Gníomhaireacht Éileamh an Stáit
State Claims Agency

Compensation for Thalidomide Survivors

April 2010

Report Prepared for the Minister for Health and Children by the State Claims Agency

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1. Terms of Reference

The State Claims Agency has been requested by the Minister for Health and Children to assess the Irish Thalidomide Association's request for additional compensation for survivors of Thalidomide against the backdrop of Irish and international provisions for survivors of Thalidomide and in the context of Irish case law and precedent and to advise the Minister accordingly.

2. International and Irish Historical Background to the Thalidomide Drugs Scandal

In 1946, a subsidiary of the long-established German family company of Dalli-Werke, Mäurer and Wirtz, a soaps and cosmetic manufacturer, was formed. This new subsidiary company was known as Chemie Grünenthal.

In 1954, after a period of rapid expansion, Chemie Grünenthal had synthesised the chemical phthalimido glutarimide, later abbreviated to Thalidomide. Thalidomide, in its early creation, proved to be non-effective as an antihistamine, an antibiotic or an anticonvulsive. Thus, the company, when searching for a suitable condition it could treat, noted that testers reported that Thalidomide had a calming effect. When the drug was tested on rats, even following high dosage, it appeared to have no toxic side effects. It was deemed, therefore, to be a perfect sedative and a powerful replacement for barbiturates.

On 1st October 1957, Chemie Grünenthal brought Thalidomide to the market as an over-the-counter drug under the brand name, Contergan. It was marketed as an anti-stress and anti-emetic drug. It was also sold under the trade name "grippex" as a medicine used to combat respiratory infections. Paediatrically, it was used as a drug to calm children. Thalidomide was eventually sold, either directly or under licence, in over 50 countries.

However, in 1959, problems began to emerge when doctors queried whether Thalidomide was causing peripheral neuritis in patients. In late 1960, Distillers, which produced the drug under licence in the UK as Distaval, placed a warning on the label. Chemie Grünenthal did not adopt this practice. In the spring of 1961, Chemie Grünenthal, after a period of pressure, commenced to add warnings on the drugs label and in August 1961, a specific warning was placed on prescriptions by a number of German states. At that stage, peripheral neuritis was affecting an estimated 40,000 patients.

The first baby affected by Thalidomide was born on Christmas day 1956 when the wife of a Chemie Grünenthal employee gave birth to a baby girl with no ears. It transpired that the employee had given his wife samples of Contergan during her pregnancy. The child became the first of thousands of such children with disabilities caused by Thalidomide. Countless children died at birth or in the womb. The spectrum of malformations attributable to the drug were as follows:

(1) Absence of the auricles with deafness.

(2) Defects of the muscles of the eye and of the face.

(3) Absence or hypoplasia of arms, preferentially affecting the radius and the thumb.

(4) Thumbs with three joints.

(5) Defects of the femur and tibia.

(6) Malformations of the heart, the bowel, the uterus and the gallbladder.

In late 1961, Widukind Lenz, a Hamburg doctor, tracked down dozens of parents of Thalidomide children. After painstakingly ruling out all other explanations, he discovered the common denominator, namely, that all of the mothers had taken Thalidomide during their pregnancy. Thus, in November 1961, Dr Lenz had sufficient evidence to contact Chemie Grünenthal with what it called the "first plausible suspicions" of a link between Thalidomide and the above malformations. On 27th November 1961, Chemie Grünenthal withdrew the drug.

A criminal trial involving Chemie Grünenthal commenced in 1968 but was halted in December 1970. The judges criticised Chemie Grünenthal for not acting more quickly in relation to the peripheral neuritis complications, arguing that the problems could have been foreseen. The judges also stated that Chemie Grünenthal could easily have included a warning that Thalidomide's safety for pregnant women had not been tested. No criminal convictions, however, ensued.

The compromise was a settlement from Chemie Grünenthal of DM100 million, worth approximately £100 million sterling in today's terms, to support the affected children. This sum amounted to three times the overall total of Contergan sales and more than the company's DM84 million total valuation in 1970.

UK Thalidomide survivors achieved compensation in 1971 when Distillers offered an all-or-nothing settlement of £3.3 million sterling to affected families. The families refused the settlement, and, ultimately, in 1973, Distillers finally caved in and increased its offer in compensation to £20 million sterling.

During successive campaigns in recent years, UK Thalidomide survivors achieved top-up funding from Distillers' new parents, first Guinness and then Diageo. Diageo agreed a complex new multi-year financial package in 2005 which it estimated would cost £153 million, the money to be paid into the Thalidomide Trust.

It is notable that the Food and Drug Administration in the United States, on account of the objections of Frances Kelsey, a novice regulator, refused to approve the drug for use. This was in 1960. It appears that Ms Kelsey had serious concerns in relation to the peripheral neuritis suffered by persons who had taken Thalidomide.

Thalidomide – The Irish Experience

Thalidomide preparations in the form of tablets, syrup, suspension, capsules, drops and suppositories, under different brand names, were marketed in Ireland between 1958 and 1962, by Messrs T.P. Whelehan, Son & Company Ltd. The preparations were sold through pharmacies as "over-the-counter" medicines. They were also available as samples from general practitioners.

On 23rd March 1963, Dr Victoria Coffey, consultant paediatrician at St Kevin's Hospital, reported to the Department of Health and Children, having carried out her examination of the children affected by Thalidomide.

On 12th October 1964 she wrote to Dr Widukind Lenz indicating that the number of infants with limb anomalies considered attributable to the drug Thalidomide was one hundred and five. Eighty seven infants were born alive. However twenty three died in the neonatal period.

Thirty four children were ultimately accepted by the Irish review board as survivors of Thalidomide. There are currently thirty one Thalidomide survivors receiving an allowance from the Department of Health and Children.

Thalidomide's Current Use

In the mid 1960s, Jacob Sheskin, an Israeli doctor, started to use Thalidomide to treat Erythema Nodosum Leprosum (ENL) with excellent results. It is also involved in trials for several serious conditions to include tuberculosis, sepsis, rheumatoid arthritis, Crohn's disease, lupus, leprosy, macular degeneration, HIV and AIDS and various cancers. In 1998 the FDA in the US approved Thalidomide which is now available under prescription in Brazil and Mexico to treat leprosy.

3. Irish Thalidomide Compensation Scheme, 1975

In May 1970, the Irish Department of External Affairs confirmed that Chemie Grünenthal, the German manufacturers of Thalidomide, had agreed to pay DM100 million (£100 million sterling in today's terms) to children born with malformations attributable to Thalidomide. The German government added a further DM50 million taking the total fund to DM150 million. On 17th December 1971, the Federal Ministry of Health established the foundation *Hilfswerk für behinderte Kinder* (institution to help handicapped children) which put the agreement on a legal basis, thereby taking over responsibility for the compensation scheme. A committee of trustees was set up to distribute the compensation. The number of Thalidomide survivors covered by the German compensation scheme was 2,866. Countries such as Canada, Italy, Japan, Sweden and the UK were not included in the compensation scheme as in these countries corporations or entities other than Chemie Grünenthal had sold Thalidomide.

The German compensation scheme took the following form:

(1) A lump sum ranging between DM7,500 (IR£1,250 approximately) and DM25,000 (IR£4,200 approx), and

(2) A monthly allowance* for life ranging between DM100 (IR£17 approx) and DM450 (IR£75 approx).

In May 1973, the Irish government decided, as a matter of principle, to significantly enlarge the compensation payable from the German compensation scheme to Thalidomide survivors and their families. Thus, the Irish government agreed the following in addition to the German compensation scheme:

(1) A lump sum ranging between IR£6,600 and IR£21,300, and

(2) A monthly allowance for life ranging between IR£31.75 and IR£95.00.

* The monthly allowance has been increased on a number of occasions by the German authorities.

The government's monthly allowance exceeded the Consumer Price Index and remained in excess of the German allowance until June of 2008 when the German foundation increased the allowance. The allowances, German and Irish, are tax-free, are not reckonable for State benefits and each of the Thalidomide survivors are the holders of medical cards. In addition, a Thalidomide survivor can also claim disability allowance of approximately €849 per month or €10,192 per annum (2010 figures).

In summary, an Irish Thalidomide survivor will receive between €924 and €2,532 tax-free per month (2010 figures). As shown in the table below, the cumulative allowance, annually, amounts to €11,092 (least severe cases) and €30,380 (most severe cases).

Table 1 - Monthly/yearly allowance excluding disability allowance

	Least severe (A)	Most severe (B)
German allowance	€371	€1,116
Irish allowance	€515	€1,109
Total monthly allowance	€886	€2,225
Total yearly allowance	€10,632	€26,700
Special German annual payment	€460	€3,680
Total yearly allowance	**€11,092**	**€30,380**

If disability allowance is added (€849 per month – 2010 figures) the total tax-free sum claimable by a Thalidomide survivor is €1,773 (least severe) or €3,381 (most severe) monthly i.e. €21,280 or €40,568 annually (2010 figures).

Table 2 - Monthly/yearly allowance including disability allowance

	Least severe (A)	Most severe (B)
German allowance	€371	€1,116
Irish allowance	€515	€1,109
Disability allowance	€849	€849
Total monthly allowance	€1,735	€3,074
Total yearly allowance	€20,820	36,888
Special German annual payment	€460	€3,680
Total annual allowance	**€21,280**	**€40,568**

Provisions Other Than Compensation

All payments, whether lump sum or monthly allowances, were disregarded for all of the purposes of the income tax acts and were judged exempt from tax, to include deposit interest retention tax with effect from 1986.

All Thalidomide survivors, resident in the State, were granted medical cards without means testing.

Thalidomide survivors can claim disability allowance should they choose to do so.

Arrangements were put in place to provide specialised artificial limbs and appliances to survivors, where necessary.

Claims in respect of medical and legal expenses, incurred by parents prior to settlement, were met by the then health boards.

The allowances were increased in line with social welfare increases on a near annual basis.

4. Trans Jurisdictional Thalidomide Survivors' Compensation Schemes

Italy, Spain, Austria and Portugal

No compensation schemes operate in respect of Thalidomide survivors in Italy, Spain, Austria and Portugal.

Italy, however, recently announced a provisional government compensation scheme of €43,000 per annum for Thalidomide survivors. It is not clear, at this point, when this will take effect from.

Germany

There are approximately 2,900 Thalidomide survivors in Germany, the largest such grouping in Europe. On average, German survivors of Thalidomide receive the equivalent of £10,000 sterling a year from a foundation funded by Chemie Grünenthal and the government, which is now putting aside an extra £900,000 sterling per year to pay for anticipated new claims having regard to a decision, in March 2009, enabling Thalidomide survivors from other countries to claim until the end of 2010.

Sweden, Denmark, Norway

Sweden (107 survivors), Denmark (20 survivors) and Norway (17 survivors) operate a similar compensation scheme for Thalidomide survivors. The compensation is paid twice a year by the original Thalidomide drug distributor, AstraZeneca (formerly known as Astra). The compensation payable by AstraZeneca is tax exempt. The average yearly payment amounts to €6,000 whilst the highest is €20,000.

On foot of a new offer from AstraZeneca, with effect from 2010, the average annual payment increases to €9,000 whilst the highest annual payment increases to €30,000.

Separately, in 2005, the Swedish government made a lump sum payment to Thalidomide survivors amounting to €55,000 per survivor. In 2009, AstraZeneca paid out an average lump sum payment of €120,000 to Thalidomide survivors – the most severely affected Thalidomide survivor received a lump sum payment of €380,000.

Thalidomide survivors, in the above countries, also receive a disablement pension (payable to all disabled persons) of approximately €250 per month.

Thalidomide survivors in all three countries also receive the following non-pecuniary benefits:

- Wheelchairs are provided free of charge.
- Services of a personal assistant for a minimum of 4 and a maximum of 24 hours assistance per day, depending on level of severity of disability.
- Free car adaptation.
- Free assistive technology at places of work.

Canada

Canada paid a once-off compensation sum of $80,000 Canadian dollars per survivor in 1991. There are approximately 125 Thalidomide survivors living in Canada.

In December 1961 Thalidomide was taken off the market in West Germany and Britain on account of birth defects associated with the taking of the drug by expectant mothers. The drug, however, remained available in Canada until April 1962 when it was formally removed from the market.

Japan

There are approximately 300 Thalidomide survivors still living in Japan. There, a national centre, known as *Ishizue*, was set up by the Japanese government to distribute compensation which had been awarded by the government and Dai Nippon, the medical company which had been licensed by Chemie Grünenthal in respect of the re-sale of Thalidomide in Japan. Thalidomide survivors are taken care of by the national centre in relation to their needs/care.

Brazil

In July 2009 a Brazilian federal court ordered the Brazilian government to compensate approximately 360 Thalidomide survivors. Under the ruling, each survivor will receive in the order of 200,000 reais (approximately US$100,000).

United Kingdom

There are approximately 466 Thalidomide survivors living in various parts of the United Kingdom, to include Northern Ireland (18).

In 1973 the Thalidomide Trust was set up to administer payments made by Distillers, who had distributed the Thalidomide drug in the UK, and the UK government. Distillers (now Diageo), in 1973, agreed to pay £20 million sterling in compensation. In 1974 the British government donated £5 million sterling to the Thalidomide Trust, which was an offset of tax on the original £20 million paid in by Distillers. In 1996 the British government, without offering any particular reason, donated a further £7 million.

In 2005, Distillers agreed a complex new multi-year financial settlement estimated to cost in the order of £153 million as additional compensation for Thalidomide survivors. The additional funding provided for covenant payments to be increased and for the payments to be extended from 2022 to 2037. This was calculated on the basis of the money required to double beneficiary annual payments from 2004 levels by 2022.

UK Thalidomide survivors currently receive on average £20,000 sterling per year from the Thalidomide Trust.

On 14th January 2010, the British Health Minister, Mike O'Brien, confirmed a new £20 million support package, which had been announced during the month of December '09. The £20 million will be administered through the Thalidomide Trust. If the £20 million was to be divided equally across all surviving Thalidomide survivors in the UK, each survivor would receive in the order of £43,000 sterling.

On 8th February 2010, Northern Ireland's Health Minister, Michael McGimpsey, announced that 18 Thalidomide survivors in Northern Ireland will receive an ex-gratia payment of £1.1 million sterling from the British government.

Comment

It is evident from the foregoing that Thalidomide survivors fared best, by way of compensation, in those jurisdictions – Sweden, Denmark, Norway and the UK – where the Thalidomide drug was manufactured and distributed under licence by a third party company and where there existed, in law, a right to sue such third party company, as a separate defendant, for compensation.

Ireland, where Thalidomide survivors and their families entered into a compensation agreement with the Thalidomide manufacturer, Chemie Grünenthal, compares most favourably with other States in the manner in which it has compensated its Thalidomide survivors.

5. Irish Thalidomide Survivors' Submissions for Further Compensation

5.1 Irish Thalidomide Association's Submissions for Further Compensation

The Irish Thalidomide Association (ITA) wrote formally to the Minister for Health and Children by letter dated 1st December '07 "seeking a review of the agreement made to (sic) the Irish Thalidomide survivors who were born in Ireland between the years 1958 – 1965". In an accompanying statement, the ITA stated that it was seeking a review and further redress to include a lump sum payment and an increase in the monthly pension paid. The Association stated that the current payments were grossly inadequate to financially sustain the beneficiaries, Thalidomide survivors with defects of limb of varying severity.

In support of their case for further redress, the Association referred to the following difficulties which they stated were unique to Thalidomide sufferers:

- Increased health and mobility difficulties which are having an impact on certain survivors' career opportunities.
- Psychological and emotional affects of living with the limitations of physical disability of varying severity.
- Educational and employment limitations caused by survivors' physical disabilities.

The Association also made reference to the following additional difficulties encountered by its members:

- Some survivors qualify for the Disabled Drivers Scheme, others do not.
- Some qualify for the Motorised Transport Grant, others do not.
- Prohibitive costs associated with the purchase of specialised equipment.

- Lack of access to specialised health care and treatment services which take account of the uniqueness of the Thalidomide survivors' disabilities.

Redress/Compensation

In its separate redress submission to the Minister for Health and Children, the ITA have sought the following:

(1) A scale of additional lump sum awards over and above those which were paid in 1975;

(2) An increase in the annual payments; and

(3) A distinct retrospective payment.

In relation to (1) the ITA advocated the payment of new lump sums between €116,000 and €250,000. The new lump sum, which varies according to the severity of the survivor's disabilities, is benchmarked against the present day value of the original lump sum, €200,000, and the current level of general damages typically awarded in a catastrophic injury case, €450,000.

In relation to (2) the ITA recommends that the payments to those in the most serious category be increased by €62 per diem, based on an equivalent gross salary of €70,000 per annum.

In relation to (3) the ITA recommends a retrospective extra lump sum, in respect of the alleged underpayment of past annual payments, of €75,000 for those in the most severe category of disability.

The ITA, accompanied by its solicitors, made an oral presentation to the Agency on 25th June '09. The ITA requested the Agency to revisit and analyse the original agreement on compensation in order to establish whether it was adequate and appropriate in respect of the losses and consequences which have occurred to the Thalidomide survivors. The Agency has not conducted such an analysis as it is outside the scope of its terms of reference.

5.2 Irish Thalidomide Survivors' Society's Submission for Further Compensation

The Irish Thalidomide Survivors' Society (ITSS), accompanied by its solicitors, made an oral presentation to the Agency on 10th March 2010.

The ITSS stated that its members wished to lay emphasis on the original agreement, its spirit and intendment, i.e., that the perpetual needs of Thalidomide survivors, necessitated by their unique handicap, would be adequately provided for. The ITSS's solicitors stated that the Society's members are seeking the establishment of a Board similar to the now defunct Irish Thalidomide Medical Board (ITMB). They stated that this is necessary on account of the fact that Thalidomide survivors' needs have not, in their view, been adequately provided for by the HSE. The Society stated that its members have endured stressful delays in securing minimal services and benefits from the HSE. It is their view, thus, that their needs would be more adequately and sympathetically met by a body, such as the ITMB, which would proactively focus on the specific needs of Thalidomide survivors. In that regard, the Society indicated that its members are seeking the appointment of a medical expert, a specialist in the treatment of Thalidomide-related medical/orthopaedic complications, to carry out individual assessments of Thalidomide survivors.

The Society's solicitors stated that their client's members' needs are best summarised by reference to the following:

(1) Transport Needs

The ITSS acknowledged that many Thalidomide survivors qualify for the Disabled Drivers Scheme – Section 92 of the Finance Act, 1989 and the Disabled Drivers and Disabled Passengers (Tax Concessions) Regulations, 1994. The Scheme, open to persons who meet the specified medical criteria, confers the following benefits:

- Relief in respect of Vehicle Registration Tax (VRT).

- Relief in respect of Value Added Tax (VAT).

- Repayment of excise duty on fuel up to a maximum of 600 gallons (2,728 litres) per annum.

The ITSS acknowledged that the Scheme's benefits were extremely beneficial to Thalidomide survivors. However, it pointed out that when Thalidomide survivors change their vehicles, they have to personally incur the cost - €3,000 to €4,000 – associated with the transfer of specialised, adaptive equipment from the "old" to the "new" vehicle.

(2) Home Adaptation Needs

Thalidomide survivors, on account of their particular disability, require specialised environmental controls in their homes in order to assist them with routine tasks such as, for example, washing and showering. Similarly, the routine opening and closing of doors is no longer possible for many survivors on account of the fact that their joints have been compromised by arthritis and over usage. Survivors' partners, who are mostly middle-aged, find they are no longer physically able to assist their partners by lifting them in and out of showers/baths and to and from bed. Thus, many survivors require adaptation to their bathrooms and bedrooms in the form of hoists and other lifting devices. The point was also made that many survivors will require personal assistants to assist them in relation to the routine aspects of their lives i.e. getting in and out of a wheelchair, showering and toileting etc.

(3) Medical Card Needs

The Society is adamant that the current medical card entitlement of its members does not adequately meet their particularised medical requirements. The Society is firmly of the view that a special medical card should be made available to all Thalidomide survivors.

This new medical card, as envisaged by the Society, would entitle Thalidomide survivors to receive services directed at their particular medical/dental problems which they outlined as follows:

- Dental problems comprising discolouration and coating of teeth, caused by the taking of tablets.
- Neuropathic pain.
- Arthritis and swelling of joints and mouth.
- Sinus under-development.
- Excessive sweating.
- Weight issues/diabetes.
- Hearing aids/hearing problems.
- Depression - need for psychological support.
- Stomach/oesophagus problems – reflux etc.
- The need for hip replacement and associated back problems.
- Kidney and bladder problems.
- Skin irritation problems.

Redress/Compensation

Whilst not seeking any adjustment to the current, index-linked, allowance payable to survivors, the Society's solicitors stated that survivors are, however, requesting additional compensation in the form of a lump sum.

They stated that many survivors have had to borrow money to pay for electronic wheelchairs, the installation of specialised driving assistance equipment in motor vehicles and home adaptations. The payment of a lump sum is required, thus, to compensate survivors in respect of "out of pocket" expenses necessarily incurred by them on account of their disability.

The Society's solicitors stated that they did not wish to make a submission as to the appropriate amount of any such lump sum compensation payment. Rather, they were of the view that this was best left to the Agency to consider, together with any other recommendations it may make, in the context of its report to the Minister for Health and Children.

6. Irish Case Law and Precedent

The Agency has considered Irish case law and precedent in relation to compensation.

The most relevant compensation scheme in Ireland, to date, is the Hepatitis C and HIV compensation scheme established by the Hepatitis C Compensation Tribunal Act, 1997. The tribunal operated as a non-statutory scheme of compensation from the date of its establishment on 16th December 1995 to 31st October 1997. On 1st November 1997 the Hepatitis C Compensation Tribunal Act came into effect. On 9th October 2002, the Hepatitis C Compensation Tribunal Act of 2002 became effective. Sections 1 and 2 of the Hepatitis C Compensation Tribunal (Amendment) Act, 2006 became effective on 20th June 2006.

The tribunal was established by the Irish government in 1995 to compensate, inter alia, persons infected with Hepatitis C as a result of the use of Human Immunoglobulin Anti-D or as a result of the receipt of a blood transfusion or blood product within the Republic of Ireland.

Under the Acts, the following persons are entitled to make a claim:

(a) A person who has been diagnosed positive for Hepatitis C resulting from the use of Human Immunoglobulin Anti-D within the State;

(b) A person who has been diagnosed positive for Hepatitis C as a result of receiving a blood transfusion or blood product within the State;

(c) Children or any spouse, of a person referred to in paragraph (a) or a person referred to in paragraph (b), who have themselves been diagnosed positive for Hepatitis C;

(d) Any person who is responsible for the care of a person referred to in paragraph (a), (b) or (c), and who has incurred or will incur financial loss or expenses as a direct result of providing such care arising from the person being cared for having contracted Hepatitis C;

(e) Where a person referred to in paragraph (a), (b) or (c) has died as a result of having contracted Hepatitis C or where Hepatitis C was a significant contributory factor to the cause of death, any dependent of such person;

(f) A person who has been diagnosed positive for HIV as a result of receiving a relevant product within the State;

(g) Children or any spouse of a person referred to in paragraph (f) who have themselves been diagnosed positive for HIV;

(h) Any person who is married to a person referred to in paragraph (a), (b) or (f), or has been living with a person referred to in paragraph (a), (b) or (f) for a continuous period of not less than three years, in respect of loss of consortium of the person, including impairment of sexual relations with the person, arising from the risk of transmission of Hepatitis C or HIV;

(i) Any person who is responsible for the care of a person referred to in paragraph (f) or (g) and who has incurred or will incur financial loss or expenses as a direct result of providing such care arising from the person being cared for having contracted HIV; and

(j) Where a person referred to in paragraph (f) or (g) has died as a result of having contracted HIV or where HIV was a significant contributory factor to the cause of death, any dependent of such person.

As of the end of the calendar year 2008, the Tribunal has dealt with 4,208 claims. The total compensation paid, together with legal costs, is approximately €1 billion.

The ITA contended that the Hepatitis C/HIV compensation scheme serves as an identical type comparator in that it is related to a pharmaceutical product which was licensed in this jurisdiction. It pointed out that there was a full and final settlement which was subsequently reversed by the government on the grounds that it was neither fair nor equitable. It noted that the original settlement which was a lump sum payment, similar to the agreement with Thalidomide survivors, was reversed as it did not take account of general and special damages.

There are marked differences, however, between the Hepatitis C and HIV compensation scheme and the Thalidomide survivors' compensation scheme. The Hepatitis C and HIV compensation scheme, whilst it operated as a non-statutory scheme of compensation up to 31st October 1997, operated on and from 1st November 1997 as a statutory scheme. Section 5 of the Hepatitis C Compensation Tribunal (Amendment) Act, 2002, stated that an award of the Tribunal shall be made on the same basis as an award of the High Court calculated by reference to the principles which govern the measure of damages in the law of tort and any relevant statutory provisions to include an award on the basis which reflects the principles of aggravated or exemplary damages.

The Thalidomide compensation scheme, established in the early 1970s, is a hybrid compensation scheme which afforded an initial lump sum payment and a monthly allowance for life. It must be understood in the context of its time and the then prevailing socio-economic circumstances. The original compensation was provided by a third party, the product manufacturer, Chemie Grünenthal, increased by the German government, and further increased by the Irish State in 1973. The Thalidomide survivors' compensation scheme is, of course, a non-statutory scheme, unlike the Hepatitis C and HIV compensation scheme. It is also notable that the Hepatitis C and HIV compensation scheme did not involve an acknowledgement of liability, in the form of a monetary contribution to that scheme, by any third party.

It is the Agency's view that the Hepatitis C and HIV compensation scheme does not serve as a useful comparator or precedent in relation to any new provision of compensation, whether by way of a top-up provision or otherwise, for Thalidomide survivors.

In its oral presentation to the Agency, the ITA, through its solicitors, contended that case law and precedent suggested that quantification of damages should be in accordance with the methodologies applied by the court, including general and special damages. The ITA's solicitors submitted that there was a very significant argument to be advanced as to why special damages-type issues required to be considered in the context of the Agency's assessment of the ITA's request for additional compensation for its members.

The payment of damages, general and special, by reference to the ordinary principles of tort law, assume a liability on the part of the tortfeasor. In relation to contamination of blood products, persons affected by contracting Hepatitis C or HIV could either prosecute their action in the courts or through the Tribunal. In either case, the statute of limitations period applied.

In relation to the Thalidomide survivors, the events giving rise to the survivors' injuries, namely the innocent taking of Thalidomide preparations by their mothers, occurred between the years 1958 and 1962. It is notable that the Public Prosecutor's Office in Aachen received its first complaints in 1961. A formal criminal prosecution was commenced on 27th May 1968 by the public prosecutor against seven named employees of Chemie Grünenthal. The prosecutor's case was that the men had placed a drug on the market which caused an unacceptable degree of bodily harm without having tested it properly, and that they had failed to react timeously to information in relation to its side effects. The court had its final session on 18th December 1970 after two years and seven months of trial. There were no criminal convictions.

The attorneys for the affected children reached an out of court agreement on compensation on 10th April 1970 whereby Chemie Grünenthal agreed to pay DM100 million to children who had suffered malformations attributable to Thalidomide. This included those persons in Ireland who were affected.

The standards in relation to the testing and marketing of drugs in the late 1950s and early 1960s cannot be judged against the rigorous standards of today. The National Drugs Advisory Board (predecessor to the Irish Medicines Board) was only established in 1966. Its function was to organise and administer a service for obtaining, assessing and disseminating information as regards the safety of new and reformulated drugs.

It is inappropriate, in the Agency's view, to apply current principles of tort law and the quantum of damages, general and special, to an event which took place in the years 1958 to 1962. General damages awarded in the 1960s and 1970s, even for catastrophic type injuries, bear no resemblance to sums awarded for similar injuries today. Similarly, it would be an impossible exercise to compute a retrospective and prospective loss of earnings – special damages – calculation for each Thalidomide survivor as this would require a predictive assessment that but for the Thalidomide event the survivor would have achieved a particular career with a particular level of earnings. Even if, arguably, this could be done, one would have to have knowledge of the survivor's parents' and siblings' careers and levels of earnings and attach certain assumptions to these.

It is for these reasons, therefore, that we do not believe that case law and precedent, in relation to the quantification of damages, provides a suitable means to revisit compensation in the case of Thalidomide survivors.

In the final chapter of this report, we set out alternative proposals in relation to Irish Thalidomide survivors' request for additional compensation.

7. Agency's Conclusions and Advices

Irish Thalidomide survivors constitute a unique and defined group of 31 persons afflicted with physical disabilities of varying degree, some of whom have been severely affected. The Irish Thalidomide Association advise that its membership includes a doctor, an engineer, a journalist, teachers, artists and entrepreneurs. It is evident, thus, that some Thalidomide survivors have achieved and managed successful careers.

Many of the survivors, however, are struggling with unforeseen health and psychological issues arising from their disability. The Irish Thalidomide Association and the Irish Thalidomide Survivors' Society have referred, in particular, to the lack of access by its members to specialised health care and treatment services which take account of the uniqueness of their disabilities. One case, for example, was brought to the attention of the Agency which relates to a Thalidomide survivor, confined to a wheelchair, who requested financial support from a State organisation to modify the front door of her dwelling to enable it to be opened electronically. It was stated that the particular Thalidomide survivor's health had deteriorated to such an extent that she was no longer able to manually open the door. The Agency was advised that the survivor's request was refused.

It is indisputable that Thalidomide survivors, and their families, have suffered greatly. The survivors believe that the original compensation, in the form of a lump sum and per diem allowances, agreed in 1970 with Chemie Grünenthal and augmented in 1973 by the Irish government, requires to be revisited on the grounds that it was inadequate. The Irish Thalidomide Association and the Irish Thalidomide Survivors' Society have stated that the present day value of the per diem allowances, though tax-free, is inadequate to meet the current needs of their members.

Both organisations have stated that Irish Thalidomide survivors' compensation compares very unfavourably to that which pertains in the UK where, in particular, in January 2010, the British government voted a £20 million sterling compensation fund to augment the Thalidomide Trust on behalf of Thalidomide survivors in the UK. The Irish Thalidomide survivors' organisations believe that the Irish State should act similarly, by offering further compensation to its members.

It is worth noting, at this juncture, that Irish Thalidomide survivors are entitled to a cumulative yearly allowance tax-free, depending on severity of disability, ranging between €11,092 and €30,380 (chapter 3, page 7). If disability allowance is added (€849 per month – 2010 figures) the total tax-free sum claimable by a Thalidomide survivor is €1,773 (least severe) or €3,381 (most severe) monthly i.e. €21,280 or €40,568 annually (2010 figures). The average net yearly take home pay for a single person on the average industrial wage, by way of comparison, is €30,885 (2009 figures) – Appendix 1.

Most of the Thalidomide survivors (65%) receive the maximum allowance – Appendix 2.

The current average yearly allowance for a UK Thalidomide survivor is approximately £20,000 sterling.

Having regard to the ITA's and the ITSS's request for additional compensation for survivors of Thalidomide and taking all matters into account, the Agency suggests that the Minister might consider the following:

(a) A once-off payment of €50,000 to each of the 31 Thalidomide survivors, amounting to €1,550,000 in total.

Alternatively, that a sum of €2,000,000 be paid into a special purpose trust for disbursement by the trustees, some of whom should be drawn from the membership of the ITA and the ITSS, to those Thalidomide survivors most in need of monetary assistance.

(b) The payment of an annual lump sum, equivalent to the special German annual payment which commenced to be paid from mid 2009. The special German annual payment amounts to €460, in the least severe category and €3,680, in the most severe category. Approximately 20 survivors fall into the most severe category.

The effect of the payment of an annual lump sum by the Irish State would be to continue to maintain the historical relativity of German and Irish compensation rates, in respect of Irish Thalidomide survivors.

(c) The appointment of a suitably-qualified expert to assess those Thalidomide survivors who, on account of the severity of their disability, require access to specialised treatment and services similar to those available to persons entitled to a Health Amendment Act Card.

Thereafter, that a special care package be devised and provided to address these survivors' particular needs, to include, for example, the need for home help and/or personal assistants.

(d) That all Thalidomide sufferers be automatically qualified to avail of the Disabled Drivers Scheme and the Motorised Transport Grant.

The Agency believes that the above, when taken together with the pre-existing compensation arrangements, would place Ireland on a similar footing with other countries who have put in place recent, additional compensation for Thalidomide survivors.

Appendix 1

Calculation of Average Net Yearly Take Home Pay for a Single Person on the Average Industrial Wage Pre-October Budget 2009.

(A) Calculation of effective rate of taxation on a salary of €35,000.

		€
Income		35,000
Tax free allowance		18,300
PAYE (35,000 less 18,300) @ 20%	3,340	
PRSI (35,000 less 6,604) @ 4%	1,136	
Income levy (35,000 less 15,000) @ 2%	400	
Health levy (35,000 less 26,000) @ 4%	360	[5,236]*
Net take home pay		**29,764**

* Effective rate of tax is 14.96%

(B) Apply effective rate to the most recently published average industrial wage.

		€
Average industrial wage Quarter 2 2009 (CSO – earnings and labour costs – 22nd December 2009)	€698.43 x 52	36,318
	Less 14.96% tax/levies	5,433
Net yearly take home pay		**30,885**

Note: The effective rate of tax post budget 2010 is in the order of 18.5%.

Appendix 2

Scale of Monthly Allowances Awarded

Name	2010 Figures	Name	2010 Figures
Survivor 1	514.59	Survivor 17	1,109.46
Survivor 2	514.59	Survivor 18	1,109.46
Survivor 3	615.64	Survivor 19	1,109.46
Survivor 4	822.54	Survivor 20	1,109.46
Survivor 5	822.54	Survivor 21	1,109.46
Survivor 6	822.54	Survivor 22	1,109.46
Survivor 7	918.24	Survivor 23	1,109.46
Survivor 8	918.24	Survivor 24	1,109.46
Survivor 9	1,011.09	Survivor 25	1,109.46
Survivor 10	1,011.09	Survivor 26	1,109.46
Survivor 11	1,011.09	Survivor 27	1,109.46
Survivor 12	1,109.46	Survivor 28	1,109.46
Survivor 13	1,109.46	Survivor 29	1,109.46
Survivor 14	1,109.46	Survivor 30	1,109.46
Survivor 15	1,109.46	Survivor 31	1,109.46
Survivor 16	1,109.46