APPENDIX IV: Narratives: Definitive Suicidal Behavior Events: MDD

The case narratives contained herein reflect subjects with major depressive disorder with either definitive suicidal behavior or rating scale emergent suicidal behavior. The case narratives are in the order presented in Table 2.11 of Appendix II.

Protocol Id:	02
Subject Number:	02.001.009
Treatment Group:	Placebo
Serious Adverse event Preferred term(s):	
Serious Adverse event Verbatim term(s):	Suicide Gesture by Suffocation

This patient is a 67-year-old white female with a diagnosis of major depressive disorder, recurrent with melancholia (DSM-III: 296.3). She has no significant medical history. She received chloral hydrate 500 mg/day (6/12-16185) for severe insomnia and FI0RINA (butalbital) 2 tablets/day (6/12-13/85) for headache.

Screen ECG was an abnormal record which could have reflected recent change. Further ECG showed that lead V-2 was technically unsatisfactory, but there was no change from screen. Left ventricular hypertrophy could have been responsible for the reading wholly or in part. No other clinical information is available.

The patient began placebo on 6/19186 and continued treatment until 6/25/85, when she made a suicide gesture by suffocation. Her husband prevented her suicide, she was brought to the investigator that same day, and her termination visit was completed. She was dropped for lack of efficacy because of the profound and rapid deterioration of her condition prior to her suicide attempt. No laboratory abnormalities were recorded and she reported no adverse clinical experiences. Post-study follow-up visit on 6/26/85 revealed her condition continued to deteriorate. She reported no withdrawal effects.

Additional Information:

This 67-year-old female was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression, with melancholia (DSM-III: 296.33).

This subject reported no concurrent clinical conditions, but she had recently been treated for headache and severe insomnia. Additionally, the patient had a previous history of depression. The subject's family history was positive for non-psychotic psychiatric disturbance (father), other major affective disturbance (mother), and suicide (mother).

The subject had previously received unspecified psychiatric treatment, including outpatient treatment for 15 years and hospitalization for two weeks. Information pertaining to medicinal treatment was not provided. The episode of major depression for which the subject was enrolled in the study was of 6-12 month's duration, and no concurrent medications were reported at study entry. The subject's current condition was best characterized as a recurrence of a similar previous condition with onset of the present episode being gradual (one or more months). A precipitating external event was

probably present. It was also noted that the subject was experiencing moderate psychosocial stressors at the time of study recruitment.

The subject had a history of suicidal ideation prior to treatment. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2, and the total HAMD-17 score at randomization was 27 and the HAMD-21 score was 30. The verbal, behaviour, and secondary symptoms of depressions scores at screening and randomization on the Raskin Depression Scale were 5,5; 5,4; and 4,4; respectively. The randomization score on MADRS item #10, reflecting suicidality, was 4, and the total MADRS score at randomization was 45.

Six days after the first dose of study medication, (placebo), the subject experienced a profound and rapid deterioration in clinical state with suicidal gesture by suffocation. Corrective treatment included immediate hospitalization. The investigator did not make a relatedness statement.

At the time of the adverse event the subject was receiving placebo at a dosage equivalent to Paxil, 20 mg/day. No concurrent medications were reported at the time of the event.

Treatment with study medication was discontinued the same day as the event and the subject was withdrawn from the study.

Observed efficacy scores by study week for the subject are listed below.

	HAMD		
Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total*	HAMD-21 total
Day -6	2	24	25
Day 0	2	27	30
Day 7	3	36	41

	Raskin Depression Scale		
Day of visit	Verbal report	Behavior	Secondary symptoms of depression
Day -6	5	5	4
Day 0	5	4	4
Day 7	5	5	4

MADRS

Day of MADRS visit	MADRS item 10: suicide	MADRS total*
Day 0	4^	45
Day 7	5	50

^ History of suicidal ideation prior to treatment.

Symptom checklist – 56 Day of visit	Item 35 - 'Thoughts of ending your life'
Day 0	2
Day 7	3

Protocol Id:	002
Subject Number:	004.089
Treatment Group:	Paxil
Adverse event Preferred term(s):	Overdose
Adverse event Verbatim term(s):	Overdose

Clinical Study Report Summary for PAR 02-04-089:

The patient is a 19-year-old white female who entered the study on 03/09/87 with a diagnosis of major depression, recurrent (DSM-III: 296.3). The patient reported a history of severe menstrual cramps, but was otherwise in good health. Concomitant medication used during the study was Tylenol (acetaminophen) 1000 mg on 03/18/97 for a headache.

Screening laboratory values revealed no significant abnormalities. ECG was normal.

On 03/16/87, the patient was begun on paroxetine 20 mg/day (days 1-8); decreased to 10 mg/day (days 9-16) because of adverse experiences; returned to 20 mg/day (days 17-40). She was on medication for 40 days. Adverse clinical experiences reported during the study were moderate dizziness and lack of energy (probably drug-related), and moderate headaches (possibly drug-related). There were no adverse laboratory experiences reported.

On 04/24/87, the patient had a fight with her spouse and in anger consumed 150 mg to 200 mg of paroxetine. The patient had no serious adverse effects and did not require hospitalization. She was able to continue on her job immediately after the overdose.

The patient was originally dropped from the study for a non-drug-related reason; however, her overdose was entered in the case report form as an adverse clinical experience and as the primary reason for termination. Because of this, the sponsor recoded her dropout reason as a drug-related experience.

Follow-up was attempted for final safety studies and physical exams. In phone contact of 05/05/87 the patient reported that she was doing well. She was then lost to follow-up. She failed to keep two scheduled appointments. The patient was contacted by telephone on 11/02/87; at that time the patient reported good general health.

Additional Information:

This 19-year-old female was enrolled in a double-blind clinical study for the treatment of major depressive disorder. According to DSM-III criteria, no personality or developmental disorder was noted (Axis II: V71.09), nor were any psychosocial stressors

identified (Axis IV), but a history of poor adaptive function over the past year was assessed (Axis V). No psychiatric history in any lineal or conjugal family members was noted.

At screening the subject's height and weight were reported as 65.25 inches and 199.25 lbs, respectively.

No prior or current treatment for depression was reported. The episode of major depression for which the subject was enrolled in the study was of more than one year in duration and was characterized as a recurrence of a previous condition. The onset of the current episode of depression was very gradual (one or more years), and no precipitating external event was identified. The subject had not received any psychiatric treatment for the current episode or prior to this episode.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were 2 and 1, respectively, and the total HAMD-17 score at randomization was 23. Additionally, the HAMD-21 score at randomization was 26. The randomization score on the MADRS item #10, reflecting suicidality, was 2, and total MADRS score at randomization was 30. The subject's Raskin Depression Score values were all four (4-considerably) in the areas of verbal report, behaviour, and secondary symptoms of depression at screening and randomization. On the 56 point Symptom Checklist item # 35, 'thoughts of ending your life,' the screening and randomization scores were both 1 (not at all).

Three days after the first dose of study medication, Paxil at a dose of 20 mg/day, the subject experienced headache, dizziness, and no energy. Her dose of study medication was subsequently reduced to Paxil 10 mg/day due to the events of dizziness and no energy, which were both assessed as moderate in intensity and probably related to study medication by the investigator. The headache was assessed as moderate in intensity and possibly related to study medication. The subject received treatment with acetaminophen, and the headache was considered resolved the same day. The dizziness and lack of energy were ongoing.

Twelve days later, while receiving Paxil at a dose of 10 mg/day, she experienced another headache that was also assessed as moderate in intensity and possibly related to study medication. She continued on study medication and the event resolved five days later. On Day 18 of study treatment the subject's dose of Paxil was advanced to a dose of 20 mg/day due to lack of efficacy.

Forty days after the first dose of study medication and while receiving Paxil at a dose of 20 mg/day, the subject contacted the investigational site to report that she had had a fight with her husband and subsequently ingested 15-20 study drug capsules in anger. She reported that she was at her job and was not experiencing any adverse effects. It was noted that the investigator did not think this was a suicide attempt. The study blind was broken and the investigator was instructed to discontinue the subject from the study

immediately. A follow-up appointment was scheduled with the subject for four days later, but the appointment was not kept. The subject was contacted at this time and another appointment was scheduled for a week later. At the time of scheduling, the subject reported that she was feeling fine and was reluctant to set-up the appointment, but she agreed to return to the investigational site to have all of her follow-up tests and return any unused medication. She did not keep this appointment and was considered lost to follow-up.

Observed efficacy scores by study week for the subject are listed below.

	HAMD		
Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total	HAMD-21 total
Day -6	2	22	24
Day 1	1	23	26
Day 9	0	10	13
Day 17	0	10	12
Day 23	0	10	12
Day 31	0	10	12

	Raskin Depression Scale		
Day of visit	Verbal report	Behaviour	Seconday symptoms of depression
Day -6	4	4	4
Day 1	4	4	4
Day 9	2	3	3
Day 17	2	3	2
Day 23	2	2	2
Day 31	2	2	2

Symptom checklist - 56	
Day of visit	Item 35 - 'Thoughts of ending your life'
Day 1	1
Day 9	1
Day 17	1
Day 23	1
Day 31	1

	MADRS	
Day of MADRS visit	MADRS item 10: suicide	MADRS total*
Day 1	2	30
Day 9	1	16
Day 17	0	9
Day 23	0	10
Day 31	0	11

Protocol Id:	09_01A
Subject Number:	006
Treatment Group:	Paxil
Adverse event Preferred term(s):	Emotional Lability
Adverse event Verbatim term(s):	Suicidal Threats

This 35-year-old male was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression, recurrent: moderate (DSM-III 296.32).

This subject also reported concurrent clinical conditions of major affective disorder, unipolar and a possible ulcer. Additionally, the patient had a family history of non-psychotic psychiatric disturbance involving his mother and imprisonment of a sibling.

The subject had no reported previous treatment for depression. The episode of major depression for which the subject was enrolled in the study was of six to twelve months duration, and concurrent medications administered at the time of study entry were reported as cimetidine. The onset of the current depressive episode was described as gradual (one or more months) and was best characterized as a recurrence of a similar previous condition. A precipitating external event was definitely present. At the time of study recruitment it was also noted that in the past three years the subject was employed full-time but was experiencing some decline in work performance and some decline in competence with regard to social functioning.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 1, and the total HAMD-17 and HAMD-21 scores at randomization were 31 and 33, respectively. The randomization score on MADRS item #10, reflecting suicidality, was 2 and the total MADRS score at randomization was 36. Screening and randomization scores for the Raskin Depression Scale on verbal report, behaviour and secondary symptoms of depression were all 3 (moderate) at screening and all 4 (considerable) at randomization. On the Symptom Checklist-56, item #35, the subject's score at randomization was 1, (no thoughts of ending your life).

On day one of treatment with study medication (Paxil), the subject experienced generalized depression that was considered severe in intensity and unrelated to study medication by the investigator. Subsequently that same day, the subject expressed suicidal threats, which were considered moderate in intensity and unrelated to study medication by the investigator. At the time of the adverse events, the subject was receiving Paxil at a dose of 10mg/day. There were no reported concomitant medications being taken at the time of the events as cimetidine had been stopped two days earlier. At the time of the events it was also noted that the subject was experiencing difficulties with a precipitating external event. He had moderate psychosocial stressors noted prior to and upon multiaxial evaluation.

Treatment with study medication was discontinued the same day as the adverse events described previously, and the subject was terminated prematurely from the study. The adverse events remained unresolved at the time of study termination.

The subject's EKG record noted that he did not undergo a final EKG exam due to hospitalization (dates not provided).

Observed efficacy scores by study week for the subject are listed below.

HAMD

Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total*	HAMD-21 total
Day -6	1	30	32
Day 0	1	31	33
Day 2	4	39	43

Raskin Depression Scale

Day of visit	Verbal report	Behaviour	Seconday symptoms of depression
Day -6	3	3	3
Day 0	4	4	4
Day 2	5	4	4

MADRS

Day of MADRS visit	MADRS item 10: suicide	MADRS total*
Day 0	2	36
Day 2	5	42

Symptom checklist – 56

Day of visit	Item 35 - 'Thoughts of ending your life'
Day 0	1

Protocol Id:	09_01E
Subject Number:	260
Treatment Group:	Paxil
Adverse event Preferred term(s):	Emotional Lability
Adverse event Verbatim term(s):	Suicide Attempt

This 51-year-old female was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression, recurrent: severe (DSM-III 303.91).

This subject also reported concurrent clinical conditions of alcohol dependence, mixed personality disorder, and Meniere's Syndrome. Additionally, she had a history of kidney infections, abdominal hysterectomy for fibroids, head injury, nasal surgery, and left ear surgery. The subject's family psychiatric history included children with major affective disturbance, children hospitalized for psychiatric disturbance, a spouse who engaged in excessive use of alcohol and was physically abusive toward her, and imprisonment of her spouse. The physical beatings she received from her spouse resulted in fractures of the face, requiring five nasal surgeries.

The subject had previously received outpatient treatment for three months and hospitalization for one week for depression and first received psychiatric treatment at the age of 43. The episode of major depression for which the subject was enrolled in the study was of more than one year duration, and there were no concurrent medications administered at the time of study entry. The onset of the present episode of depression was best characterized as an exacerbation of a chronic condition with a very gradual onset (one or more years). A precipitating external event was definitely present, and the subject had severe psychosocial stressors noted on multi-axial evaluation. At the time of study recruitment it was noted that the subject was employed full-time and was divorced.

The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2 and the total HAMD-17 and HAMD-21 score at randomization was 21 and 22, respectively. On the Raskin Depression Scale for verbal report, behaviour and secondary symptoms of depression, the screening and randomization scores were 4 (considerable) and 4, 4 and 3 (moderate) and 2 (somewhat) and 3, respectively. The randomization scores on the MADRS item #10, reflecting suicidality, was 2, and the total MADRS score at randomization was 20. On the Symptom Checklist-56, item #35 'thoughts of ending your life', the subject scored 2 (a little) at randomization.

The subject received 41 days of study treatment with Paxil at a dose of 30 mg/day. On day 42 of study treatment the subject was admitted to a detoxification unit for alcohol abuse. During this admission all laboratory studies were within normal limits but the subject's blood alcohol level was 0.182. She did not require treatment with chlorodiazepoxide (Librium).

Forty-four days after the first dose of study medication, the subject attempted suicide. The event was assessed as severe in intensity and possibly related to study medication by the investigator. On the same day, the subject was noted to have an ear infection and to be engaging in alcohol abuse. The alcohol abuse was also assessed as severe in intensity and possibly related to study medication, and the ear infection was considered moderate in intensity and unrelated to study medication. At the time of the adverse events, the subject was not receiving study medication as she had been hospitalized from days 42-50 of study treatment for detoxification. There were no reported concomitant medications being taken at the time of the adverse events.

Hospital records available from an admission for detoxification during the study noted that the subject felt that the study medication helped, but she continued to be overwhelmed by the situational distress in her life.

Treatment with study medication was interrupted during hospitalization and the subject was treated with amoxicillin and erythromycin for the ear infection. It was reported that the subject attempted suicide via an overdose with alcohol and amoxicillin. The final diagnoses made during her hospitalization were: acute chronic alcoholism, hearing loss, and depression. The reported events of suicide attempt, alcohol abuse, and ear infection were all considered resolved one day after onset. Fifty one days after the first dose of study drug and following hospitalization, the subject resumed treatment with Paxil at a dose of 30mg/day.

Observed efficacy scores by study week for the subject are listed below.

HAMD

Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total	HAMD-21 total
Day -8	2	19	20
Day 0	2	21	22
Day 7	0	8	9
Day 14	0	4	4
Day 21	0	7	8
Day 27	0	4	4
Day 41	0	5	5
Day 63	2	11	12

Raskin Depression Scale

Day of visit	Verbal report	Behaviour	Seconday symptoms of depression
Day -8	4	4	2
Day 0	4	3	3
Day 7	3	3	1
Day 14	1	2	1
Day 21	2	3	1
Day 27	1	2	1
Day 41	1	2	1
Day 63	2	2	2

MADRS

Day of MADRS visit	MADRS item 10: suicide	MADRS total*
Day 0	2	20
Day 7	0	11
Day 14	0	5
Day 21	0	8
Day 27	0	6
Day 41	0	3
Day 63	2	20

Symptom checklist – 56

Day of visit	Item 35 - 'Thoughts of ending your life'
Day 0	2
Day 7	2
Day 14	1
Day 21	1
Day 27	2
Day 41	2
Day 63	2

Protocol Id:	279
Subject Number:	1.12.037
Treatment Group:	PAROXETINE
Adverse event Preferred term(s):	Trauma
Adverse event Verbatim term(s):	Patient Stabbed His Abdomen

This 20 year old male patient had a history of alcohol intolerance. He did not have any concurrent illnesses or medication during the study. The patient made an attempt to stab himself in the abdomen on day 49 which resulted in minor injury only. This was not considered a true suicide attempt by the investigator and no action was taken. He had one double flagged laboratory value: a transient increase in blood urea level, rising from 4.5 mol/l at baseline to 7.6 mol/l at week 1, which returned to and stayed within the normal range for the remainder of the study. Hence it was not considered to be clinically significant. There were no other double flagged laboratory values or vital signs.

Additional Information:

This 20-year-old male was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression according to DSM-III criteria.

This subject reported no concurrent clinical conditions; however, the subject's family medical history included a father who has suffered from manic depressive psychosis, paternal grandmother with possible depressive illness, and mother and maternal grandmother who were both treated for depressive illness. The subject reported weekend alcohol intake, use of LSD on two occasions, as well as use of marijuana.

The subject had previously received treatment for depression with lorazepam for three weeks and Prothiaden for six weeks and had a poor response to treatment with both of these medications. The episode of major depression for which the subject was enrolled in the study was of 14 days duration, and there were no concurrent medications administered at the time of study entry. The subject's current episode of depression included symptoms of irrational fears, self-pity, and moderate loss of pleasure. It was also noted that the subject was unemployed at the time of study entry.

The subject had a history of suicidal ideation prior to treatment. The screening score on the HAMD item #3, reflecting suicidality, was 3, and the total HAMD-17 and HAMD-21 scores at screening were 20 and 21, respectively. No HAMD evaluation was performed at the time of treatment randomization.

Forty-nine days after the first dose of study medication, Paxil, the subject stabbed himself in the abdomen. At the time of the adverse event, the subject was receiving Paxil at a dose of 30mg/day. There were no reported concomitant medications being administered

at the time of the event. It was also noted that, at the time of the event, the subject lost his flatmate who had also stolen his girlfriend, and his puppy had died the day prior to the event.

Treatment with study medication was discontinued and the subject was withdrawn from the study.

During the course of the double-blind phase of the study, the subject also experienced alcohol intolerance and epigastric pain eight and 15 days, respectively, after the first dose of study medication. Both of these events were assessed as mild in intensity and related to study medication by the investigator. The alcohol intolerance lasted for greater than two weeks, and the epigastric pain lasted over a period of two weeks.

One day after the last dose of study medication and 50 days after commencing study treatment, the subject experienced lethargy, constipation, diarrhea and sweating. The sweating was assessed as being related to study medication. The outcome of these events was unknown.

Observed efficacy scores by study week for the subject are listed below.

	HAMD		
Day of HAMD Visit	HAMD item 3: suicide	HAMD-17 total	HAMD-21 total
-6	3^	20	21
8	0	19	20
15	0	14	16
36	0	12	13
50	2	15	18
64	3	18	21
78	2	10	12

^History of suicidal ideation prior to treatment

Protocol Id:	115
Subject Number:	003.0062
Treatment Group:	Paxil
Adverse event Preferred term(s):	Emotional Lability
Adverse event Verbatim term(s):	Suicide attempt

This 29-year-old female was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression, single episode (DSM-IIIR 296.22).

No concurrent clinical conditions were reported at the time of study entry; however, the patient reported a previous history of allergic reaction (nausea) to meperidine, kidney removal, and bladder infections. The subject had previously received treatment with amitriptyline, nortriptyline (for > 8 weeks), and temazepam (for 0-2 weeks) for this episode of depression; with a good treatment response noted for both amitriptyline and nortriptyline. The episode of major depression for which the subject was enrolled in the study was of five years duration.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2. The total HAMD-17 score at randomization was 24 and the total HAMD-21 score was 27.

Fifty-five days after the first dose of study medication (Paxil), the subject attempted suicide. The event was assessed by the investigator as moderate in intensity and unrelated to the use of study medication. The subject allegedly ingested approximately 20 chloral hydrate 500mg capsules after leaving a suicide note and picture for her daughter. A clinical drug safety note reflecting a discussion between the safety group and investigator reported his assessment of the event as "possibly related to study medication, but probably unrelated (this category can not be captured)." It was also noted that the subject was involved in a pending divorce proceeding. At the time of the event, the subject was receiving Paxil 30mg/day and had been on this dose for approximately one month. There were no reported concomitant medications. She survived the suicide attempt and the event was considered resolved that day. Treatment with study medication was discontinued and the subject was withdrawn from the study.

The subject also experienced increased insomnia which commenced 14 days after the start of study medication while the subject was receiving 20mg dose of study medication. The investigator assessed the event as mild in intensity and probably unrelated to study medication. Corrective therapy was prescribed and the event was noted as unresolved at the time of study discontinuation.

During the course of the double-blind study, the subject also reported the following non-serious adverse events: sinus congestion (beginning three days before starting study medication) and indigestion (beginning four days after starting study medication). The subject was treated with Sinutab for 11 days following randomization, and the event was assessed by the investigator as unrelated and resolved during the study. The indigestion resolved in four days, with corrective therapy (Tums), and was considered probably related by the investigator.

Observed efficacy scores by study week for the subject are listed below.

HAMD

Day of HAMD Visit	HAMD item 3: suicide	HAMD-17 total*	HAMD-21 total*
-7	2	28	32
0	2	24	27
7	2	29	30
14	0	16	17
21	0	21	23
29	2	18	19
42	0	10	11

Raskin Depression Scale

Day of Visit*	Verbal Report	Behavior	Secondary Symptoms Depression
-7	5	3	5
0	4	3	4
7	5	4	4
14	2	2	3
21	2	1	4
29	2	1	4
42	2	2	3

Symptom Checklist SCL-90

Day of Visit	Thoughts of Ending Your Life	Thoughts of Death or Dying
0	1	2
7	1	1
14	0	0
21	0	0
29	0	0
42	0	0

Protocol Id:	29060 128
Subject Number:	128.001.0759
Treatment Group:	Paxil
Case ID Number:	B0152218A
Adverse event Preferred term(s):	Emotional Lability
Adverse event Verbatim term(s):	Suicide Attempt

Medical Monitor Comments: 23-Aug-1991 (Dr. xxxxx) This thirty year old male patient, was enrolled in study PAR128 on 16-Jul-1991. On 21-Aug-1991, the patient decided to discontinue the study coded medication. On this same date, while at his girlfriend's apartment having "some drinks," he was involved in a serious argument with her. The police were called in, and the patient taken into custody. At the police station he attempted suicide by hanging with his belt. The clinical investigator requested the immediate opening of this patient's coded study medication. The code was opened at SKB, the patient was receiving PAROXETINE study medication. Following the suicide attempt, the patient was hospitalized at a State Hospital. The investigator categorized this patient's suicide attempt as not related to PAROXETINE. . WORLDWIDE CLINICAL SAFETY - 26-AUG-1991: NON-EXPEDITE PER CLINICAL SAFETY PHYSICIAN. . ae coordinator comments: 27-Aug-1991 (xx) per WWCS mail request the following change has been made to the "m" page: - study med. = PAROXETINE . WORLDWIDE CLINICAL SAFETY - 27-AUG-91: CASE MAINTENANCE NOTED; FILED. . ae coordinator comments: 29-Oct-1991 (xx) per CRF review the following changes were made to the "m" page: - birth date = xx-xxx-1960 - weight = 84.5 Kg. . CLIN. SAFETY: 29-OCT-1991: CASE MAINTENANCE NOTED; FILED. F/U Clinical Safety Analyst (xx) Narrative Per CRF Review: 21-Nov-1991 Probably unrelated on CRF = not related in WWCS data base. ae coordinator comments: 22-Nov-1991 (xx) per CRF review the following changes were made to the "m" page: - severity = mod - complete = y - outcome = rec - clear date = 21-Aug-1991 - rx start = 17-Jul-1991 - rx stop = 20-Aug-1991 (est) - abate = y - reintro. = n . CLINICAL SAFETY - 25-NOV-1991 CASE UPDATE REVIEWED; CIRCULATED. F/U Clinical Safety Analyst (xx) Narrative: 16-Dec-1991 Per CRF: There are three documented ae's that caused study drug withdrawl: - argumentative - 21-Aug to 22-Aug-91/severe/unrelated. - increased hopelessness - 20-Aug to 23-Aug-1991/severe/unrelated. - anxiety - 21-Aug to 25-Aug-91/severe/probably related. Both increased hopelessness and anxiety were noted as present before or at baseline. ae coordinator comments: 16-Dec-1991 (xx) per CRF review: est was deleted from rx end date. . CLINICAL SAFETY: 16-DEC-1991 CASE NOTE REVIEWED; CIRCULATED. ae coordinator comments: 10-Jan-1992 (xx) in response to WWCS mail request relevant medical history has been added to the "h" page. . CLINICAL SAFETY - 10-JAN-1992: CASE MAINTENANCE NOTED; FILED.

Additional Information:

This 30-year-old male was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression (DSM-IIIR: 296.22) and personality disorder, not otherwise specified (DSM-IIIR 301.90).

This subject reported no concurrent clinical conditions. Additionally, the patient had a previous history of an unspecified personality disorder.

The subject had previously received treatment with trazodone, lithium carbonate, isocarboxazid, desipramine, nortriptyline, fluoxetine, sibutramine, and Wellbutrin for depression and reported a poor to fair response to each of these medications. The episode of major depression for which the subject was enrolled in the study was of more than one year in duration with the first appearance of symptoms 10 years previously. No concurrent medications were reported as being administered at the time of study entry. At the time of study entry it was also noted that the subject had stopped working because of his present illness.

The subject had no documented history of suicide attempt or self-harm at the time of study entry, but suicidal thoughts were identified at baseline in the context of the Symptom Checklist- 90. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2, and the total HAMD-17 and HAMD-21 scores at randomization were 26 and 29, respectively. The scores at the baseline visit on the Symptom Checklist- 90 were both 3 (quite a bit) for "thoughts of ending your life" and "thoughts of death or dying."

Thirty-six days after the first dose of study medication (Paxil) that the subject discontinued study medication and withdrew himself from the study. On the same date, the subject was at his girlfriend's apartment having "some drinks" and was subsequently involved in a serious argument with her. The police were notified and the subject was taken into custody. At the police station the subject attempted suicide by hanging with his belt. The investigator requested immediate breaking of the study blind. The investigator subsequently assessed the event as moderate in intensity and probably unrelated to study medication. Corrective treatment included hospitalization, and the event was considered resolved within one day.

Prior to discontinuing study treatment the subject was receiving Paxil at a dose of 50mg/day and no reported concomitant medications were being taken at the time of the adverse event.

The subject also experienced agitation (two episodes), increased hopelessness, anxiety, and being argumentative during the course of the study. The agitation commenced two days and 21days after the start of study medication while the subject was receiving Paxil 20mg/day and Paxil 30mg/day, respectively. The investigator assessed the events as moderate in intensity and probably unrelated to study medication. The agitation resolved 18 days after the first episode and 19 days after the second episode. The increased hopelessness occurred 35 days after the start of study medication while the subject was

receiving Paxil 50mg/day. The investigator assessed the event as severe in intensity and unrelated to study medication. Study medication was discontinued on this date, and the event resolved after three days. The events of anxiety and being argumentative commenced one day after the subject discontinued study medication. The investigator assessed both of these events as severe in intensity and felt that the argumentativeness was unrelated to study medication and the anxiety was probably unrelated to study medication. The anxiety resolved after four days, and the argumentativeness resolved after one day.

Observed efficacy scores by study week for the subject are listed below.

HAMD

Day of HAMD Visit	HAMD item 3: suicide	HAMD-17 total	HAMD-21 total
-7	2	23	26
0	2	26	29
8	2	25	28
14	1	21	24
21	1	18	21
28	1	20	23
37	4	34	38

Raskin Depression Scale

Day of Visit*	Verbal Report	Behavior	Secondary Symptoms of Depression
-7	4	3	3
0	4	3	3
8	3	3	3
14	3	3	3
21	3	3	3
28	3	3	3

Symptom Checklist SCL-90

Day of Visit	Thoughts of Ending Your Life	Thoughts of Death or Dying
0	3	3
8	1	2
14	1	1
21	1	2
28	1	2

Protocol Id:	251
Subject Number:	002.0285
Treatment Group:	Paxil
Adverse event Preferred term(s):	Emotional lability
Adverse event Verbatim term(s):	Suicide gesture

This 30-year-old male was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the patient had a diagnosis of major depression, single chronic episode, moderate (DSM 296.2).

This subject also reported concurrent clinical conditions of dependent personality (DSM 301.60), daily headaches, exogenous obesity, environmental allergies and allergy to penicillin.

The subject had no reported previous treatment for depression. The episode of major depression for which the subject was enrolled in the study was of 14 years duration and paracetamol was reported as a concurrent medication at the time of study entry. It was also noted that the subject was unemployed at the time of study recruitment.

The subject had no documented history of suicide attempt or self-harm at the time of study entry, but he did experience suicidal thoughts. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2, and the total HAMD-17 and HAMD-21 scores at Randomization were 27 and 32, respectively. For the Symptom Checklist-90, item #15 (thoughts of ending your life) the subject's score at screening and randomization was 3 (quite a bit) and 2 (moderately), respectively.

Twenty-five days after the first dose of study medication (Paxil), the subject demonstrated suicidal gestures. The subject took two diphenhydramine 25mg capsules, eight over the counter diphenhydramine 25mg capsules and anti-anxiety medications which he could not identify(small blue and white capsules) to help him sleep, not caring "whether or not he woke up." Concomitant medication records later documented the subject's use of diphenhydramine (a total of 300 mg) and hydroxyzine (100 mg) related to the suicide gesture. He awoke the next morning feeling dizzy and groggy but with no problems or sequelae. The subject was not suicidal when seen by the study coordinator three days after the event. The coordinator stated that the event was probably due to psychosocial stressors and not related to study medication. The event was considered to be of mild intensity and probably unrelated to study drug by the investigator. The event was considered resolved within 18 hours of onset.

At the time of the adverse event, the subject was receiving Paxil at a dose of 30 mg/day. Reported concomitant medications being taken at the time of the adverse event included paracetamol and vitamins, of which the vitamins had been started after treatment with study medication had been initiated.

Treatment with study medication was discontinued three days after the onset of the adverse event, and the subject was terminated from the study prior to completion due to lack of efficacy as well as the adverse event.

Observed efficacy scores by study week for the subject are listed below.

	HAMD		
Day of HAMD Visit	HAMD item 3: suicide	HAMD-17 total	HAMD-21 total
-7	2	23	28
0	2	27	32
7	0	18	21
18	0	17	21
28	3	25	30

	Symptom Checklist SCL-90	
Day of Visit	Thoughts of Ending Your Life	Thoughts of Death or Dying
-7	3	3
0	2	2
7	0	0
18	2	2
28	4	3

Protocol Id:	29060 448
Investigator Number:	010
Patient Number:	00044
Treatment Number:	
Case Id:	A0251781A
Suspect Drugs:	Paxil IR
Serious Events Preferred terms:	Emotional Lability
Serious Events Verbatim terms:	Suicide Attempt Overdose

Patient was randomized to a double-blind placebo controlled depression/affective disorders study Protocol 448. On 06 December 1996 the patient overdosed on Flexeril (cyclobenzaprine), Valium (diazepam), Anaprox (naproxen sodium), and possibly study medication. The investigator indicated that the event was of severe intensity. The patient was hospitalized for approximately 48 hours and was doing well. She was last seen at the study site on 02 December 1996 where there was a mild improvement in her mood. On 18 December 1996 she came in for visit #7 and reported that she had taken a drug overdose (06 December 1996) after an argument with her boyfriend. Study medication was discontinued on 28 December 1996. The patient was terminated from the study and entered the taper phase. The event resolved. Investigator attribution: not related to study medication. Investigator Assessment: the experience could be associated with the primary condition. Further information will be forthcoming. OVERDOSE

Additional Information:

At the time of study entry, this 25 year old female had a diagnosis of major depressive disorder according to DSM-IV criteria. The subject also reported the concurrent clinical condition of irritable bowel syndrome. The subject had previously received treatment with fluoxetine and sertraline, and it was reported that she had a fair response to both medications. The subject had received trazodone for treatment of the current episode of major depression to which she had a fair response. The episode of major depression for which the subject was enrolled in the study was of one year duration, and at the time of study entry she received dofamium concurrently.

She had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were 1 and 2, respectively, and the total HAMD score at randomization was 27.

Forty-nine days after the first dose of study medication, the subject attempted suicide by overdose. At the time of the adverse event, the subject was receiving Paxil IR at a dose of 40mg/day.

During the course of the double-blind phase of the study the subject also experienced dizziness, nausea, dilated pupils (two days after first dose of investigational product),

backache, diarrhea (three days after first dose of study medication), sinus infection (17 days after first dose of study medication), bloody nose and cold symptoms (19 days after first dose of study medication). All events resolved during the course of the study.

Observed efficacy scores by study week for the subject are listed below.

		HAMD		
Date of HAMD visit	Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total	
11OCT1996	Day -7	1	23	
17OCT1996	Day -1	2	27	
25OCT1996	Day 7	2	27	
04NOV1996	Day 17	2	27	
11NOV1996	Day 24	1	21	
18NOV1996	Day 31	1	16	
02DEC1996	Day 45	1	14	
19DEC1996	Day 62	4	24	

Protocol Id:	29060 448
Investigator Number:	019
Patient Number:	00391
Treatment Number:	
Case Id:	A0254833A
Suspect Drugs:	Paxil IR
Serious Events Preferred terms:	Emotional Lability
Serious Events Verbatim terms:	Suicide Attempt Via Overdose

Patient entered double-blind, placebo-controlled study on 20-Dec-96. Patient was seen in week 3 visit on 21-Jan-97 admitting to feeling that "life was empty," but denied thoughts of death or suicide. Patient continued on level 3 of study medication dosing. On 24-Jan-97, the patient's husband reported that the patient was hospitalized subsequent to an overdose the previous night following a fight between the patient and her husband (23-Jan-97) with chloral hydrate 500 mg (possible 9 {tablets}), and Tylenol with codeine (number of tablets and dosage unknown). The patient did not take an overdose of the study medication. The investigator considered the event severe in intensity, life-threatening, unrelated to the study medication, and attributable to the patient's primary condition. The patient was discharged from the hospital on 24-Jan-97 and study medication was stopped on 23-Jan-1997, after 24 days of therapy. Medical records indicated that the patient was dysphoric and patient reported "being tired of feeling down," but denied active suicidal ideation. Following discussion of patient's goals, it was decided to terminate the patient from the protocol and to initiate treatment with Serzone 50 mg bid starting the next day (25-Jan-97). Patient was instructed to increase Serzone dosing to 100 mg bid on 28-Jan-97, and it was noted that she was not suicidal after 1 week. OVERDOSE

Additional Information:

This 27-year-old female was enrolled in a double-blind clinical study for the treatment of major depressive disorder. At the time of study entry, the subject had a diagnosis of major depressive disorder according to DSM-IV criteria. Thie subject reported concurrent clinical conditions of frequent headaches and hypoglycaemia. Additionally, the subject had a previous history of miscarriages and a motor vehicle accident.

The subject had previously received treatment for the current episode of depression with an unknown antidepressant and nefazodone. The subject had a fair response to the unknown antidepressant and a good response to the nefazodone. The episode of major depression for which the subject was enrolled in the study was of six years and eleven months duration.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the HAMD item #3, reflecting suicidality, were both 2, and the total HAMD score at randomization was 22.

It was noted that one day after the first dose of study medication, the subject experienced insomnia, which was assessed as moderate in intensity and probably related to study medication. The subject was taking Paxil IR at a dose of 20mg/day at the time of the event. The insomnia remained unresolved at the time of discontinuation of study medication.

On day eleven of study treatment the subject was up-titrated to Paxil IR at a dose of 30 mg/day. Five days later (16 days after the first dose of study medication) she was subsequently advanced to Paxil IR at a dose of 40 mg/day.

Twenty days after the first dose of study medication medication she experienced the non-serious events of chills, diarrhea, fever, and headache. All of the events resolved within one day and she continued on study treatment.

Twenty-four days after the first dose of study medication, the subject attempted suicide by overdose while receiving study treatment with Paxil IR at a dose of 40mg/day. Reported concomitant medications being taken at the time of the suicide attempt were ibuprofen and Ovcon-50, both of which had been started after starting treatment with study medication.

It was also noted at the time of the subject's early termination visit that she had not been to work in a week because of her depression.

Observed efficacy scores by study week for the subject are listed below.

		HAMD	
Date of HAMD visit	Day of HAMD visit	HAMD item 3: suicide	HAMD-17 total
20DEC1996	Day -10	2	24
30DEC1996	Day 0	2	22
09JAN1997	Day 10	2	24
14JAN1997	Day 15	2	20
21JAN1997	Day 22	1	17

Protocol Id:	29060 449
Investigator Number:	021
Patient Number:	00788
Treatment Number:	000777
Case Id:	A0258041A
Suspect Drugs:	Paxil IR
Serious Events Preferred terms:	Emotional Lability
Serious Events Verbatim terms:	Drug Overdose

This patient with major depression was enrolled in study 29060/449, a double-blind, placebo controlled trial to evaluate the clinical effects of immediate release paroxetine and modified release paroxetine in the treatment of major depression. She began blinded study medication on 10-Jan-1997. On 20-Jan-1997 the patient began to experience mild fatigue, which is considered by investigator as ongoing, non-serious and possibly related to study medication. On 16-Mar-1997 after having a fight with her boyfriend, the patient took an overdose of 70 Motrin tablets and eight Robaxacet tablets as a suicide gesture. Gastric lavage with charcoal was performed in the emergency unit at a local hospital. Patient experienced moderate nausea, considered by investigator as a non-serious event unrelated to study medication, for four hours. She was given Gravol 50 mg intravenously for nausea. Patient was then discharged from the hospital. The patient spoke with the investigator by phone on 17-Mar-1997 and stated she was fine. She was to meet with the investigator on 18-Mar-1997. Per case report form, study medication was discontinued on 18-Mar-1997 and Paxil 20 mg daily was initiated on 27-Mar-1997. The investigator reported that the overdose was severe, unrelated to the study medication and could be associated with the patient's primary condition. DRUG OVERDOSE

Additional Information

At the time of study entry, this 18 year old female had a diagnosis of major depression according to DSM-IV criteria. The subject reported a concurrent clinical condition of vaginitis, and she had a previous history of post traumatic stress disorder. The episode of major depression for which the subject was enrolled in the study was of three months duration, and concurrent use of ethinylestradiol/levonorgestrel (Triphasil) was reported at the time of study entry.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on HAMD item #3, reflecting suicidality, were 2 and 1, respectively, and the total HAMD score at randomization was 21.

Fifty-two days after the start of study medication and two weeks before the subject’s drug overdose, she experienced a dislocated left shoulder while receiving Paxil IR at a dose of

20 mg/day. The event was considered resolved the next day. The investigator assessed the event as moderate in intensity and unrelated to study medication.

In the setting of the subject's drug overdose (66 days after the start of study medication, at a dose of Paxil IR, 20 mg/day), she also sustained abrasions on the knees and experienced left hand pain and excoriations on the hands. These events subsequently resolved approximately one month following the subject's withdrawal from the study.

Observed efficacy scores by study week for the subject are listed below.

		HAMD		
Date of HAMD visit	Day of HAMD visit		HAMD item 3: suicide	HAMD-17 total*
02JAN1997	Day	-7	2	25
09JAN1997	Day	0	1	21
16JAN1997	Day	7	0	17
23JAN1997	Day	14	2	23
30JAN1997	Day	21	2	23
04FEB1997	Day	26	0	8
20FEB1997	Day	42	1	9
04MAR1997	Day	54	0	0
18MAR1997	Day	68	3	23

Protocol Id:	29060 625
Investigator Number:	500
Patient Number:	02062
Treatment Number:	
Case Id:	A0301493A
Suspect Drugs:	Paxil
Serious Events Preferred terms:	Emotional Lability
Serious Events Verbatim terms:	Tylenol Overdose

Case reference number 1999008231-1 is a clinical trial report from study 29060/625, a double-blind, placebo-controlled multi-centre study to evaluate the efficacy and tolerability of paroxetine in the treatment of post-stroke depression. This case refers to a 50-year-old male (patient identification number 625.500.02062). The patient started the blinded study medication on 09-Feb-99 at a dose of 1 tablet per day. On 24-Mar-99, the dose was increased to 2 tablets per day. The patient's relevant medical history includes post stroke depression. Concomitant medications include Diabinese (chlorpropamide), Norvasc (amlodipine), Beza lip SR (bezafibrate), Avapro (irbesartan), ASA (acetylsalicylic acid), Altace (ramipril), and Risperidone. On 05-Apr-99, the patient overdosed on Tylenol (paracetamol) extra strength by taking 12 to 15 tablets at one time. The event resolved on the 05-Apr-99, he was not admitted to the hospital. The patient discontinued blinded study medication on 06-Apr-1999, and has been switched to open-label paroxetine. The investigator reported this event to be unrelated to treatment with the blinded study medication and associated the overdose to be related to the patient's primary condition. On 26-Apr-1999, the patient again overdosed on Tylenol (paracetamol) extra strength, taking 23 tablets at one time. The event was reported to be resolved later that day. The investigator reported the event to be unrelated to treatment with the blinded study medication, and probably associated with the patient's primary condition. OVERDOSE OVERDOSE

Additional Information:

At the time of study entry, the subject met the diagnostic criteria for a current depressive episode (moderate depressive episode; F32.2) according to ICD-10 diagnostic criteria. The subject also reported concurrent clinical conditions of angina pectoris, diabetes mellitus, hypertension, speech dysfunction, high cholesterol and a non-specific T-wave abnormality. The episode of major depression for which the subject was enrolled in the study was of 91 days duration. Concurrent medications administered at the time of study entry were reported as chlorpropamide, amlodipine, bezafibrate, irbesartan, acetylsalicylic acid, and ramipril.

The subject had a history of suicidal ideation prior to treatment as evidenced by his MADRS item #10 results related to suicidal thoughts. The screening and randomization

scores on MADRS item #10, reflecting suicidality, were 2 and 3 respectively, and the total MADRS score at randomization was 32.

The subject experienced the serious adverse event of Tylenol overdose described above on day 56 of study treatment while receiving Paxil at a dose of 30mg/day.

During the course of the double-blind phase of the study, the subject also experienced biting of the tongue and feeling lightheaded, 53 and 57 days after the first dose of study medication, respectively. Both of these non-serious adverse events were assessed as mild in intensity and unrelated to study medication by the investigator. The events resolved without corrective treatment. At the time of these adverse events, the subject was receiving Paxil at a dose of 30mg/day.

Observed efficacy scores by study week for the subject are listed below.

	MADRS	
Date (Day)	MADRS Item 10: Suicidal Thoughts	MADRS Total Score
02FEB1999 (Day -6)	2	30
08FEB1999 (Day 0)	3^	32
15FEB1999 (Day 7)	0	12
23FEB1999 (Day 15)	0	11
08MAR1999 (Day 28)	0	14
23MAR1999 (Day 43)	0	9
06APR1999 (Day 57)	4	36

^History of suicidal ideation prior to treatment

Protocol Id:	29060 785
Investigator Number:	720
Patient Number:	00695
Treatment Number:	10309
Case Id:	A0349686A
Suspect Drugs:	Paxil CR
Serious Events Preferred terms:	Abnormal Laboratory Value, Emotional Lability, Emotional Lability
Serious Events Verbatim terms:	Accidental Overdose, Suicidal, Suicide Attempt

Case reference number 2001016626-1 is a clinical trial report from double-blind study 29060/785 for the treatment of major depressive disorder with anxiety. This report refers to a 34-year-old female (patient identification number 785.720.00695). The patient's medical history included bilateral tubal ligation, chronic lower back pain, constipation, facial acne, fever blisters, fungal infection toenail right foot, heartburn, insomnia, intermittent headaches, and intermittent urinary tract infections. The patient had no concomitant medication use. The patient received study medication from 12-Jun-2001 to 09-Jul-2001. On 08-Jul-2001, 26 days after the start of study medication, the patient indicated she may have taken an extra study medication pill by mistake. Upon receiving the study medication bottle back from the patient, it was noted the bottle contained only two capsules instead of three capsules from the original number of ten capsules. The patient was diagnosed with overdose (accidental/ asymptomatic). Treatment with study medication was not stopped due to this event. The event was reported as resolved on 08-Jul-2001. The investigator reported the overdose (accidental/asymptomatic) as not related to treatment with study medication. On 08-Jul-2001, 26 days after the start of treatment with study medication, the patient attempted suicide and it was noted the attempted suicide was not related to the accidental overdose. The patient had suicidal feelings and on 10-Jul-2001, she was hospitalized. The patient was treated with valproate semisodium (Depakote). The patient discharged herself from the hospital on 14-Jul-2001 against medical advice. The investigator reported that the patient's follow-up visit to the clinic on 18-Jul-2001 revealed the patient was doing well. Treatment with study medication was discontinued due to these events. The event of attempted suicide resolved on 08-Jul-2001 and the event of suicidal feelings resolved on 12-Jul-2001. The investigator reported the suicidal attempt and suicidal feelings as life-threatening and not related to treatment with study medication, and probably associated with condition under study. OVERDOSE (ACCIDENTAL/ASYMPTOMATIC)

Additional Information

At the time of study entry, the patient had a diagnosis of major depressive disorder according to DSM-IV criteria. The episode of major depression for which the subject was enrolled in the study was of approximately10 years (3814 days) duration.

The subject had no documented history of suicidal thoughts, suicide attempt or self-harm at the time of study entry. The screening and randomization scores on the MADRS item #10, reflecting suicidality, were both 1, and the total MADRS score at randomization was 30.

Eight days after the first dose of study medication (Paxil CR) and one day after up-titration from Paxil CR 12.5 mg/day to Paxil CR 25 mg/day, the subject experienced moderate dizziness, nausea, decreased appetite, and lack of concentration. All of the events resolved without corrective therapy, and the subject continued on study drug. Sixteen days after the first dose of study medication, the subject experienced moderate fatigue and a mildly increased appetite. Both events resolved and there was no interruption in study treatment.

Twenty-two days after the first dose of study medication (Paxil CR, 25 mg/day) and five days before the serious adverse event (SAE) described above (Accidental Overdose and Suicide Attempt), the subject experienced a severely decreased appetite that resolved over a period of eight days. On the same day she also experienced a moderate panicky feeling. The panicky feeling was evaluated as probably unrelated to study medication and resolved after 13 days without corrective therapy. At the time of these adverse events and the SAE, the subject was receiving Paxil CR at a dose of 25 mg/day.

Observed efficacy scores by study week for the subject are listed below.

Date (Day)		MADRS Item 10: Suicidal Thoughts	MADRS Total Score
01JUN2001	(Day -10)	1	28
11JUN2001	(Day 0)	1	30
18JUN2001	(Day 7)	1	26
26JUN2001	(Day 15)	1	17
02JUL2001	(Day 21)	1	15
10JUL2001	(Day 29)	5	32