referring their patients, is medically necessary and that it will meet the patient’s needs. Again, while this may be relatively straightforward in cases of surgical treatment, it may not be quite so straightforward in the case of medical treatments.

In the case of referrals for second and specialist opinion, which are eligible for support under the TAS scheme, clearly this condition cannot be met. Indeed, to ask consultants to certify that any treatment, whether surgical or medical, will succeed in meeting the patient's needs seems generally a rather unrealistic question.

Recommendation

This condition should be revised and amended to reflect reality in all cases of referral abroad for treatment

Condition 7: That the treatment for which the patient is being referred is a proven form of treatment and is not an experimental or test treatment

It is not in the TAS scheme's remit to fund patients to receive experimental or test treatment at the taxpayer's expense.

New and cutting edge treatments become recognised as proven forms of treatment after lengthy periods of trial and evidence. It appears that certain new and cutting edge treatments are deemed to be proven forms of treatment in other EU countries, and available through the public healthcare system in those countries, but may not be recognised as such in Ireland.

The Department of Health's 'Updated guidance in regard to treatment abroad, with particular reference to EU law', dated September 2008, states, inter alia, - "...the fact that the treatment is not available to public patients in the Irish public health system should not automatically mean that the treatment is not among the benefits provided for by Irish legislation. E112 have traditionally provided scope for referring patients for medically necessary procedures or treatments that, because of their highly specialised nature, are not available Ireland and this approach should continue."

It goes on to state - "At the same time, E112 arrangements should not be used to fund a treatment solely on the grounds that it is taking place in another European country; the fact that a treatment is part of the public system in another European country does not of itself mean that the patient is eligible for the same or similar treatment within the Irish public healthcare system".

Of course confirming that a treatment is a proven form of treatment and is not experimental or test treatment applies to treatments in Ireland as well as abroad. One consultant interviewed described determining whether a new and cutting edge treatment is deemed to be a proven form of treatment as a 'quagmire'.

In one of the cases examined by the Ombudsman the referring consultant confirmed that the treatment was not experimental or test treatment and that it was available in the public healthcare system of another EU state. But the TAS office refused the application, having taken advice from another 'medical advisor', on the grounds that it was not a proven form of treatment.

The TAS central office has compiled several useful protocols to act as a guide for both consultants and



TAS assessment staff when considering funding applications. However there is no protocol in place to ensure that this TAS condition can be established objectively and transparently; and where there is a differing view between the referring consultant and other medical advice, that it can be resolved through a satisfactory process.

Recommendation

- (i) That a protocol be introduced to provide an objective and transparent mechanism to determine whether a treatment is a proven from of treatment for the purposes of TAS funding eligibility.
- (ii) The protocol should make provision for a patient or referring consultant to challenge a contrary medical opinion as to the status of a particular treatment, through an independent appeals process.

Condition 8: That the hospital or other institution providing the treatment is recognised and is under the control of a registered medical practitioner

The hospital or other institution abroad must be a public healthcare facility which accepts TAS referrals (known as E112 referrals) from Irish based public consultants. The referring consultant must make the necessary arrangements with the medical institution abroad for the acceptance of the E112 referral and confirm so on a patient's TAS application form.

The Ombudsman has not received any complaints from applicants centring on this condition.

Chapter 3

TAS Information, Protocols and Communication

TAS Information, Protocols and Communication

Treatment Abroad Scheme Information and Communications

While the Irish healthcare system is resourced with some of the most highly qualified and dedicated professional staff, it is not always feasible from an investment and resource perspective, to provide some low volume specialist treatments in Ireland. For consultants to develop and maintain the clinical expertise necessary to provide uniquely specialised low volume treatments they need to be treating a certain ‘critical mass’ of patients.

An essential value of the Treatment Abroad Scheme for Irish public patients, is that it gives them access to specialist expertise which is not available in Ireland, but which is provided in the EU / EEA.

The HSE describes the TAS as “a progressive scheme allowing access to advanced and necessary healthcare for patients in the broader European healthcare setting” and “a very valuable referral pathway for consultants”.

A fundamental strategy in the management of healthcare is health promotion. The HSE regularly runs health promotion campaigns in the media to promote many of its services. Whereas it is acknowledged that the HSE should not encourage patients to receive medical care in other Member States’ jurisdictions, it should widely disseminate appropriate information about the potential health gains for certain patients through the healthcare pathway available under the Treatment Abroad Scheme. Information available on the HSE’s website and in documentary format about the TAS scheme is not sufficiently comprehensive or explanatory.

Recommendation

- (i) Consultants (and their teams) should have easy access to clear and comprehensive information on the TAS scheme in an online information resource, and where necessary through an appropriate national clinical contact point.
- (ii) The HSE should also make available clear and comprehensive information for patients about the TAS scheme as a valuable treatment pathway for certain patients.

Treatment Abroad Scheme Protocols

Over the past few years the TAS office compiled a suite of protocols to assist consultants who may be considering a patient referral under the TAS scheme. These protocols explain the conditions and processes which apply in particular circumstances, and with regard to certain medical conditions. The protocols are also used as a guide by administrative staff assessing TAS funding applications.

There is a range of protocols dealing with matters such as –

- Referrals when the treatment required may be available in Ireland but not within a reasonable time-frame
- Referrals for second or specialist opinion
- Applications for TAS funding which are routinely referred by assessment staff to named medical advisors for a view on the appropriateness of the referral by the consultant
- Applications for funding from patients with certain medical conditions for which automatic approval is given under the TAS scheme

While the practice of drafting protocols for the purpose of bringing clarity and efficiency to the TAS application process is sound, the HSE should develop more comprehensive protocols to address the many complexities arising for patients and consultants which cause difficulty for them.

The following concerns were identified relating to the TAS protocols-

- (i) There is an absence of transparency and clarity in many of the protocols.
- (ii) The protocols are not posted on the HSE's website or provided to patients who wish to apply for funding under the TAS scheme.
- (iii) The protocol on referring a patient for second or specialist opinion states that 'it is not the purpose of the TAS to fund second or specialist opinion'. Other HSE documentation states clearly that the TAS does not fund second or specialist opinion. Consultants must seek second or specialist opinion, where needed, in Ireland in the first instance. However, the HSE advised the Ombudsman that if the level of expertise required for a second or expert opinion is not available in Ireland, but is available in the EU / EEA, such referrals are appropriate for funding under the TAS. The protocol and all associated HSE information relating to referrals for second or specialist opinion should clearly explain this.
- (iv) In cases refused on the grounds that the treatment is available in Ireland, the location of a 'tertiary service' or specialist treatment where the treatment can be accessed is not routinely provided by the TAS office to the referring consultant or the patient.
- (v) The names of medical advisors who are consulted by the TAS office for an opinion as to whether the referral abroad is appropriate are not revealed to the patient.
- (vi) Neither the referring consultant nor the patient are advised about how they can challenge 'medical advice' provided to the TAS office which resulted in a refusal.

There is a protocol which consultants must follow when referring a patient for treatment abroad on the grounds that the treatment is not available in Ireland within the time necessary for obtaining it'.



A referring consultant must –

- (i) Provide an objective medical assessment of the patient’s clinical needs
- (ii) Set out the patient’s medical history and probable course of the illness, and where appropriate, set out the degree of pain the patient may be suffering
- (iii) Sign a declaration that the patient cannot obtain the treatment in Ireland within a time-frame necessary for obtaining it
- (iv) Specify in detail how and the extent to which the condition of the patient would deteriorate if they had to wait until their turn came around on the waiting list
- (v) In the case of hospitals which are funded to provide the treatment in question – the referring consultant must provide confirmation that the hospital will cover the costs associated with the referral of the patient, including all travel costs, out of the hospital’s budget. (Note: The treatment will not be funded by the TAS and the E112 will not issue until the referring hospital transfers the funds to the TAS office).

Notwithstanding that there is no reference to this protocol on the TAS application form, and no provision on the form for a referring consultant to provide answers to the requirements the protocol demands, it remains the consultant’s responsibility to meet the requirements set out in this protocol if a successful outcome in the TAS application is to be achieved.

Under the present TAS assessment process, this protocol can potentially lead to unreasonable delay in a patient’s treatment. This is of particular concern in cases where a patient’s health may be deteriorating rapidly or for those who are enduring severe pain.

The following is an example of how this protocol can result in stress and delay for patients who were expecting a funding approval –

The TAS assessment office, having received an opinion from a medical advisor, refuses an application on the grounds that ‘the treatment is available in Ireland’ or that ‘all avenues of treatment in Ireland have not been exhausted’. As refusals of applications are sent to applicants, (who are the patients or their representatives), they must then contact their consultant to explore and exhaust possible treatments in Ireland. If it turns out that there is a specialist treatment potentially available in Ireland the referring consultant must refer the patient to that service for an assessment and possible treatment.

As there is no procedure within the TAS scheme for a patient in these circumstances to be facilitated with an urgent appointment for this Irish based specialist service, the patient must add their name to a waiting list for perhaps 12 or 18 months before they can be seen.

Recommendation

- (i) The HSE should revise all protocols with a view to providing clear and comprehensive guidance for patients and consultants on the purpose and process of availing of the TAS scheme.

(ii) The HSE should draft new protocols which will address the complexity of the TAS scheme in light of difficulties experienced by patients and consultants in their applications and referrals.

(iii) The HSE should publish all protocols on its website.

Chapter 4

TAS Application and Assessment Process

TAS Application and Assessment Process

For the majority of applicants the Treatment Abroad Scheme application and assessment process appears to have worked satisfactorily since the assessment process was centralised in Kilkenny in 2012.

The HSE stated that the vast majority of applications relate to referrals for necessary surgical treatment, which is not provided in Ireland. In these circumstances the referring consultant initiates the referral abroad, arranges a date for the specified treatment to be provided and the TAS central processing office simply carries out the supporting administrative function relating to the referral, the application and the funding. The application and assessment process is more complex in cases of non-surgical referrals. For example, patients may be presenting with debilitating or painful symptoms, which are outside a treating consultant's specialist area of expertise. For patients such as these, referrals can be for medical treatment, medical assessments, specialist opinion, rehabilitation, etc.

In general, a consultant who wishes to refer a patient abroad will have formed the view that there is either a treatment or specialist expertise available abroad which will benefit their patient's health.

Before initiating a referral under the TAS scheme consultants are required to exhaust all possible avenues for the provision of care and treatment in Ireland first. It is a fundamental condition under the TAS scheme that the treatment for which a patient is being referred is not available in Ireland, or not available within a time-frame necessary for the provision of the required care or treatment. In this regard consultants should confer with their colleagues or other tertiary services based specialists. Consultants also have access to National Clinical Leads and other national clinical contact points for advice and information about where a possible treatment or medical response can be sourced in Ireland, or if not, abroad.

It is only when consultants have exhausted these possible avenues for treatment in Ireland that they should initiate a referral for treatment abroad under the TAS scheme. When consultants initiate a referral and advise their patient to complete a funding application there should be no possibility that the application will be refused.

At present the TAS central processing office in Kilkenny is the authorised decisions office for all TAS applications. The TAS office refers applications to a 'medical advisor' in cases where there may be a medical reason not to approve the application. The system for obtaining this medical advice which is then relied upon as a deciding factor in assessing applications for TAS funding is arbitrary and unsatisfactory. The assessment process, as it is currently configured, is unsustainable.

There are other important reasons why the TAS assessment and approval process should change.

Consultants are not restricted from making referrals to other public healthcare consultants, specialists or tertiary care services in Ireland. There should be no administrative impediment restricting consultants in their exercise of care and treatment decisions or choosing a medical care pathway for



their patients under the TAS scheme, provided all other conditions are satisfied.

The current system for deciding TAS applications can lead to inappropriate refusals for patients, causing unnecessary delay and distress for them and their families.

Updated guidance in regard to treatment abroad with particular reference to EU law, issued by the Department of Health in September 2008 states, inter alia, *“The HSE should also be cognisant of the fact that criteria for assessment of requests for treatment abroad should not be more rigorous than those imposed for treatment at home. It is only on the basis that these criteria apply equally to all treatment provided by the HSE that they are acceptable under European Law in relation to cross-border treatment”*.

Recommendation

- (i) The assessment and deciding process in TAS funding applications should be revised so that ‘pre-application’ and ‘pre-referral’ checks are conducted to ensure a patient will meet all the qualifying conditions under the scheme, before a patient is invited to complete a TAS application form E112.
- (ii) In making this recommendation the Ombudsman is cognisant that there is a need to replace the existing assessment process with one which ensures that the purpose and conditions of the Treatment Abroad Scheme are properly considered and applied in all applications.

Administration

The Ombudsman has no specific recommendation to make regarding the administrative support role necessary for the management of the TAS scheme. However, he wishes to highlight some considerations.

In the exercise of their administrative responsibilities in TAS applications, consultants will need additional administrative support to carry out ‘pre-referral checks’ and ‘pre-application checks’ to avoid unnecessary applications and upsetting refusals. Whether this administrative support is provided at local or central level is a matter for the HSE to consider. Whatever the case there is a need to ensure that there is a consistency and uniformity in the operation of the scheme nationally. Certain administrative functions lend themselves to a centralised administration, for example –

- Corporate governance
- Quality control
- The development and maintenance of guidelines and protocols
- Statistical and financial analysis
- Management information

The Ombudsman also noted that whereas public based referring consultants, (the key personnel in determining the necessity for TAS referrals), are managed within the Acute Hospitals Division of the HSE, the TAS central processing and decisions office falls within the Primary Care Division.

Management Information

In order to ensure that any scheme is being correctly applied it is important to gather sufficient management information about how the scheme operates, trends emerging, matters of concern being highlighted and suchlike. Circulating TAS scheme management information to consultants, managers and administrative staff involved in the scheme is vital to ensure the smooth operation of the scheme.

In the course of this investigation the Ombudsman requested the HSE to provide an analysis of TAS applications including –

- Number of applications for surgical treatment
- Number of applications for medical treatment
- Number of applications for other reasons
- Breakdown of approvals by treatment to establish the most common reasons for TAS funding
- Breakdown of refusals to establish the most common reason for unsuccessful TAS applications
- Time-frame analysis from date of applications to date of conclusion – broken down by approvals and refusals
- Number and breakdown of applications where the patient needed urgent treatment abroad
- Number of applications referred by TAS administration for –
 - National Clinical Lead
 - Medical advisor on panel
 - Tertiary services specialist
 - Other

With regard to all information requested above the HSE replied that it does not gather information in this way.

The following statistical and financial information was provided to the Ombudsman.

Year	Applications	Approved Applications	Declined Applications	Cost of Treatment	Travel Costs
2012	858	791	41	€7,324,258	€91,312
2013	798	640	23	€7,866,628	€44,141
2014	732	574	41	€11,113,347	€43,895
2015	785	619	41	€10,219,938	€52,447
2016	793	661	29	€8,751,653.13	€83,526



TREATMENT ABROAD

An Investigation by the Ombudsman into the administration of the Treatment Abroad Scheme by the Health Service Executive (HSE)

Year	Application	% Approved Applications	% Declined Applications	% Difference in Approvals on previous year	% Difference in declines on previous year
2012	858	95% (of 832)	5% (of 832)	N/A	N/A
2013	798	97% (of 663)	3% (of 663)	+2%	-2%
2014	732	93% (of 615)	6.7% (of 615)	-4%	+3.7%
2015	785	94% (of 660)	6.2% (of 660)	+1%	-0.5%
2016	793	96% (of 690)	4% (of 690)	+2%	-2%

Chapter 5

Appeals

Appeals and Reviews

Where an applicant is unhappy with the outcome from their application they have a right to appeal that decision. The decision is then reviewed by the Appeals Officer, who is also the HSE's Assistant National Director for Contracts. Overall responsibility for the administration and operation of the TAS scheme falls within this Assistant National Director's remit.

There is a protocol in place for the conduct of appeals. Patients who receive notification that their application has been refused may submit an appeal within 10 days of receiving the notification. Details of the appeals process are included with refusal notifications.

Many TAS applications fail because of medical advice received by the TAS central administrative office for reasons such as – 'all avenues for treatment in Ireland have not been exhausted' or 'the treatment is available in Ireland'. To prepare an appeal against such refusals requires the input of the patient's consultant. Ten days is an unreasonable time limit for patients to formulate and submit an appeal.

The Appeals Officer, who is not a medically qualified member of the HSE staff, is then required to consider medical argument presented in an appeal. Clearly the Appeals Officer must then seek his own medical advice on the argument made.

There is an absence of clarity and transparency about the appeals process in such circumstances. There appears to be no opportunity for the medical advice provided to the TAS office or the Appeals Officer to be contested. There is no provision for an oral appeal. The Appeals Officer's decision is binding.

Applications which have been deemed to be incomplete or invalid cannot be appealed. There have been complaints to the Ombudsman from patients who believe they have submitted a complete and valid application and have been denied their right of appeal. Following discussion between the Ombudsman's office and TAS management the HSE has agreed that it will discontinue closing applications for the reason that the application was invalid, so that an applicant can exercise their right of appeal.

An analysis of TAS appeals shows that following engagement between the Ombudsman's office and the HSE the rate of appeals going in applicants' favour has significantly increased compared to previous years. It is acknowledged that the number of appeals per year is low.

Also following engagement between the Ombudsman's office and the HSE the TAS office introduced a protocol for quality management in relation to refused applications. A random sample is reviewed periodically for this purpose.

These developments are acknowledged and welcomed.

The following case summary illustrates not just the necessity for a more comprehensive and inclusive appeals process, but also the complexities which can arise for patients who wish to travel abroad for treatment under the provisions of the TAS scheme. In this case the complexities faced by the patient arose as a result of decisions by both clinicians and administrative staff regarding the patient's pursuit of treatment abroad.

Ms S Complaint

Background according to the complainant

The mother of a young woman (Ms S) who had suffered with a severe spinal condition for many years, complained to the Ombudsman. By 2016 Ms S had undergone six spinal operations. The operations were not a success and her condition was deteriorating. She suffers with severe pain and cannot walk.

Ms S's mother and father have been caring for and supporting her in every way they can. They have been accompanying her to medical appointments with medical practitioners and specialists, in search of a medical or surgical remedy for her. In her complaint to the Ombudsman the woman stated that her daughter was unfairly denied funding by the HSE, for treatment abroad in a medical facility described by her consultant as "a world class centre" in the UK.

The healthcare pathway, leading eventually to an application for funding for treatment abroad under the TAS scheme, began in 2009. The woman stated that at that time her daughter's spinal condition was worsening considerably. Her GP recommended and initiated a referral to a specialist he described as "the only person in Ireland who could take on her case...". However, the specialist was available on a private healthcare basis only. Ms S (with the support of her family) accepted the GP's recommendation believing that this specialist offered her the best possible hope for a solution to her deteriorating health condition. Ms S and her family were unaware of the consequences of going 'privately' could have on her future application for TAS funding.

At the time of the initial GP referral to the specialist Ms S was a medical card holder, and she is a medical card holder today. Because of the seriousness of her health condition her family had included their daughter on their family medical insurance policy. They had no idea that the healthcare journey their daughter was about to embark upon with her specialist would have been so long and arduous. Between 2009 and mid-2015, her specialist operated on her four times. She had two other operations performed by another specialist in Ireland, in consultation with her treating specialist. The operations were not a success. The patient's spinal condition continued to deteriorate and the family was devastated.

In August 2015, Ms S submitted an application for funding under the TAS scheme to travel to the UK for what she hoped and believed could be 'life changing' surgery. Her treating Irish based consultant made the referral. On the E112 application form he wrote that the patient suffers from severe back pain; failed spinal surgery; failed spinal cord stimulator. He stated he was referring her to "Stanmore - a world class centre". He stated - "I have treated this patient since 2009 and operated several times. She now needs a world class second opinion". He specified the treatment she needed as - "Specialist Consultation - second opinion. Possible revision spinal surgery, to address severe back pain; immobility". The TAS application failed as it was deemed 'invalid'.

The Treatment Abroad Scheme has many conditions which must be met for an application for funding under the scheme to be approved. Ms S's application failed firstly because she was seeing her consultant as a private patient, not a public patient.

Secondly, her referring consultant was not a 'public based Irish referring consultant', which is another condition of the scheme.

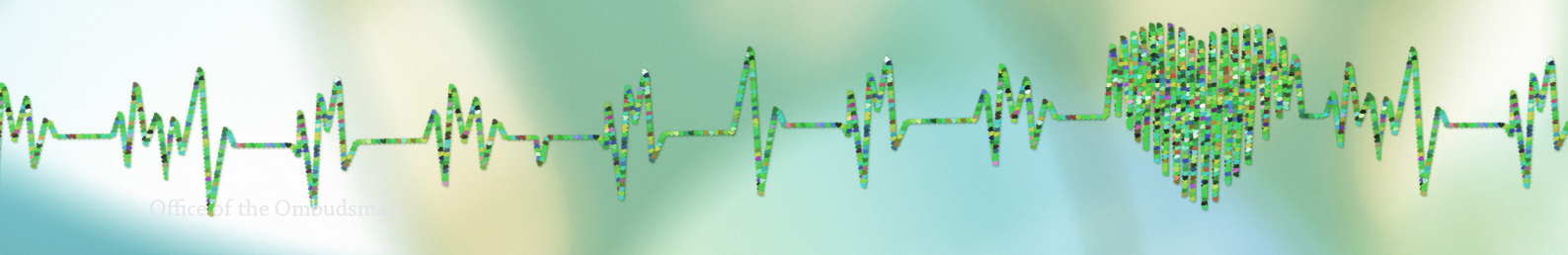
Thirdly, because specialist or second opinions are not as a general rule covered by the TAS. Fourthly, because her consultant had not reviewed her at his clinic for some 9 months prior to the date of the TAS application – the TAS scheme requires that patients are medically reviewed by their referring consultant within circa two weeks of the date of application. And finally it failed because the TAS office had not received a copy of the referral letter to Stanmore signed by her consultant. These are all valid reasons for not approving an application for funding under the TAS scheme. For these reasons the Ombudsman did not uphold Ms S’s complaint.

However, the TAS office sent Ms S a letter in response to her application stating - “As your application was invalid no decision was issued therefore it is not possible to appeal that application at this stage”. The Ombudsman does not consider a refusal of an application which denies an applicant their right of appeal to be appropriate.

In her complaint to the Ombudsman Ms S’s mother highlighted several aspects of her daughter’s healthcare journey, which caused severe frustration and upset. In discussion with the Ombudsman’s office however, she became most upset when she recalled her conversations with the TAS office in Kilkenny.

In correspondence with the TAS office, she stated –

- i. “Regarding being referred to a public consultant we have repeatedly asked our GP over the last number of years for a referral to the public system and he has continuously refused to do so. Also, [her consultant] has also told us that ‘he could not possibly do this’”
- ii. “We have now been over two years trying to sort out the TAS funding. Ms S, our daughter is now into her third year confined to a bed and is continuing to deteriorate at a rapid rate...”
- iii. “As far as skipping queues by seeking private treatment are concerned [our daughter] has more than earned her surgery abroad at this stage”.
- iv. “[Our daughter] is on a huge amount of pain medication which is paid for using her medical card.... She has undergone countless Ketamine infusions, epidurals, nerve blocks, etc., in [named Irish] Hospitals under the public system”.
- v. “We have it in writing from RNOH Stanmore that if we use [our private health insurance], [our daughter] cannot be seen in Stanmore Hospital and will instead have to attend [named] Hospital... This is not acceptable as the [named] Hospital cannot offer the same level of care e.g. services, facilities, resources, expertise, etc., as the RNOH Stanmore. Her consultant has clearly stated that she must be seen in Stanmore Hospital as it will best meet her complex needs”.
- vi. “The [private health insurers] have told us that we must pay up front for [our daughter’s] treatment and claim back later. This is something that we cannot afford to do”.
- vii. “Regarding your suggestion of taking out a loan. This is not an option for us as we have already taken out loans for housing adaptations and an adapted vehicle. The bank was very reluctant to approve these loans and we had to fight very hard to obtain them. There is no possibility of us being able to obtain another loan”.
- viii. “[Our daughter’s consultant] had referred her to a [named specialist] in Stanmore Hospital, a world renowned Spinal Hospital, for urgent surgery that he cannot perform himself. He is refusing to refer her to any other Hospital or to any other Consultant”.



Ms S's mother expressed her family's "utter disappointment" in the Irish healthcare system and its failure to meet her daughter's needs. However, she did not ask the Ombudsman to consider anything other than her daughter's refused application for funding under the TAS scheme.

Matters of clinical judgement are outside the Ombudsman's remit to examine anyway. But there are more HSE assessment processes and procedures which patients must navigate to access treatment abroad under the TAS scheme, than just the administrative actions of the TAS office in assessing applications for funding. The first step in the journey for treatment abroad normally begins with the patient's consultant. It is vital that the HSE has in place a comprehensive information and advice resource for consultants (public and private) to ensure patients are not imbued with false hope and expectation that they are eligible for treatment abroad with funding under the TAS scheme, when they do not qualify.

An examination of documentation provided by Ms S's mother and from the TAS office indicates that Ms S's application did not meet the conditions necessary for approval of funding under the TAS scheme, but the HSE, as a whole, did not respond to her application in a satisfactory manner.

In the first place Ms S was informed that her TAS application was not refused. She was informed that it was invalid. Because it was deemed 'invalid' and not 'refused' she was advised that she could not appeal. She should have received a formal refusal and been allowed to appeal. Her appeal may not have been upheld, but she should have had the opportunity to make a case and have it reviewed independently of the original decision makers. And although her appeal may not have been upheld, she may have felt that at least she had a fair hearing, rather than an unfair denial of a right.

Ms S's mother stated that the family had been seeking approval for TAS funding for her daughter for more than two years without success. Their pursuit of TAS funding for such a long time implies that the family does not understand the conditions for qualifying under the TAS scheme or what steps need to be taken to meet them. In its report to the Ombudsman the TAS office stated, *inter alia*, - "... some people choose to use the private health service... Where a person exercises this choice they place themselves outside the terms of the EU Regulation".

This is cited as another reason why Ms S's TAS application did not meet the TAS qualifying conditions. The report goes on to state - "... patients are however, free to re-enter the public system by seeking a public appointment for their treatment subject to the terms and conditions of circular 1/91 and thus become eligible to use TAS".

The conditions for TAS funding are very complex and difficult to understand. They involve interpretation and there is provision for discretion. The HSE's published information about the scheme for both patients and consultants is inadequate. Section 4a of the Ombudsman Act 1980, as amended, obliges reviewable agencies in the performance of administrative functions 'to provide reasonable assistance to applicants wishing to avail of a right, privilege or other benefit to which an eligible person is or may be entitled'.

The fact that Ms S, with her family's help, has been trying to access TAS funding for more than two years without success indicates that they have not received the 'reasonable assistance' they need to have either taken the steps necessary to meet the qualifying conditions for TAS or to understand that Ms S cannot meet the qualifying conditions.



It is the Ombudsman's view that a patient's consultant should not initiate a referral for treatment abroad under the TAS scheme until they are satisfied that the patient meets all the qualifying conditions for the scheme. The adverse affects for patients who have been given hope of a health solution abroad, only to have their hopes dashed because of a TAS refusal can be devastating.

The evidence suggests that Ms S's consultant did not understand the qualifying conditions for TAS funding approval. In this case the patient's referring consultant was a private specialist not a public based consultant employed by the HSE. Only public based consultants are allowed to make a referral for treatment abroad under the TAS scheme.

Ms S encountered additional barriers to TAS approval according to her mother, as, she said, her daughter's consultant and GP refused to refer her to a public based Irish consultant, who could perhaps have made an appropriate referral for her under the TAS scheme.

Analysis

Ms S and her family's experience in trying to access appropriate healthcare services has left them feeling angry and upset. It is easy to understand why this should be the case. One obvious reason for this is that Ms S's surgical treatments did not improve her condition or relieve her pain, and her spinal condition continues to deteriorate. Complaints to the Ombudsman often highlight the pain and suffering patients and their families experience when medical treatments fail. It is a sad reality for many patients that the medical treatment they receive does not resolve their health need.

Ms S and her family pursued a healthcare course on the advice they received from their healthcare providers. They trusted and believed their daughter's GP that the consultant he referred her to was the best qualified specialist in Ireland for spinal problems, and perhaps he is. Because of the urgency of Ms S's condition, which was deteriorating rapidly, they decided Ms S should see the consultant privately.

This was a perfectly reasonable and understandable choice in the circumstances. None of the family could have imagined at that time that they were embarking on an eight year healthcare journey leading to several unsuccessful surgical procedures, and the refusal of an application for treatment abroad in the UK, which they eventually saw as their only hope for a successful medical remedy for Ms S. This is a clear example of how the two tier public and private healthcare structure in Ireland resulted in unforeseen consequences for this family, when it came to TAS funding. Today the family is still searching for a surgical procedure for Ms S.

In its response the HSE thanked the Ombudsman for bringing this case to its attention, promising a prompt follow up on its part. A meeting has been offered to Ms S and her family at a time of their choosing to advise them on a future TAS application to avoid the problems that were encountered. Since then Ms S's mother advised the Ombudsman that the HSE has invited Ms S and her family to a meeting and that they were preparing themselves for that meeting. The Ombudsman is grateful to the HSE for following up on the matter in this way

The Ombudsman does not criticise the HSE's decision not to approve TAS funding for Ms S on the basis of the application submitted, as the decision was in accordance with the conditions governing the scheme. However, this complaint illustrates some of the intrinsic complexities in the TAS scheme for patients who may wish to avail of it.

Recommendation

The Ombudsman recommends that a review of the appeals process be undertaken which will consider –

- A reasonable time scale for submitting an appeal
- A process for appealing refusals on medical grounds
- Access to oral appeals for patients
- Comprehensive explanations of reasons for not upholding an applicant's appeal
- Appropriate signposting to the Ombudsman's office.

Appendices

Appendix 1 a

Summary of the Treatment Abroad Scheme's underpinning legislation and explanation

Regulation (EEC) No 1408/71

Social security schemes and free movement of persons: Basic Regulation

This Regulation coordinates national social security legislation in order to protect the social security rights of persons moving within the European Union.

ACT Regulation (EEC) No 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons and their families moving within the Community [See amending acts].

SUMMARY This Regulation is accompanied by implementing Regulation (EEC) No 574/72, which covers the practical implementation (competent national authorities, administrative formalities, etc.).

Persons covered

The Regulation applies to workers (employed and self-employed) who are nationals of a Member State or third country, or stateless persons/refugees residing in the territory of a Member State to whom the legislation of one or several Member States applies, and to the members of their families and their survivors. It also applies to survivors of these workers irrespective of the nationality of the latter, provided the survivors are Community nationals, and to civil servants and persons treated as such in accordance with the legislation applicable.

The Regulation also applies to persons who are studying or undergoing vocational training and to the members of their families.

Equality of treatment

Persons residing in the territory of a Member State to whom the Regulation applies are subject to the same obligations and enjoy the same benefits under the legislation of a Member State as the nationals of that State.

As regards sickness and maternity benefits, the Regulation makes it possible for European citizens to obtain health care while residing in a Member State other than that in which they are registered. However, this is possible only under certain conditions and in accordance with specific procedures. European citizens may obtain health care when they are staying abroad or if they choose to receive treatment in another Member State.

References

Act Entry into force - Date of expiry Deadline for transposition in the Member States Official Journal Regulation (EEC) No 1408/71 01.10.1972 - L 149 of 05.07.1971

Successive amendments and corrections to Regulation (EEC) No 1408/71 have been incorporated in the basic text. This consolidated version is for reference purposes only.

Social security schemes and freedom of movement of persons: implementing rules This Council

Regulation lays down practical rules for implementing Regulation (EEC) No 1408/71 on the coordination of social security schemes for persons moving within the Community.

ACT Council Regulation (EEC) No 574/72 of 21 March 1972 fixing the procedure for implementing Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons and their families moving within the Community [See amending acts].

Summary

The Regulation identifies the competent institutions in each Member State, the documents to be produced and the formalities to be completed in order to receive benefits. It sets out the procedures for administrative and medical checks and the reimbursement conditions for benefits provided by an institution in one Member State on behalf of an institution in another Member State. It also describes the functions of the Audit Board.

Repealing Regulation (EEC) No 574/72 Regulation (EC) No 883/2004 was adopted in order to simplify and clarify the coordination of Member States' social security systems. This new reference framework will facilitate the free movement of European citizens within the Community territory. It strengthens the cooperation requirements of national administrations with regard to social security and makes electronic exchange of data between administrations obligatory.

Regulation (EEC) No 574/72 is repealed. However, some of the Regulation's provisions remain in force in order to ensure the legal certainty of related Community acts and agreements.

Appendix 1 b

The following is a précis of information available to the public and the medical profession derived from HSE information documentation and the HSE website.

The HSE operates a Treatment Abroad Scheme (TAS), for persons entitled to treatment in another EU/EEA member state or Switzerland under EU Regulation 1408/71, as per the procedures set out in EU Regulation 574/72, and in accordance with the Department of Health guidelines. Within the governing regulations and guidelines, the TAS provides for the cost of approved treatments in another EU/EEA member state or Switzerland through the issue of form E112 (IE).

The TAS provides the cost of approved treatments in another EU/EEA member state or Switzerland. The TAS allows a Consultant based in Ireland to refer a patient that is normally resident in Ireland for treatment in another EU member state or Switzerland, where the treatment in question meets the following criteria:

- (a) The application to refer a patient abroad has been assessed and a determination given before that patient goes abroad.
- (b) Following clinical assessment, the referring Consultant certifies the following: - They recommend the patient be treated in another EU/EEA country or Switzerland; - The treatment is medically necessary and will meet the patient's needs; - The treatment is a proven form of medical treatment and is not experimental or test treatment; - The treatment is in a recognised hospital or other institution and is under the control of a registered medical practitioner; - The hospital outside the state will accept EU/EEA form E112 (IE).

Accessing the Scheme

A person may be entitled to access the scheme and avail of treatment in the public healthcare system of another EU/EEA member state or Switzerland where the conditions, criteria and procedures set out below are all adhered to.

Conditions and Criteria

A person ordinarily resident in the Republic of Ireland may be referred abroad by an Irish based consultant for treatment that is:

- (a) Among the benefits provided for by Irish legislation and
- (b) (i) not available in Ireland or
- (ii) not available within the time normally necessary for obtaining it in Ireland, taking account of his/her current state of health and the probable course of the disease.

Self-referrals or referrals by a G.P. are not acceptable.

An application form must be completed by both the patient and the patient's referring Consultant. The completed application form must be submitted to the HSE for assessment and a decision must be given by the HSE prior to the patient travelling abroad or blood samples being sent abroad. The

HSE will not be responsible for any costs associated with a treatment or consultation abroad where prior approval was not given and an E112 was not issued.

Following clinical assessment, medical evidence must be provided by the referring hospital Consultant, giving details of the patient's medical condition, the type of treatment envisaged and the proposed provider of the treatment abroad. A copy of the referral letter to the Consultant outside the state may be sufficient. The referring Consultant having reviewed the patient in the immediately previous two weeks must certify the following:

- They recommend the patient be treated in another EU/EEA country;
- The treatment is medically necessary and will meet the patient's needs;
- The treatment is a proven form of medical treatment and is not experimental or test treatment;
- The treatment is in a recognised hospital or other institution and is under the control of a registered medical practitioner;
- The hospital or other institution accepts form E112 (IE);
- The treatment is not available in Ireland.

Not available within the time normally necessary for obtaining it in Ireland, taking account of his/her current state of health and the probable course of the disease.

The application and referral letter must be submitted to the HSE TAS Office in sufficient time as to allow assessment and decision prior to the patient travelling abroad. The decision making process is estimated at 15 to 20 working days following the receipt of a fully completed application and suitable referral letter. Only information pertaining to the estimated date for issue of a decision can be provided by TAS

office staff. TAS office staff are not permitted to give confirmation of a decision in advance of the issuing of the decision letter to the applicant.

Approval, where granted, is for specific medical treatment as per evidence provided by the referring Consultant and the submission of a completed application form. Requests for additional treatments or associated examinations or consultations which may arise while visiting the foreign facility will not be considered or included in the payment to be made by the HSE. Any costs associated with any such additional treatment, or associated examination or consultation availed of, will be the responsibility of the applicant.

In some cases patients may require subsequent visits to the accepting hospital abroad. Treatments subsequent to that specified in the initial approval will require submission of a new fully completed application form to be processed as outlined above.

Where the decision has been made to decline an application, the patient/applicant is informed of the decision rationale and provided with a copy of the appeals process

The Patient's Responsibility

The patient/applicant must submit a fully completed application form accompanied by the appropriate referring Consultant's letter in sufficient time to allow the HSE assess and make a decision on same. The onus is on the patient to submit a fully completed application form and to provide the necessary information from the referring Consultant. Incomplete applications will be returned to the patient/applicant for provision of the appropriate information prior to re-submitting to the TAS office.

If approved, the patient/applicant must provide confirmation of every appointment they are due to attend to allow the issue of the E112 form to cover the cost of their visit. Failure to produce the document at their appointment may result in them being charged for their hospital visit. Reimbursement of any fees incurred due to the failure to produce the documents at an appointment will not be reimbursable by the HSE.

The Consultant's Responsibility

The Consultant must fully complete the application form and provide sufficient information, giving details of the patient's medical condition, the type of treatment envisaged and the provider of treatment abroad.

Referrals must be on the basis of medical necessity confirmed by a clinical review of the patient, to the public healthcare system of another EU/EEA member state or Switzerland through the issue of model form E112 (IE). Therefore the consultant must be currently treating the patient and be filling in the application form on the basis of his/her medical opinion and not at the request of another member of his/her team or the patient.

Should a Consultant wish to make a referral abroad that is outside the TAS qualifying criteria, this will be a matter for the Consultant and the referring Hospital. In this case the CEO of the referring Hospital should be notified in consideration of the implications this may have from a hospital budget perspective.

The TAS Office

The TAS office will return any incomplete applications to the patient/applicant outlining information needed. The TAS office aims to provide a decision on an application within 15 to 20 working days. The TAS office will notify the patient/applicant and the Consultant on decision without undue delay by letter.

Travel Policy

The Treatment Abroad Scheme as provided for in EU Regulations and Department of Health and Children Guidelines, does not include a provision for Travel and or Subsistence expenses for patients or their relatives travelling abroad to avail of approved treatments. However, the HSE and specifically the TAS may provide assistance towards reasonable economic air or sea travel fares for patients, and a travelling companion where appropriate. The HSE Treatment Abroad Scheme National Travel Policy was implemented in November 2009 to standardise and provide equity to the provision of entitlements relating to travel expenses. This policy supersedes all previous arrangements on the provision of travel and subsistence expenses regardless of the date of approval granted or the value of coverage provided previously.

The following is an extract from a HSE guidance note for referring Consultants.

Guidance for Hospital Consultants Referring Public Patients for Funding under the HSE Treatment Abroad Scheme

The purpose of this document is to provide advice, support and guidance to consultants in relation to the completing and submitting of an application form for funding for a treatment that is not available in Ireland. This guidance is not intended to provide a comprehensive response to all such possible questions but seeks to address the more common queries.

All consultants initiating a referral to the TAS are bound by the duties of care for the patient when making a referral to a service abroad.

In the case of E112, and in fulfilment of those duties, applications should only be filled out for a patient in the following instances:

- The consultant must have reviewed the patient in the immediately preceding time frame (circa 2 weeks).
- The decision to refer a patient abroad must be that of the treating consultant. The referral should not be on the basis of a third party request (e.g. a patient, a parent, an advocate, a hospital abroad etc), but is being recommended by the consultant in his/her provision of care to that patient.
- The treatment being sought is a proven treatment.
- The treatment must not be part of a clinical trial.
- The treatment being sought is provided for under Irish legislation.
- The treatment being sought is unavailable in Ireland. (Every effort should be made by the referring consultant to ascertain if the treatment is in fact available in Ireland. One of the most common reasons for decline of an application is that the treatment or an equivalent treatment is available in

Ireland.)

- There is no equivalent treatment available for the specific condition in Ireland.
- That all options for treatment up to and including referral to a tertiary centre within Ireland have been utilised in the first instance.
- The referring consultant must specify the specific treatment: describing the patient's condition does not suffice for the purposes of applying to the TAS even in the case of a rare disease. The referring consultant must identify the specific treatment and affirm as to the suitability of the treatment for the patient. When completing a TAS application form the consultant must also enclose a copy of his/her letter of referral to the service abroad and ensure the following criteria are met:
 - (i) That the service the patient is being referred to is a public facility and thus will accept Model Form E112.
 - (ii) That the form is signed by the consultant and not pp'ed (per persona) by a secretary or junior doctor on his/her behalf.
 - (iii) That the specific treatment being requested is clearly specified.
 - (iv) It is the responsibility of the referring consultant to identify the facility and appropriate clinician to whom he/she is referring his/her patient.
 - (v) Applications for second or specialist opinions will only be processed where evidence is provided that same has been accessed in the relevant speciality here in Ireland and/or through advice from the HSE Clinical Leads in the first instance.

When a patient is referred abroad the E112 is issued on the basis that the patient is referred for the treatment on the application form only, unless otherwise amended. The patient may only avail of the approved treatment.

When the episode of care abroad is completed, the treating facility is required to provide the referring consultant with an appropriate medical report for the patient to ensure the smooth transfer of the patient's care back to the referring consultant. The patient's care immediately reverts to the Irish based referring consultant.

In general any additional or subsequent treatments will require a new application (there are exceptions to this rule e.g. organ transplants etc). An application form may specify more than one episode of care if same can reasonably be justified. For example in the case of an organ transplant patient it is expected the application may include an assessment, the surgery and a specified number of follow up visits for the patient. An application form may not be open ended and does not transfer the care of the patient abroad indefinitely.

The purpose of this guide is to provide guidance on the issues most frequently raised with us by Consultants. However, if you have further specific questions which you wish to have addressed please feel free to contact Ms Catherine Donohoe at catherinet.donohoe@hse.ie or treatmentabroad.scheme@hse.ie.

Please be aware that applications are just that, an application and the decision on the application may result in an approval or a decline.

Appendix 1 c

Department of Health Guideline on TAS & associated documents

16 September 2008
Professor Brendan Drumm
Chief Executive
Health Service Executive
Dr Steeven's Hospital
Dublin 8

Dear Professor Drumm

I am writing to you concerning the entitlement of persons with full or limited eligibility to be sent abroad for treatment under EU law.

Circular 21/85 dated 23 December 1985 has until now dealt with treatment abroad under EU law. I am attaching now a revised Circular which takes account of some changes in entitlement to treatment abroad following the judgement of the European Court of Justice in Case C -372/04 (the Watts case).

The Watts case, which arose in the UK, relates to the question of patient mobility and, specifically, the circumstances in which a person is entitled to have medical treatment in another member state at the cost of the home state's healthcare system. The Watts case has implications for the manner in which Article 22 (1) (C) of Regulation 1408/71 is to be interpreted; for this reason, the Circular as attached has been updated to take account of this judgement.

However, a second route for treatment abroad exists under Article 49 of the EC Treaty. This allows persons attached to the healthcare system of one member state to have treatment in another member state at the cost of the home system. Where the treatment is hospital treatment, a system of prior authorisation may be implemented in the home state to assist in planning and control. At the same time, authorisation must be granted where the treatment is among the benefits provided by the home state and where the patient cannot get the treatment in the home system without undue delay. There are a number of differences between the E112 and the Article 49 arrangements including those relating to the assumption of costs by the home Member State (under Article 49 patients are reimbursed up to the amount that would have been paid had they obtained the treatment at home but they bear the financial risk of any additional costs arising).

Accessing services under Article 49 of the Treaty raises a number of issues, not least in relation to the management of patient safety and continuity of care in cross-border situations. These and other issues relating to cross-border healthcare are currently the focus of discussions at EU level and a Directive is currently being discussed by all Member States.

For these reasons, the attached Circular does not deal with entitlement to treatment under Article 49 of the Treaty per se, and reflects the Watts judgement only insofar as it affects the operation of E1 12 arrangements.

Yours sincerely
Dermot Smyth
Assistant Secretary

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16 September 2008

Updated guidance in regard to treatment abroad with particular reference to EU law -

Dear Chief Executive Officer

I am directed by the Minister for Health and Children to refer to entitlement to receive healthcare outside of Ireland under the provisions of EU Regulations on the coordination of social security, including healthcare, taking into account the case law of the European Court of Justice (ECJ), in particular case C-372/04 (Watts).

The area of cross-border healthcare, including patient mobility, is currently the focus of discussions at EU level and a Directive is being proposed in this area. Separately, it is expected that Regulations (EC) 1408/71 and 574/72 will be replaced within the next two years by revised and simplified Regulations. You should bear in mind, therefore, that the guidance set out below may need to be revised again in the future to take account of developments and should therefore be regarded as interim guidance.

1. Conditions under which authorisation for treatment abroad under E112 arrangements must be granted.

Regulation (EC) 1408/71 sets out entitlements of insured persons of one member state who receive public health services in another member state. Regulation (EC) 574/72 sets out the procedures to be followed in implementing Regulation 1408/71. These arrangements apply in all EU / EEA member states and Switzerland (full list at Annex 1). References in this guidance to "Europe" and "European" should be understood accordingly.

Article 22 (1) (c) of Regulation 1408/71 governs the referral of patients for public health services to another European country. In accordance with this article, a person eligible for health services in Ireland may be authorised by the HSE to go to another country for treatment in the public health system there. When a person is authorised to receive treatment abroad under the above provisions, Form E112 is issued by the HSE. Issue of this form by the HSE involves a commitment by the Executive to pay the cost of treatment. This is reimbursed to the competent institution of the country that has provided the service, in accordance with Article 93 of Regulation 574/72. Form E125 is issued for the purpose of claiming this reimbursement by the competent institution of the country which provided the service for the patient. .

The HSE may not refuse to give authorisation for treatment abroad under Article 22 (1) (c) of Regulation 1408/71 if: [My emphasis]

- (i) the treatment in question is among the benefits provided for by Irish legislation (see below) and
- (ii) the individual cannot be given this treatment within the time normally necessary for obtaining it in Ireland, taking account of his/her current state of health and the probable course of the disease. In the course of its judgement in the Watts case, the European Court of Justice has ruled

on the interpretation of this condition, as set out in more detail in paragraph 1 (ii).

1(i) The treatment in question is among the benefits provided for by Irish legislation

This criterion must be met before the patient is entitled to receive treatment in another member state under E112 arrangements. It means that there can be no entitlement to receive a particular treatment in another European country at the cost of the HSE unless the patient is eligible for the same or similar treatment within the Irish public healthcare system.

In general, if the treatment is available to public patients in the Irish public health system, then it must be considered that the treatment is among the benefits provided for by Irish legislation.

However, the fact that the treatment is not available to public patients in the Irish public health system should not automatically mean that the treatment is not among the benefits provided for by Irish legislation. E112 arrangements have traditionally provided scope for referring patients for medically necessary procedures or treatments that, because of their highly specialised nature, are not available in Ireland and this approach should be continued. At the same time, E112 arrangements should not be used to fund a treatment solely on the grounds that it is taking place in

another European country; the fact that a treatment is part of the public system in another European country does not of itself mean that the patient is eligible for the same or similar treatment within the Irish public healthcare system.

If the treatment is not available in Ireland because to provide it would be illegal, then it must be considered that the treatment is not among the benefits provided for by the Irish public health system.

1(ii) The patient cannot obtain the treatment at home within the time normally necessary for obtaining it”.

Where the patient can obtain the treatment at home within the time normally necessary for obtaining it”, there is no obligation under Regulation 1408/71 to authorise treatment outside Ireland.

If the criterion at (i) above is met and if the treatment is either not available or not available within the time normally necessary for obtaining it” from the HSE, then, having regard to the procedures set out below, the patient is legally entitled to be issued with a Form E112 to have the service in another European country.

As referred to above, the ECJ has ruled on what the phrase within the time normally necessary for obtaining it” means in practice. Where the treatment is available in this country, then in accordance with the ECJ’s ruling the HSE must take into account the medical circumstances of the individual case. This requires the HSE to arrange for an objective medical assessment of the patient’s clinical needs, in the light of his or her medical condition, the history and probable course of the illness, the degree of pain the patient is in and/or the nature of his or her disability at the time the request for authorisation is made or renewed, as the case may be. If the delay in obtaining treatment arising from waiting lists exceeds an acceptable time based on the medical circumstances as outlined above, then authorisation to go to another member state to obtain the treatment more quickly cannot be refused.

The key factor here is the medical circumstances of the individual patient. The fact that a waiting list exists, that others are waiting a similar length of time for a similar treatment, or that the waiting time is within defined national parameters for the condition, does not mean that the waiting time for this particular patient is acceptable.

2. Procedures

The application to refer a patient abroad must be assessed before that patient goes abroad except in cases of extreme urgency. The request for a form E112 should include the following:-

- (i) The recommendation of the patient's consultant that they be treated in the other EU/EEA country with full details of the type of treatment and the proposed provider. It should also show that a clinical assessment has been carried out to demonstrate that the treatment is medically necessary and will meet patient needs.
- (ii) The treatment is regarded as a proven form of medical treatment and is not experimental or test treatment.
- (iii) The treatment is in a recognised hospital or other institution and is under the control of a registered medical practitioner.

The ECJ has ruled on what is required from a prior authorisation system for treatment abroad, such as the E112 procedure. The system must be based on objective, non-discriminatory criteria which are known in advance, in such a way as to limit the exercise of discretion, so that it is not used arbitrarily. It must be based on a procedural system which is easily accessible and capable of ensuring that a request for authorisation will be dealt with objectively and impartially within a reasonable time. Refusals to grant authorisation must be capable of being challenged in judicial or quasi-judicial proceedings. It will therefore be necessary to ensure that the procedures and processes involved in the request for a Form E112 adhere to these principles.

It should be borne in mind that the provisions of Regulation (EC) 1408/71 coordinate public healthcare systems and, consequently, E112 arrangements apply only in relation to referral of patients for healthcare in another European country's public system.

The HSE should also be cognisant of the fact that criteria for assessment of requests for treatment abroad should not be more rigorous than those imposed for treatment at home. It is only on the basis that these criteria apply equally to all treatment provided by the HSE that they are acceptable under European Law in relation to cross-border treatment.

3. E112 arrangements where the essential criteria for entitlement are not met

While the two criteria referred to in section 1 above must be met if the patient is to have an entitlement to receive treatment abroad under E112 arrangements, nothing in the Regulations prevents the HSE from making a decision to issue the form E112 for treatment in the public health system of one of the countries listed in Annex 1 even if the essential criteria are not met. However, as stated above, decisions on requests for the form E 112 may not be based on the arbitrary use of discretion but must be based on clear, objective and non-discriminatory criteria and adhere to the principles set out by the ECJ. .

This guidance deals only with referrals for treatment abroad under E112 arrangements. Any arrangements for treatment abroad outside the European countries covered are at the discretion of the HSE and are not subject to the criteria set out in this guidance.

4. Refusal of E112 applications

As already referred to above, the ECJ has ruled that refusals to grant authorisation for treatment abroad, in this case the form E112, must be capable of being challenged in judicial or quasi-judicial

proceedings. It will be necessary to ensure that, where a decision is made to refuse an application for an E112, the applicant is advised of their right to appeal the decision and that an appropriate process is in place to deal with that appeal.

The guidance set out above should be brought to the attention of all staff involved in assessing patients for treatment abroad.

Circular 21/85 is hereby withdrawn.

Yours sincerely

Dermot Smyth Assistant Secretary — Eligibility Division .

Appendix 2 a

Cross Border Directive

What is the Cross Border Directive?

The Cross Border Directive is a scheme operated by the Health Service Executive (HSE), on behalf of the Member State of affiliation (MSA), in accordance with Directive 2011/14/EU, for those ordinarily resident in Ireland who have the proper referral for public healthcare to access health services in another EU/EEA (European Union/European Economic Area) country or Switzerland. CBD covers treatments that are publicly funded and available in Ireland. The cost of the treatment is paid in advance by the patient and the HSE reimburses the cost in line with published rates.

The Directive establishes rules for facilitating access to safe and high-quality cross border health care in the EU/EEA and to ensure patients can move freely between states, in accordance with the principles established by the Court of Justice.

The Directive provides that patients should be provided with healthcare in a Member State, other than the MSA, along with the prescription, dispensation and provision of medicinal products and medical devices where these are provided in the context of a health service. The Directive also says that it should cover a situation where a patient buys medicinal products and devices in a Member State other than the MSA, along with where a patient buys such medicinal products and devices in another Member State, than that in which the prescription was issued. All patients must be treated equitably on the basis of their health care needs, as opposed to the basis of their MSA.

The Directive says that patients should enjoy a guarantee of assumption of the cost of that healthcare at least at the level that would be provided for the same healthcare, had it been provided in the MSA. This should fully respect the responsibility of the Member States to determine the extent of the sickness cover available to their citizens. For patients, the two systems should be coherent – either the Directive applies or the Union regulations on the coordination of social security systems apply.

The obligation to reimburse costs of cross border health care are limited in healthcare to which the insured person is entitled according to the legislation of the MSA. The Directive does not apply to those needing assistance with everyday tasks, such as long term care services provided by a nursing home. It doesn't apply to access to and allocation of organs for the purpose of organ transplants.

Who is eligible?

Patients entitled to public patient services in Ireland can apply under the CBD to have the treatment abroad in the Member State of treatment (MST). Funding will be reimbursed for healthcare that is publicly funded and available in Ireland and which is not contrary to Irish legislation. CBD can be accessed in either the public or the private healthcare system of the MST. Those who have private medical insurance, i.e., private patients, are not deemed to be public patients for the purpose of the CBD.

What is covered by the CBD?

Acute/psychiatric hospital services, day, in-patient and out-patient care, community based outpatient care, including dental, ophthalmic, orthodontics, along with speech and language services.

Application Process

The HSE has established a National Contact Point (NCP) for the administration of the CBD. The NCP allows the patient's GP/Consultant etc to identify the clinician abroad and satisfy him/herself in relation to the qualifications of that clinician, along with the quality and safety of the services provided.

The patient must obtain prior approval from the GP, a hospital consultant or from other HSE professionals, for all overnight hospital accommodation, including any treatment that might present a risk to the patient or others. This allows the patient to have full information and make an informed decision. It also allows the patient to know the precise reimbursement rate that applies to the procedure identified on the application form. The amount reimbursed will be at the cost of the treatment availed of abroad or the cost of providing the healthcare in Ireland, whichever is the lesser. CBD covers treatment costs only. CBD does not cover travel and subsistence costs, nor does it cover the cost of translation of any documents.

There is no application process for out-patient or day-case care. Once you have a referral from a GP etc, the patient submits the invoice, receipts, pro-forma invoice, proof of travel etc to the HSE for reimbursement. The patient should bring the pro forma invoice with them when travelling abroad for treatment. The treating clinicians abroad must complete this form in English as it contains the information the HSE will need to process a claim for reimbursement. The patient must provide the invoice from the foreign provider and proof of payment. If the pro forma invoice is not completed in English, the patient has to provide a certified translation of the invoice from the foreign provider.

The patient must seek prior authorisation for all instances of in-patient (over night stay) care prior to accessing that care. The patient must submit a fully completed application form accompanied by the appropriate referring letter in good time to allow the HSE to assess and make a decision. The onus is on the patient to submit a fully completed application form and provide all necessary information from the referring clinician. A decision can take between 15 and 20 working days.

Reimbursement

Reimbursement will be made to the patient only. There are exceptions, such as parents or guardian of a child if the patient is a child, or an executor of an estate, if the patient is deceased, but the paperwork must be in order.

Appendix 2 b

European Health Insurance Card

As an Irish resident you are entitled to get healthcare through the public system in countries of the European Union (EU), European Economic Area (EEA) or Switzerland if you become ill or injured while on a temporary stay there.

Until now, you needed an E form – such as the E111 or the E128 - to get such treatment. Now, these paper forms are being replaced by the European Health Insurance Card. One Card is needed for each individual or member of the family.

The Card was introduced on 1 June 2004. It means that you can get necessary healthcare in the public system of any EU / EEA country or Switzerland, if you become ill or injured while on a temporary stay in that country.

Apply for the European Health Insurance Card if you:

- Plan to go on holiday to another EU / EEA country or Switzerland
- Regularly visit any of these countries, for example, on business, as a transport worker or for leisure
- Plan to go to any of these countries to seek work
- Are being sent by your employer to work in any of these countries temporarily but will continue to pay tax in Ireland
- Intend to undertake a course of study in any of these countries but still consider yourself as ordinarily resident in Ireland
- Intend to visit any of these countries for any other type of temporary stay where healthcare in itself is not the aim of the visit

Travelling to Great Britain or Northern Ireland

You don't need a European Health Insurance Card to get necessary healthcare while on a temporary visit to the UK. It is enough to show proof that you are ordinarily resident in Ireland – in practice, this means a driving license, passport or similar document.

If you would like more information, contact your local HSE Office

Appendix 2 c

Private Health Insurance Cover For Treatment Abroad

The Cross Border Directive (CBD) entitles persons ordinarily resident in Ireland who have an appropriate referral for public healthcare to avail of that healthcare in another EU/EEA country or Switzerland. CBD covers treatments that are publicly funded and available in Ireland. CBD can be accessed in either the public or the private healthcare system of the Member State of Treatment. However, those who have private medical insurance, i.e, private patients, are not deemed to be public patients for the purposes of CBD.

TREATMENT ABROAD

An Investigation by the Ombudsman into the administration of the Treatment Abroad Scheme by the Health Service Executive (HSE)

Some private health insurance companies provide cover for treatment abroad. For example, some insurance policies provide benefits in certain circumstances, subject to prior written approval and satisfaction in full of specified criteria, for planned treatment abroad during a temporary stay abroad. Insurance policies can provide insurance for surgical treatment that is available in Ireland. They can pay benefit for medically necessary surgical procedures that are listed in their schedule of benefits. Insurance companies normally pay up to the average benefit that they would have paid in respect of the same surgical procedure in Ireland under the customer's level of cover (including professional fees). For a therapeutic procedure that is not available in Ireland, some insurance companies will pay up to the plan amounts specified in their tables of benefits applicable to the customer's plan, unless a reasonable alternative therapeutic procedure is available in Ireland.



Ombudsman

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