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DEPARTMENT
OF HEALTH
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Shaping a
Healthier Future

Press Release

issued by

Minister for Health

Michael Noonan TD

12 September 1995

p. 4 ~~after~~ correction
to follow

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Announcement of Membership of Compensation Tribunal

Extension of Compensation Scheme to cover Blood Transfusion or Blood Product Recipients

Health care for persons who have contracted Hepatitis C from Anti D, a blood transfusion or a blood product

Targeted Lookback Programme

Optional Testing Programme for Blood transfusion and blood product recipients.

Membership of Compensation Tribunal

The Minister for Health, Mr Michael Noonan, T.D., today (12th September 1995) announced the appointment of the members of the Compensation Tribunal to compensate persons who have contracted Hepatitis C from the use of Anti D. The tribunal will be chaired by the Hon. Mr Justice Seamus P Egan, Judge of the Supreme Court. The other members of the Tribunal are Alison Cross, Barrister-at-law, Sheila Cooney, Solicitor and Eileen Leyden, Barrister-at-law.

The Minister for Health will formally announce the working arrangements of the Tribunal in the coming weeks. A copy of the Scheme of Compensation is at Appendix 1.

Extension of Compensation Scheme

The Minister announced today that the Government has decided to extend the scheme of compensation to include individuals who contracted Hepatitis C from a blood transfusion or a blood product.

Minister Noonan said:-

"I am very hopeful that all those affected will consider the tribunal an acceptable, prompt and informal setting in which to deal with the compensation issue".

The Minister confirmed that the Tribunal will be established before the end of the year. The Department of Health is in detailed discussion with the Attorney General's Office with regard to the amendment of the Scheme to facilitate the inclusion of blood transfusion and blood product recipients in the Compensation Scheme.

Health Care for Hepatitis C patients

Detailed consideration has been given by the Minister to the submissions made to him in relation to the long-term health care needs of Hepatitis C patients. In particular, the Minister is committed to ensuring that the future health care needs of Hepatitis C patients will continue to be met in the most appropriate and effective manner. The Minister is therefore pleased to announce that the Government has approved the following package of health care measures.

Hospital In-Patient and Out-Patient Services

The special hospital in-patient and out-patient services and counselling services which have been put in place under the Health Acts to meet the needs of Anti-D recipients who have been diagnosed positive for Hepatitis C antibodies/virus will remain in place for as long as they are required and blood transfusion and blood product recipients will also have access to these special hospital services.

General Practitioner Services

The Health Act, 1970, will be amended, at the earliest possible opportunity, not later than December, 1995 to place an obligation on health boards to arrange for the provision, without charge, of a general practitioner medical service for specified categories of persons suffering from Hepatitis C for the treatment and care of Hepatitis C and related conditions.

The legislation will provide for the making of regulations by the Minister which will, inter alia, specify the categories of persons entitled to avail of these services.

The draft legislation and draft regulations will be the subject of consultation with interested parties.

Research on Hepatitis C

The Minister for Health will arrange with the Health Research Board (HRB) for the establishment and funding of a special programme of research on Hepatitis C. This will have a national and international dimension and will be funded on an ongoing basis.

An information note on Hepatitis C is at Appendix 2.

Monitoring Body

Under the powers conferred on him by the Health Acts 1947 and 1953, the Minister for Health will by Order before December 1995 establish a Statutory Consultative Council to advise him on matters relating to Hepatitis C. The functions of the consultative Council will include:

- the monitoring of health and counselling services for persons with Hepatitis C;
- the making of recommendations on the organisation and delivery of services for persons with Hepatitis C;
- publication of information on Hepatitis C.

Minister Noonan stated that the needs of blood transfusion and blood product recipients diagnosed as positive for Hepatitis C will be reassessed on an ongoing basis to ensure that the necessary services are provided to meet their needs.

The primary purpose of the monitoring body will be to ensure that an independent view is available to the Minister of the continuing adequacy and appropriateness of services which will be provided for Hepatitis C patients.

Targeted Lookback Programme

The programme is

- targeting recipients of blood transfusion prior to 1 October 1991 by tracing the past donations of donors now identified with evidence of Hepatitis C virus infection.

The donors whose past donations are being traced are

- a number of women who were identified as Hepatitis C positive following the administration of Anti-D;
- persons who were identified as Hepatitis C positive following the introduction of routine screening of blood donations in October 1991;
- persons who have been diagnosed as Hepatitis C positive. The BTSB has asked Hepatologists (Liver Specialists) and other Medical Practitioners to advise the BTSB of patients with a diagnosis of Hepatitis C; and
- persons who are identified as Hepatitis C positive under the Targeted Lookback Programme.

The Targeted Lookback Programme has two phases

- the first phase has identified and will continue to identify donors who have tested positive for Hepatitis C, the product - whole blood, red blood cells, platelets or plasma and its derivatives - the hospital to which the product was issued and the recipients.
- The second phase has traced and will continue to trace the recipients who will be offered testing. The programme is well underway and contact has been made and is being made with recipients through their general practitioners, with a view to assessment and obtaining blood samples for testing for Hepatitis C.

The Targeted Lookback Programme will continue indefinitely as donors present with Hepatitis C who may have made donations prior to the introduction of routine screening in October 1991.

Information from Targeted Lookback Programme and implications for blood transfusion/blood product recipients

The results of the Targeted Lookback Programme to date are set out in Appendix 3.

The following information has been gleaned from the Targeted Lookback Programme to date;

- The vast majority of individuals who have been given a blood transfusion will not have been infected with Hepatitis C. Blood transfusion recipients can be reassured that the risk is small.
- Since the introduction of screening on 1 October 1991, the risk of Hepatitis C transmission from blood transfusion is very low. The risk is of the order of 1 in 170,000.
- Prior to the introduction of screening on 1 October 1991, up to 1 in 3,000 donations may have been potentially infectious for Hepatitis C virus.
- Not everybody who is exposed to Hepatitis C will remain infected: a significant number of persons infected with Hepatitis C will clear the virus.
- 400 individuals who have received potentially infected blood are expected to be traced under the Targeted Lookback Programme. To date 103 individuals have been traced and tested for evidence of Hepatitis C infection.
- Approximately 70 individuals who received potentially infected blood will not be traced by the Targeted Lookback Programme .

Therefore, the risk of any individual having Hepatitis C following blood transfusion is extremely small, particularly after October 1991. The majority of individuals who are at risk will be traced under the Targeted Lookback Programme.

The Targeted Lookback Programme has been very successful to date in tracing recipients of potentially infected blood. It is confidently expected that its success in tracing recipients will continue. It is accepted internationally that the best method to identify those blood transfusion recipients truly at risk is to trace them from identified infectious donations.

However, it will not be possible to trace all individuals who may have been exposed to Hepatitis C through blood transfusion or blood products. This is because not all transfusion records are available and traceable. Furthermore, some donors who had Hepatitis C prior to the introduction of routine screening of donations in 1991 have not come back to donate since 1991 and therefore cannot be identified.

Optional Testing Programme

While the Targeted Lookback Programme is the most effective means of identifying the majority of persons who are at risk of having contracted Hepatitis C from a blood transfusion, it is estimated at this time that 70 individuals who received potentially infected blood will not be traced by the Targeted Lookback Programme.

To supplement the Targeted Lookback Programme the Government has decided that free testing should be available for anybody who has received a blood transfusion or blood product. Anyone who has received blood or blood products may wish to discuss their concerns and/or symptoms with their general practitioner. General Practitioners will be happy to make an appointment and if following a full consultation a blood test is considered appropriate, a blood sample will be taken by the G.P. and forwarded to the BTSB. No fee will be charged in respect of these services.

Risk of Infection from Transfusion

The actual risk of any individual (who has not been identified as part of the Targeted Lookback Programme) having Hepatitis C following blood transfusion in the past, is extremely small. In Ireland 1 in 3,000 blood donors show evidence that they may have been infected with Hepatitis C at some stage in the past, while only 30% of these show continuing presence of the virus. For individuals who received blood transfusions prior to the introduction of routine screening for Hepatitis C on 1 October, 1991, it is estimated that they had up to a 1 in 3,000 risk of receiving blood from an infected donor. For those patients who received 3 units of red cells the risk could be 1 in 1,000.

Because the Targeted Lookback Programme is in place, and many of the infectious transfusions have or will be identified, the residual risk to other recipients of having transfusion related Hepatitis C is substantially lower than this and of the order of 1 in 10,000.

Persons at particular risk

Persons who have had multiple transfusions or women who have had serious bleeding in association with pregnancy or childbirth and who may have received multiple transfusions and other blood products such as fibrinogen may be at a greater risk of having contracted Hepatitis C and are invited to present themselves for testing to their G.P. Likewise, children who have had multiple transfusions or serious surgery accompanied by transfusion prior to 1 October, 1991 are also invited to avail of the testing programme. No fee will be charged in respect of these services.

Importance of Blood Donations to the Health Services

The Minister stated that "Because of the goodwill and generosity of voluntary, unpaid Irish donors, the BTSB is able to supply hospitals in Ireland with vital blood and blood products for patients undergoing medical and surgical procedures. Without a continuous supply of blood and blood products, it would be impossible for the Irish Health Service to provide proper care for all patients".

The shelf life of blood is approximately five weeks. Therefore it is imperative that the BTSB has a continuous supply of blood from volunteer donors. The BTSB require in the region of 175,000 donations per annum to support the hospital service. For example, heart bypass operations, hip replacement operations and the transplant programmes could not take place without an adequate blood supply. Blood is also required on a daily basis to treat serious medical conditions such as cancer and leukaemia. The BTSB is continuously grateful to their voluntary donors for their overwhelming support.

The BTSB takes extreme care in its efforts to screen out donors who might inadvertently transmit infection to the recipients of blood or blood products. This is achieved by a combination of a comprehensive questionnaire together with the use of the most advanced technology available to screen all blood and blood products for all known bloodborne infective agents and viruses. These tests are carried out on every single unit of blood collected by the BTSB.

APPENDIX 1

SCHEME TO COMPENSATE CERTAIN PERSONS WHO HAVE CONTRACTED HEPATITIS C FROM THE USE OF HUMAN IMMUNOGLOBULIN - ANTI-D

June, 1995

SCHEME TO COMPENSATE CERTAIN PERSONS WHO HAVE CONTRACTED HEPATITIS C FROM THE USE OF HUMAN IMMUNOGLOBULIN - ANTI-D

The Purpose of the Scheme

1. The purpose of the Scheme is to provide compensation to women who have been diagnosed positive for Hepatitis C antibodies or Hepatitis C virus resulting from the use of Human Immunoglobulin - Anti-D and also to provide compensation for children and partners of such women who have been diagnosed positive for Hepatitis C antibodies and/or Hepatitis C virus.

The Basis on which Compensation will be paid

2. Compensation under the Scheme will be paid by the State on an ex gratia basis.

The Administration of the Scheme

3. The Scheme will be administered by a Tribunal, the members of which shall be appointed by the Minister for Health.

Persons who may make a claim to the Tribunal

4. The following persons may make claims to the Tribunal:

   (a) the persons referred to at Clause 1 above

   (b) any person responsible for the maintenance of any of the persons referred to at Clause 1 above, and who has incurred financial loss, and/or incurred expenses, as a direct result of providing such maintenance

   (c) where any of the persons mentioned at Clause 1 above has died as the result of having contracted Hepatitis C, any dependant of such person.

Preservation of Right of Action

5. The making of a claim to the Tribunal under the Scheme will not involve a waiver of any right of action. If a claimant receives an award from the Tribunal, the claimant will have a period of one month from the date of receiving notice of the making of the award during which the claimant can decide either to accept or reject the award. If a claimant neither accepts nor rejects the award within that period, the claimant will be deemed to have rejected the award. Only if the claimant accepts the award will the claimant be required to agree to waive any right of action which the claimant may otherwise have had against any party arising out of the circumstances of the claimant's claim and to discontinue any other proceedings instituted by the claimant. The execution of such a written agreement will be a condition precedent to the payment of any award under the Scheme.

In the case of an award to a claimant who is a minor, the acceptance of the award shall be subject to the approval of the High Court, which approval shall be sought within one month of notification of the making of the award, and the claimant shall have one month from the date of such approval within which to accept such approved award.

Proceedings before the Tribunal

6. (a) The Tribunal will operate with maximum informality consistent with the terms of the Scheme.

(b) The Tribunal will conduct its proceedings in private.

(c) The claimant may be legally represented before the Tribunal.

(d) Claimants will not be required to produce any evidence of negligence on the part of the Blood Transfusion Service Board or on the part of any other party.

(e) Claimants will be required to establish, on the balance of probabilities, that the Hepatitis C antibodies or Hepatitis C virus in respect of which they have been diagnosed positive resulted from the use of Human Immunoglobulin - Anti-D or was transmitted from their mother or partner as the case may be.

(f) Claimants will be entitled to adduce medical or other relevant expert evidence on their behalf.

(g) In considering individual claims, the Tribunal will rely primarily on written medical reports prepared by medical experts who have treated or examined the claimant. Only in exceptional cases will the Tribunal require doctors to attend in person to give evidence.

(h) Medical reports shall be submitted to the Tribunal not later than 6 weeks before the date fixed by the Tribunal for the hearing of any particular claim, so as to enable the members of the Tribunal to read and consider the medical reports in advance of the hearing.

(i) Items of special damage which are claimed should be vouched to the Tribunal not later than 6 weeks before the date of the hearing. The Tribunal will inform the claimant in advance of the hearing of the claim what items of special damage will have to be formally proved by the claimant.

(j) If a claimant fails to comply with (h) and/or (i) above, or if, in the opinion of the Tribunal, a claimant's case is presented at excessive length, the Tribunal may reduce the amount in respect of costs which might otherwise be awarded to such claimant under Clause 19 below by such amount as the Tribunal, in its sole discretion, may decide.

(k) Counsel to the Tribunal may be appointed, and may call expert witnesses as the Tribunal requires.

(l) The Tribunal may appoint medical and/or other experts to advise it as it sees fit, and the Tribunal may take such other steps to inform itself as it considers appropriate.

(m) The claimants and any witnesses on behalf of claimants whom the Tribunal may require to hear may be asked questions by the Tribunal and/or by counsel for the Tribunal.

7. Subject to Clause 6 above, the Tribunal shall determine its own procedures.

Awards of the Tribunal

8. The awards of the Tribunal will be calculated by reference to the principles which govern the measure of damages in the law of tort, provided that no award of compensation will be made on a basis which reflects the principle of exemplary or aggravated damages. In calculating any award, the Tribunal may take into account any statutory or non statutory benefits to which the claimant has become entitled or has received as a result of the condition which gives rise to the claimant's claim.

9. It will be a condition of the making of a claim by a claimant, and of the making of any award by the Tribunal, that the claimant shall not have received any award from any court in respect of the matters giving rise to the claim.

10. No appeal will lie from any award of the Tribunal.

Types of Awards

11. The Tribunal may make either single lump sum awards of compensation, or provisional awards of compensation, as described in Clauses 12 to 15 below. Each application to the Tribunal must specify whether the claimant is seeking a single lump sum award or a provisional award. The Tribunal may, in its discretion, in advance of hearing any particular claim, permit the claimant to alter her or his choice.

Single Lump Sum Awards

12. In cases in which the claimant requests the Tribunal to approach the claim on the basis of a single lump sum award, the Tribunal, in the event that it decides to award compensation to the claimant, will make a single and final award of compensation calculated in accordance with the provisions of Clause 8 above.

Provisional Awards

13. In cases where the claimant requests the Tribunal to approach the claim on the basis of a provisional award, the Tribunal, in the event that it decides to award compensation to the claimant, may, in its discretion, treat the claim as a provisional compensation claim. The provisional compensation claim envisages the possibility of compensation being assessed in stages. Where the Tribunal is of the view that there is a possibility, but no more than a possibility, that the claimant, as a result of Hepatitis C antibodies/virus suffered by the claimant, may suffer a particular serious consequence or consequences in the future, the Tribunal may make an award of provisional compensation, calculated in accordance with Clause 8 above, but assessed on the assumption that such serious consequence or consequences will not occur. In such cases, the award of provisional compensation will identify the serious consequence or consequences which may occur, and specify the time period within which the claimant may apply in the event of such consequence or consequences occurring. In the event that such consequence or consequences do occur, the claimant may apply for an award of further compensation in accordance with the terms of the award of provisional compensation.

14. If a claimant does not accept a provisional award of compensation, the claimant will not be entitled to apply for any further compensation.

15. It will be a condition of payment of a provisional award of compensation to a claimant that the claimant agrees to waive any right of action and to discontinue any other proceedings in accordance with the provisions of Clause 5.

Methods of Payment of Awards

16. If in any particular case a claimant does not wish to receive the entire amount of an award by means of a single payment, the Tribunal, having heard the claimant, may in its absolute discretion decide that the payment of the award to such claimant shall be effected by instalments.

Timing of payments of Awards

17. Subject to Clause 16 above, payment of the amount of an award will be made within 28 days of receipt by the Tribunal of notification of acceptance of the award.

Legal Costs

18. In the event of an award by the Tribunal to a claimant being accepted by that claimant, the Tribunal may in its absolute discretion award to such claimant such sum in respect of the claimant's legal costs, and in respect of the expenses of any witnesses called on behalf of the claimant, relating to such award, as the Tribunal shall consider reasonable, subject to Clause 6(j) above.

The time within which Claimants must apply

19. Claimants must apply to the Tribunal within 3 months of the date upon which they first become aware of the fact that they have been diagnosed positive for Hepatitis C antibodies or Hepatitis C virus or of the date of the establishment of the Tribunal, which ever date is the latest. In exceptional cases the Tribunal may in its absolute discretion extend the time limit fixed by this clause.

Reports of the Tribunal

20. The Tribunal shall forward a report to the Minister for Health on the operation of the scheme together with its accounts, from time to time, as he or she may direct and the Minister shall cause copies of the report to be laid before each House of the Oireachtas.

Amendments of the Scheme

21. The Minister for Health, if he considers it appropriate, may amend the Scheme, but no such amendment shall operate to remove, restrict or diminish in any way rights or benefits conferred on persons entitled to claim under the Scheme in its unamended form.

Establishment

22. The Tribunal shall be established on such day as the Minister for Health may determine.

Procedure for making an Application

23. On the establishment of the Tribunal, an application to the Tribunal should be made on the application form which can be obtained from the Secretary to the Tribunal.

Hepatitis C - Information Note

Hepatitis C is a significant problem worldwide with perhaps five hundred million carriers of the virus. There may be up to 16 million carriers in Europe. The Centre for Disease Control in Atlanta has reported that less than 4% of Hepatitis C infection in the United States is transfusion related. In Ireland, 1 in 3,000 blood donors have evidence of past infection with Hepatitis C. However only 50% of these show continuing infection. The BTSB began screening blood donors for antibodies to the Hepatitis C virus on October 1st 1991. Recipients of blood transfusions after that date have a very low risk of Hepatitis C infection by blood transfusion. The risk is of the order of 1 in 170,000.

Worldwide, the commonest route of transmission is percutaneous exposure to infected blood. This includes sharing needles or equipment during intravenous drug misuse. Clotting factor concentrates made from pooled blood products prior to the use of virus inactivation procedures, carried a risk of infection. Other pooled blood products, such as intravenous immunoglobulin, which were not virally inactivated have recently been implicated in the transmission of Hepatitis C. Transfusion of blood or fresh components (platelets, fresh frozen plasma or cryoprecipitate) prior to the introduction of routine screening on the 1 October, 1991 was associated with some risk of Hepatitis C transmission (approximate risk of 1 in 3,000 units). However, the vast majority of units transfused were not infectious.

Appendix 3

Results of Targeted Lookback Programme to date

- The donors whose past donations require to be traced by the BTSB can be broken down into two distinct categories:

  (i) 113 donors who were Anti-D recipients and who were identified as Hepatitis C positive under the National Blood Screening Programme or identified under routine screening;

  (ii) 97 "other" donors who were identified as Hepatitis C positive under the routine screening of donations for Hepatitis C introduced in October 1991.

- To date the BTSB has identified 1,464 blood or blood products which were potentially infective. As a substantial proportion of these products (464) were from virus negative donors, it is likely that the actual number of infected blood or blood products issued was approximately 1,000.

- To date the BTSB has recipient information from the hospitals in relation to 587 of these potentially infective issues to enable the BTSB to trace the recipients.

- Work is continuing and will continue with the hospital services to identify the remaining recipients of the issues identified by the BTSB as potentially infective.

- To date the BTSB has identified 402 recipients of these potentially infective issues.

- Because many people requiring blood transfusions would have a very serious underlying illness, it is expected from international experience that 50% at least of recipients will have died from their underlying medical condition.

- Of the 402 recipients identified by the BTSB in the Targeted Lookback Programme, 189(47%) living recipients have been traced.

- Of the 189 living recipients traced to date 103 have been tested for Hepatitis C antibodies, and 60 or 58% have evidence of previous Hepatitis C infection.

- Of the 103 who have been tested for Hepatitis C antibodies, 69 have been tested for Hepatitis C virus and 34 or 49% have evidence of continuing Hepatitis C infection.

- The expert care of young infants and children will at times require the administration of blood. The Targeted Lookback Programme has to date identified 26 children who received potentially infected blood transfusions prior to October 1991. At present these children and their families are being contacted, counselled and tested. The preliminary results indicate that the majority of those tested to date are free of the virus.